

Lantheus Holdings, Inc.  
Form 10-Q  
November 01, 2016  
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, 2016**

**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**  
**(State of incorporation)**

**35-2318913**  
**(IRS Employer**

**Identification No.)**

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

**01862**  
**(Zip Code)**

**(978) 671-8001**

**(Registrant's telephone number, including area code)**

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes  No

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

Edgar Filing: Lantheus Holdings, Inc. - Form 10-Q

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

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 35,724,793 of common stock, \$0.01 par value per share, issued and outstanding as of October 31, 2016.

**Table of Contents****TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
Item 1. <u>Financial Statements</u>	
<u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2016 and 2015</u>	1
<u>Condensed Consolidated Statements of Comprehensive Income (Loss) for the Three and Nine Months Ended September 30, 2016 and 2015</u>	2
<u>Condensed Consolidated Balance Sheets as of September 30, 2016 and December 31, 2015</u>	3
<u>Condensed Consolidated Statement of Stockholders' Deficit for the Nine Months Ended September 30, 2016</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2016 and 2015</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	18
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	32
Item 4. <u>Controls and Procedures</u>	32
<b><u>PART II. OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	33
Item 1A. <u>Risk Factors</u>	33
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	35
Item 3. <u>Defaults Upon Senior Securities</u>	35
Item 4. <u>Mine Safety Disclosures</u>	35
Item 5. <u>Other Information</u>	35
Item 6. <u>Exhibits</u>	36
<u>SIGNATURES</u>	37
<u>EXHIBIT INDEX</u>	38

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****Lantheus Holdings, Inc.****Condensed Consolidated Statements of Operations****(Unaudited)****(in thousands, except share and per share data)**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Revenues	\$ 73,063	\$ 74,123	\$ 227,503	\$ 222,260
Cost of goods sold	39,382	40,418	124,370	120,119
Gross profit	33,681	33,705	103,133	102,141
Operating expenses				
Sales and marketing	8,706	8,633	27,856	26,934
General and administrative	10,091	9,206	28,842	33,773
Research and development	2,849	2,458	8,493	11,292
Total operating expenses	21,646	20,297	65,191	71,999
Gain on sales of assets	560		6,505	
Operating income	12,595	13,408	44,447	30,142
Interest expense, net	(6,786)	(7,100)	(20,782)	(31,599)
Debt retirement costs	(1,415)		(1,415)	
Loss on extinguishment of debt				(15,528)
Other (expense) income, net	(154)	(183)	300	234
Income (loss) before income taxes	4,240	6,125	22,550	(16,751)
Provision for income taxes	20	739	657	1,911
Net income (loss)	\$ 4,220	\$ 5,386	\$ 21,893	\$ (18,662)
Net income (loss) per weighted-average common share outstanding:				
Basic	\$ 0.14	\$ 0.18	\$ 0.71	\$ (0.83)
Diluted	\$ 0.13	\$ 0.18	\$ 0.71	\$ (0.83)

Edgar Filing: Lantheus Holdings, Inc. - Form 10-Q

Weighted-average common shares outstanding:				
Basic	31,220,877	30,359,516	30,657,623	22,443,257
Diluted	32,402,297	30,761,771	31,049,351	22,443,257

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

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Net income (loss)	\$ 4,220	\$ 5,386	\$ 21,893	\$ (18,662)
Other comprehensive income (loss):				
Reclassification adjustment for gains on sales of assets included in net income (loss)	435		435	
Foreign currency translation	234	(443)	490	(817)
Total other comprehensive income (loss)	669	(443)	925	(817)
Comprehensive income (loss)	\$ 4,889	\$ 4,943	\$ 22,818	\$ (19,479)

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

**Table of Contents****Lantheus Holdings, Inc.****Condensed Consolidated Balance Sheets****(Unaudited)****(in thousands, except share and per share data)**

	<b>September 30, 2016</b>	<b>December 31, 2015</b>
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 53,195	\$ 28,596
Accounts receivable, net of allowance of \$907 and \$881	34,844	37,293
Inventory	16,057	15,622
Other current assets	6,369	3,851
Assets held for sale		4,644
<b>Total current assets</b>	<b>110,465</b>	<b>90,006</b>
Property, plant & equipment, net	84,980	86,517
Capitalized software development costs, net	7,676	9,137
Intangibles, net	16,406	20,496
Goodwill	15,714	15,714
Other long-term assets	19,728	20,509
<b>Total assets</b>	<b>\$ 254,969</b>	<b>\$ 242,379</b>
<b>Liabilities and Stockholders Deficit</b>		
<b>Current liabilities:</b>		
Current portion of long-term debt	\$ 3,650	\$ 3,650
Accounts payable	13,617	11,657
Accrued expenses and other current liabilities	21,850	18,502
Liabilities held for sale		1,715
<b>Total current liabilities</b>	<b>39,117</b>	<b>35,524</b>
Asset retirement obligation	8,710	8,145
Long-term debt, net	294,582	349,858
Other long-term liabilities	33,716	34,141
<b>Total liabilities</b>	<b>376,125</b>	<b>427,668</b>
<b>Commitments and contingencies (See Note 14)</b>		
<b>Stockholders deficit:</b>		
Preferred stock (\$0.01 par value, 25,000,000 shares authorized; no shares issued and outstanding)		



Edgar Filing: Lantheus Holdings, Inc. - Form 10-Q

Common stock (\$0.01 par value, 250,000,000 shares authorized; 35,714,792 and 30,364,501 shares issued and outstanding, respectively)	357	303
Additional paid-in capital	216,814	175,553
Accumulated deficit	(337,267)	(359,160)
Accumulated other comprehensive loss	(1,060)	(1,985)
<b>Total stockholders deficit</b>	<b>(121,156)</b>	<b>(185,289)</b>
<b>Total liabilities and stockholders deficit</b>	<b>\$ 254,969</b>	<b>\$ 242,379</b>

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

**Table of Contents****Lantheus Holdings, Inc.****Condensed Consolidated Statement of Stockholders Deficit****(Unaudited)****(in thousands, except share data)**

	<b>Common Stock</b>		<b>Additional</b>	<b>Accumulated</b>	<b>Accumulated</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>	<b>Paid-In</b>	<b>Deficit</b>	<b>Other</b>	<b>Stockholders</b>
			<b>Capital</b>		<b>Comprehensive</b>	<b>Deficit</b>
					<b>Loss</b>	
Balance at December 31, 2015	30,364,501	\$ 303	\$ 175,553	\$ (359,160)	\$ (1,985)	\$ (185,289)
Other comprehensive income					925	925
Vesting of restricted stock awards	197,392	2	(2)			
Issuance of common stock from follow-on offering, net of \$1,663 issuance costs	5,200,000	52	39,885			39,937
Shares withheld to cover taxes	(58,077)		(552)			(552)
Stock option exercises	10,976		61			61
Stock-based compensation			1,869			1,869
Net income				21,893		21,893
Balance at September 30, 2016	35,714,792	\$ 357	\$ 216,814	\$ (337,267)	\$ (1,060)	\$ (121,156)

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

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

	<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>
<b>Operating Activities</b>		
Net income (loss)	\$ 21,893	\$ (18,662)
Adjustments to reconcile net income (loss) to cash flows from operating activities:		
Depreciation and amortization	13,200	16,648
Debt retirement costs	1,415	
Provision for excess and obsolete inventory	982	1,073
Stock-based compensation expense	1,869	1,524
Loss on extinguishment of debt		15,528
Gain on sales of assets	(6,505)	
Other	445	2,513
Changes in operating assets and liabilities:		
Accounts receivable	1,071	790
Inventory	(1,658)	(2,441)
Other current assets	(1,032)	(1,075)
Accounts payable	2,684	(2,765)
Accrued expenses and other liabilities	2,497	(3,997)
Cash provided by operating activities	36,861	9,136
<b>Investing Activities</b>		
Proceeds from sales of assets	10,541	
Capital expenditures	(4,976)	(8,419)
Redemption of certificate of deposit restricted	74	
Cash provided by (used in) investing activities	5,639	(8,419)
<b>Financing Activities</b>		
Proceeds from issuance of common stock in public offering	41,600	73,539
Payments for offering costs	(1,266)	(6,821)
Proceeds from issuance of long-term debt		360,438
Principal payments on long-term debt	(57,790)	(969)
Principal payments on senior notes		(400,000)
Payment for call premium on senior notes		(9,752)
Repayments of amounts borrowed under revolving line of credit		(8,000)
	(552)	(97)

Payments of minimum statutory tax withholdings on net share settlements of equity awards		
Proceeds from stock option exercises	61	
Deferred financing costs	(11)	(6,297)
Cash (used in) provided by financing activities	(17,958)	2,041
Effect of foreign exchange rates on cash and cash equivalents	57	(575)
Increase in cash and cash equivalents	24,599	2,183
Cash and cash equivalents, beginning of period	28,596	19,739
Cash and cash equivalents, end of period	\$ 53,195	\$ 21,922

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

**Table of Contents**

**Lantheus Holdings, Inc.**

**Notes to Condensed Consolidated Financial Statements**

**(Unaudited)**

Unless the context otherwise requires, references to the Company and Lantheus refer to Lantheus Holdings, Inc. and its 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, we refer to trademarks, service marks and trade names without the <sup>TM</sup>, <sup>SM</sup> and <sup>®</sup> 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. Business Overview**

*Description of Business*

Holdings, a Delaware corporation, is the parent company of LMI, also a Delaware corporation.

The Company develops, manufactures and commercializes innovative diagnostic medical imaging agents and products that assist clinicians in the diagnosis and treatment of cardiovascular and other diseases. The Company's commercial products are used by cardiologists, nuclear physicians, radiologists, internal medicine physicians, sonographers, and technologists working in a variety of clinical settings. The Company sells its products to radiopharmacies, hospitals, clinics, group practices, integrated delivery networks and group purchasing organizations. The Company sells its products globally and has operations in the United States, Puerto Rico and Canada and third-party distribution relationships in Europe, Australia, Asia Pacific and Latin America.

The Company's portfolio of nine commercial products is diversified across a range of imaging procedures. The Company's imaging agents and products include the following:

DEFINITY is the leading ultrasound contrast imaging agent used by cardiologists and sonographers during cardiac ultrasound, or echocardiography, exams based on revenue and usage. DEFINITY is an injectable agent that, in the United States, is indicated for use in patients with suboptimal echocardiograms to assist in the visualization of the left ventricle, the main pumping chamber of the heart. The use of DEFINITY in echocardiography allows physicians to significantly improve their assessment of the function of the left ventricle.

TechneLite is a self-contained system, or generator, of technetium (Tc99m), a radioisotope with a six hour half-life, used by radiopharmacies to prepare various nuclear imaging agents.

Xenon Xe 133 Gas ( Xenon ) is a radiopharmaceutical gas that is inhaled and used to assess pulmonary function and also cerebral blood flow.

Neurolite is an injectable, technetium-labeled imaging agent used with Single Photon Emission Computed Tomography ( SPECT ), technology to identify the area within the brain where blood flow has been blocked or reduced due to stroke.

Cardiolite is an injectable, technetium-labeled imaging agent, also known by its generic name Sestamibi, used with SPECT technology in myocardial perfusion imaging ( MPI ), procedures that assess blood flow distribution to the heart.

