Table of Contents

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2020

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

For the transition period from _____ to _____

Commission File Number 001-36569

LANTHEUS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

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

(978) 671-8001

(Registrant's telephone number, including area code)

Not Applicable

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

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

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

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

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

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

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging Growth Company	☐

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

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

The registrant had 66,871,355 shares of common stock, $0.01 par value, outstanding as of October 30, 2020.

LANTHEUS HOLDINGS, INC.
TABLE OF CONTENTS

		Page
PART I. FINANCIAL INFORMATION		
Item 1.	Financial Statements (Unaudited)	
	Condensed Consolidated Balance Sheets	1
	Condensed Consolidated Statements of Operations	2
	Condensed Consolidated Statements of Comprehensive (Loss) Income	3
	Condensed Consolidated Statements of Changes in Stockholders' Equity	4
	Condensed Consolidated Statements of Cash Flows	6
	Notes to Condensed Consolidated Financial Statements	8
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	26
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	47
Item 4.	Controls and Procedures	47
PART II. OTHER INFORMATION		
Item 1.	Legal Proceedings	49
Item 1A.	Risk Factors	51
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	53
Item 3.	Defaults Upon Senior Securities	53
Item 4.	Mine Safety Disclosures	53
Item 5.	Other Information	53
Item 6.	Exhibits	54
SIGNATURES		55

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

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

	September 30, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 87,994	$ 92,919
Accounts receivable, net	49,206	43,529
Inventory	37,623	29,180
Other current assets	9,709	7,283
Total current assets	184,532	172,911
Property, plant and equipment, net	122,381	116,497
Intangibles, net	384,747	7,336
Goodwill	57,765	15,714
Deferred tax assets, net	69,345	71,834
Other long-term assets	60,824	21,627
Total assets	$ 879,594	$ 405,919
Liabilities and stockholders' equity		
Current liabilities		
Current portion of long-term debt and other borrowings	$ 18,138	$ 10,143
Accounts payable	24,070	18,608
Accrued expenses and other liabilities	39,792	37,360
Total current liabilities	82,000	66,111
Asset retirement obligations	13,962	12,883
Long-term debt, net and other borrowings	204,669	183,927
Other long-term liabilities	65,384	28,397
Total liabilities	366,015	291,318
Commitments and contingencies (See Note 17)		
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; 66,850 and 39,251 shares issued and outstanding, respectively)	668	393
Additional paid-in capital	661,955	251,641
Accumulated deficit	(146,534)	(136,473)
Accumulated other comprehensive loss	(2,510)	(960)
Total stockholders' equity	513,579	114,601
Total liabilities and stockholders' equity	$ 879,594	$ 405,919

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues	$ 88,544	$ 85,776	$ 245,258	$ 257,991
Cost of goods sold	52,284	44,187	145,148	127,745
Gross profit	36,260	41,589	100,110	130,246
Operating expenses				
Sales and marketing	11,609	10,151	28,044	31,496
General and administrative	18,217	18,061	55,586	43,943
Research and development	11,684	4,860	20,150	15,584
Total operating expenses	41,510	33,072	103,780	91,023
Operating (loss) income	(5,250)	8,517	(3,670)	39,223
Interest expense	2,808	2,356	6,668	11,491
Loss on extinguishment of debt	—	—	—	3,196
Other (income) loss	(596)	804	(1,702)	(1,695)
(Loss) income before income taxes	(7,462)	5,357	(8,636)	26,231
Income tax (benefit) expense	(1,076)	501	1,425	5,014
Net (loss) income	$ (6,386)	$ 4,856	$ (10,061)	$ 21,217
Net (loss) income per common share:				
Basic	$ (0.10)	$ 0.12	$ (0.20)	$ 0.55
Diluted	$ (0.10)	$ 0.12	$ (0.20)	$ 0.53
Weighted-average common shares outstanding:				
Basic	66,820	39,123	49,858	38,901
Diluted	66,820	40,286	49,858	40,123

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net (loss) income	$ (6,386)	$ 4,856	$ (10,061)	$ 21,217
Other comprehensive income (loss):				
Foreign currency translation	185	(33)	(9)	111
Unrealized loss on cash flow hedges, net of tax	(89)	—	(1,541)	—
Total other comprehensive income (loss)	96	(33)	(1,550)	111
Comprehensive (loss) income	$ (6,290)	$ 4,823	$ (11,611)	$ 21,328

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

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

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

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

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

	Nine Months Ended September 30, 2019					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance, January 1, 2019	38,466	$ 385	$ 239,865	$ (168,140)	$ (1,108)	$ 71,002
Net income	—	—	—	9,949	—	9,949
Other comprehensive income	—	—	—	—	56	56
Stock option exercises and employee stock plan purchases	37	—	606	—	—	606
Vesting of restricted stock awards and units	365	4	(4)	—	—	—
Shares withheld to cover taxes	(50)	(1)	(1,119)	—	—	(1,120)
Stock-based compensation	—	—	2,720	—	—	2,720
Balance, March 31, 2019	38,818	$ 388	$ 242,068	$ (158,191)	$ (1,052)	$ 83,213
Net income	—	—	—	6,412	—	6,412
Other comprehensive income	—	—	—	—	88	88
Stock option exercises and employee stock plan purchases	9	—	120	—	—	120
Vesting of restricted stock awards and units	253	3	(3)	—	—	—
Shares withheld to cover taxes	(37)	(1)	(943)	—	—	(944)
Stock-based compensation	—	—	3,358	—	—	3,358
Balance, June 30, 2019	39,043	$ 390	$ 244,600	$ (151,779)	$ (964)	$ 92,247
Net income	—	—	—	4,856	—	4,856
Other comprehensive loss	—	—	—	—	(33)	(33)
Stock option exercises and employee stock plan purchases	49	1	1,019	—	—	1,020
Vesting of restricted stock awards and units	153	2	(2)	—	—	—
Shares withheld to cover taxes	(16)	(1)	(346)	—	—	(347)
Stock-based compensation	—	—	3,423	—	—	3,423
Balance, September 30, 2019	39,229	$ 392	$ 248,694	$ (146,923)	$ (997)	$ 101,166

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

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

	Nine Months Ended September 30,	
	2020	**2019**
Operating activities		
Net (loss) income	$ (10,061)	$ 21,217
Adjustments to reconcile net (loss) income to net cash flows from operating activities:		
Depreciation, amortization and accretion	16,295	9,840
Impairment of long-lived assets	7,275	—
Amortization of debt related costs	199	809
Changes in fair value of contingent assets and liabilities	800	—
Loss on extinguishment of debt	—	3,196
Provision for bad debt	215	107
Provision for excess and obsolete inventory	1,870	1,699
Stock-based compensation	10,452	9,501
Deferred taxes	(781)	3,790
Long-term income tax receivable	(1,664)	(842)
Long-term income tax payable and other long-term liabilities	2,114	1,113
Other	819	229
Increases (decreases) in cash from operating assets and liabilities:		
Accounts receivable	(703)	3,078
Inventory	(9,593)	728
Other current assets	1,563	(196)
Accounts payable	3,762	1,454
Accrued expenses and other liabilities	(6,735)	2,240
Net cash provided by operating activities	15,827	57,963
Investing activities		
Capital expenditures	(8,689)	(17,320)
Lending on bridge loan	(10,000)	—
Cash acquired in acquisition of business	17,562	—
Net cash used in investing activities	(1,127)	(17,320)
Financing activities		
Proceeds from issuance of long-term debt	—	199,461
Payments on long-term debt and other borrowings	(11,166)	(272,821)
Equity issuance costs	(3,777)	—
Deferred financing costs	(1,223)	(2,034)
Proceeds from stock option exercises	77	1,173
Proceeds from issuance of common stock	683	573
Payments for minimum statutory tax withholding related to net share settlement of equity awards	(2,082)	(2,410)
Net cash used in financing activities	(17,488)	(76,058)
Effect of foreign exchange rates on cash, cash equivalents and restricted cash	4	76
Net decrease in cash, cash equivalents and restricted cash	(2,784)	(35,339)
Cash, cash equivalents and restricted cash, beginning of period	92,919	113,401
Cash, cash equivalents and restricted cash, end of period	$ 90,135	$ 78,062

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

	Nine Months Ended September 30,	
	2020	**2019**
Reconciliation to amounts within the condensed consolidated balance sheets		
Cash and cash equivalents	$ 87,994	$ 78,062
Restricted cash included in other long-term assets	2,141	—
Cash, cash equivalents and restricted cash at end of period	$ 90,135	$ 78,062

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, and references to "LMI" refer to Lantheus Medical Imaging, Inc., the direct subsidiary of Holdings. 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 Pharmaceuticals, Inc., a Delaware corporation ("Progenics") for the period from June 19 through September 30, 2020 (see "Acquisition of Progenics" below), and have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these condensed consolidated financial statements do not include all of the information and notes required by generally accepted accounting principles in the United States of America ("U.S. GAAP") for complete financial statements. In the opinion of management, all adjustments (consisting of normal and recurring adjustments) considered necessary for a fair statement have been included. The results of operations for the three and nine months ended September 30, 2020 are not necessarily indicative of the results that may be expected for the year ended December 31, 2020 or any future period.

The condensed consolidated balance sheet at December 31, 2019 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, 2019 filed with the Securities Exchange Commission ("SEC") on February 25, 2020.

Acquisition of Progenics

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 "Merger").

In accordance with the Merger Agreement, at the effective time of the Merger (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 Transaction, exceed 19.9% (which we estimate could be approximately $100 million) of the total consideration the Company pays in the Progenics Transaction. No fractional shares of Holdings common stock were issued in the Merger, and Progenics' former stockholders have received cash in lieu of any fractional shares of Holdings common stock.

In addition, in accordance with the Merger Agreement, at the Effective Time, each Progenics stock option with a per share exercise price less than or equal to $4.42 (an "in-the-money Progenics stock option") received in exchange for each such in-the money Progenics stock option: (i) an option to purchase Holdings common stock (each, a "Replacement Stock Option") converted based on the Exchange Ratio, and (ii) a vested or unvested CVR depending on whether the underlying in-the-money Progenics stock option was vested at the Effective Time. Each Progenics stock option with a per share exercise price greater than $4.42 (an "out-of-the-money Progenics stock option") received in exchange for such out-of-the-money Progenics stock options a Lantheus Stock Option converted at an exchange ratio determined based on the average of the volume weighted average price per share of common stock of Progenics and Lantheus Holdings prior to the Effective Time, which exchange ratio was 0.31, the same as the Exchange Ratio.

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. 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 Lantheus Stock Options as noted above. In addition, Lantheus assumed Progenics equity plans, which, on an as-converted basis, increased the number of Lantheus shares available for issuance by an aggregate of 4,211,290 shares prior to converting the stock options noted above, subject to certain limitations as to eligibility for issuance.

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 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 severity of 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 are 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 is currently unable to accurately predict the impact of COVID-19 on its overall 2020 operations and financial results or cash flows for the foreseeable future and whether the impact of COVID-19 could lead to potential future impairments.

2. Summary of Significant Accounting Policies

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. To qualify for hedge accounting, the hedging instrument must be highly effective at reducing the risk from the exposure being hedged. Further, the Company must formally document the hedging relationship at inception and, on at least a quarterly basis, continually reevaluate the relationship to ensure it remains highly effective throughout the life of the hedge. The Company does not enter into derivative financial instruments for speculative or trading purposes.

Business Combinations

The Company accounts for business combinations using the acquisition method of accounting. The Company recognizes the assets acquired and liabilities assumed in business combinations on the basis of their fair values at the date of acquisition. The Company assesses the fair value of assets acquired, including intangible assets, and liabilities assumed using a variety of methods. Each asset acquired and liability assumed is measured at fair value from the perspective of a market participant. The method used to estimate the fair values of intangible assets incorporates significant assumptions regarding the estimates a market participant would make in order to evaluate an asset, including a market participant’s use of the asset and the appropriate discount rates. Acquired in-process research and development (“IPR&D”) is recognized at fair value and initially characterized as an indefinite-lived intangible asset, irrespective of whether the acquired IPR&D has an alternative future use. Any excess purchase price over the fair value of the net tangible and intangible assets acquired is allocated to goodwill. Transaction costs and restructuring costs associated with a business combination are expensed as incurred.

During the measurement period, which extends no later than one year from the acquisition date, the Company may record certain adjustments to the carrying value of the assets acquired and liabilities assumed with the corresponding offset to goodwill. After the measurement period, all adjustments are recorded in the condensed consolidated statements of operations as operating expenses or income.

Contingent Consideration Liabilities

The estimated fair value of contingent consideration liabilities, initially measured and recorded on the acquisition date, are considered to be a Level 3 instrument and are reviewed quarterly, or whenever events or circumstances occur that indicate a change in

fair value. The contingent consideration liabilities are recorded at fair value at the end of each reporting period with changes in estimated fair values recorded in general and administrative expenses in the condensed consolidated statements of operations.

The estimated fair value is determined based on probability adjusted discounted cash flows and Monte Carlo simulation models that include 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 would result in a significantly higher or lower fair value measurement. Significant changes in the probabilities as to the periods in which milestones will be achieved would result in a significantly lower or higher fair value measurement.