In the United States, the Company sells DEFINITY through its sales team that calls on healthcare providers in the echocardiography space, as well as group purchasing organizations and integrated delivery networks. The Company s radiopharmaceutical products are primarily distributed through third party commercial radiopharmacies.

The Company s International operations consist of sales directly to end users through its wholly owned radiopharmacy in Puerto Rico and sales through the Company s distributors in Canada, Europe, Australia, Asia Pacific and Latin America.

#### *Basis of Presentation*

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ( U.S. GAAP ) for interim information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the Securities and Exchange Commission ( SEC ). Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These condensed consolidated financial statements and accompanying notes are unaudited and should be read in conjunction with the consolidated financial statements and notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2015 filed with the SEC on March 2, 2016 and updated, as necessary, in this quarterly report. There were no other changes to the Company s accounting policies since December 31, 2015.

---

**Table of Contents**

In the opinion of management, the accompanying unaudited condensed consolidated financial statements of Lantheus Holdings, Inc. include all normal and recurring adjustments necessary for a fair statement of the Company's condensed consolidated financial position as of September 30, 2016 and December 31, 2015, results of operations and comprehensive earnings for the three and nine months ended September 30, 2016 and 2015, and cash flows for the nine months ended September 30, 2016 and 2015. The results of operations for the nine months ended September 30, 2016 are not necessarily indicative of the operating results to be expected for the full fiscal year or any future period.

*Principles of Consolidation*

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

*Manufacturing and Customer Concentrations, Liquidity and Management's Plans*

The Company currently relies on Jubilant HollisterStier ( JHS ) as its sole source manufacturer of DEFINITY, NeuroLite and evacuation vials for TechneLite. The Company recently completed its technology transfer activities at JHS and received Food and Drug Administration ( FDA ) approval for its Cardiolite product supply. The Company has technology transfer activities ongoing at Pharmalucence for the manufacture and supply of DEFINITY, but such activities have been further delayed and the Company cannot predict when or if Pharmalucence will be able to manufacture and supply DEFINITY.

Until the Company successfully becomes dual sourced for its principal products, the Company is vulnerable to future supply shortages. Disruption in the financial performance of the Company could also occur if it experiences significant adverse changes in customer mix, broad economic downturns, adverse industry or Company conditions or catastrophic external events. If the Company experiences one or more of these events in the future, it may be required to implement additional 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.

The Company has historically been dependent on key customers and group purchasing organizations for the majority of the sales of its medical imaging products. The Company's ability to maintain and profitably renew those contracts and relationships with those key customers and group purchasing organizations is an important aspect of the Company's strategy.

Borrowing capacity under the Company's \$50.0 million revolving credit facility (the Revolving Facility ), is calculated by reference to a borrowing base consisting of a percentage of certain eligible accounts receivable, inventory and machinery and equipment minus any reserves (the Borrowing Base ). If the Company is not successful in achieving its forecasted operating results, the Company's accounts receivable and inventory could be negatively affected, thus reducing the Borrowing Base and limiting the Company's borrowing capacity. As of September 30, 2016, the aggregate Borrowing Base was approximately \$40.4 million, which was reduced by the \$8.8 million unfunded Standby Letter of Credit and \$0.1 million in accrued interest, resulting in a net Borrowing Base availability of approximately \$31.5 million. The Company's senior secured term loan facility (the Term Facility ), contains a number of affirmative, negative, reporting and financial covenants, in each case subject to certain exceptions and materiality thresholds. Incremental borrowings under the Revolving Facility may affect the Company's ability to comply with the covenants in the Term Facility, including the financial covenant restricting total net leverage. Accordingly, the Company may be limited in utilizing its net Borrowing Base availability as a source of liquidity.

Based on the Company's current operating plans, the Company believes its existing cash and cash equivalents, results of operations and availability under the Revolving Facility will be sufficient to continue to fund the Company's

liquidity requirements for at least the next twelve months.

*Use of Estimates*

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. The more significant estimates reflected in the Company's condensed consolidated financial statements include certain judgments regarding revenue recognition, goodwill, tangible and intangible asset valuation, inventory valuation, asset retirement obligations, income tax liabilities and related indemnification receivable, deferred tax assets and liabilities and accrued expenses. Actual results could materially differ from those estimates or assumptions.



---

**Table of Contents***Recent Accounting Pronouncements*

In August 2016, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update ( ASU ) 2016-15, *Statement of Cash Flows (Topic 230) Classification of Certain cash Receipts and Cash Payments*. ASU 2016-15 will make eight targeted changes to how certain cash receipts and cash payments are presented and classified in the statement of cash flows in order to reduce existing diversity in practice. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. Adoption is required on a retrospective basis unless it is impracticable to apply, in which case the amendments for those issues are to be applied prospectively as of the earliest date practicable. The Company is currently evaluating the impact this ASU will have on our cash flows and disclosures.

In March 2016, the FASB, issued ASU 2016-09, *Compensation Stock Compensation (Topic 719), Improvements to Employee Share-Based Payment Accounting*. ASU 2016-09 simplifies several aspects of accounting for employee share-based payment transactions, including the accounting for income tax consequences, the classification of awards as either equity or liabilities, an accounting policy election for forfeitures, statutory tax withholding requirements and certain classifications on the statement of cash flows. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016, including interim periods within those annual reporting periods. Early adoption is permitted. The Company is currently evaluating the impact this ASU will have on our financial position, results of operations, cash flows and disclosures.

In February 2016, the FASB, issued ASU 2016-02, *Leases (Topic 842)*. ASU 2016-02 supersedes the existing guidance for lease accounting, *Leases (Topic 840)*. ASU 2016-02 was issued to increase transparency and comparability among organizations by requiring lessees to recognize all lease transactions (with terms in excess of 12 months) on the balance sheet as a lease liability and a right-of-use asset (as defined). The accounting for lessors remains largely unchanged. ASU 2016-02 retains a distinction between finance leases and operating leases. For leases with a term of twelve months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize a lease liability and right-of-use asset. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted for all entities. ASU 2016-02 requires a modified retrospective approach for all leases existing at, or entered into after, the date of initial application, with an option to elect to use certain transition relief. The Company is currently evaluating the impact this ASU will have on our financial position, results of operations, cash flows and disclosures.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* or ASU 2014-09. ASU 2014-09 represents a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which a company expects to be entitled to receive in exchange for those goods or services. This ASU sets forth a new five-step revenue recognition model which replaces the prior revenue recognition guidance in its entirety and is intended to eliminate numerous industry-specific pieces of revenue recognition guidance that have historically existed. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606), Deferral of the Effective Date*, which defers the effective date of ASU 2014-09 to annual reporting periods beginning after December 15, 2017 with early adoption permitted as of its original effective date of December 15, 2016. In March 2016 and April 2016, the FASB issued ASU 2016-08, *Revenue from Contracts with Customers (Topic 606), Principal versus Agent Considerations (Reporting Revenue Gross versus Net)* and ASU 2016-10, *Revenue from Contracts with Customers (Topic 606), Identifying Performance Obligations and Licensing*, respectively, which further clarifies the implementation guidance on principal versus agent considerations, identification of performance obligations and accounting for intellectual property licenses. In May 2016, the FASB issued ASU 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients* or ASU 2016-12, which provides clarification on assessing the collectability criterion, presentation of sales taxes, measurement date for noncash

consideration and completed contracts at transition. The Company is currently evaluating the impact these ASUs will have on our financial position, results of operations, cash flows and disclosures.

## **2. Fair Value of Financial Instruments**

The tables below present information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2016 and December 31, 2015, and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points from active markets that are observable, such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability.

**Table of Contents**

(in thousands)	Total fair value	September 30, 2016		
		Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Money market <sup>(1)</sup>	\$ 3,050	\$ 3,050	\$	\$
Total	\$ 3,050	\$ 3,050	\$	\$

(in thousands)	Total fair value	December 31, 2015		
		Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Money market <sup>(1)</sup>	\$ 1,586	\$ 1,586	\$	\$
Certificates of deposit restricted	74		74	
Total	\$ 1,660	\$ 1,586	\$ 74	\$

<sup>(1)</sup> Money market funds are included in cash and cash equivalents in the accompanying consolidated balance sheets; valued at quoted market prices in active markets.

The estimated fair values of the Company's financial instruments, including its cash and cash equivalents, receivables, accounts payable and accrued expenses approximate the carrying values of these instruments due to their short term nature. The estimated fair value of the Company's Term Facility at both September 30, 2016 and December 31, 2015, approximated the carrying value because the interest rate is subject to change with market interest rates.

**3. 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 fiscal year in addition to discrete events which impact the interim period. The Company's effective tax rate differs from the U.S. statutory rate principally due to the rate impact of uncertain tax positions, valuation allowance changes and state taxes. Cumulative adjustments to the tax provision are recorded in the interim period in which a change in the estimated annual effective rate is determined. The Company's tax provision was \$20,000 and \$0.7 million for the three and nine months ended September 30, 2016, respectively, and \$0.7 million and \$1.9 million for the three and nine months ended September 30, 2015, respectively.

During the first quarter of 2016, the Company early adopted ASU No. 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes* on a retrospective basis. This standard requires all deferred taxes and liabilities, and any related valuation allowances, to be classified as non-current on the balance sheet. Adoption of this standard resulted in the reclassification of \$0.1 million of current deferred tax assets to noncurrent deferred tax assets and \$0.2 million of current deferred tax liabilities to noncurrent deferred tax liabilities on the balance sheet at December 31, 2015.

**4. Sales of Certain International Segment Assets**

*Sale of Certain Canadian Assets*

During the fourth quarter of 2015, the Company committed to a plan to sell certain assets and liabilities associated with the Company's international business in Canada. This event qualified for held for sale accounting and the Company determined that the fair value of the net assets being sold significantly exceeded the carrying value as of December 31, 2015. The transaction was finalized in the first quarter of 2016.

Effective January 7, 2016, the Canadian subsidiary of the Company entered into an asset purchase agreement ( Canadian Purchase Agreement ) pursuant to which it would sell substantially all of the assets of its Canadian radiopharmacy businesses and Gludef manufacturing and distribution business to one of its existing Canadian radiopharmacy customers.

The purchase price for the asset sale was \$9.0 million in cash and also included a working capital adjustment of \$0.5 million, which was settled in the third quarter of 2016. The Canadian Purchase Agreement contained customary representations, warranties and covenants by each of the parties. Subject to certain limitations, the buyer will be indemnified for damages resulting from breaches or inaccuracies of the Company's representations, warranties and covenants in the Canadian Purchase Agreement.

**Table of Contents**

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

The Company did not believe the sale of certain net assets in the international segment constituted a strategic shift that would have a major effect on its operations or financial results. As a result, this transaction was not classified as discontinued operations in the Company's financial statements and was classified as assets and liabilities held for sale as of December 31, 2015.

The following table summarizes the major classes of assets and liabilities sold as of January 12, 2016 (date of the sale) and held for sale as of December 31, 2015:

<b>(in thousands)</b>	<b>January 12, 2016</b>	<b>December 31, 2015</b>
<b>Current Assets:</b>		
Accounts receivable, net	\$ 2,620	\$ 2,512
Inventory	730	806
Other current assets	15	26
<b>Total current assets</b>	<b>3,365</b>	<b>3,344</b>
<b>Non-Current Assets:</b>		
Property, plant & equipment, net	760	791
Intangibles, net	462	480
Other long-term assets	28	29
<b>Total assets held for sale</b>	<b>\$ 4,615</b>	<b>\$ 4,644</b>
<b>Current Liabilities:</b>		
Accounts payable	\$ 435	\$ 430
Accrued expense and other liabilities	858	1,285
<b>Total liabilities held for sale</b>	<b>\$ 1,293</b>	<b>\$ 1,715</b>

The sale resulted in a pre-tax book gain of \$5.9 million, which was recorded within gain on sales of assets in the accompanying condensed consolidated statement of operations for the nine months ended September 30, 2016.

*Sale of Australian Radiopharmacy Servicing Subsidiary*

Effective August 11, 2016, the Company entered into a share purchase agreement ( Australian Purchase Agreement ) pursuant to which it sold all of the stock of its Australian radiopharmacy servicing subsidiary to one of its existing radiopharmacy customers.

The sale price was AUD\$2.0 million (approximately \$1.5 million U.S. Dollars) in cash and also included a working capital adjustment of approximately AUD\$2.0 million (approximately \$1.5 million U.S. Dollars) for total proceeds of approximately AUD\$4.0 million (approximately \$3.0 million U.S. Dollars) from the sale. As a result of this sale, the Company disposed of net assets of \$2.2 million primarily comprised of working capital accounts of \$2.0 million.

The sale resulted in a pre-tax book gain of \$0.6 million, which was recorded within gain on sales of assets in the accompanying condensed consolidated statement of operations for the three and nine months ended September 30, 2016. As a result of the sale of the Australian subsidiary, the Company reclassified \$0.5 million from other comprehensive income to gain on sale of assets in the accompanying condensed consolidated statement of operations for the three and nine months ended September 30, 2016.

The Australian Purchase Agreement contained customary representations, warranties and covenants by each of the parties. Subject to certain limitations, the buyer will be indemnified for damages resulting from breaches or inaccuracies of the Company's representations, warranties and covenants in the Australian Purchase Agreement.

As part of the transaction, the Company and the buyer also entered into a long-term supply and distribution contract under which the Company will supply the buyer and its subsidiaries with the Company's products on commercial terms and under which the buyer has agreed to certain product purchase commitments.

**Table of Contents**

The Company did not believe the sale of certain net assets in the international segment constituted a strategic shift that would have a major effect on its operations or financial results. As a result, this transaction was not classified as discontinued operations in the Company's accompanying condensed consolidated financial statements.

**5. Inventory**

Inventory was comprised of the following as of the end of each period:

(in thousands)	September 30, 2016	December 31, 2015
Raw materials	\$ 6,951	\$ 7,506
Work in process	4,597	2,407
Finished goods	4,509	5,709
Total Inventory	\$ 16,057	\$ 15,622

As of September 30, 2016 and December 31, 2015, the Company had \$1.2 million of inventory classified within other long-term assets, which represent raw materials that are not expected to be used by the Company during the next 12 months.

**6. Property, Plant & Equipment, net**

Property, plant & equipment consisted of the following:

(in thousands)	September 30, 2016	December 31, 2015
Land	\$ 14,950	\$ 14,950
Buildings	70,294	68,941
Machinery, equipment and fixtures	66,229	60,787
Sub-total	151,473	144,678
Less: Accumulated depreciation	(72,174)	(67,260)
Property, plant & equipment in service	79,299	77,418
Construction in progress	5,681	9,099
Property, plant & equipment, net	\$ 84,980	\$ 86,517

For the three and nine months ended September 30, 2016, the Company recorded depreciation expense of \$2.1 million and \$6.2 million, respectively, and \$1.9 million and \$9.6 million for the three and nine months ended September 30, 2015.

Property, plant & equipment dedicated to research and development ( R&D ), activities, which were impacted by the March 2013 R&D strategic shift, have a carrying value of \$3.9 million as of September 30, 2016. The Company

believes these assets will be utilized for either internally funded ongoing R&D activities or R&D activities funded by a strategic partner. If the Company is not successful in finding a strategic partner and there are no alternative uses for these assets, then they could be subject to impairment in the future.

## **7. Asset Retirement Obligations**

The Company considers the legal obligation to remediate its facilities upon a decommissioning of its radioactive production facilities as an asset retirement obligation. The operations of the Company have radioactive production facilities at its North Billerica, Massachusetts and San Juan, Puerto Rico sites.

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 the 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, which itself is currently secured by an \$8.8 million unfunded Standby Letter of Credit provided to the third party issuer of the bond.

The fair value of a liability for asset retirement obligations is recognized in the period in which the liability is incurred. As of September 30, 2016, the liability is measured at the present value of the obligation expected to be incurred, of approximately \$26.1 million, and is adjusted in subsequent periods as accretion expense is recorded. The corresponding asset retirement costs are capitalized as part of the carrying value of the related long-lived assets and depreciated over the asset's useful life.



**Table of Contents**

The following is a reconciliation of the Company's asset retirement obligations for the nine months ended September 30, 2016:

(in thousands)	
Balance at December 31, 2015	\$ 8,145
Net increase due to changes in estimated future cash flows	322
Accretion expense	698
Balance at September 30, 2016	9,165
Less: Amounts included in accrued expenses and other liabilities	(455)
Asset retirement obligation, long-term	\$ 8,710

**8. Intangibles, net**

Intangibles, net consisted of the following:

(in thousands)	Cost	September 30, 2016		
		Accumulated Amortization	Net	Amortization Method
Trademarks	\$ 13,540	\$ (8,298)	\$ 5,242	Straight-line
Customer relationships	99,018	(89,115)	9,903	Accelerated
Patents	42,780	(41,519)	1,261	Straight-line
Total	\$ 155,338	\$ (138,932)	\$ 16,406	

(in thousands)	Cost	December 31, 2015		
		Accumulated Amortization	Net	Amortization Method
Trademarks	\$ 13,540	\$ (6,934)	\$ 6,606	Straight-line
Customer relationships	100,737	(88,564)	12,173	Accelerated
Patents	42,780	(41,063)	1,717	Straight-line
Total	\$ 157,057	\$ (136,561)	\$ 20,496	

For the three and nine months ended September 30, 2016, the Company recorded amortization expense for its intangible assets of \$1.3 million and \$3.9 million, respectively, as compared to \$1.5 million and \$4.5 million for the prior year comparative periods.

Expected future amortization expense related to the intangible assets is as follows:

Edgar Filing: Lantheus Holdings, Inc. - Form 10-Q

(in thousands)

Remainder of 2016	\$ 1,277
2017	3,341
2018	2,647
2019	1,804
2020	1,569
2021 and thereafter	5,768
	\$ 16,406

**Table of Contents****9. Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities are comprised of the following:

(in thousands)	September 30, 2016	December 31, 2015
Compensation and benefits	\$ 12,216	\$ 10,525
Freight, distribution and operations	3,435	2,962
Accrued rebates, discounts and chargebacks	2,593	2,085
Accrued professional fees	1,636	1,493
Marketing expense	600	490
Research and development services	229	360
Other	1,141	587
 Total accrued expenses and other current liabilities	 \$ 21,850	 \$ 18,502

**10. Financing Arrangements***Term Facility*

On June 30, 2015, the Company entered into a \$365.0 million seven-year Term Facility, which was issued net of a 1.25% discount of \$4.6 million. The Company has a right to request an increase of the Term Facility in an aggregate amount up to \$37.5 million plus additional amounts subject to certain leverage ratios. The net proceeds of the Term Facility, together with the net proceeds of the initial public offering ( IPO ), and cash on hand, were used to refinance in full the aggregate principal amount of the \$400.0 million 9.750% Senior Notes ( the Notes ) and pay related premiums, interest and expenses.

The term loans under the Term Facility bear interest, with pricing based from time to time at the Company's election at (i) LIBOR plus a spread of 6.00% (with a LIBOR rate floor of 1.00%) or (ii) the Base Rate (as defined in our Term Facility) plus a spread of 5.00%. Interest under term loans based on (i) the LIBOR rate is payable at the end of each Interest Period (as defined in our Term Facility) and (ii) the Base Rate is payable at the end of each quarter. At September 30, 2016, the Company's interest rate under the Term Facility was 7.00%.

The Company is permitted to voluntarily prepay the Term Facility, in whole or in part, without premium or penalty. The Company is required to make quarterly payments, which began on September 30, 2015, in an amount equal to a quarter of a percent (0.25%) per annum of the original principal amount of the Term Facility. The remaining unpaid principal amount of the Term Facility will be payable on the maturity date, or June 30, 2022.

The Term Facility will require the Company to prepay outstanding term loans, subject to certain exceptions, with:

100% of the net cash proceeds of all non-ordinary course sales or other dispositions of assets (including as a result of casualty or condemnation, subject to certain exceptions); the Company may reinvest or commit to reinvest certain of those proceeds in assets useful in our business within twelve months;

100% of the net cash proceeds from issuances or incurrence of debt, other than proceeds from debt permitted under the Term Facility and Revolving Facility; and

50% (with two leverage-based stepdowns) of the Company's excess cash flow.

The foregoing mandatory prepayments will be applied to the scheduled installments of principal of the Term Facility as directed by LMI, or in the absence of direction, in direct order of maturity.

The Term Facility is guaranteed by the Company and Lantheus Real Estate, and obligations under the Term Facility are secured by substantially all the property and assets and all interests of the Company, LMI and Lantheus Real Estate.

In September 2016, the Company made a voluntary prepayment of \$55.0 million on the Term Facility with the net proceeds of \$39.9 million received from a follow-on underwritten primary offering of the Company's common stock and approximately \$15.1 million from available cash on hand. This voluntary prepayment represented a partial extinguishment of the Term Facility. Accordingly, the Company recognized debt retirement costs totaling \$1.4 million in the accompanying condensed consolidated statement of operations representing the pro-rata portion of the unamortized debt issuance costs and original issue discount at the date of the payment.

**Table of Contents**

The Company's maturities of principal obligations under the Term Facility are as follows as of September 30, 2016:

<b>(in thousands)</b>	
Remainder of 2016	\$ 913
2017	3,650
2018	3,650
2019	3,650
2020	3,650
2021 and thereafter	289,925
<b>Total debt</b>	<b>305,438</b>
Less: Unamortized debt discount	(3,139)
Less: Unamortized debt issuance costs	(4,067)
<b>Total</b>	<b>298,232</b>
Less: Current portion of long-term debt	(3,650)
<b>Total Long-term debt, net</b>	<b>\$ 294,582</b>

*Term Facility Covenants*

The Term Facility contains a number of affirmative, negative, reporting and financial covenants, in each case subject to certain exceptions and materiality thresholds. The Term Facility requires the Company to be in quarterly compliance, measured on a trailing four quarter basis. The financial covenants are displayed in the table below:

**Term Facility Financial Covenants**

<b>Period</b>	<b>Total Net Leverage Ratio</b>
Q2 2016 to Q4 2016	6.00 to 1.00
Q1 2017 to Q2 2017	5.50 to 1.00
Thereafter	5.00 to 1.00

The Term Facility contains usual and customary restrictions on the ability of the Company and its subsidiaries to: (i) incur additional indebtedness (ii) create liens; (iii) consolidate, merge, sell or otherwise dispose of all or substantially all of its assets; (iv) sell certain assets; (v) pay dividends on, repurchase or make distributions in respect of capital stock or make other restricted payments; (vi) make certain investments; (vii) repay subordinated indebtedness prior to stated maturity; and (viii) enter into certain transactions with its affiliates.