Intangible and Long-Lived Assets

The Company's IPR&D represents intangible assets acquired in a business combination that are used in research and development activities but have not yet reached technological feasibility, regardless of whether they have alternative future use. The primary basis for determining the technological feasibility or completion of these projects is obtaining regulatory approval to market the underlying products in an applicable geographic region. Because obtaining regulatory approval can include significant risks and uncertainties, the eventual realized value of the acquired IPR&D projects may vary from their fair value at the date of acquisition. The Company classifies IPR&D acquired in a business combination as an indefinite-lived intangible asset until the completion or abandonment of the associated research and development efforts. Upon completion of the associated research and development efforts, the Company will determine the useful life and begin amortizing the assets to reflect their use over their remaining lives. Upon permanent abandonment, the Company writes-off the remaining carrying amount of the associated IPR&D intangible asset. IPR&D assets are tested at least annually or when a triggering event occurs that could indicate a potential impairment and any impairment loss is recognized in the Company's condensed consolidated statements of operations.

Recent Accounting Pronouncements

Standard	Description	Effective Date for Company	Effect on the Condensed Consolidated Financial Statements
Recently Issued Accounting Standards Not Yet Adopted			
Accounting Standards Adopted During the Nine Months Ended September 30, 2020			
ASU 2020-04, "Reference Rate Reform (Topic 848)"	This ASU provides optional guidance for a limited period of time to ease the potential burden in accounting for (or recognizing the effects of) reference rate reform on financial reporting.	January 1, 2020	The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.
ASU 2016-13, "Financial Instruments-Credit Losses (Topic 326)"	This ASU requires financial instruments measured at amortized cost and accounts receivable to be presented at the net amount expected to be collected. The new model requires an entity to estimate credit losses based on historical information, current information and reasonable and supportable forecasts that affect the collectability of the reported amount.	January 1, 2020	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 and reportable segment as follows:

Major Products/Service Lines by Segment (in thousands)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
U.S.				
Product revenue, net[1]	$ 73,080	$ 74,650	$ 208,482	$ 225,274
License and royalty revenues	4,395	—	5,137	—
Total U.S. revenues	77,475	74,650	213,619	225,274
International				
Product revenue, net[1]	10,581	10,587	30,319	31,123
License and royalty revenues	488	539	1,320	1,594
Total International revenues	11,069	11,126	31,639	32,717
Total revenues	$ 88,544	$ 85,776	$ 245,258	$ 257,991

(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'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 12, "Derivative Instruments", for further details on the interest rate swaps. The Company recorded a contingent receivable and the contingent consideration liabilities resulting from the acquisition of Progenics at fair value based on inputs that are not observable in the market. Please refer to Note 8, "Business Combinations", for further details on the acquisition.

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

	September 30, 2020			
(in thousands)	Total Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market	$ 43,710	$ 43,710	$ —	$ —
Contingent receivable	10,200	—	—	10,200
Total assets	$ 53,910	$ 43,710	$ —	$ 10,200
Liabilities:				
Interest rate swaps	$ 2,073	$ —	$ 2,073	$ —
Contingent consideration liabilities	17,200	—	—	17,200
Total liabilities	$ 19,273	$ —	$ 2,073	$ 17,200

	December 31, 2019			
(in thousands)	Total Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market	$ 39,530	$ 39,530	$ —	$ —
Total assets	$ 39,530	$ 39,530	$ —	$ —

During the three and nine months ended September 30, 2020, there were no transfers into or out of Level 3.

As part of the acquisition of Progenics, 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 acquisition of Progenics, 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. These contingent consideration liabilities include potential payments of up to $70.0 million if the Company attains certain net sales targets for AZEDRA and 1095 and a $5.0 million 1095 commercialization milestone. 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 September 30, 2020.

(in thousands)	Fair Value at September 30, 2020	Valuation Technique	Unobservable Input	Assumption
Contingent receivable:				
Regulatory milestone	$ 3,100	Probability adjusted discounted cash flow model	Period of expected milestone achievement	2021
			Probability of success	90 %
			Discount rate	23 %
Royalties	7,100	Probability adjusted discounted cash flow model		
			Probability of success	13% - 77%
			Discount rate	23 %
Total	$ 10,200			

(in thousands)	Fair Value at September 30, 2020	Valuation Technique	Unobservable Input	Assumption
Contingent consideration liability:				
Net sales targets - PyL (CVRs)	$ 3,900	Monte-Carlo simulation	Period of expected milestone achievement	2022 - 2023
			Discount rate	24 %
1095 commercialization milestone	2,200	Probability adjusted discounted cash flow model	Period of expected milestone achievement	2026
			Probability of success	45 %
			Discount rate	0.48 %
Net sales targets - AZEDRA and 1095	11,100	Monte-Carlo simulation	Probability of success	40% - 100%
			Discount rate	23% - 24%
Total	$ 17,200			

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

	Financial Assets	Financial Liabilities
(in thousands)	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2020
Fair value, beginning of period	$ —	$ —
Progenics acquisition	10,100	16,300
Changes in fair value included in net loss	100	900
Fair value, end of period	$ 10,200	$ 17,200

The change in fair value of the contingent financial asset and contingent financial liabilities of $0.8 million for the three and nine months ended September 30, 2020 were primarily due to 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:

(in thousands)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Income tax (benefit) expense	$ (1,076)	$ 501	$ 1,425	$ 5,014

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 has recorded valuation allowances of $3.2 million against the net deferred tax assets of certain foreign subsidiaries, as well as a valuation allowance of $0.7 million against net U.S. deferred tax assets due to the potential expiration of certain tax losses and state tax credits prior to utilization.

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 acquired the stock of Progenics Pharmaceuticals, Inc. in a transaction that is expected to qualify as a tax-deferred reorganization under Section 368 of the Internal Revenue Code of 1986, as amended. The transaction resulted in an ownership change of Progenics under Section 382 and a limitation on the utilization of Progenics' pre-transaction tax attributes. All of Progenics' pre-transaction 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 also recorded as part of the purchase accounting, resulting in a small net overall deferred tax liability for Progenics after the application of purchase accounting.

6. Inventory

Inventory consisted of the following:

(in thousands)	September 30, 2020	December 31, 2019
Raw materials	$ 15,774	$ 11,417
Work in process	14,330	9,450
Finished goods	7,519	8,313
Total inventory	$ 37,623	$ 29,180

7. Property, Plant and Equipment, Net

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

(in thousands)	September 30, 2020	December 31, 2019
Land	$ 13,450	$ 13,450
Buildings	70,263	75,654
Machinery, equipment and fixtures	92,012	87,763
Computer software	20,974	20,739
Construction in progress	14,395	10,546
	211,094	208,152
Less: accumulated depreciation and amortization	(88,713)	(91,655)
Total property, plant and equipment, net	$ 122,381	$ 116,497

Depreciation and amortization expense related to property, plant and equipment, net, was $3.4 million and $2.5 million for the three months ended September 30, 2020 and 2019, respectively, and $9.1 million and $7.5 million for the nine months ended September 30, 2020 and 2019, respectively.

The Company tests long-lived assets for recoverability whenever events or changes in circumstances suggest that the carrying value of an asset or group of assets may not be recoverable. During the three months ended 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 in the U.S. segment, the Company determined certain impairment triggers had occurred. Accordingly, the Company performed an undiscounted cash flow analysis as of March 31, 2020. Based on the undiscounted cash flow analysis, the Company determined that the manufacturing assets had net carrying values that exceeded their estimated undiscounted future cash flows. The Company then estimated the fair values of the asset group based on their discounted cash flows. The carrying value exceeded the fair value and as a result, the Company recorded a non-cash impairment of $7.3 million for the nine months ended September 30, 2020 in cost of goods sold in the condensed consolidated statement of operations.

8. Business Combinations

On June 19, 2020, the Company completed the acquisition of Progenics, an oncology company developing innovative medicines and artificial intelligence to find, fight and follow cancer. The acquisition combines the commercialization, supply chain and manufacturing expertise of the Company with the currently commercialized products and R&D pipeline of Progenics. Progenics brings 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 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 options related to pre-acquisition 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:

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

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

The transaction was accounted for as a business combination which requires that assets acquired and liabilities assumed be recognized at their fair value as of the acquisition date. While the Company uses its best estimates and assumptions as part of the purchase price allocation process to value the assets acquired and liabilities assumed on the acquisition date, its estimates and assumptions are subject to refinement. Fair value estimates are based on a complex series of judgments about future events and uncertainties and rely heavily on estimates and assumptions. The judgments used to determine the estimated fair value assigned to each class of assets acquired and liabilities assumed, as well as asset lives, can materially impact the Company's results of operations. The purchase price allocation is preliminary and is subject to change, including for the valuation and amortization of intangible assets, income taxes and related valuation allowances and certain assets and liabilities among other items. The amounts recognized will be finalized as the information necessary to complete the analysis is obtained, but no later than one year after the acquisition date. Any potential adjustments made could be material in relation to the preliminary values presented below.

The preliminary fair value of the assets acquired and liabilities assumed were as follows:

(in thousands)	Amount
Cash and cash equivalents	$ 15,421
Accounts receivable	5,787
Inventory	915
Other current assets	3,250
Property, plant and equipment	14,972
Identifiable intangible assets (weighted average useful life):	
Currently marketed product (15 years)	142,100
Licenses (11.5 years)	87,500
Developed technology (9 years)	3,000
IPR&D	150,900
Other long-term assets	37,631
Accounts payable	(1,616)
Accrued expenses and other liabilities	(8,207)
Other long-term liabilities	(30,778)
Long-term debt and other borrowings	(40,200)
Deferred tax liabilities	(3,717)
Goodwill	42,051
Total consideration transferred	$ 419,009

Intangible assets acquired consist of currently marketed products, licenses, developed technology and 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 24.0% 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 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 $42.1 million recognized in connection with the acquisition is not deductible for tax purposes and has been assigned to the U.S. operating segment.

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

Progenics Pro Forma Financial Information

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

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

	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
(in thousands)	Amount	Amount
Pro forma revenue	$ 256,163	$ 277,851
Pro forma net loss	27,143	47,032

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

9. 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 and San Juan, Puerto Rico sites. As of September 30, 2020, the liability is measured at the present value of the obligation expected to be incurred, of approximately $26.9 million.

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

(in thousands)	Amount
Balance at January 1, 2020	$ 12,883
Accretion expense	1,079
Balance at September 30, 2020	$ 13,962

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.

10. Intangibles, Net

Intangibles, net, consisted of the following:

(in thousands)	Amortization Method	September 30, 2020 Cost	Accumulated Amortization	Net
Trademarks	Straight-Line	$ 13,540	$ (10,820)	$ 2,720
Customer relationships	Accelerated	98,966	(95,528)	3,438
Currently marketed product	Straight-Line	142,100	(2,658)	139,442
Licenses	Straight-Line	87,500	(2,159)	85,341
Developed technology	Straight-Line	3,000	(94)	2,906
IPR&D	N/A	150,900	—	150,900
Total		$ 496,006	$ (111,259)	$ 384,747

(in thousands)	Amortization Method	December 31, 2019 Cost	Accumulated Amortization	Net
Trademarks	Straight-Line	$ 13,540	$ (10,407)	$ 3,133
Customer relationships	Accelerated	99,019	(94,816)	4,203
Total		$ 112,559	$ (105,223)	$ 7,336

The Company recorded amortization expense for its intangible assets of $4.8 million and $0.5 million for the three months ended September 30, 2020 and 2019, respectively, and $6.1 million and $1.4 million for the nine months ended September 30, 2020 and 2019, respectively.

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

(in thousands)	Amount
2020	$ 4,769
2021	18,813
2022	18,684
2023	18,074
2024	17,998
2025 and thereafter	155,509
Total	$ 233,847

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

As of September 30, 2020, the Company's maturities of principal obligations under its long-term debt and other borrowings are as follows:

(in thousands)	Amount
Remainder of 2020	$ 4,328
2021	19,588
2022	26,217
2023	22,928
2024	148,750
Total principal outstanding	221,811
Unamortized debt premium	1,230
Unamortized debt issuance costs	(644)
Finance lease liabilities	410
Total	222,807
Less: current portion	(18,138)
Total long-term debt, net and other borrowings	$ 204,669

At September 30, 2020, the Company's interest rate under the 2019 Term Facility was 3.4%.

On June 19, 2020, the Company amended its 2019 Credit Agreement ("the Amendment") as a result of the impact of the COVID-19 pandemic on the business and operations of the Company and the near-term higher level of indebtedness resulting from the Company's decision not to immediately repay the Progenics debt secured by the RELISTOR royalties following the Company's acquisition of Progenics. The Company accounted for the Amendment as a debt modification and capitalized $1.2 million of associated costs.

The Amendment provides for, among other things, modifications to LMI's financial maintenance covenants. The covenant related to Total Net Leverage Ratio (as defined in the Amended Credit Agreement) has been 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
Q3 2020 to 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 LMI delivers a compliance certificate for the fiscal quarter ending March 31, 2021.

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 LMI's 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 LMI's Total Net Leverage Ratio.