*Revolving Line of Credit*

At September 30, 2016, the Company had a Revolving Facility with an aggregate principal amount not to exceed \$50.0 million. The loans under the Revolving Facility bear interest with pricing based from time to time at the election of LMI at (i) LIBOR plus a spread of 2.00% or (ii) the Reference Rate (as defined in the Revolving Facility) plus 1.00%. The Revolving Facility also includes an unused line fee of 0.375% and expires on June 30, 2020.

As of September 30, 2016, the Company has an unfunded Standby Letter of Credit for up to \$8.8 million. The unfunded Standby Letter of Credit requires an annual fee, payable quarterly, which is set at LIBOR plus a spread of 2.00% and expires in February 2017. It automatically renewed for a one year period and will continue to automatically renew for a one year period at each anniversary date, unless the Company elects not to renew in writing within 60 days prior to such expiration.

The Revolving Facility is guaranteed by Holdings and Lantheus Real Estate and is secured by a pledge of substantially all of the assets of each of the loan parties including accounts receivable, inventory and machinery and equipment. Borrowing capacity is determined by reference to a Borrowing Base, which is based on a percentage of certain eligible accounts receivable, inventory and machinery and equipment minus any reserves. As of September 30, 2016, the aggregate Borrowing Base was approximately \$40.4 million, which was reduced by an outstanding \$8.8 million unfunded Standby Letter of Credit and \$0.1 million in accrued interest, resulting in a net Borrowing Base availability of approximately \$31.5 million.

**Table of Contents***Revolving Line of Credit Covenants*

The Revolving Facility contains a number of affirmative, negative, reporting and financial covenants, as well as a financial covenant during trigger periods in the form of a consolidated fixed charge coverage ratio of not less than 1:00:1:00. Upon an event of default, the lender has the right to declare the loans and other obligations outstanding immediately due and payable and all commitments immediately terminated or reduced, and the lender may, after such events of default, require the Company to make deposits with respect to any outstanding letters of credit in an amount equal to 105% of the greatest amount for which such letter of credit may be drawn.

**11. Stock-Based Compensation**

As of June 24, 2015, the Company adopted the 2015 Equity Incentive Plan, which was further amended on April 26, 2016 (the 2015 Plan ).

The Company's employees are eligible to receive awards under the 2015 Plan. The 2015 Plan is administered by the Board of Directors and permits the granting of stock options, stock appreciation rights ( SARs ), restricted stock, restricted stock units and dividend equivalent rights ( DERs ) to employees, officers, directors and consultants of the Company. The Board of Directors may, at its sole discretion, grant DERs with respect to any award and such DERs are treated as separate awards. The number of shares authorized for issuance under the 2015 Plan increased to 4,555,277 on April 26, 2016. Option awards under the 2015 Plan are granted with an exercise price equal to the fair value of the Company's common stock at the date of grant. Time based option awards vest based on time, typically four years, and performance based option awards vest based on the performance criteria specified in the grant. All option awards have a ten-year contractual term. The Company recognizes compensation costs for its time based awards on a straight-line basis equal to the vesting period. The compensation cost for performance based awards is recognized on a graded vesting basis, based on the probability of achieving the performance targets over the requisite service period for the entire award. The fair value of each option award is estimated on the date of grant using a Black-Scholes valuation model. Expected volatilities are based on the historic volatility of a selected peer group. Expected dividends represent the dividends expected to be issued at the date of grant. The expected term of options represents the period of time that options granted are expected to be outstanding. The risk-free interest rate assumption is the U.S. Treasury rate at the date of the grant which most closely resembles the expected life of the options.

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

(in thousands)	Three Months Ended		Nine Months Ended	
	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
Cost of goods sold	\$ 120	\$ 51	\$ 259	\$ 102
General and administrative	487	417	1,065	1,095
Sales and marketing	123	71	251	186
Research and development	147	52	294	141
<b>Total stock-based compensation expense</b>	<b>\$ 877</b>	<b>\$ 591</b>	<b>\$ 1,869</b>	<b>\$ 1,524</b>

**12. Net Income (Loss) Per Common Share**

Basic income (loss) per share is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings per common share is computed by dividing net income by the weighted-average number of shares of common stock outstanding during the period, plus the potential dilutive effect of other securities if those securities were converted or exercised. During periods in which the Company incurs net losses, both basic and diluted loss per share is calculated by dividing the net loss by the weighted-average shares outstanding and potentially dilutive securities are excluded from the calculation because their effect would be antidilutive.



**Table of Contents**

(in thousands, except share and per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net income (loss)	\$ 4,220	\$ 5,386	\$ 21,893	\$ (18,662)
Basic weighted-average common shares outstanding	31,220,877	30,359,516	30,657,623	22,443,257
Effect of dilutive restricted stock awards	1,084,571	289,911	391,728	
Effect of dilutive stock options	96,849	112,344		
Diluted weighted-average common shares outstanding	32,402,297	30,761,771	31,049,351	22,443,257
Basic income (loss) per weighted-average common share outstanding	\$ 0.14	\$ 0.18	\$ 0.71	\$ (0.83)
Diluted income (loss) per weighted-average common share outstanding	\$ 0.13	\$ 0.18	\$ 0.71	\$ (0.83)

The stock options and nonvested restricted stock excluded from weighted-average common shares because of their antidilutive effect for the three and nine months ended September 30, 2016 and 2015 include:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Stock Options	428,121	646,329	1,068,156	1,321,771
Restricted Stock	19,662	6,993	804,624	1,092,361

**13. Other (Expense) Income, net**

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Foreign currency losses	\$ (349)	\$ (628)	\$ (330)	\$ (989)
Tax indemnification income	196	439	632	1,216
Other (expense) income	(1)	6	(2)	7
Total Other (expense) income, net	\$ (154)	\$ (183)	\$ 300	\$ 234

**14. Legal Proceedings and Contingencies**

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 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. 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, 2016, the Company had no material ongoing litigation in which the Company was a defendant or any material ongoing regulatory or other proceedings and had no knowledge of any investigations by government or regulatory authorities in which the Company is a target that could have a material adverse effect on its current business.

### **15. Related Party Transactions**

Avista, the Company's largest shareholder, provided certain advisory services to the Company pursuant to an advisory services and monitoring agreement. The Company was required to pay an annual fee of \$1.0 million and other reasonable and customary advisory fees, as applicable, paid on a quarterly basis. The initial term of the agreement was seven years. On June 25, 2015, the Company exercised its right to terminate its advisory services and monitoring agreement with Avista. In connection with such termination, the Company has paid Avista Capital Holdings, L.P. an aggregate termination fee of \$6.5 million, which was included in general and administrative expenses in the condensed consolidated statement of operations during the quarter ended June 30, 2015.

**Table of Contents**

During both the three months ended September 30, 2016 and 2015, the Company did not incur any costs associated with this agreement. During the nine months ended September 30, 2016, the Company did not incur any costs associated with this agreement as compared to \$7.0 million for the prior year comparative period. At September 30, 2016 and December 31, 2015, there were no amounts outstanding.

In the first quarter of 2016, the Company entered into a services agreement with INC Research, LLC ( INC ), to provide pharmacovigilance services. Avista and certain of its affiliates are principal owners of both INC and the Company. The agreement has a term of three years. During the three and nine months ended September 30, 2016, the Company incurred costs associated with this agreement of approximately \$0.3 million and \$0.6 million, respectively. At September 30, 2016, \$0.2 million was included in accrued expenses and other liabilities.

The Company purchases inventory supplies from VWR Scientific ( VWR ). Avista and certain of its affiliates have ownership interests in each of VWR and the Company. During each of the three and nine months ended September 30, 2016 and 2015, the Company made purchases of \$0.1 million and \$0.2 million, respectively. At September 30, 2016 and December 31, 2015, \$1,200 and \$10,000, respectively, were included in accounts payable and accrued expenses.

**16. Segment Information**

The Company reports two operating segments, United States 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 manufacturing, marketing, selling and distribution of medical imaging products, focused primarily on cardiovascular diagnostic imaging. All goodwill has been allocated to the United States operating segment.

Selected information for each business segment are as follows:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
<b>Revenues</b>				
United States	\$ 68,896	\$ 64,420	\$ 211,911	\$ 194,897
International	10,443	14,911	34,816	44,003
Total revenues	79,339	79,331	246,727	238,900
Less: inter-segment revenue	(6,276)	(5,208)	(19,224)	(16,640)
Total revenues, less inter-segment revenues	\$ 73,063	\$ 74,123	\$ 227,503	\$ 222,260
<b>Revenues from external customers</b>				
United States	\$ 62,620	\$ 59,212	\$ 192,687	\$ 178,257
International	10,443	14,911	34,816	44,003
Total revenues from external customers	\$ 73,063	\$ 74,123	\$ 227,503	\$ 222,260

<b>Operating income</b>				
United States	\$ 14,135	\$ 13,303	\$ 43,469	\$ 29,424
International	(1,411)	2	1,281	587
Total operating income, including inter-segment	12,724	13,305	44,750	30,011
Inter-segment operating (loss) income	(129)	103	(303)	131
Operating income	12,595	13,408	44,447	30,142
Interest expense, net	(6,786)	(7,100)	(20,782)	(31,599)
Debt retirement costs	(1,415)		(1,415)	
Loss on extinguishment of debt				(15,528)
Other (expense) income, net	(154)	(183)	300	234
Income (loss) before income taxes	\$ 4,240	\$ 6,125	\$ 22,550	\$ (16,751)

---

**Table of Contents**

**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 are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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, hopes and similar expressions. Examples of forward-looking statements include, but are not limited to, statements we make regarding: (i) our outlook and expectations including, without limitation, in connection with continued market expansion and penetration for our commercial products, particularly DEFINITY, in the face of increased competition; (ii) our outlook and expectations in connection with future performance of Xenon in the face of increased competition; (iii) our outlook and expectations related to products manufactured at JHS and Pharmeducence and global isotope supply; (iv) our outlook and expectations related to our engagement of strategic partners to assist in developing and potentially commercializing development candidates; and (v) our liquidity, including our belief that our existing cash, cash equivalents, anticipated revenues and availability under our Revolving Facility, are sufficient to fund our existing operating expenses, capital expenditures and liquidity requirements for at least the next twelve months.

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, they 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. They 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 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:

our ability to continue to increase segment penetration for DEFINITY in suboptimal echocardiograms and the increased segment competition from other echocardiography contrast agents;

risks associated with revenues and unit volumes for Xenon in pulmonary studies with increased segment competition resulting from Mallinckrodt's recent re-launch of their Xenon product;

our dependence on key customers and group purchasing organization arrangements for our medical imaging products, and our ability to maintain and profitably renew our contracts and relationships with those key customers and group purchasing organizations;

our dependence upon third parties for the manufacture and supply of a substantial portion of our products, including for DEFINITY at JHS;

risks associated with the technology transfer programs to secure production of our products at alternate contract manufacturer sites, including for DEFINITY at Pharmeducence where activities have been

significantly delayed;

risks associated with the manufacturing and distribution of our products and the regulatory requirements related thereto;

the instability of the global Molybdenum-99 ( Moly ), supply;

the dependence of certain of our customers upon third party healthcare payors and the uncertainty of third party coverage and reimbursement rates;

uncertainties regarding the impact of U.S. healthcare reform on our business, including related reimbursements for our current and potential future products;

our being subject to extensive government regulation and our potential inability to comply with those regulations;

potential liability associated with our marketing and sales practices;

the occurrence of any side effects with our products;

our exposure to potential product liability claims and environmental liability;

risks associated with our most advanced agent in development, flurpiridaz F 18, including our ability to:

attract strategic partners to successfully complete the Phase 3 clinical program and possibly manufacture and commercialize the agent;

obtain FDA approval; and

gain post-approval market acceptance and adequate reimbursement;

**Table of Contents**

risks associated with being able to negotiate in a timely manner relationships with potential strategic partners to advance our other development programs on acceptable terms, or at all;

the extensive costs, time and uncertainty associated with new product development, including further product development relying on external development partners, all against an evolving diagnostic landscape;

our inability to protect our intellectual property and the risk of claims that we have infringed on the intellectual property of others;

risks associated with prevailing economic conditions and financial, business and other factors beyond our control;

risks associated with our international operations;

our inability to adequately protect our facilities, equipment and technology infrastructure;

our inability to hire or retain skilled employees and key personnel;

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;

our inability to utilize or limitations in our ability to utilize net operating loss carryforwards to reduce our future tax liability; and

risks related to the ownership of our common stock.

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 Securities and Exchange Commission. Any forward-looking statement made by us in this quarterly report 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.

*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 Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2016 and June 30, 2016 and in Part II Item 1A. Risk Factors of this Quarterly Report on Form 10-Q.*

## Overview

We are a global leader in the development, manufacture and commercialization of innovative diagnostic medical imaging agents and products that assist clinicians in the diagnosis and treatment of cardiovascular and other diseases. Our agents are routinely used to diagnose coronary artery disease, congestive heart failure, pulmonary diseases, stroke and other diseases. Clinicians use our imaging agents and products across a range of imaging procedures, including echocardiography and nuclear imaging. 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, internal medicine physicians, sonographers and technologists working in a variety of clinical settings. We sell our products to radiopharmacies, hospitals, clinics, group practices, integrated delivery networks and group purchasing organizations.

We sell our products globally and have operations in the United States, Puerto Rico and Canada and third-party distribution relationships in Europe, Australia, Asia Pacific and Latin America.

### *Our Products*

Our principal products include the following:

DEFINITY is an ultrasound 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 United States 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 launched DEFINITY in 2001, and its last issued patent in the United States will currently expire in 2021 and in numerous foreign jurisdictions in 2019. We also have an active next generation development program for this agent.



**Table of Contents**

TechneLite is a technetium generator which provides the essential nuclear material used by radiopharmacies to radiolabel Cardiolite, Neurolite and other technetium-based radiopharmaceuticals used in nuclear medicine procedures. TechneLite uses Moly as its main active ingredient.

Xenon is a radiopharmaceutical gas that is inhaled and used to assess pulmonary function and also cerebral blood flow. Xenon is manufactured by a third party and packaged by us and in certain circumstances finished by us.

Sales of our contrast agent, DEFINITY, are made in the United States and Canada through our sales team of approximately 80 employees. In the United States, our nuclear imaging products, including TechneLite, Xenon, Cardiolite and Neurolite, are primarily distributed through commercial radiopharmacies, the majority of which are controlled by or associated with Cardinal, UPPI, GE Healthcare and Triad. A small portion of our nuclear imaging product sales in the United States are made through our direct sales force to hospitals and clinics that maintain their own in-house radiopharmaceutical capabilities. Outside the United States, we own one radiopharmacy in Puerto Rico. On January 12, 2016, we sold our Canadian radiopharmacies to Isologic and entered into a long-term supply agreement with Isologic under which we will supply Isologic with certain of our products on commercial terms, including certain product purchase commitments by Isologic. The agreement expires on January 12, 2021 and may be terminated upon the occurrence of specified events, including a material breach by the other party, bankruptcy by either party or certain force majeure events. On August 11, 2016, we sold our Australian radiopharmacy servicing business to Global Medical Solutions (GMS), and entered into a long-term supply agreement with GMS under which we will supply GMS with certain of our products on commercial terms, including certain minimum product purchase commitments by GMS. The agreement expires on August 11, 2020 and may be terminated in whole or in part on a product-by-product basis upon the occurrence of specified events, including a material breach by the other party, bankruptcy by either party or certain force majeure events. We also maintain our own direct sales force in Canada so we can control the importation, marketing, distribution and sale of our imaging agents in Canada. In Europe, Asia Pacific and Latin America, we also 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.

The following table sets forth our revenue derived from our principal products:

(in thousands)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2016	% of Total Revenues	2015	% of Total Revenues	2016	% of Total Revenues	2015	% of Total Revenues
DEFINITY	\$ 32,604	44.6%	\$ 28,883	39.0%	\$ 97,499	42.9%	\$ 82,977	37.3%
TechneLite	24,533	33.6	17,223	23.2	74,621	32.8	55,445	24.9
Xenon	6,677	9.1	12,723	17.2	21,625	9.5	37,965	17.1
Other	9,249	12.7	15,294	20.6	33,758	14.8	45,873	20.6
Total Revenues	\$ 73,063	100.0%	\$ 74,123	100.0%	\$ 227,503	100.0%	\$ 222,260	100.0%

**Key Factors Affecting Our Results**

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

*Growth of DEFINITY*

We believe the market opportunity for our contrast agent, DEFINITY, remains significant. DEFINITY is currently our fastest growing and highest margin commercial product. We believe that DEFINITY sales will continue to grow and that DEFINITY will constitute a greater share of our overall product mix. As we better educate the physician and healthcare provider community about the benefits and risks of this product, we believe we will experience further penetration of suboptimal echocardiograms.

The future growth of our DEFINITY sales are dependent on our ability to continue to increase segment penetration for DEFINITY in suboptimal echocardiograms and, as discussed below in Inventory Supply, on the ability of JHS, and, if approved Pharmalucence, to continue to manufacture and release DEFINITY on a timely and consistent basis. See Part 1 Item 1A. Risk Factors The growth of our business is substantially dependent on increased market penetration for the appropriate use of DEFINITY in suboptimal echocardiograms of our annual report on Form 10-K for the fiscal year ended December 31, 2015.

There are three echocardiography contrast agents approved by the FDA for sale in the United States DEFINITY which as of December 2015 had an approximately 78% segment share, Optison from GE Healthcare, and Lumason from Bracco Diagnostics

---

**Table of Contents**

( Bracco ), which was approved by the FDA in October 2014. Lumason is known as SonoVue outside of the United States and is already approved for sale in Europe and certain Asian markets, including China, Japan and Korea. While we believe that additional promotion in the United States echocardiography segment will help raise awareness around the value that echocardiography contrast brings and potentially increase the overall contrast penetration rate, if Bracco successfully grows the use of Lumason in the United States without otherwise increasing the overall usage of ultrasound contrast agents, our own growth expectations for DEFINITY revenue, gross profit and gross margin may have to be adjusted.

*Competition for Xenon*

Xenon gas for lung ventilation diagnosis is our third largest product by revenue. Historically, several companies, including Mallinckrodt, sold packaged Xenon as a pulmonary imaging agent in the United States, but from 2010 through the first quarter of 2016 we have been the only supplier of this imaging agent in the United States. In March 2016, Mallinckrodt received regulatory approval from the FDA to again sell packaged Xenon in the United States and has begun to do so. Depending upon the pricing, extent of availability and market penetration of Mallinckrodt's offering, we believe we are at risk for volume loss and price erosion from those customers that are not subject to price or volume commitments with us. In order to increase the predictability of our Xenon business, we have entered into Xenon supply agreements at committed volumes and substantially reduced prices with previously non-contracted customers. These steps have resulted in predictable Xenon unit volumes in 2016, but with sales at substantially lower revenue and gross margin contributions as compared to 2015. See Part II Item 1A. Risk Factors We face potential supply and demand challenges for Xenon.

*Inventory Supply*

Our products consist of contrast imaging agents and radiopharmaceuticals (including technetium generators). We obtain a substantial portion of our imaging agents from third party suppliers. JHS is currently our sole source manufacturer of DEFINITY, Neurolite, Cardiolite and evacuation vials, an ancillary component for our TechneLite generators. Until JHS is approved by certain foreign regulatory authorities to manufacture certain of our products, we will face continued limitations on where we can sell those products outside of the United States.

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. Our technology transfer activities with Pharmeducence to manufacture and supply DEFINITY are ongoing, but such activities have been further delayed and we cannot predict when or if Pharmeducence will be able to manufacture and supply DEFINITY. See Part I Item IA. Risk Factors Our dependence upon third parties for the manufacture and supply of a substantial portion of our products could prevent us from delivering our products to our customers in the required quantities, within the required timeframes, or at all, which could result in order cancellations and decreased revenues of our annual report on Form 10-K for the fiscal year ended December 31, 2015.

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 useful lives and are subject to just-in-time manufacturing, processing and distribution, which takes place at our North Billerica, Massachusetts facility.

*Global Isotope Supply*

Historically, an important supplier of Moly and Xenon was Nordion, which relied on the NRU reactor in Chalk River, Ontario. For Moly and Xenon, we had supply agreements with Nordion that expired on October 31, 2016. We currently have Moly supply agreements with NTP of South Africa, ANSTO of Australia, and IRE of Belgium, each

running through December 31, 2017 and a Xenon supply agreement with IRE which runs through June 30, 2019, subject to extensions.

We believe we are well-positioned with ANSTO, IRE and NTP to have a secure supply of Moly, including Moly produced from the use of low-enriched uranium ( LEU Moly ). The NRU reactor will transition beginning on November 1, 2016 from providing regular supply of medical isotopes to providing only an emergency back-up supply of high-enriched uranium ( HEU ), based medical isotopes through March 2018. ANSTO has already significantly increased its Moly production capacity from its existing facility in August 2016 and has under construction, in cooperation with NTP, a new Moly processing facility that ANSTO believes will expand its production capacity up to approximately 3,500 six-day Curies/week, which is expected to be in commercial operation in the second half of 2017. In addition, IRE recently received approval from its regulator to expand its production capability by up to 50% of its former capacity. The new ANSTO and IRE production capacity is expected to replace and exceed the NRU s current routine production.

## **Table of Contents**

We are also now receiving bulk unprocessed Xenon from IRE which we are processing and finishing for our customers. We believe we are well-positioned to supply Xenon to our customers as the NRU reactor will transition beginning on November 1, 2016 from providing regular supply of bulk Xenon to providing only an emergency back-up supply of bulk Xenon through March 2018.