On June 19, 2020, as a result of the acquisition, the Company 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 have 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 Health Companies Inc. ("Bausch"). The RELISTOR royalty payments will be used to repay the principal and interest on the loan. The Royalty-Backed Loan bears interest at a per annum rate of 9.5% and matures 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 Transaction 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, are 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 are used to repay the principal of the loan, with the balance retained by the Company. Starting on September 30, 2021, all of the RELISTOR royalties received since the immediately-preceding payment date will be used to repay the interest and outstanding principal balance until the balance is fully repaid.

12. Derivative Instruments

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

(in thousands)		September 30, 2020	December 31, 2019
Derivatives type	**Classification**		
Liabilities:			
Interest rate swap	Accrued expenses and other liabilities	$ 2,073	$ —

13. Accumulated Other Comprehensive Loss

The components of Accumulated Other Comprehensive Loss, net of tax of $0.5 million and $0.0 million for the nine months ended September 30, 2020 and 2019, respectively, consisted of the following:

(in thousands)	Foreign currency translation	Unrealized loss on cash flow hedges	Accumulated other comprehensive loss
Balance at January 1, 2020	$ (960)	$ —	$ (960)
Other comprehensive loss before reclassifications	(9)	(1,784)	(1,793)
Amounts reclassified to earnings	—	243	243
Balance at September 30, 2020	$ (969)	$ (1,541)	$ (2,510)
Balance at January 1, 2019	$ (1,108)	$ —	$ (1,108)
Other comprehensive income before reclassifications	111	—	111
Amounts reclassified to earnings	—	—	—
Balance at September 30, 2019	$ (997)	$ —	$ (997)

14. Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2020	2019	2020	2019
Cost of goods sold	$ 864	$ 568	$ 2,127	$ 1,539
Sales and marketing	621	518	1,268	1,477
General and administrative	1,926	1,948	5,735	5,403
Research and development	581	389	1,322	1,082
Total stock-based compensation expense	$ 3,992	$ 3,423	$ 10,452	$ 9,501

15. Net (Loss) Income Per Common Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share amounts)	2020	2019	2020	2019
Net (loss) income	$ (6,386)	$ 4,856	$ (10,061)	$ 21,217
Basic weighted-average common shares outstanding	66,820	39,123	49,858	38,901
Effect of dilutive stock options	—	85	—	82
Effect of dilutive restricted stock	—	1,078	—	1,140
Diluted weighted-average common shares outstanding	66,820	40,286	49,858	40,123
Basic (loss) income per common share	$ (0.10)	$ 0.12	$ (0.20)	$ 0.55
Diluted (loss) income per common share	$ (0.10)	$ 0.12	$ (0.20)	$ 0.53
Antidilutive securities excluded from diluted net (loss) income per common share	2,588	48	1,657	44

16. Other (Income) Loss

Other (income) loss consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2020**	**2019**	**2020**	**2019**
Foreign currency (gains) losses	$ (33)	$ 96	$ 187	$ 7
Tax indemnification (income) expense, net	(555)	762	(1,664)	(842)
Interest income	(7)	(54)	(221)	(613)
Other	(1)	—	(4)	(247)
Total other (income) loss	$ (596)	$ 804	$ (1,702)	$ (1,695)

17. Commitments and Contingencies

Legal Proceedings

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

As of September 30, 2020, the Company had the following material ongoing litigation in which the Company was a party:

RELISTOR Subcutaneous Injection

Between November 19, 2015 and September 18, 2017, Progenics, Salix, Valeant (now Bausch) and Wyeth filed multiple lawsuits against Mylan Pharmaceuticals and certain of its affiliates (collectively, "Mylan") in the United States District Court for the District of New Jersey (the "Court") for infringement of certain U.S. patents based upon Mylan's filing of multiple ANDAs seeking to obtain approval to market a generic version of RELISTOR subcutaneous injection before some or all of those patents expire. These actions were later consolidated into two separate actions in the District of New Jersey.

On May 1, 2018, in the lead action, the Court granted Plaintiffs' motion for partial summary judgment as to the validity of a particular claim that Mylan had admitted it infringed. On May 23, 2018, the Court entered an order for final judgment in favor of Plaintiffs and against Mylan on that particular claim. As a result, trial on the merits in the lead action was adjourned, allowing trial, if necessary, to be consolidated with the lagging, second action. On August 20, 2020, the parties agreed to dismiss all claims, affirmative defenses, and counterclaims in the lagging action and proceed to a full trial on the merits for the patents asserted in the lead action. A date for trial has not yet been set.

On May 25, 2018, Mylan filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit ("CAFC"). On April 8, 2020, the CAFC issued its decision reversing the Court's grant of summary judgment and remanding for further proceedings. On June 22, 2020, Plaintiffs filed a petition for rehearing/rehearing en banc, and on July 24, 2020, that petition was denied.

RELISTOR Tablets - Actavis

Between December 6, 2016 and December 8, 2017, Progenics, Salix, Bausch, and Wyeth filed suit against Actavis, Actavis LLC, Teva Pharmaceuticals USA, Inc., and Teva Pharmaceuticals Industries Ltd. (collectively, "Actavis") in the Court for infringement of certain U.S. patents based upon Actavis's filing of an ANDA seeking to obtain approval to market a generic version of RELISTOR tablets before some or all of those patents expire. The actions were later consolidated into a single action in the Court.

On May 6-9, 2019, a bench trial was held, and on July 17, 2019, the Court issued an Order finding the asserted claims of a certain U.S. patent valid and infringed. The Court additionally ordered that the effective date of any approval of Actavis's ANDA may not be earlier than the expiration date of that patent. Actavis filed an appeal of the Court's decision with the CAFC on August 13, 2019. The matter is currently pending on appeal at the CAFC and merits briefing is underway. Actavis's opening brief was filed

February 6, 2020. The Plaintiffs filed their responsive brief on September 15, 2020. Actavis's reply brief is currently due on November 5, 2020.

On June 13, 2019, Progenics, Salix, Bausch, and Wyeth filed another suit against Actavis in the Court for infringement of a separate, and at that time, recently granted U.S. patent based upon Actavis's filing of an ANDA seeking to obtain approval to market a generic version of RELISTOR tablets before this patent expires. Litigation in this action is underway, and fact discovery has begun.

RELISTOR European Opposition Proceedings

In addition to the above described ANDA notifications, in October 2015, Progenics received notices of opposition to three European patents relating to methylnaltrexone. 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 are on appeal with the European Patent Office. Oral proceedings for 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. Oral proceedings are set to occur on November 17, 2020 and November 18, 2020 for EP2368553 and EP2368554, respectively.

For each of the above-described RELISTOR proceedings, Progenics and Bausch continue to cooperate closely to vigorously defend and enforce RELISTOR intellectual property rights. Pursuant to the RELISTOR license agreement between Progenics and Bausch, Bausch has the first right to enforce the intellectual property rights at issue and is responsible for the costs of such enforcement. Because the outcome of litigation is uncertain and in these RELISTOR proceedings the Company does not control the enforcement of the intellectual property rights at issue, no assurance can be given as to how or when any of these RELISTOR proceedings 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 of Mannheim in 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 the corresponding US patent applications. 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. On March 6, 2020, MIP filed with the USPTO a notice stating that the Power of Attorney in certain pending US 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.

On September 24, 2020, MIP filed a Notice of Appeal of the German District Court's decision. 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 District 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, we cannot predict how or when this matter will ultimately be resolved.

Whistleblower Complaint

In July 2019, Progenics received notification of a complaint submitted by Dr. Syed Mahmood, the former Vice President of Medical Affairs for Progenics, to the Occupational Safety and Health Administration of the United States Department of Labor ("DOL"), alleging that the termination of his employment by Progenics was in violation of Section 806 of the Sarbanes-Oxley Act of

2002 (“SOX”). Dr. Mahmood sought reinstatement to his former position of Vice President of Medical Affairs, back pay, front pay in lieu of reinstatement, interest, attorneys’ fees and costs incurred, and special damages. In March 2020, Dr. Mahmood filed a complaint in the U.S. District Court for the Southern District of New York (as permitted by SOX because the DOL had not issued a decision within 180 days). Dr. Mahmood’s federal complaint asserts claims of violation of Section 806 of SOX. The DOL action has been dismissed and the matter will proceed in federal district court. Progenics filed an answer to Dr. Mahmood’s complaint on August 26, 2020 and the initial pre-trial conference was held on September 16, 2020.

The Company believes the claims in this matter are without merit, and the Company has meritorious defenses to the claims. The Company intends to vigorously defend against the claims.

The Company is unable to estimate the potential liability with respect to the legal matters noted above. There are numerous factors that make it difficult to estimate reasonably possible loss or range of loss at the various stages of the legal proceedings noted above, including the significant number of legal and factual issues still to be resolved in those various legal proceedings.

18. Segment Information

The Company reports two operating segments, U.S. and International, based on geographic customer base. The results of these operating segments are regularly reviewed by the Company's chief operating decision maker, the President and Chief Executive Officer. The Company's segments derive revenues through the manufacture, marketing, selling and distribution of innovative diagnostic and therapeutic agents and products. All goodwill has been allocated to the U.S. operating segment. The Company does not identify or allocate assets to its segments.

Selected information regarding the Company's segments is provided as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2020**	**2019**	**2020**	**2019**
Revenue by product from external customers				
U.S.				
DEFINITY	$ 53,792	$ 50,917	$ 148,346	$ 154,099
TechneLite	17,652	18,281	52,599	55,204
Other nuclear	11,571	9,355	26,437	28,006
Rebates and allowances	(5,540)	(3,903)	(13,763)	(12,035)
Total U.S. Revenues	77,475	74,650	213,619	225,274
International				
DEFINITY	1,637	1,478	4,239	4,036
TechneLite	3,837	3,466	10,897	10,794
Other nuclear	5,596	6,186	16,507	17,901
Rebates and allowances	(1)	(4)	(4)	(14)
Total International Revenues	11,069	11,126	31,639	32,717
Worldwide				
DEFINITY	55,429	52,395	152,585	158,135
TechneLite	21,489	21,747	63,496	65,998
Other nuclear	17,167	15,541	42,944	45,907
Rebates and allowances	(5,541)	(3,907)	(13,767)	(12,049)
Total Revenues	$ 88,544	$ 85,776	$ 245,258	$ 257,991

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2020**	**2019**	**2020**	**2019**
Operating (loss) income				
U.S.	$ (6,621)	$ 6,389	$ (7,634)	$ 33,662
International	1,371	2,128	3,964	5,561
Total operating (loss) income	(5,250)	8,517	(3,670)	39,223
Interest expense	2,808	2,356	6,668	11,491
Loss on extinguishment of debt	—	—	—	3,196
Other (income) loss	(596)	804	(1,702)	(1,695)
(Loss) income before income taxes	$ (7,462)	$ 5,357	$ (8,636)	$ 26,231

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

Cautionary Note Regarding Forward-Looking Statements

Some of the statements contained in this Quarterly Report on Form 10-Q are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements, including, in particular, statements about our plans, strategies, prospects and industry estimates are subject to risks and uncertainties. These statements identify prospective information and 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 or prospects, or 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) the global Molybdenum-99 ("Mo-99") supply; (iv) our products manufactured at Jubilant HollisterStier ("JHS") and our plans to develop a modified formulation of DEFINITY ("DEFINITY RT") with Samsung Biologics ("SBL"); (v) our efforts in new product development, including for PyL, the Progenics prostate cancer diagnostic imaging agent, including our ability to obtain FDA approval of PyL in 2021, and new clinical applications for our products; (vi) our dependence upon third parties for the manufacture and supply of PyL and the timing of that manufacturing capacity becoming available; (vii) the continued integration of the Progenics product and product candidate portfolio following the consummation of the Progenics transaction (the "Progenics Transaction"); (viii) our capacity to use in-house manufacturing; (ix) our ability to commercialize our products in new ex-U.S. markets; (x) the expected timing for commercialization of products we or our strategic partners may develop, including flurpiridaz F 18; and (xi) our ability to develop highly contextualized assessments of disease burden using PSMA 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. Important factors that could cause actual results to differ materially from those in the forward-looking statements include regional, national or global political, economic, business, competitive, market and regulatory conditions and the following:

- The impact of the on-going global COVID-19 pandemic on our business, financial condition or prospects, including a decline in the volume of procedures and treatments using our products, potential delays and disruptions to global supply chains, manufacturing activities, logistics, operations, clinical development programs, employees and contractors, the business activities of our suppliers, distributors, customers and other business partners, as well as the effects on worldwide economies, financial markets, social institutions, labor markets and healthcare systems;
- Our ability to continue to grow the appropriate use of DEFINITY in suboptimal echocardiograms in the face of segment competition from other echocardiography contrast agents, including Optison from GE Healthcare Limited ("GE Healthcare") and Lumason from Bracco Diagnostics Inc. ("Bracco"), and potential generic competition as a result of patent and regulatory exclusivity expirations;
- The instability of the global Mo-99 supply, including (i) periodic outages at the NTP Radioisotopes ("NTP") processing facility in South Africa in 2017, 2018 and 2019, and (ii) a recently resolved production volume limitations at the Australian Nuclear Science and Technology Organisation's ("ANSTO") new Mo-99 processing facility in Australia, in each case resulting in our inability to fill some or all of the demand for our TechneLite generators on certain manufacturing days during the outage periods;
- Our dependence upon third parties for the manufacture and supply of a substantial portion of our products, raw materials and components, including DEFINITY at JHS;
- Risks related to the continued integration of the Progenics Transaction, including:
    - The integration of the Progenics Transaction may involve unexpected costs, liabilities or delays;
    - The ability of our combined business to retain and hire key personnel and maintain relationships with customers, suppliers and others with whom we or Progenics do business,
    - Unanticipated risks to our integration plan including in connection with timing, talent, and the potential need for additional resources;
    - New or previously unidentified manufacturing, regulatory, or research and development issues in the Progenics business;