### *Demand for TechneLite*

We believe there has been a decline in the MPI study market because of industry-wide cost containment initiatives that have resulted in a transition of where imaging procedures are performed, from free-standing imaging centers to the hospital setting. While the total number of patient studies has not returned to pre-shortage levels, the total MPI market was essentially flat for the period 2011 through 2015.

In November 2015, CMS announced the 2016 final Medicare payment rules for hospital outpatient settings. Under the final rules, each technetium dose produced from a generator for a diagnostic procedure in a hospital outpatient setting is reimbursed by Medicare at a higher rate if that technetium dose is produced from a generator containing Moly sourced from at least 95% LEU. In January 2013, we began to offer a TechneLite generator which contains Moly sourced from at least 95% LEU and which satisfies the requirements for reimbursement under this incentive program. Although demand for LEU generators appears to be growing, we do not know when, or if, this incremental reimbursement for LEU Moly generators will result in a material increase in our generator sales.

### *Research and Development Expenses*

To remain a leader in the marketplace, we have historically made substantial investments in new product development. As a result, the positive contributions of those internally funded R&D programs have been a key factor in our historical results and success. In March 2013, we began to implement a strategic shift in how we fund our important R&D programs. We have reduced our internal R&D resources while at the same time we are seeking to engage strategic partners to assist us in the further development and commercialization of our important agents in development, including flurpiridaz F 18, 18F LMI 1195 and LMI 1174. As a result of this shift, we are seeking strategic partners to assist us with the further development and possible commercialization of flurpiridaz F18. For our other two important agents in development, 18F LMI 1195 and LMI 1174, we are also seeking to engage strategic partners to assist us with the ongoing development activities relating to these agents.

## **Segments**

We report our results of operations in two operating segments: United States and International. We generate a greater proportion of our revenue and net income in the United States segment, which consists of all regions of the United States with the exception of Puerto Rico.

## **Executive Overview**

Our results for the three and nine months ended September 30, 2016 reflect the following:

Increased revenues and segment penetration for DEFINITY in the suboptimal echocardiogram segment as a result of our sales efforts and sustained availability of product supply;

Increased revenues for TechnoLite, mainly the result of contracts with significant customers;

Decreased revenues for Xenon, mainly the result of lower selling prices;

\$5.9 million gain on the sale of our Canadian radiopharmacies;

\$0.6 million gain on the sale of our Australian radiopharmacy servicing business;

\$1.4 million debt retirement costs associated with the \$55.0 million voluntary principal prepayment on our Term Facility;

Lower international revenues as a result of the sale of our Canadian radiopharmacies and Australian radiopharmacy servicing business and unfavorable exchange rates;

Decreased depreciation over the prior year period associated with the scheduled decommissioning of certain long-lived assets in the prior year,

Decreased interest expense due to the refinancing of long-term debt in connection with the IPO,

Decreased general and administrative expenses due to a \$6.5 million payment for the termination of our advisory services and monitoring agreement with Avista in the prior year; and

**Table of Contents**

Decrease of \$15.5 million loss on extinguishment of debt costs related to the redemption of LMI s outstanding Notes in the prior year.

**Results of Operations**

(in thousands)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Revenues	\$ 73,063	\$ 74,123	\$ 227,503	\$ 222,260
Cost of goods sold	39,382	40,418	124,370	120,119
Gross profit	33,681	33,705	103,133	102,141
Operating expenses				
Sales and marketing	8,706	8,633	27,856	26,934
General and administrative	10,091	9,206	28,842	33,773
Research and development	2,849	2,458	8,493	11,292
Total operating expenses	21,646	20,297	65,191	71,999
Gain on sales of assets	560		6,505	
Operating income	12,595	13,408	44,447	30,142
Interest expense, net	(6,786)	(7,100)	(20,782)	(31,599)
Debt retirement costs	(1,415)		(1,415)	
Loss on extinguishment of debt				(15,528)
Other (expense) income, net	(154)	(183)	300	234
Income (loss) before income taxes	4,240	6,125	22,550	(16,751)
Provision for income taxes	20	739	657	1,911
Net income (loss)	\$ 4,220	\$ 5,386	\$ 21,893	\$ (18,662)

*Revenues*

Revenues by segment are summarized as follows:

(dollars in thousands)	Three Months Ended				Nine Months Ended			
	September 30,				September 30,			
	2016	2015	Change		2016	2015	Change	
	Amount	Amount	Amount	%	Amount	Amount	Amount	%
United States								
DEFINITY	\$ 32,007	\$ 28,323	\$ 3,684	13.0%	\$ 95,497	\$ 81,333	\$ 14,164	17.4%
TechneLite	20,906	14,557	6,349	43.6%	64,282	47,367	16,915	35.7%

Edgar Filing: Lantheus Holdings, Inc. - Form 10-Q

Xenon	6,675	12,713	(6,038)	(47.5)%	21,620	37,937	(16,317)	(43.0)%
Other	3,033	3,619	(586)	(16.2)%	11,288	11,620	(332)	(2.9)%
<b>Total United States Revenues</b>	<b>62,621</b>	<b>59,212</b>	<b>3,409</b>	<b>5.8%</b>	<b>192,687</b>	<b>178,257</b>	<b>14,430</b>	<b>8.1%</b>
<b>International</b>								
DEFINITY	597	560	37	6.6%	2,002	1,644	358	21.8%
TechneLite	3,627	2,666	961	36.0%	10,339	8,078	2,261	28.0%
Xenon	2	10	(8)	(80.0)%	5	28	(23)	(82.1)%
Other	6,216	11,675	(5,459)	(46.8)%	22,470	34,253	(11,783)	(34.4)%
<b>Total International Revenues</b>	<b>10,442</b>	<b>14,911</b>	<b>(4,469)</b>	<b>(30.0)%</b>	<b>34,816</b>	<b>44,003</b>	<b>(9,187)</b>	<b>(20.9)%</b>
<b>Total Revenues</b>	<b>\$ 73,063</b>	<b>\$ 74,123</b>	<b>\$ (1,060)</b>	<b>(1.4)%</b>	<b>\$ 227,503</b>	<b>\$ 222,260</b>	<b>\$ 5,243</b>	<b>2.4%</b>

The increase in United States segment revenues for the three and nine months ended September 30, 2016, as compared to the prior year periods is primarily due to a \$6.3 million and \$16.9 million increase, respectively, in TechneLite revenues as a result of contracts with customers that increased unit volumes and a \$3.7 million and \$14.2 million, respectively, increase in DEFINITY



**Table of Contents**

revenues as a result of higher unit volumes. Offsetting these increases was a \$6.0 million and \$16.3 million, respectively, decrease in Xenon revenues over the prior year periods primarily as a result of contracts with significant customers that reduced unit pricing in exchange for committed volume purchases.

The decreases in International segment revenues for the three and nine months ended September 30, 2016, as compared to the corresponding periods in the prior year are primarily the result of the decreases in revenues in Canada and Australia attributable to the sale of our radiopharmacy businesses. These decreases were offset by foreign currency favorability of \$0.8 million for the nine month period ended September 30, 2016 compared to the prior year period. The impact of foreign currency for the three month period ended September 30, 2016 was immaterial.

**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 and other liabilities. These rebates result from performance-based offers that are primarily based on attaining contractually specified sales volumes and growth, Medicaid rebate programs, administrative fees of group purchasing organizations, royalties 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 or commission rate(s) to be earned over a contractual period.

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

<b>(in thousands)</b>	<b>Rebates</b>	<b>Allowances</b>	<b>Total</b>
Balance, as of December 31, 2015	\$ 2,303	\$ 38	\$ 2,341
Current provisions relating to revenues in current year	5,289	189	5,478
Adjustments relating to prior years' estimate	(66)		(66)
Payments/credits relating to revenues in current year	(3,527)	(173)	(3,700)
Payments/credits relating to revenues in prior years	(1,406)	(38)	(1,444)
Balance, as of September 30, 2016	\$ 2,593	\$ 16	\$ 2,609

Accrued sales rebates were approximately \$2.6 million and \$2.3 million at September 30, 2016 and December 31, 2015, respectively.

***Costs of Goods Sold***

Cost of goods sold consists of manufacturing, distribution, intangible asset amortization and other costs related to our commercial products. In addition, it includes the write-off of excess and obsolete inventory.

Cost of goods sold is summarized as follows:

**Three Months Ended  
September 30,**

**Nine Months Ended  
September 30,**

<b>(dollars in thousands)</b>	<b>2016</b>	<b>2015</b>	<b>Change</b>		<b>2016</b>	<b>2015</b>	<b>Change</b>	
	<b>Amount</b>	<b>Amount</b>	<b>Amount</b>	<b>%</b>	<b>Amount</b>	<b>Amount</b>	<b>Amount</b>	<b>%</b>
United States	\$ 31,133	\$ 26,930	\$ 4,203	15.6%	\$ 96,791	\$ 81,360	\$ 15,431	19.0%
International	8,249	13,488	(5,239)	(38.8)%	27,579	38,759	(11,180)	(28.8)%
<b>Total Cost of goods sold</b>	<b>\$ 39,382</b>	<b>\$ 40,418</b>	<b>\$ (1,036)</b>	<b>(2.6)%</b>	<b>\$ 124,370</b>	<b>\$ 120,119</b>	<b>\$ 4,251</b>	<b>3.5%</b>

The increase in the United States segment cost of goods sold for the three and nine months ended September 30, 2016 over the prior year periods is primarily due to unit volumes noted in the revenue discussion above. Offsetting these increases was a \$0.3 million and \$0.2 million, respectively, decrease in technology transfer expenses.

The decrease in the International segment cost of goods sold in the three and nine months ended September 30, 2016, as compared to the prior year periods, is primarily due to lower manufacturing costs for certain products as a result of the sale of our Canadian and Australian radiopharmacy businesses.

**Table of Contents***Gross Profit*

(dollars in thousands)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2016 Amount	2015 Amount	Change		2016 Amount	2015 Amount	Change	
			Amount	%			Amount	%
United States	\$ 31,488	\$ 32,282	\$ (794)	(2.5)%	\$ 95,896	\$ 96,897	\$ (1,001)	(1.0)%
International	2,193	1,423	770	54.1%	7,237	5,244	1,993	38.0%
<b>Total Gross profit</b>	<b>\$ 33,681</b>	<b>\$ 33,705</b>	<b>\$ (24)</b>	<b>(0.1)%</b>	<b>\$ 103,133</b>	<b>\$ 102,141</b>	<b>\$ 992</b>	<b>1.0%</b>

The decreases in the United States segment gross profit for the three and nine months ended September 30, 2016 over the prior year periods is primarily due to lower Xenon unit volumes and lower selling price. Offsetting these decreases were increases in DEFINITY and TechneLite gross profit due to higher unit volumes.

The increase in the International segment gross profit for the three months ended September 30, 2016 over the prior year period is primarily due to increased operational efficiencies as a result of the sale of our Canadian radiopharmacies and the shutdown of one of our Puerto Rican radiopharmacies in the third quarter of 2015, combined with lower manufacturing costs for certain products.