  - Risks that the anticipated benefits of the Progenics Transaction or other commercial opportunities may otherwise not be fully realized or may take longer to realize than expected;
  - Risks that contractual contingent value rights ("CVRs") we issued as part of the Progenics Transaction may result in substantial future payments and could divert the attention of our management; and
  - The impact of legislative, regulatory, competitive and technological changes on the combined business;
- Risks related to the commercialization of AZEDRA, including in connection with market acceptance and reimbursement, that may cause the product not to meet revenue or operating income expectations;
- Risks related to RELISTOR, commercialized by Bausch, and that the revenues generated for us thereby may not meet expectations;
- Risks associated with our lead agent in development, PyL, for which we filed a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") on September 29, 2020, including:
  - Our ability to obtain FDA approval of PyL in 2021; and
  - Our ability to successfully gain post-approval market acceptance and adequate reimbursement for PyL in the U.S. and on a global basis (other than Europe, where the agent has been previously out-licensed to Curium, and in Australia and New Zealand, where we do not have commercialization rights);
  - Our dependence upon third parties for the manufacture and supply of PyL and the timing of that manufacturing capacity becoming available;
- Risks associated with flurpiridaz F 18, which in 2017 we out-licensed to GE Healthcare, including:
  - GE Healthcare's ability to successfully complete the Phase 3 development program, including delays in enrollment that have resulted from the COVID-19 pandemic;
  - GE Healthcare's ability to obtain FDA approval; and
  - GE Healthcare's ability to gain post-approval market acceptance and adequate reimbursement;
- Risks associated with our DEFINITY RT candidate, including our ability to obtain FDA approval and gain post-approval market acceptance and adequate reimbursement;
- Risks associated with 1095, including delays in enrollment that have resulted from the COVID-19 pandemic and our ability to successfully complete the Phase 2 study in metastatic castrate-resistant prostate cancer ("mCRPC");
- Our ability to identify and acquire or in-license additional products, businesses or technologies to drive our future growth;
- Our ability to protect our intellectual property and the risk of claims that we have infringed on the intellectual property of others;
- Risks associated with the technology transfer programs to secure production of our products at additional contract manufacturer sites, including DEFINITY RT at Samsung BioLogics ("SBL") in South Korea;
- Risks associated with our investment in, and construction of, additional specialized manufacturing capabilities at our North Billerica, Massachusetts facility, including our ability to bring the new capabilities online by 2021;
- Our dependence on key customers for certain of our products, and our ability to maintain and profitably renew our contracts with those key customers, including GE Healthcare, Cardinal Health ("Cardinal"), United Pharmacy Partners ("UPPI"), Jubilant Radiopharma formerly known as Triad Isotopes, Inc. ("Jubilant Radiopharma") and PharmaLogic Holdings Corp ("PharmaLogic");
- Risks associated with the manufacturing and distribution of our products and the regulatory requirements related thereto;
- The dependence of certain of our customers upon third-party healthcare payors and the uncertainty of third-party coverage and reimbursement rates;
- The existence and market success of competitor products;
- Uncertainties regarding the impact of U.S. and state healthcare reform measures and proposals on our business, including measures and proposals related to reimbursement for our current and potential future products, controls over drug pricing, drug pricing transparency and generic drug competition;
- Our being subject to extensive government regulation and oversight, our ability to comply with those regulations and the costs of compliance;
- Potential liability associated with our marketing and sales practices;

- The occurrence of any serious or unanticipated side effects with our products;
- Our exposure to potential product liability claims and environmental, health and safety liability;
- Our ability to introduce new products and adapt to an evolving technology and medical practice landscape;
- Risks associated with prevailing economic or political conditions and events and financial, business and other factors beyond our control;
- Risks associated with our international operations, including potential global disruptions in air transport due to COVID-19, which could adversely affect our international supply chains for radioisotopes and other critical materials as well as international distribution channels for our commercial products;
- Our ability to adequately qualify, operate, maintain and protect our facilities, equipment and technology infrastructure;
- Our ability to hire or retain skilled employees and key personnel;
- Our ability to utilize, or limitations in our ability to utilize, net operating loss carryforwards to reduce our future tax liability;
- Risks related to our outstanding indebtedness and our ability to satisfy those obligations;
- Costs and other risks associated with the Sarbanes-Oxley Act and the Dodd-Frank Act, including in connection with becoming a large accelerated filer as of December 31, 2019;
- Risks related to the ownership of our common stock; and
- Other factors that are described in Part I, Item 1A. “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2019, in Part II, Item 1A. “Risk Factors” in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2020 and June 30, 2020, and in Part II, Item 1A. “Risk Factors” in this Quarterly Report on Form 10-Q.

Factors that could cause or contribute to such differences include, but are not limited to, those that are discussed in other documents we file with the SEC. 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 in 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, 2019, in Part II, Item 1A. “Risk Factors” in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2020 and June 30, 2020, and in Part II, Item 1A. “Risk Factors” in this Quarterly Report on Form 10-Q.

Overview

Our Business

We are a global leader in the development, manufacture and commercialization of innovative diagnostic and therapeutic agents and products that assist clinicians in the diagnosis and treatment of heart disease, cancer and other diseases. For our diagnostic agents, 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 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 sell our products globally and operate our business in two reportable segments, which are further described below:

- *U.S. Segment* produces and markets our agents and products throughout the U.S. In the U.S., we primarily sell to radiopharmacies, integrated delivery networks, hospitals, clinics and group practices.
- *International Segment* operations consist of production and distribution activities in Puerto Rico and some direct distribution activities in Canada. Additionally, within our International Segment, we have established and maintain third-party distribution relationships under which different products are marketed and sold in Europe, Canada, Australia, Asia-Pacific and Latin America.

Acquisition of Progenics

On June 19, 2020, we completed the acquisition of Progenics. 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 therapeutic agents designed to target cancer (AZEDRA, 1095 and PSMA TTC), as well as imaging agents designed to target PSMA for prostate cancer (PyL and 1404). Progenics' current revenue is generated from two principal sources: first AZEDRA sales, and second, royalties, development and commercial milestones from strategic partnerships, in particular royalties from Bausch from sales of RELISTOR.

Holdings issued 26,844,877 shares of Holdings common stock and 86,630,633 CVRs to former Progenics stockholders in connection with the Merger. 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 Lantheus Stock Options at an exchange ratio of 0.31.

As a result of the Progenics Transaction, Lantheus added the following products and product candidates to its portfolio:

Product / Product Candidate	Description	Status	Market	Rights
Ultra-Orphan Therapeutic				
AZEDRA (iobenguane I 131) 555 MBq/mL injection	Unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma	Approved	U.S	Progenics
Prostate Cancer Diagnostics and Therapeutics				
PyL (18F-DCFPyL)	PSMA-targeted PET/CT imaging agent for prostate cancer	NDA filed on September 29, 2020	Worldwide (ex. EU, AU, & NZ)	Progenics
PyL (18F-DCFPyL)	PSMA-targeted PET/CT imaging agent for prostate cancer	Discussions with European Medicines Agency (EMA)	Europe	Curium
1095 (I 131 1095)	PSMA-targeted small molecule therapeutic for treatment of metastatic prostate cancer	Phase 2	Worldwide	Progenics
PSMA TTC (BAY 2315497)	PSMA-targeted antibody conjugate therapeutic for treatment of metastatic prostate cancer	Phase 1	Worldwide	Bayer
1404	Technetium-99m PSMA-targeted SPECT/CT imaging agent for prostate cancer	Discussions with EMA	Europe	ROTOP
Digital Solutions				
PSMA AI	Imaging analysis technology that uses artificial intelligence and machine learning to assist readers in the quantification and standardized reporting of PSMA-targeted imaging	Investigational Use Only	Worldwide	Progenics
Automated Bone Scan Index (aBSI)	Automated reading and quantification of bone scans of prostate cancer patients using artificial intelligence and deep learning	Approved in the U.S. and E.U. 510(k) cleared in the U.S. CE marked (E.U. countries)	Worldwide	Progenics
Automated Bone Scan Index (BONENAVI)	Automated reading and quantification of bone scans of prostate cancer patients using artificial intelligence and deep learning	Approved	Japan	FUJIFILM
Other Partnerships				
RELISTOR Subcutaneous Injection (methylnaltrexone bromide)	OIC in adults with chronic non-cancer pain or advanced-illness adult patients	Approved	Worldwide	Bausch
RELISTOR Tablets (methylnaltrexone bromide)	OIC in adults with chronic non-cancer pain	Approved	U.S.	Bausch
Leronlimab (PRO 140)	HIV Infection	CytoDyn is working to provide information required by the FDA in order to resubmit a BLA	U.S.	CytoDyn

See Part I, Item 1A. “Risk Factors” in our Annual Report on form 10-K for the year ended December 31, 2019, and Part II, Item 1A. “Risk Factors” in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2020 and June 30, 2020 for information regarding certain risks associated with our acquisition of Progenics.

Our Expanded Portfolio

Our commercial products now include the following:

- DEFINITY is a microbubble contrast agent used in ultrasound exams of the heart, also known as echocardiography exams. DEFINITY contains perflutren-containing lipid microspheres and is indicated in the U.S. for use in patients with suboptimal echocardiograms to assist in imaging the left ventricular chamber and left endocardial border of the heart in ultrasound procedures. We believe we are currently the leading provider of ultrasound microbubble contrast agents in the world.
- TechneLite is a Technetium (“Tc-99m”) generator that provides the essential nuclear material used by radiopharmacies to radiolabel Cardiolite, Neurolite and other Tc-99m-based radiopharmaceuticals used in nuclear medicine procedures. TechneLite uses Mo-99 as its active ingredient.
- Neurolite is an injectable, Tc-99m-labeled imaging agent used with SPECT technology to identify the area within the brain where blood flow has been blocked or reduced due to stroke.

- Xenon Xe 133 Gas ("Xenon") is a radiopharmaceutical gas that is inhaled and used to assess pulmonary function and also to image cerebral blood flow. Our Xenon is manufactured by a third party as a bi-product of Mo-99 production and is processed and finished by us. We believe we are currently the leading provider of Xenon in the U.S.
- RELISTOR (methylnaltrexone bromide) is a treatment for opioid-induced constipation ("OIC") that decreases the constipating side effects induced by opioid pain medications such as morphine and codeine without diminishing their ability to relieve pain. RELISTOR is approved in two forms: a subcutaneous injection (12 mg and 8 mg) and an oral tablet (450 mg once daily).
- FDG is an injectable, fluorine-18-radiolabeled imaging agent used with PET technology to identify and characterize tumors in patients undergoing oncologic diagnostic procedures. We manufacture and distribute FDG from our Puerto Rico radiopharmacy.
- Cardiolite, also known by its generic name sestamibi, is an injectable, Tc-99m-labeled imaging agent used in myocardial perfusion imaging ("MPI") procedures to assess blood flow to the muscle of the heart using SPECT. Cardiolite was approved by the FDA in 1990 and its market exclusivity expired in July 2008. Included in Cardiolite revenues are branded Cardiolite and generic sestamibi revenues.
- Thallium TI 201 is an injectable radiopharmaceutical imaging agent used in MPI studies to detect cardiovascular disease. We manufacture Thallium using cyclotron technology.
- Gallium (Ga 67) is an injectable radiopharmaceutical imaging agent used to detect certain infections and cancerous tumors, especially lymphoma. We manufacture Gallium using cyclotron technology.
- AZEDRA (iobenguane I 131) is a radiotherapeutic, approved for the treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy. AZEDRA is the first and only FDA-approved therapy for this indication.
- Quadramet is an injectable radiopharmaceutical used to treat severe bone pain associated with osteoblastic metastatic bone lesions. We serve as the direct manufacturer and supplier of Quadramet in the U.S.
- Automated Bone Scan Index ("aBSI") calculates the disease burden of prostate cancer by quantifying the hotspots on bone scans and automatically calculating the bone scan index value, representing the disease burden of prostate cancer shown on the bone scan. This quantifiable and reproducible calculation of the bone scan index value is intended to aid in the diagnosis and treatment of men with prostate cancer and may have utility in monitoring the course of the disease. The Japanese rights to the stand-alone aBSI have been transferred and sold to FUJIFILM Toyama Chemical Co. Ltd. ("FUJIFILM") under the name BONENAVI®. The cloud based aBSI was cleared by the FDA for clinical use in the U.S. on August 5, 2019. In February 2020, Progenics received CE marking for the standalone workstation model of aBSI, meeting the quality standards set by the European Economic Area. In September 2020, the FDA granted 510(k) clearance for the use of aBSI on a GE Healthcare system.
- Cobalt (Co 57) is a non-pharmaceutical radiochemical used in the manufacture of sources for the calibration and maintenance of SPECT imaging cameras.