The increase in the International segment gross profit for the nine months ended September 30, 2016 over the prior year period is primarily due to lower Thallium cost of goods per unit, lower manufacturing costs for certain products as a result of the sale of our Canadian radiopharmacies and increased operational efficiencies as a result of the shutdown of one of our Puerto Rican radiopharmacies in the third quarter of 2015. These increases were partially offset by a \$0.5 million unfavorable foreign exchange.

*Sales and Marketing*

(dollars in thousands)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2016 Amount	2015 Amount	Change		2016 Amount	2015 Amount	Change	
			Amount	%			Amount	%
United States	\$ 8,021	\$ 7,840	\$ 181	2.3%	\$ 24,902	\$ 24,192	\$ 710	2.9%
International	685	793	(108)	(13.6)%	2,954	2,742	212	7.7%
<b>Total Sales and marketing</b>	<b>\$ 8,706</b>	<b>\$ 8,633</b>	<b>\$ 73</b>	<b>0.8%</b>	<b>\$ 27,856</b>	<b>\$ 26,934</b>	<b>\$ 922</b>	<b>3.4%</b>

Sales and marketing expenses consist primarily of salaries and other related costs for personnel in field sales, marketing, business development 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.

The increase in the United States segment sales and marketing expenses for the three months ended September 30, 2016 over the prior year period is primarily due to employee related expenses and travel.

## Edgar Filing: Lantheus Holdings, Inc. - Form 10-Q

The increase in the United States segment sales and marketing expenses for the nine months ended September 30, 2016 over the prior year period is primarily due to incentive compensation, as well as the timing of sales force meetings, training and travel, partially offset by the timing of advertising and promotional activities.

The decrease in the International segment sales and marketing expenses for the three months ended September 30, 2016 over the prior year period is primarily due to lower headcount associated with the International commercial team.

The increase in the International segment sales and marketing expenses for the nine months ended September 30, 2016 over the prior year period is primarily due to increased employee related expenses for the International commercial team.

**Table of Contents***General and Administrative*

(dollars in thousands)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2016 Amount	2015 Amount	Change Amount	%	2016 Amount	2015 Amount	Change Amount	%
United States	\$ 9,693	\$ 8,792	\$ 901	10.2%	\$ 27,629	\$ 32,425	\$ (4,796)	(14.8)%
International	398	414	(16)	(3.9)%	1,213	1,348	(135)	(10.0)%
<b>Total General and administrative</b>	<b>\$ 10,091</b>	<b>\$ 9,206</b>	<b>\$ 885</b>	<b>9.6%</b>	<b>\$ 28,842</b>	<b>\$ 33,773</b>	<b>\$ (4,931)</b>	<b>(14.6)%</b>

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.

The increase in the United States segment general and administrative expenses for the three months ended September 30, 2016 over the prior year period is primarily due to higher amortization of capitalized software, higher employee related expenses, and higher legal fees.

The decrease in the United States segment general and administrative expenses for the nine months ended September 30, 2016 over the prior year period is primarily due to the \$6.5 million termination fee paid to terminate the advisory services and monitoring agreement with Avista in the prior year and lower employee related expenses. This was partially offset by higher amortization of capitalized software, increased insurance costs and higher legal fees.

Total International segment general and administrative expenses remained consistent for the three months ended September 30, 2016 as compared to the prior year period.

The decrease in the International segment general and administrative expenses for the nine months ended September 30, 2016 over the prior year period is primarily due to lower employee headcount and related expenses.

*Research and Development*

(dollars in thousands)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2016 Amount	2015 Amount	Change Amount	%	2016 Amount	2015 Amount	Change Amount	%
United States	\$ 2,685	\$ 2,245	\$ 440	19.6%	\$ 7,985	\$ 10,726	\$ (2,741)	(25.6)%
International	164	213	(49)	(23.0)%	508	566	(58)	(10.2)%
<b>Total Research and development</b>	<b>\$ 2,849</b>	<b>\$ 2,458</b>	<b>\$ 391</b>	<b>15.9%</b>	<b>\$ 8,493</b>	<b>\$ 11,292</b>	<b>\$ (2,799)</b>	<b>(24.8)%</b>

Research and development expenses relate primarily to the development of new products to add to our portfolio and costs related to its medical affairs, medical information and regulatory functions. We do not allocate research and development expenses incurred in the United States to our International segment.

The increase in the United States segment research and development expenses for the three months ended September 30, 2016 over the prior year period is primarily due to higher employee related expenses.

The decrease in the United States segment research and development expenses for the nine months ended September 30, 2016 over the prior year period is primarily due to a reduction in depreciation expense as a result of the scheduled decommissioning of certain long-lived assets associated with research and development operations, partially offset by higher employee related expenses and pharmacovigilance expenses due to the transition to a new vendor.

Total International segment research and development expenses remained consistent for the three and nine months ended September 30, 2016 as compared to the prior year periods.

**Table of Contents***Gain on Sales of Assets*

Effective January 7, 2016, our Canadian subsidiary entered into an asset purchase agreement, pursuant to which it sold substantially all of the assets of our Canadian radiopharmacies and Gludef manufacturing and distribution business to one of our existing Canadian radiopharmacy customers. The sale price was \$9.0 million in cash and also included a working capital adjustment of \$0.5 million, resulting in a pre-tax book gain of \$5.9 million, which was recorded within operating income for the nine months ended September 30, 2016.

Effective August 11, 2016, we entered into a share purchase agreement, pursuant to which we sold 100% of the stock of our Australian subsidiary to one of our existing radiopharmacy customers. This sale included the radiopharmacy business as well as all the direct/bulk business. The sale price for the share sale was AUD\$2.0 million (approximately \$1.5 million U.S. Dollars) in cash and also included a working capital receivable adjustment of approximately AUD\$2.0 million (approximately \$1.5 million U.S. Dollars), resulting in a pre-tax book gain of \$0.6 million, which was recorded within operating income for the nine months ended September 30, 2016.

*Other (Expense) Income, Net*

(dollars in thousands)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2016 Amount	2015 Amount	Change Amount	%	2016 Amount	2015 Amount	Change Amount	%
Interest expense	\$ (6,792)	\$ (7,105)	\$ 313	(4.4)%	\$ (20,799)	\$ (31,617)	\$ 10,818	(34.2)%
Interest income	6	5	1	20.0%	17	18	(1)	(5.6)%
Debt retirement costs	(1,415)		(1,415)	100.0%	(1,415)		(1,415)	100.0%
Loss on extinguishment of debt						(15,528)	15,528	(100.0)%
Other (expense) income, net	(154)	(183)	29	(15.8)%	300	234	66	28.2%
Total Other (expense) income, net	\$ (8,355)	\$ (7,283)	\$ (1,072)	14.7%	\$ (21,897)	\$ (46,893)	\$ 24,996	(53.3)%

**Interest Expense**

For the three months ended September 30, 2016, compared to the same period in 2015, interest expense decreased by \$0.3 million as a result of a lower principal balance outstanding on our Term Facility due to required quarterly principal payments.

For the nine months ended September 30, 2016, compared to the same period in 2015, interest expense decreased by \$10.8 million, as a result of the June 2015 refinancing of our long-term debt at a lower principal amount with a lower interest rate.

**Debt Retirement Costs**

For the three and nine months ended September 30, 2016, we incurred \$1.4 million in debt retirement costs related to the \$55.0 million voluntary prepayment of principal on our Term Facility.

Extinguishment of Debt

For the nine months ended September 30, 2015, we incurred a \$15.5 million loss on extinguishment of debt related to the redemption of LMI s Notes.

Other (Expense) Income, net

For the three months ended September 30, 2016, compared to the same period in 2015, other income remained consistent.

For the nine months ended September 30, 2016, compared to the same period in 2015, other income increased by \$0.1 million, primarily due a \$0.7 million decrease in foreign currency losses, which was partially offset by a \$0.6 million decrease in tax indemnification income.



**Table of Contents***Provision for Income Taxes*

(dollars in thousands)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2016 Amount	2015 Amount	Change Amount	%	2016 Amount	2015 Amount	Change Amount	%
Provision for income taxes	\$ 20	\$ 739	\$ (719)	(97)%	\$ 657	\$ 1,911	\$ (1,254)	(66)%

Considering our history of losses, we continue to maintain a valuation allowance against substantially all of our net deferred tax assets. Our provision for income taxes results primarily from reversals of uncertain tax positions as statutes lapse or are settled during the year, offset by taxes due in certain foreign jurisdictions where we generate taxable income, as well as interest and penalties associated with uncertain tax positions. For the nine months ended September 30, 2016 and 2015, our effective tax rate was 2.9% and 11.4%, respectively. The \$0.7 million and \$1.3 million decrease in the tax provision for the three months and nine months ended September 30, 2016, as compared to the same periods in 2015, was primarily due to changes in our uncertain tax positions relating to state tax nexus and the release of tax reserves.

**Liquidity and Capital Resources***Cash Flows*

The following table provides information regarding our cash flows:

(in thousands)	Nine Months Ended September 30,	
	2016	2015
Cash provided by operating activities	\$ 36,861	\$ 9,136
Cash provided by (used in) investing activities	\$ 5,639	\$ (8,419)
Cash (used in) provided by financing activities	\$ (17,958)	\$ 2,041
Effect of foreign exchange rates on cash and cash equivalents	\$ 57	\$ (575)

*Net Cash Provided by Operating Activities*

Cash provided by operating activities of \$36.9 million in the first nine months of 2016 was driven primarily by net income of \$21.9 million plus \$14.0 million of depreciation and amortization and \$1.4 million of debt retirement costs less the gain on sale of assets of \$6.5 million. In addition, our working capital decrease during the first nine months of 2016 was driven primarily by an increase of \$2.7 million in accounts payable due to the timing of payment runs, a \$2.5 million increase in accrued expenses due to the timing of payroll and accrued bonuses, offset by an increase of \$1.7 million in inventory due to the timing of production and receipt of inventory, a decrease in accounts receivable of \$1.0 million due to improved collections, and an increase of \$1.0 million in prepaid expenses due to insurance renewals.

Cash provided by operating activities of \$9.1 million in the first nine months of 2015 was driven primarily by a net loss of \$18.7 million plus \$16.6 million of depreciation and amortization and \$15.5 million loss on extinguishment of debt. These net sources of cash were partially offset by a net increase in working capital. Our working capital increase during the first nine months of 2015 was driven primarily by a \$4.0 million decrease in accrued expenses as a result of

the debt refinancing in June 2015, a decrease of \$2.8 million in accounts payable due to the timing of payment runs, an increase of \$2.4 million in inventory due to the timing of production and receipt of inventory, a \$1.1 million increase in prepaid expenses due to additional costs associated with becoming a public company and a \$1.0 million decrease in accounts receivable due to improved collections.

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

Net cash provided by investing activities during the nine months ended September 30, 2016 was primarily due to cash proceeds of \$10.5 million received for the sale of assets from our Canadian and Australian radiopharmacy businesses, which was offset by \$5.0 million for capital expenditures.

Net cash used in investing activities during the nine month ended September 30, 2015 was \$8.4 million for capital expenditures.