Sales of our microbubble contrast agent, DEFINITY, are made in the U.S. and Canada through a DEFINITY direct sales team. In the U.S., our nuclear imaging products, including TechneLite, Xenon, Neurolite and Cardiolite, are primarily distributed through commercial radiopharmacies, the majority of which are controlled by or associated with GE Healthcare, Cardinal, UPPI, Jubilant Radiopharma and PharmaLogic. A small portion of our nuclear imaging product sales in the U.S. are made through our direct sales force to hospitals and clinics that maintain their own in-house radiopharmaceutical preparation capabilities. We own one radiopharmacy in Puerto Rico where we sell our own products as well as products of third parties to end-users. AZEDRA is also sold in the U.S. through an AZEDRA direct sales team. RELISTOR was licensed to Bausch, and we collect quarterly royalties based on those sales.

We also maintain our own direct sales force in Canada for certain of our products. In Europe, Australia, Asia-Pacific and Latin America, we generally rely on third-party distributors to market, sell and distribute our nuclear imaging and contrast agent products, either on a country-by-country basis or on a multi-country regional basis. Our headquarters are located in North Billerica, MA with offices in New York, NY, Somerset, NJ, San Juan, PR, Montreal, Canada and Lund, Sweden.

Product Candidates

In addition to our commercial products, we now have an extensive portfolio of product candidates in clinical development, including:

- **PyL** (also known as 18F-DCFPyL) is a fluorine 18-based PSMA-targeted PET imaging agent that enables 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 NDA with the FDA on September 29, 2020, requesting priority review.
- **Flurpiridaz F 18** is a fluorine 18-based PET MPI agent designed to assess blood flow to the heart. On April 25, 2017, we announced entering into a definitive, exclusive Collaboration and License Agreement with GE Healthcare for the agent's continued Phase 3 development and worldwide commercialization. The second Phase 3 trial is now underway; however, because of the COVID-19 pandemic, enrollment in the global clinical development program had been delayed and has now resumed at a slower recruiting pace. GE Healthcare now expects to complete enrollment by mid-2021 and, assuming regulatory approval, begin commercialization in early 2023.
- **LMI 1195** is a fluorine 18-based PET imaging agent for the norepinephrine pathway. We are currently designing two Phase 3 clinical trials for the use of LMI 1195 for the diagnosis and management of neuroendocrine tumors in pediatric and adult populations, respectively. The FDA has granted an Orphan Drug designation for the use of LMI 1195 in the management indication. We have also received notice of eligibility for a rare pediatric disease priority review voucher for a subsequent human drug application so long as LMI 1195 is approved by the FDA for its rare pediatric disease indication prior to September 30, 2022.
- **1095** (also known as I-131-1095) is a PSMA-targeted iodine-131 labeled small molecule that is designed to deliver a dose of beta radiation directly to prostate cancer cells with minimal impact on the surrounding healthy tissues. Following the removal of the import alert on Centre for Probe Development & Commercialization ("CPDC"), Progenics initiated eleven clinical sites in the U.S. along with the six active sites in Canada to support enrollment in the Company's multicenter, randomized, controlled, ARROW Phase 2 study in mCRPC. Because of the COVID-19 pandemic, Progenics new enrollment in the Phase 2 trial was paused to minimize the risk to subjects and healthcare providers during the pandemic. For subjects who are active and have been randomized for the study, they continue to receive treatment doses and are being monitored for safety and efficacy in a manner that is permissible by each clinical site. New enrollment in the ARROW Phase 2 study restarted in October 2020.
- **PSMA TTC** is a thorium-227 labeled PSMA-targeted antibody therapeutic. PSMA TTC is designed to deliver a dose of alpha radiation directly to prostate cancer cells with minimal impact on the surrounding healthy tissues. Bayer AG ("Bayer") has exclusive worldwide rights to develop and commercialize products using our PSMA antibody platform in combination with Bayer's alpha-emitting radionuclides. Bayer is conducting a Phase 1 trial of PSMA TTC in subjects with mCRPC.
- **1404** is a Tc-99m labeled small molecule which binds to PSMA and is used as a SPECT/CT imaging agent to diagnose and detect localized prostate cancer as well as soft tissue and bone metastases. ROTOP has exclusive rights to develop, manufacture and commercialize 1404 in Europe.
- **PSMA AI** is an imaging analysis technology that uses artificial intelligence and machine learning to assist readers in the quantification and standardized reporting of PSMA-targeted imaging. Progenics recently completed a performance study of automated segmentation algorithms with PyL/CT images from our PyL research access initiative. The study demonstrated the efficiency and effectiveness of a fully automated segmentation algorithm of the 49 bones and 12 soft tissue regions of the whole body from PyL-PSMA PET/CT images. This technology provides automated generation of lesion quantification, localization and staging. We believe this leads to highly contextualized assessments of disease burden.
- **Leronlimab** (PRO 140) is an investigational humanized IgG4 mAb that blocks CCR5, a cellular receptor that is important in HIV infection, tumor metastases, and other diseases including certain liver diseases. It is owned by CytoDyn Inc. ("CytoDyn") pursuant to our agreement with CytoDyn, as described below. In May 2020, CytoDyn announced it submitted a Biologics License Application ("BLA") to the FDA for approval of Leronlimab in combination therapy for HIV infection. On July 13, 2020, CytoDyn announced that it had received a refusal to file letter from the FDA for the BLA. On August 20, 2020, CytoDyn announced that the FDA recommended that CytoDyn conduct its Type A meeting in writing with the FDA. In September 2020, CytoDyn submitted its questions to the FDA, received written responses from the FDA, and held a telephonic meeting with the FDA to obtain further clarity on what additional information was required by the FDA with respect to CytoDyn's BLA filing. CytoDyn reports that it is currently working to provide the information required by the FDA in order to resubmit its BLA, which it anticipates will occur by the end of calendar year 2020.

Strategic Partnerships

In connection with our commercial products and product candidates, we now have a number of strategic partnerships, including:

- **Bausch Agreement** -- Under its agreement with Salix Pharmaceuticals, Inc., a wholly-owned subsidiary of Bausch, Progenics received a $40.0 million development milestone upon U.S. marketing approval for subcutaneous RELISTOR in non-cancer pain patients in 2014, a $50.0 million development milestone for the U.S. marketing approval of an oral formulation of RELISTOR in July 2016, and a $10.0 million sales milestone for RELISTOR achieving U.S. net sales in excess of $100.0 million in 2019. We are also eligible to receive additional one-time sales milestone payments upon achievement of specified U.S. net sales targets, including:

U.S. Net Sales Levels in any Single Calendar Year	Payment ($)
	(In thousands)
In excess of $150 million	15,000
In excess of $200 million	20,000
In excess of $300 million	30,000
In excess of $750 million	50,000
In excess of $1 billion	75,000

Each sales milestone payment is payable one time only, regardless of the number of times the condition is satisfied, and all six payments could be made within the same calendar year. We are also eligible to receive royalties from Bausch and its affiliates based on the following royalty scale: 15% on worldwide net sales up to $100.0 million, 17% on the next $400.0 million in worldwide net sales, and 19% on worldwide net sales over $500.0 million each calendar year, and 60% of any upfront, milestone, reimbursement or other revenue (net of costs of goods sold, as defined, and territory-specific research and development expense reimbursement) Bausch receives from sublicensees outside the U.S.

- **GE Healthcare Agreement –** Under our April 2017 Collaboration and License Agreement, GE Healthcare will complete the worldwide development of flurpiridaz F 18, pursue worldwide regulatory approvals, and, if successful, lead a worldwide launch and commercialization of the agent, with us collaborating on both development and commercialization through a joint steering committee. We also have the right to co-promote the agent in the U.S. GE Healthcare's development plan initially focuses on obtaining regulatory approval in the U.S., Japan, Europe and Canada. Under the agreement, we received an upfront cash payment of $5.0 million and are eligible to receive up to $60.0 million in regulatory and sales milestone payments, tiered double-digit royalties on U.S. sales, and mid-single digit royalties on sales outside of the U.S.
- **Curium Agreement** – Curium has licensed exclusive rights to develop and commercialize PyL in Europe. Under the terms of the collaboration, Curium is responsible for the development, regulatory approvals and commercialization of PyL in Europe, and we are entitled to royalties on net sales of PyL. Curium is in discussions with EMA regarding the development path in Europe.
- **Bayer Agreement** – Under Progenics' April 2016 agreement with a subsidiary of Bayer granting Bayer exclusive worldwide rights to develop and commercialize products using our PSMA antibody platform, in combination with Bayer's alpha-emitting radionuclides, Progenics received an upfront payment of $4.0 million and milestone payments totaling $5.0 million. We could receive up to an additional $44.0 million in potential clinical and development milestones. We are also entitled to single-digit royalties on net sales, and potential net sales milestone payments up to an aggregate of $130.0 million. In addition, in October 2020, Progenics entered into a PyL Clinical Supply Agreement with Bayer to include PyL in their clinical trial for prostate cancer. PyL will be used by Bayer to assess PSMA expression levels at baseline and during treatment.
- **CytoDyn Agreement** -- Leronlimab (PRO 140) is an investigational humanized IgG4 mAb that blocks CCR5, a cellular receptor that is important in HIV infection, tumor metastases, and other diseases including certain liver diseases. Progenics sold Leronlimab to CytoDyn in 2012, which sale included milestone and royalty payment obligations to Progenics. Under the 2012 agreement, CytoDyn is responsible for all development, manufacturing and commercialization efforts. Pursuant to such agreement, Progenics received $5.0 million in upfront and milestone payments, and we have the right to receive an additional $5.0 million upon the first U.S. or E.U. approval for the sale of the drug, and a 5% royalty on the net sales of approved products.
- **ROTOP Agreement** -- In May 2019, Progenics entered into an exclusive license agreement with ROTOP, a Germany-based developer of radiopharmaceuticals for nuclear medicine diagnostics, to develop, manufacture and commercialize 1404 in Europe. Under the terms of the collaboration, ROTOP is responsible for the development, regulatory approvals and commercialization of 1404 in Europe while we are entitled to double-digit, tiered royalties on net sales of 1404 in Europe. ROTOP is in discussions with EMA regarding the development path in Europe.

- **FUJIFILM Agreement** -- In June 2019, Progenics entered into a transfer agreement with FUJIFILM for the rights to the aBSI product in Japan for use under the name BONENAVI. Under the terms of the transfer agreement, FUJIFILM acquired, by a combination of purchase and license, the Japanese software, source code, supporting data and all Japanese patents associated with the aBSI product from Progenics for use in Japan. In exchange, Progenics received $4.0 million in an upfront payment and FUJIFILM agreed to pay Progenics support and service fees for aBSI and other AI products over the next three years in Japan. BONENAVI has been licensed to FUJIFILM for use in Japan since 2011.
- **Regeneron Agreement** – In June 2020, Progenics entered into a PyL Clinical Supply Agreement with Regeneron Pharmaceuticals, Inc. ("Regeneron") under which Progenics will supply PyL to Regeneron as an imaging agent to evaluate and follow subjects for a Phase 1/2 clinical study of Regeneron's PSMA-targeted mCRPC therapeutic candidate.

Key Factors Affecting Our Results

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 will 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 procedures and treatments using our products. For example, there has been a substantial reduction in pulmonary ventilation studies in which our Xenon-133 gas is used because of institutional concerns and professional society guidelines relating to a hospital's ability to adequately decontaminate examination rooms and related equipment used to administer those studies during the COVID-19 pandemic, thereby reducing Xenon-133 sales. We cannot predict the magnitude or duration of the pandemic's impact on our business.

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.

We can give no assurances that we will not have to take additional cost reduction measures if the pandemic continues to adversely affect the volume of procedures and treatments using our products.

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 2020 operations and financial results, we ended the third quarter of 2020 with $88.0 million of cash and cash equivalents. With our available liquidity and prudent expense management, we believe we will be able to maintain a state of preparedness to resume full business activities to support our customers as external conditions allow, although we can give no assurances that we will have sufficient liquidity if the pandemic continues to adversely affect the volume of procedures and treatments using our products for an extended period of time.

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

We believe the market opportunity for our ultrasound microbubble contrast agent, DEFINITY, continues to be significant. DEFINITY is our fastest growing and highest margin commercial product. We anticipate DEFINITY sales will continue to grow over the longer term. 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 contrast agents approved by the FDA, we estimate that DEFINITY had over 80% of the market as of December 31, 2019.

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

- Patents - We continue to actively pursue additional patents in connection with DEFINITY, both in the U.S. and internationally. In the U.S., three of our recently issued method of use patents covering DEFINITY were listed in the Orange Book. We now have 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. Outside of the U.S., while our DEFINITY patent protection and regulatory exclusivity have generally expired, we are

currently prosecuting additional patents to try to obtain similar method of use and manufacturing patent protection as granted in the U.S.

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. With respect to any Orange Book-listed patent covering the innovator product, the ANDA applicant must give a notice to the innovator (a "Notice") that the ANDA applicant certifies that its generic candidate will not infringe the innovator's Orange Book-listed patent or that the Orange Book-listed patent is invalid. The innovator can then challenge the ANDA applicant in court within 45 days of receiving that Notice, and FDA approval to commercialize the generic candidate will be stayed (that is, delayed) for up to 30 months (measured from the date on which a Notice is received) while the patent dispute between the innovator and the ANDA applicant is resolved in court. The 30 month stay could potentially expire sooner if the courts determine that no infringement had occurred or that the challenged Orange Book-listed patent is invalid or if the parties otherwise settle their dispute.

As of the date of filing of this Quarterly Report on Form 10-Q, we have not received any Notice from an ANDA applicant. If we were to (i) receive any such Notice in the future, (ii) bring a patent infringement suit against the ANDA applicant within 45 days of receiving that Notice, and (iii) successfully obtain the full 30 month stay, then the ANDA applicant would be precluded from commercializing a generic version of DEFINITY prior to the expiration of that 30 month stay period and, potentially, thereafter, depending on how the patent dispute is resolved. Solely by way of example and not based on any knowledge we currently have, if we received a Notice from an ANDA applicant in November 2020 and the full 30 month stay was obtained, then the ANDA applicant would be precluded from commercialization until at least May 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.

- *Modified Formulation* - We are developing DEFINITY RT, a modified formulation of DEFINITY, at SBL. We believe DEFINITY RT will provide an enhanced product profile enabling storage as well as shipment at room temperature (DEFINITY's current formulation requires refrigerated storage), will give clinicians additional choice, and will allow for greater utility of this formulation in broader clinical settings. We have a composition of matter patent on DEFINITY RT which runs through 2035. If DEFINITY RT is approved by the FDA, then this patent would be eligible to be listed in the Orange Book. We currently believe that, if approved by the FDA, DEFINITY RT could become commercially available in early 2021, although that timing cannot be assured. Given its physical characteristics, DEFINITY RT may also be 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 next paragraph).
- *Vialmix RFID* – In August 2020, the FDA approved a supplemental NDA for our next-generation activation device designed specifically for both DEFINITY and DEFINITY RT product candidate. 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. The RFID tag, which is affixed to the vial label, enables the DEFINITY vial to be appropriately activated when utilized with the Vialmix RFID activation device. A U.S. issued patent on the use of the new Vialmix RFID with an expiration date of 2037 has been listed in the Orange Book, and additional patent applications have been submitted in major markets throughout the world.
- *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 contrast 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 target improving 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., an Israeli company ("Insightec") which will use our microbubbles in connection with Insightec's transcranial guided focused ultrasound device for the treatment of glioblastoma as well as other neurodegenerative conditions.

- *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 be in a position to use this in-house manufacturing capability in 2021, although that timing cannot be assured.
- *DEFINITY in China* - On March 19, 2020 in connection with our Chinese development and distribution arrangement with Double Crane Pharmaceutical Company, we filed an Import Drug License application with the National Medical Products Administration, or the NMPA, for the use of DEFINITY for the echocardiography indication. We believe this is an important milestone in our efforts to commercialize DEFINITY in China. Double Crane is also in the process of analyzing the clinical results relating to the liver and kidney indications and will also work with us to prepare an Import Drug License application for those indications.

Global Mo-99 Supply

We currently have Mo-99 supply agreements with Institute for Radioelements ("IRE"), running through December 31, 2022, and renewable by us on a year-to-year basis thereafter, and with NTP and 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 the second quarter of 2019, ANSTO experienced technical issues in its existing Mo-99 processing facility which resulted in a decrease in Mo-99 available to us. In addition, as ANSTO transitioned from its existing Mo-99 processing facility to its new Mo-99 processing facility in the second quarter of 2019, ANSTO experienced start-up and transition challenges, which also resulted in a decrease in Mo-99 available to us. Further, starting in late June 2019 until April 2020, ANSTO's new Mo-99 processing facility had production volume limitations imposed on it by the Australian Radiation Protection and Nuclear Safety Agency which limited our ability to receive Mo-99 from ANSTO. During that time we relied on IRE and NTP to limit the impact of those ANSTO outages and volume limitations. As ANSTO increases its production volume over the course of 2020, we expect to receive increasing supply from ANSTO. Because of the COVID-19 pandemic, in the second quarter of 2020 we experienced challenges receiving regularly scheduled orders of Mo-99 from our global suppliers due to the partial or complete delay or cancellation of international flights by our airfreight carriers. As of the filing of this report, these COVID-19-related transportation challenges have been largely eliminated. Because of these various supply chain constraints, depending on reactor and processor schedules and operations, we have historically not been able to fill some or all of the demand for our TechneLite generators on certain manufacturing days.

ANSTO's new Mo-99 processing facility could eventually increase ANSTO's Mo-99 production capacity from approximately 2,000 curies per week to 3,500 curies per week with additional committed financial and operational resources. At full ramp-up capacity, ANSTO's new facility could provide incremental supply to our globally diversified Mo-99 supply chain and therefore mitigate some risk among our Mo-99 suppliers, although we can give no assurances to that effect. In addition, we also have a strategic arrangement with SHINE Medical Technologies, Inc. ("SHINE"), a Wisconsin-based company, for the future supply of Mo-99. Under the terms of that agreement, SHINE will provide us Mo-99 once SHINE's facility becomes operational and receives all necessary approvals, which SHINE now estimates will occur in 2022.

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 are also currently working to secure additional alternative suppliers for our key products as part of our ongoing supply chain diversification strategy. We have ongoing development and technology transfer activities for DEFINITY RT with SBL, which is located in South Korea. We currently believe that if approved by the FDA, DEFINITY RT could be commercially available in 2021, although that timing cannot be assured. We have also completed construction of specialized, in-house manufacturing capabilities at our North Billerica, Massachusetts facility, as part of a larger strategy to create a competitive advantage in specialized manufacturing, 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 North Billerica, Massachusetts facility.

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 Transaction brings additional and substantial clinical development expense. We filed the PyL NDA with the FDA on September 29, 2020, requesting priority review. For 1095, the ARROW Phase 2 study in mCRPC patients had been paused to minimize risk to subjects and healthcare providers during the pandemic, and new enrollment in that study restarted in October 2020. In 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 Transaction, 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 Transaction 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 by entering into a strategic collaboration and license agreement with NanoMab Technology Limited, 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. 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 both Regeneron and Bayer for use of PyL in prostate cancer clinical trials. We can give no assurance as to when or if any of these Pharma Services collaborations will be successful or accretive to earnings.

Results of Operations

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2020**	**2019**	**2020**	**2019**
Revenues	$ 88,544	$ 85,776	$ 245,258	$ 257,991
Cost of goods sold	52,284	44,187	145,148	127,745
Gross profit	36,260	41,589	100,110	130,246
Operating expenses				
Sales and marketing	11,609	10,151	28,044	31,496
General and administrative	18,217	18,061	55,586	43,943
Research and development	11,684	4,860	20,150	15,584
Total operating expenses	41,510	33,072	103,780	91,023
Operating (loss) income	(5,250)	8,517	(3,670)	39,223
Interest expense	2,808	2,356	6,668	11,491
Loss on extinguishment of debt	—	—	—	3,196
Other (income) loss	(596)	804	(1,702)	(1,695)
(Loss) income before income taxes	(7,462)	5,357	(8,636)	26,231
Income tax (benefit) expense	(1,076)	501	1,425	5,014
Net (loss) income	$ (6,386)	$ 4,856	$ (10,061)	$ 21,217

Comparison of the Periods Ended September 30, 2020 and 2019

Revenues

Segment revenues are summarized by product as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
(in thousands)	2020	2019	Change $	Change %	2020	2019	Change $	Change %
U.S.								
DEFINITY	$ 53,792	$ 50,917	$ 2,875	5.6 %	$ 148,346	$ 154,099	$ (5,753)	(3.7)%
TechneLite	17,652	18,281	(629)	(3.4)%	52,599	55,204	(2,605)	(4.7)%
Other nuclear	11,571	9,355	2,216	23.7 %	26,437	28,006	(1,569)	(5.6)%
Rebates and allowances	(5,540)	(3,903)	(1,637)	41.9 %	(13,763)	(12,035)	(1,728)	14.4 %
Total U.S. revenues	77,475	74,650	2,825	3.8 %	213,619	225,274	(11,655)	(5.2)%
International								
DEFINITY	1,637	1,478	159	10.8 %	4,239	4,036	203	5.0 %
TechneLite	3,837	3,466	371	10.7 %	10,897	10,794	103	1.0 %
Other nuclear	5,596	6,186	(590)	(9.5)%	16,507	17,901	(1,394)	(7.8)%
Rebates and allowances	(1)	(4)	3	(75.0)%	(4)	(14)	10	(71.4)%
Total International revenues	11,069	11,126	(57)	(0.5)%	31,639	32,717	(1,078)	(3.3)%
Worldwide								
DEFINITY	55,429	52,395	3,034	5.8 %	152,585	158,135	(5,550)	(3.5)%
TechneLite	21,489	21,747	(258)	(1.2)%	63,496	65,998	(2,502)	(3.8)%
Other nuclear	17,167	15,541	1,626	10.5 %	42,944	45,907	(2,963)	(6.5)%
Rebates and allowances	(5,541)	(3,907)	(1,634)	41.8 %	(13,767)	(12,049)	(1,718)	14.3 %
Total revenues	$ 88,544	$ 85,776	$ 2,768	3.2 %	$ 245,258	$ 257,991	$ (12,733)	(4.9)%

The increase in the U.S. segment revenues for the three months ended September 30, 2020, as compared to the prior year period is primarily due to a $2.9 million increase in DEFINITY revenue as a result of higher unit volumes and a $2.2 million increase in Other nuclear revenue driven by the addition of the Progenics revenue portfolio, offset in part by lower Xenon volume as a result of COVID-19. TechneLite revenue was $0.6 million lower driven by COVID-19 impact, partially offset by supplier disruptions in 2019. Rebate and allowance provisions drove an additional decrease of $1.6 million.

The decrease in the U.S. segment revenues for the nine months ended September 30, 2020, as compared to the prior year period is primarily due to a $5.8 million decrease in DEFINITY revenue as a result of lower unit volumes as a result of COVID-19 that was concentrated in the second quarter, offset, in part, by third quarter performance. TechneLite revenue was $2.6 million lower driven by COVID-19, partially offset by supplier disruptions in 2019. Other Nuclear revenue was lower than the prior year primarily associated with lower Xenon volume as a result of COVID-19, offset, in part, by the addition of Progenics revenue portfolio.

The decrease in the International segment revenues for the three months ended September 30, 2020, as compared to the prior year period is primarily due to $0.6 million lower revenue in Other nuclear product as a result of COVID-19, offset, in part, by $0.4 million higher TechneLite revenue driven by supplier disruptions in 2019 and $0.2 million higher DEFINITY revenue driven by increased volume.

The decrease in the International segment revenues for the nine months ended September 30, 2020, as compared to the prior year period is primarily due to lower volume as a result of COVID-19. Offsetting these decreases was an increase in DEFINITY revenue of $0.2 million driven by volume.

Rebates and Allowances

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

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

(in thousands)	Rebates and Allowances
Balance, January 1, 2020	$ 6,985
Provision related to current period revenues	13,816
Adjustments relating to prior period revenues	(49)
Payments or credits made during the period	(13,266)
Balance, September 30, 2020	$ 7,486

Gross Profit

Gross profit is summarized by segment as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
(in thousands)	2020	2019	Change $	Change %	2020	2019	Change $	Change %
U.S.	$ 33,282	$ 38,614	$ (5,332)	(13.8)%	$ 93,042	$ 122,198	$ (29,156)	(23.9)%
International	2,978	2,975	3	0.1 %	7,068	8,048	(980)	(12.2)%
Total gross profit	$ 36,260	$ 41,589	$ (5,329)	(12.8)%	$ 100,110	$ 130,246	$ (30,136)	(23.1)%

The decrease in the U.S. segment gross profit for the three months ended September 30, 2020, as compared to the prior year period is primarily due to lower Xenon, TechneLite and other nuclear product unit volumes due to COVID-19, along with a decrease driven by rebate and allowance provisions. These decreases were offset, in part, by and increase in DEFINITY gross profit driven by an increase in volume over the prior year period.

The decrease in the U.S. segment gross profit for the nine months ended September 30, 2020, as compared to the prior year period is primarily due to lower DEFINITY, TechneLite, and Xenon unit volumes due to COVID-19 and an asset impairment loss on other nuclear products.

The decrease in the International segment gross profit for the nine months ended September 30, 2020, as compared to the prior year period is primarily due to lower other nuclear product unit volumes due to COVID-19.

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 expense is summarized by segment as follows:

(in thousands)	Three Months Ended September 30, 2020	2019	Change $	Change %	Nine Months Ended September 30, 2020	2019	Change $	Change %
U.S.	$ 11,176	$ 9,571	$ 1,605	16.8 %	$ 26,613	$ 29,909	$ (3,296)	(11.0)%
International	433	580	(147)	(25.3)%	1,431	1,587	(156)	(9.8)%
Total sales and marketing	$ 11,609	$ 10,151	$ 1,458	14.4 %	$ 28,044	$ 31,496	$ (3,452)	(11.0)%

The increase in the U.S. segment sales and marketing expenses for the three months ended September 30, 2020, as compared to the prior year period is primarily due to the addition of the Progenics business and increase in market research which was partially offset by reduced marketing promotional programs and travel due to COVID-19 and lower employee related costs. The Progenics business contributed approximately $2.7 million of expense to the U.S. segment for the three months ended September 30, 2020.

The decrease in the U.S. segment sales and marketing expenses for the nine months ended September 30, 2020, as compared to the prior year period is primarily due to reduced marketing promotional programs and travel due to COVID-19, as well as lower employee-related costs offset by the addition of the Progenics business. The Progenics business contributed approximately $3.0 million of expense to the U.S. segment for the nine months ended September 30, 2020.

The decrease in the International segment sales and marketing expenses for the three and nine months ended September 30, 2020, as compared to the prior year period is primarily due to lower marketing promotional activities.

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 expense is summarized by segment as follows:

(in thousands)	Three Months Ended September 30, 2020	2019	Change $	Change %	Nine Months Ended September 30, 2020	2019	Change $	Change %
U.S.	$ 17,873	$ 17,926	$ (53)	(0.3)%	$ 54,950	$ 43,597	$ 11,353	26.0 %
International	344	135	209	154.8 %	636	346	290	83.8 %
Total general and administrative	$ 18,217	$ 18,061	$ 156	0.9 %	$ 55,586	$ 43,943	$ 11,643	26.5 %

The U.S. segment general and administrative expenses decreased for the three months ended September 30, 2020 as compared to the prior year period. The primary driver in the current year was lower acquisition-related costs associated with the acquisition of Progenics offset by unrealized losses related to changes in fair value of contingent consideration liabilities and the addition of the Progenics business. The Progenics business contributed approximately $3.4 million of expense to the U.S. segment for the three months ended September 30, 2020.

The U.S. segment general and administrative expenses increased for the nine months ended September 30, 2020 as compared to the prior year period. The primary driver was an increase in acquisition-related costs associated with the acquisition of Progenics and the addition of the Progenics business offset by lower medical insurance costs. The Progenics business contributed approximately $6.3 million of expense to the U.S. segment for the nine months ended September 30, 2020.

The International segment general and administrative expenses increased for the three and nine months ended September 30, 2020 as compared to the prior year period driven primarily by the addition of the Progenics business and an insurance benefit received in 2019 which was partially offset by lower employee related costs in 2020. The Progenics business contributed approximately $0.2 million of expense to the International segment for each of the three and nine months ended September 30, 2020.

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. We do not allocate research and development expenses incurred in the U.S. to our International segment.

Research and development expense is summarized by segment as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
(in thousands)	2020	2019	Change $	Change %	2020	2019	Change $	Change %
U.S.	$ 10,856	$ 4,729	$ 6,127	129.6 %	$ 19,114	$ 15,031	$ 4,083	27.2 %
International	828	131	697	532.1 %	1,036	553	483	87.3 %
Total research and development	$ 11,684	$ 4,860	$ 6,824	140.4 %	$ 20,150	$ 15,584	$ 4,566	29.3 %

The increase in the U.S. segment research and development expenses for the three and nine months ended September 30, 2020, as compared to the prior year is primarily driven by the addition of the Progenics business, including the PyL NDA filing fee, partially offset by clinical research expenses related to DEFINITY studies completing and lower employee related expenses. The Progenics business contributed approximately $7.6 million and $8.7 million of expense to the U.S. segment for the three and nine months ended September 30, 2020, respectively.

The increase in the International segment research and development expenses for the three and nine months ended September 30, 2020, as compared to the prior year period is primarily driven by the addition of the Progenics business partially offset by regulatory costs related to Brexit matters. The Progenics business contributed approximately $0.6 million of expense to the International segment for the three and nine months ended September 30, 2020.

Interest Expense

Interest expense decreased by approximately $4.8 million for the nine months ended September 30, 2020 as compared to the prior year period due to the refinancing of our existing indebtedness in the second quarter of 2019 which reduced our underlying principal amount and decreased interest rates on our long-term debt.

Income Tax (Benefit) Expense

Income tax (benefit) expense is summarized as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
(in thousands)	2020	2019	Change $	Change %	2020	2019	Change $	Change %
Income tax (benefit) expense	$ (1,076)	$ 501	$ (1,577)	(314.8)%	$ 1,425	$ 5,014	$ (3,589)	(71.6)%

The income tax benefit recorded for the three months ended September 30, 2020 was primarily due to the pre-tax losses incurred during the quarter, partially offset by the accrual of interest associated with uncertain tax positions.

The income tax expense recorded for the nine months ended September 30, 2020 was primarily due to the recording of non-deductible transaction costs and the accrual of interest associated with uncertain tax positions, partially offset by the income tax benefit recorded due to the pre-tax losses incurred during the nine month period.

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. As of September 30, 2020, we recorded valuation allowances of $3.2 million against the net deferred tax assets of certain foreign subsidiaries, as well as a valuation allowance of $0.7 million against net U.S. deferred tax assets due to the potential expiration of certain tax losses and state tax credits prior to utilization.

On June 19, 2020, we acquired the stock of Progenics Pharmaceuticals, Inc. in a transaction that is expected to qualify as a tax-deferred reorganization under Section 368 of the Internal Revenue Code of 1986, as amended. The transaction resulted in an

ownership change of Progenics under Section 382 and a limitation on the utilization of Progenics' pre-transaction tax attributes. All of Progenics' pre-transaction 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.

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

	Nine Months Ended September 30,	
	2020	**2019**
Effective tax rate	(16.5)%	19.1%

Our effective tax rate in fiscal 2020 differs from the U.S. statutory rate of 21% principally due to the impact of U.S. state taxes, non-deductible transaction costs, and the accrual of interest on uncertain tax positions.

The decrease in the effective income tax rate for the nine months ended September 30, 2020 as compared to the prior year period is primarily due to the lower amount of pre-tax income and a lower tax benefit of stock compensation deductions in the current nine month period.

Liquidity and Capital Resources

Cash Flows

The following table provides information regarding our cash flows:

(in thousands)	Nine Months Ended September 30, 2020	2019
Net cash provided by operating activities	$ 15,827	$ 57,963
Net cash used in investing activities	$ (1,127)	$ (17,320)
Net cash used in financing activities	$ (17,488)	$ (76,058)

Net Cash Provided by Operating Activities

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

Net cash provided by operating activities of $58.0 million in the nine months ended September 30, 2019 was driven primarily by net income of $21.2 million plus $9.8 million of depreciation, amortization and accretion expense, stock-based compensation expense of $9.5 million, changes in deferred taxes of $3.8 million and debt extinguishment expense of $3.2 million. These net sources of cash were further increased by a net increase of $7.3 million related to movements in our working capital accounts during the period. The overall increases in cash from our working capital accounts were primarily driven by improved collections related to our accounts receivables and the timing of purchases.

Net Cash Used in Investing Activities

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

Net cash used in investing activities during the nine months ended September 30, 2019 reflected $17.3 million in capital expenditures.

Net Cash Used in Financing Activities

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

Net cash used in financing activities during the nine months ended September 30, 2019 is primarily attributable to the net cash outflow of approximately $73.0 million in connection with the refinancing of our previous 2017 Facility, payments on long-term debt 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 $2.4 million. Starting in 2019, we require certain senior executives to cover tax liabilities resulting from the vesting of their equity awards pursuant to sell-to-cover transactions under 10b5-1 plans.

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 the 2019 Revolving 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 (the “2019 Credit Agreement”). 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 prepay 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 5.00% 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, 2019 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 our acquisition of Progenics.

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) has been 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
Q3 2020 to 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.

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 Transaction, 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 have 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 will be used to repay the principal and interest on the loan. The Royalty-Backed Loan bears interest at a per annum rate of 9.5% and matures 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 Transaction 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, are 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 are used to repay the principal of the loan, with the balance retained by us. Starting on September 30, 2021, all of the RELISTOR royalties received since the immediately-preceding payment date will be used to repay the interest and outstanding principal balance until the balance is fully repaid.

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 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 implement further expense reductions, such as a delay or elimination of discretionary spending in all functional areas, as well as scaling back select operating and strategic initiatives.

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

At September 30, 2020, our only current committed external source of funds is our borrowing availability under our 2019 Revolving Facility. We had $88.0 million of cash and cash equivalents at September 30, 2020. 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.

In addition, in connection with the Progenics Transaction, which we closed in June 2020, we incurred legal, accounting, financial advisory, consulting and printing fees, and transition, integration and other costs which we funded from our available cash and the available cash of Progenics. The CVRs we issued in the Progenics Transaction 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 Transaction, exceed 19.9% (which we estimate could be approximately $100.0 million) of the total consideration we pay in the Progenics Transaction. 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 nine months ended September 30, 2020, except as set forth below. 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, 2019.

Business Combinations

We account for business combinations using the acquisition method of accounting. We recognize the assets acquired and liabilities assumed in business combinations on the basis of their fair values at the date of acquisition. We assess the fair value of assets acquired, including intangible assets, and liabilities assumed using a variety of methods. Each asset acquired and liability assumed is measured at fair value from the perspective of a market participant. The method used to estimate the fair values of intangible assets incorporates significant assumptions regarding the estimates a market participant would make in order to evaluate an asset, including a market participant’s use of the asset and the appropriate discount rates. Acquired in-process research and development (“IPR&D”) is recognized at fair value and initially characterized as an indefinite-lived intangible asset, irrespective of whether the acquired IPR&D has an alternative future use. Any excess purchase price over the fair value of the net tangible and intangible assets acquired is allocated to goodwill. Transaction costs and restructuring costs associated with a business combination are expensed as incurred.

The fair values assigned to tangible and intangible assets acquired and liabilities assumed are based on our estimates and assumptions, as well as other information we have compiled, including valuations that utilize customary valuation procedures and techniques. If the actual results differ from the estimates and assumptions used in these estimates, it could result in a possible impairment of the intangible assets and goodwill, a required acceleration of the amortization expense of finite-lived intangible assets or the recognition of additional consideration, which would be expensed.

During the measurement period, which extends no later than one year from the acquisition date, we may record certain adjustments to the carrying value of the assets acquired and liabilities assumed with the corresponding offset to goodwill. After the measurement period, all adjustments are recorded in the condensed consolidated statements of operations as operating expenses or income.

Intangible and Long-Lived Assets

We test intangible and 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. We measure the recoverability of assets to be held and used by comparing the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. If those assets are considered to be impaired, the impairment equals the amount by which the carrying amount of the assets exceeds the fair value of the assets. Any impairments are recorded as permanent reductions in the carrying amount of the assets. Long-lived assets, other than goodwill and other intangible assets, that are held for sale are recorded at the lower of the carrying value or the fair market value less the estimated cost to sell.

Intangible assets, consisting of trademarks, customer relationships, currently marketed products, licenses and developed technology are amortized in a method equivalent to the estimated utilization of the economic benefit of the asset.

Our IPR&D represents intangible assets acquired in a business combination that are used in research and development activities but have not yet reached technological feasibility, regardless of whether they have alternative future use. The primary basis for determining the technological feasibility or completion of these projects is whether we have obtained regulatory approval to market the underlying products in an applicable geographic region. Because obtaining regulatory approval can include significant risks and uncertainties, the eventual realized value of the acquired IPR&D projects may vary from their fair value at the date of acquisition. We classify IPR&D acquired in a business combination as an indefinite-lived intangible asset until the completion or abandonment of the associated research and development efforts. Upon completion of the associated research and development efforts, we will determine the useful life and begin amortizing the assets to reflect their use over their remaining lives. Upon permanent abandonment, we write-off the remaining carrying amount of the associated IPR&D intangible asset. We test our IPR&D assets at least annually or when a triggering event occurs that could indicate a potential impairment and we recognize any impairment loss in our condensed consolidated statements of operations.

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, except as set forth below, 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, 2019. Our exposures to market risk have not changed materially since December 31, 2019.

Interest Rate Risk

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. As of September 30, 2020, the Company had 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 as of September 30, 2020 was 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. Please refer to Note 12, “Derivative Instruments”, for further details on the interest rate swaps.

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

As of September 30, 2020, management is in the process of evaluating and integrating the internal controls of the acquired Progenics business into the Company's existing operations. The Company implemented controls over the accounting and disclosures related to the business combination and integration of the Progenics business. There were no material changes in the Company's

internal control over financial reporting during the quarter ended September 30, 2020, that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. Additionally, as a result of the COVID-19 pandemic, certain employees began working remotely in March 2020. Notwithstanding these changes to the working environment, we have not identified any material changes in our internal control over financial reporting due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation 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

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.

As of September 30, 2020, the Company had the following material ongoing litigation to which the Company was a party:

RELISTOR Subcutaneous Injection

Between November 19, 2015 and September 18, 2017, Progenics, Salix, Valeant (now Bausch) and Wyeth filed multiple lawsuits against Mylan Pharmaceuticals and certain of its affiliates (collectively, "Mylan") in the United States District Court for the District of New Jersey (the "Court") for infringement of certain U.S. patents based upon Mylan's filing of multiple ANDAs seeking to obtain approval to market a generic version of RELISTOR subcutaneous injection before some or all of those patents expire. These actions were later consolidated into two separate actions in the District of New Jersey.

On May 1, 2018, in the lead action, the Court granted Plaintiffs' motion for partial summary judgment as to the validity of a particular claim that Mylan had admitted it infringed. On May 23, 2018, the Court entered an order for final judgment in favor of Plaintiffs and against Mylan on that particular claim. As a result, trial on the merits in the lead action was adjourned, allowing trial, if necessary, to be consolidated with the lagging, second action. On August 20, 2020, the parties agreed to dismiss all claims, affirmative defenses, and counterclaims in the lagging action and proceed to a full trial on the merits for the patents asserted in the lead action. A date for trial has not yet been set.

On May 25, 2018, Mylan filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit ("CAFC"). On April 8, 2020, the CAFC issued its decision reversing the Court's grant of summary judgment and remanding for further proceedings. On June 22, 2020, Plaintiffs filed a petition for rehearing/rehearing en banc, and on July 24, 2020, that petition was denied.

RELISTOR Tablets - Actavis

Between December 6, 2016 and December 8, 2017, Progenics, Salix, Bausch, and Wyeth filed suit against Actavis, Actavis LLC, Teva Pharmaceuticals USA, Inc., and Teva Pharmaceuticals Industries Ltd. (collectively, "Actavis") in the Court for infringement of certain U.S. patents based upon Actavis's filing of an ANDA seeking to obtain approval to market a generic version of RELISTOR tablets before some or all of those patents expire. The actions were later consolidated into a single action in the Court.

On May 6-9, 2019, a bench trial was held, and on July 17, 2019, the Court issued an Order finding the asserted claims of a certain U.S. patent valid and infringed. The Court additionally ordered that the effective date of any approval of Actavis's ANDA may not be earlier than the expiration date of that patent. Actavis filed an appeal of the Court's decision with the CAFC on August 13, 2019. The matter is currently pending on appeal at the CAFC and merits briefing is underway. Actavis's opening brief was filed February 6, 2020. The Plaintiffs filed their responsive brief on September 15, 2020. Actavis's reply brief is currently due on November 5, 2020.

On June 13, 2019, Progenics, Salix, Bausch, and Wyeth filed another suit against Actavis in the Court for infringement of a separate, and at that time, recently granted U.S. patent based upon Actavis's filing of an ANDA seeking to obtain approval to market a generic version of RELISTOR tablets before this patent expires. Litigation in this action is underway, and fact discovery has begun.

RELISTOR European Opposition Proceedings

In addition to the above described ANDA notifications, in October 2015, Progenics received notices of opposition to three European patents relating to methylnaltrexone. 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 are on appeal with the European Patent Office. Oral proceedings for 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. Oral proceedings are set to occur on November 17, 2020 and November 18, 2020 for EP2368553 and EP2368554, respectively.

For each of the above-described RELISTOR proceedings, Progenics and Bausch continue to cooperate closely to vigorously defend and enforce RELISTOR intellectual property rights. Pursuant to the RELISTOR license agreement between Progenics and Bausch, Bausch has the first right to enforce the intellectual property rights at issue and is responsible for the costs of such enforcement. Because the outcome of litigation is uncertain and in these RELISTOR proceedings the Company does not control the enforcement of the intellectual property rights at issue, no assurance can be given as to how or when any of these RELISTOR proceedings 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 of Mannheim in 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 the corresponding US patent applications. 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. On March 6, 2020, MIP filed with the USPTO a notice stating that the Power of Attorney in certain pending US 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.

On September 24, 2020, MIP filed a Notice of Appeal of the German District Court's decision. 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 German District 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, we cannot predict how or when this matter will ultimately be resolved.

Whistleblower Complaint

In July 2019, Progenics received notification of a complaint submitted by Dr. Syed Mahmood, the former Vice President of Medical Affairs for Progenics, to the Occupational Safety and Health Administration of the United States Department of Labor ("DOL"), alleging that the termination of his employment by Progenics was in violation of Section 806 of the Sarbanes-Oxley Act of 2002 ("SOX"). Dr. Mahmood sought reinstatement to his former position of Vice President of Medical Affairs, back pay, front pay in lieu of reinstatement, interest, attorneys' fees and costs incurred, and special damages. In March 2020, Dr. Mahmood filed a complaint in the U.S. District Court for the Southern District of New York (as permitted by SOX because the DOL had not issued a decision within 180 days). Dr. Mahmood's federal complaint asserts claims of violation of Section 806 of SOX. The DOL action has been dismissed and the matter will proceed in federal district court. Progenics filed an answer to Dr. Mahmood's complaint on August 26, 2020 and the initial pre-trial conference was held on September 16, 2020.

The Company believes the claims in this matter are without merit, and the Company has meritorious defenses to the claims. The Company intends to vigorously defend against the claims.

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, 2019 and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2020 and June 30, 2020, except as set forth below:

The COVID-19 pandemic could have a material impact on our business, results of operation and financial condition, operating results, cash flows and prospects.

In December 2019, a novel strain of coronavirus (COVID-19) emerged in Wuhan China. Less than four months later, in March 2020, the World Health Organization declared COVID-19 a pandemic. While the outbreak initially was largely concentrated in China and caused significant disruptions in its economy, the virus has now spread to many other countries and regions, and every state within the United States, including Massachusetts, where our primary offices and manufacturing facility are located, as well as New York, New Jersey, Puerto Rico, Canada and Sweden, where our other offices and manufacturing facilities are located.

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 procedures using our products. In response to the pandemic, healthcare providers have, and may need to further, reallocate resources, such as physicians, staff and facilities, as they prioritize limited resources and personnel capacity to focus on the treatment of patients with COVID-19 and implement limitations on access to hospitals and other medical institutions due to concerns about the potential spread of COVID-19 in such settings. These actions have significantly delayed the provision of other medical care including procedures involving our products, having an adverse effect on our revenue. These measures and challenges may continue for the duration of the COVID-19 pandemic, and such duration is uncertain and may significantly reduce our revenue and cash flows while the pandemic continues and thereafter until we and our customers are able to resume normal business operations. We cannot predict the magnitude or duration of the pandemic's impact on our business.

In connection with the COVID-19 pandemic, the following risks could have a material effect on our business, financial condition, results of operations and prospects:

- The delay or cancellation by hospitals and clinics of the procedures in which our products are used as a result of their COVID-19 response efforts and the duration of such effects, thereby reducing sales of our products for an unknown period of time;
- The inability or unwillingness of some patients to visit hospitals or clinics in order to undergo procedures in which our products are used, thereby reducing sales of our products for an unknown period of time;
- The inability of some patients to pay for procedures and/or the co-pay associated with those procedures in which our products are used due to job loss or lack of insurance, thereby reducing sales of our products for an unknown period of time;
- The inability of our distributors, radiopharmacy customers, PET manufacturing partners, hospitals, clinics and other customers to conduct their normal operations, including supplying or conducting procedures in which our products are used, because of their COVID-19 response efforts, or the reduced capacity or productivity of their employees and contractors as a result of possible illness, quarantine or other inability to work, thereby reducing sales of our products for an unknown period of time;
- The reduction in pulmonary ventilation studies in which our Xenon-133 gas is used because of institutional concerns and professional society guidelines relating to a hospital's ability to adequately decontaminate examination rooms and related equipment used to administer those studies during the COVID-19 pandemic, thereby reducing Xenon-133 sales for an unknown period of time;
- The inability of global suppliers of raw materials or components used in the manufacture of our products, or contract manufacturers of our products, to supply and/or transport those raw materials, components and products to us in a timely and cost effective manner due to shutdowns, interruptions or delays, limiting and potentially precluding the production of our finished products, impacting our ability to supply customers, reducing our sales, increasing our costs of goods sold, and reducing our absorption of overhead;
- The partial or complete delay or cancellation of international or domestic flights by our airfreight carriers, resulting in our inability to receive raw materials, components and products from our global suppliers or to ship and deliver our finished products to our domestic and international customers in a timely or cost effective manner, thereby potentially increasing

our freight costs as we seek alternate, potentially more expensive, methods to ship raw materials, components or products, and negatively impacting our sales;

- The reduced capacity or productivity of our complex, on-campus operations as a result of possible illness, quarantine or other inability of our employees and contractors to work, despite all of the preventative measures we continue to undertake to protect the health and safety of our workforce;
- The illiquidity or insolvency of our suppliers, contract manufacturer (including our PET manufacturing partners) or freight carriers whose business activities could be shut down, interrupted or delayed;
- The illiquidity or insolvency of our distributors or customers, or their inability to pay our invoices in full or in a timely manner, due to the reduction in their revenues caused by the cancellation or delay of procedures and other factors, which could potentially reduce our cash flow, reduce our liquidity and increase our bad debt reserves;
- A portion of our raw materials or finished product inventory may expire due to reduced demand for our drugs;
- Delays in our ability, and the ability of our contract research organizations and development partners to conduct, enroll and complete clinical development programs such as our ARROW Phase 2 study in mCRPC, the flurpiridaz F 18 Phase 3 clinical development program currently being conducted by GE Healthcare, or the Phase 1 trial of PSMA TTC being conducted by Bayer AG;
- Delays of regulatory reviews and approvals, including with respect to our product candidates, by the FDA or other health or regulatory authorities;
- Decreased sales of those of our products that are promotionally sensitive, like DEFINITY, due to the reduction of in-person sales and marketing activities and training caused by travel restrictions, quarantines, other similar social distancing measures and more restrictive hospital access policies;
- Our ability to maintain employee morale and motivate and retain management personnel and other key employees as a result of our previous work week and salary reductions;
- A disruption or delay in regulatory approval for, and operation of, our new, on-campus manufacturing facility, which would delay implementation of our supply diversification strategy for certain of our key products and impact our ability to benefit from a lower cost of goods for those products;
- A reduction in revenue with continued incurrence of high fixed costs relating to our already-existing, complex and expensive radiopharmaceutical manufacturing facility could adversely affect our cash flows, liquidity and ability to comply with the financial covenants in our 2019 Facility, and there can be no assurance that any required waiver or consent related to any such failure to comply would be granted by our current lenders similar to the waiver of total net leverage ratio in exchange for a consolidated liquidity covenant recently included in the Amendment;
- The increased reliance on our personnel working from home, which may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business;
- A delay in achieving, or inability to achieve, successful integration of Lantheus and Progenics, or the synergies, cost savings, innovation and other anticipated benefits of the acquisition due to impact of the COVID-19 pandemic on the operations, financial condition and prospects of our Company;
- The instability to worldwide economies, financial markets, social institutions, labor markets and the healthcare systems as a result of the COVID-19 pandemic, which could result in an economic downturn that could adversely impact our business, results of operations and financial condition, as well as that of our suppliers, distributors, customers or other business partners; and
- A recurrence of the COVID-19 pandemic after social distancing and other similar measures have been relaxed.

The extent to which the COVID-19 pandemic impacts our business and our results of operations and financial condition will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge in connection with the severity of the virus, the ability to treat and ultimately prevent it, its potential recurrence, and actions that may be taken to contain its impact.

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 quarter ended September 30, 2020. 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 and April 24, 2019 (the "2015 Plan"), provides for the withholding of shares to satisfy minimum statutory tax withholding obligations. It does not specify a maximum number of shares that can be withheld for this purpose. The shares of common stock withheld to satisfy minimum tax withholding obligations may be deemed to be "issuer purchases" of shares that are required to be disclosed pursuant to this Item 2. These shares are then sold in compliance with Rule 10b5-1 into the market to allow the Company to satisfy the tax withholding requirements in cash.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Program
July 2020**	1,455	$ 15.75	*	*
August 2020**	1,745	$ 13.45	*	*
September 2020**	319	$ 12.85	*	*
Total	3,519		*	

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

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

Dividend Policy

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

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

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

* Filed herewith.

** Furnished herewith.

SIGNATURES

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

LANTHEUS HOLDINGS, INC.

By:	/s/ MARY ANNE HEINO
Name:	Mary Anne Heino
Title:	*President and Chief Executive Officer (Principal Executive Officer)*
Date:	November 5, 2020

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:	November 5, 2020

Exhibit 31.1

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

I, Mary Anne Heino, certify that:

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

Date: November 5, 2020

/s/ MARY ANNE HEINO

Name: Mary Anne Heino

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

Exhibit 31.2

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

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

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

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2020

/s/ ROBERT J. MARSHALL, JR.

Name: Robert J. Marshall, Jr.

Title: *Chief Financial Officer and Treasurer*

(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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

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

1. The Quarterly Report on Form 10-Q for the period ended September 30, 2020 (the "Report") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: November 5, 2020

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

Date: November 5, 2020

/s/ ROBERT J. MARSHALL, JR.
Name: Robert J. Marshall, Jr.
Title: *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.