**Table of Contents***Net Cash (Used in) Provided by Financing Activities*

During the nine months ended September 30, 2016, we completed a follow-on underwritten primary offering, raising \$39.9 million of net proceeds, and used these net proceeds and cash on hand of \$15.1 million to prepay \$55.0 million of the principal balance of our Term Facility. We also used approximately \$2.7 million of cash on hand for our quarterly Term Facility payments. As a result of this debt prepayment, we expect to reduce our annual interest expense by approximately \$3.9 million.

During the nine months ended September 30, 2015, our financing activities provided a source of cash of \$2.0 million as a result of generating \$421.4 million from the net proceeds of the Term Facility together with the net proceeds from the IPO. The net proceeds generated from the Term Facility and the IPO were used to repay in full the aggregate principal amount of the \$400.0 million Notes, pay related premiums and expenses and pay down the \$8.0 million of outstanding borrowings under the Revolving Facility, which totaled \$417.8 million. The net proceeds were further offset by our first quarterly payment on the Term Facility.

*External Sources of Liquidity*

On June 30, 2015, we completed our initial public offering, entered into a new \$365.0 million seven-year Term Facility and amended and restated our Revolving Facility that has a borrowing capacity of \$50.0 million. The net proceeds of the Term Facility and the initial public offering together with available cash were used to repay in full the aggregate principal amount of the \$400.0 million Notes, and pay related premiums, interest and expenses and pay down \$8.0 million of borrowings under the Revolving Facility. As noted above, in September 2016, we completed a follow-on underwritten primary offering of 5,200,000 shares of common stock and utilized the net proceeds from this offering, combined with cash on hand, to prepay \$55.0 million of the principal balance of our Term Facility. As of September 30, 2016, the principal balance outstanding on our Term Facility was \$305.4 million.

We have the right to request an increase of the Term Facility in an aggregate amount up to \$37.5 million plus additional amounts subject to certain leverage ratios. The term loans under the Term Facility bear interest, with pricing based from time to time at our election at (i) LIBOR plus a spread of 6.00% (with a LIBOR rate floor of 1.00%) or (ii) the Base Rate (as defined in our Term Facility) plus a spread of 5.00%. Interest under term loans based on (i) the LIBOR rate is payable at the end of each interest period (as defined in our Term Facility) and (ii) the Base Rate is payable at the end of each quarter. At September 30, 2016, our interest rate under the Term Facility was 7.00%. Our Term Facility is guaranteed by the Lantheus Holdings and Lantheus Real Estate, and obligations under the Term Facility are secured by substantially all the property and assets and all interests of Lantheus Holdings, LMI and Lantheus Real Estate.

Our Term Facility contains a number of affirmative, negative, reporting and financial covenants, in each case subject to certain exceptions and materiality thresholds. Incremental borrowings under the Revolving Facility may affect our ability to comply with the covenants in the Term Facility, including the financial covenant restricting total net leverage. Accordingly, we may be limited in utilizing our net Borrowing Base availability as a source of liquidity. Our Term Facility requires us to be in quarterly compliance, measured on a trailing four quarter basis. The financial covenants are displayed in the table below:

**Term Facility Financial Covenants****Period****Total Net Leverage Ratio**

Edgar Filing: Lantheus Holdings, Inc. - Form 10-Q

Q2 2016 to Q4 2016	6.00 to 1.00
Q1 2017 to Q2 2017	5.50 to 1.00
Thereafter	5.00 to 1.00

The Term Facility contains usual and customary restrictions on the ability of us and our subsidiaries to: (i) incur additional indebtedness (ii) create liens; (iii) consolidate, merge, sell or otherwise dispose of all or substantially all of our assets; (iv) sell certain assets; (v) pay dividends on, repurchase or make distributions in respect of capital stock or make other restricted payments; (vi) make certain investments; (vii) repay subordinated indebtedness prior to stated maturity; and (viii) enter into certain transactions with our affiliates.

As of September 30, 2016, we had an unfunded Standby Letter of Credit of \$8.8 million. The unfunded Standby Letter of Credit requires annual fees, payable quarterly, which, subsequent to the amendment, is set at LIBOR plus a spread of 2.00% and expires in February 2017. It automatically renewed for a one year period and will continue to automatically renew for a one year period at each anniversary date, unless we elect not to renew in writing within 60 days prior to such expiration.

Our Revolving Facility is secured by a pledge of substantially all of our assets, including accounts receivable, inventory and machinery and equipment, and is guaranteed by each of Lantheus Holdings and Lantheus Real Estate. Borrowing capacity is

---

**Table of Contents**

determined by reference to the Borrowing Base, which is based on (i) a percentage of certain eligible accounts receivable, inventory and machinery and equipment minus (ii) any reserves. As of September 30, 2016, the aggregate Borrowing Base was approximately \$40.4 million, which was reduced by an outstanding \$8.8 million unfunded Standby Letter of Credit and \$0.1 million in accrued interest, resulting in a net borrowing base availability of approximately \$31.5 million.

The loans under our Revolving Facility bear interest with pricing based from time to time at our election at (i) LIBOR plus a spread of 2.00% or (ii) the Reference Rate (as defined in our Revolving Facility) plus a spread of 1.00%. Our Revolving Facility also includes an unused line fee of 0.375% and expires on June 30, 2020.

Our Revolving Facility contains affirmative and negative covenants, as well as restrictions on the ability of LMI, us and our subsidiaries to: (i) incur additional indebtedness or issue preferred stock; (ii) repay subordinated indebtedness prior to its stated maturity; (iii) pay dividends on, repurchase or make distributions in respect of capital stock or make other restricted payments; (iv) make certain investments; (v) sell certain assets; (vi) create liens; (vii) consolidate, merge, sell or otherwise dispose of all or substantially all of our assets; and (viii) enter into certain transactions with our affiliates. Our Revolving Facility also contains customary default provisions as well as cash dominion provisions which allow the lender to sweep our accounts during the period (x) certain specified events of default are continuing under our Revolving Facility or (y) excess availability under our Revolving Facility falls below (i) the greater of \$7.5 million or 15% of the then-current Line Cap (as defined in the Revolving Facility) for a period of more than five consecutive Business Days or (ii) \$5.0 million. During a covenant trigger period, we are required to comply with a consolidated fixed charge coverage ratio of not less than 1:00: 1:00. The fixed charge coverage ratio is calculated on a consolidated basis for us for a trailing four-fiscal quarter period basis, as (i) annualized EBITDA (as defined in the Revolving Facility) minus capital expenditures minus certain restricted payments divided by (ii) interest expense plus taxes paid or payable in cash plus certain restricted payments made in cash plus scheduled principal payments paid or payable in cash.

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 open market repurchases of any notes outstanding, 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 repurchased or otherwise retired, if any, would be decided at the sole discretion of our Board of Directors and will depend on market conditions, trading levels of our debt from time to time, our cash position and other considerations.

*Funding Requirements*

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

our ability to have product manufactured and released from JHS and other manufacturing sites in a timely manner in the future;

the pricing environment and the level of product sales of our currently marketed products, particularly DEFINITY and any additional products that we may market in the future;

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 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 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;

the extent to which we acquire or invest in products, businesses and technologies;

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.

## **Table of Contents**

Until we successfully become dual sourced for our principal products, we are vulnerable to future supply shortages. Disruption in the financial performance could also occur if we experience significant adverse changes in customer mix, broad economic downturns, adverse industry or company conditions or catastrophic external events. If we experience one or more of these events in the future, we may be required to implement additional 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, assets securitizations, debt financings, sale-leasebacks or other financing or strategic alternatives, to the extent such transactions are permissible under the covenants of the agreements governing our senior secured credit facilities. 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 the agreements governing our senior secured credit facilities, 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, 2016, our only current committed external source of funds is our borrowing availability under our Revolving Facility. We had \$53.2 million of cash and cash equivalents at September 30, 2016. Availability under our Revolving Facility is calculated by reference to the Borrowing Base. If we are not successful in achieving our forecasted results, our accounts receivable and inventory could be negatively affected, reducing the Borrowing Base and limiting our borrowing availability. Our new Term Facility contains a number of affirmative, negative, reporting and financial covenants, in each case subject to certain exceptions and materiality thresholds. Incremental borrowings under the Revolving Facility may affect our ability to comply with the covenants in the Term Facility, including the financial covenant restricting total net leverage. Accordingly, we may be limited in utilizing our net Borrowing Base availability as a source of liquidity.

Based on our current operating plans, we believe that our existing cash and cash equivalents, results of operations and availability under our Revolving Facility will be sufficient to continue to fund our liquidity requirements for at least the next twelve months.

## **Critical Accounting Policies and Estimates**

The discussion and analysis of our financial position and results of operations is 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 in accordance with U.S. GAAP requires us to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition and related allowances, inventory, impairments of long-lived assets including intangible assets, impairments of goodwill, income taxes including the valuation allowance for deferred tax assets. 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.

During the first quarter of 2016, we early adopted ASU No. 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes* on a retrospective basis. This standard requires all deferred taxes and liabilities, and any related valuation allowances, to be classified as non-current on the balance sheet. Adoption of this standard resulted in the reclassification of \$0.1 million of current deferred tax assets to noncurrent deferred tax assets and \$0.2 million of current deferred tax liabilities to noncurrent deferred tax liabilities on the balance sheet at December 31,

2015.

There have been no additional material changes to our critical accounting policies or in the underlying accounting assumptions and estimates used in such policies as of September 30, 2016. For further information, refer to our summary of significant accounting policies and estimates in our annual report on Form 10-K filed for the fiscal year ended December 31, 2015.

**Off-Balance Sheet Arrangements**

We are required to provide the U.S. Nuclear Regulatory Commission ( NRC ), 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 and an \$8.8 million letter of credit.

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



## **Table of Contents**

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to market risk from changes in interest rates and foreign currency exchange rates. We do not hold or issue financial instruments to reduce these risks or for trading purposes and historically we have not used derivative financial instruments or other financial instruments to hedge these economic exposures.

#### **Interest Rate Risk**

As a result of our new Term Facility, we have substantial variable rate debt. Fluctuations in interest rates may affect our business, financial condition, results of operations and cash flows. As of September 30, 2016, we had \$305.4 million outstanding under our Term Facility with a variable interest rate that only varies to the extent LIBOR exceeds one percent.

Furthermore, we are subject to interest rate risk in connection with the Revolving Facility, which is variable rate indebtedness. Interest rate changes could increase the amount of our interest payments and thus negatively impact our future earnings and cash flows. As of September 30, 2016, there was an \$8.8 million unfunded Standby Letter of Credit and \$0.1 million accrued interest, which reduced availability to \$31.5 million on the Revolving Facility. Any increase in the interest rate under the Revolving Facility may have a negative impact on our future earnings to the extent we have outstanding borrowings under the Revolving Facility. The effect of a 100 basis points adverse change in market interest rates, in excess of minimum floors, on our interest expense would be approximately \$2.7 million in the nine months ended September 30, 2016.

Historically, we have not used derivative financial instruments or other financial instruments to hedge such economic exposures.

#### **Foreign Currency Risk**

We face exposure to movements in foreign currency exchange rates whenever we, or any of our subsidiaries, enter into transactions with third parties that are denominated in currencies other than ours, or that subsidiary's functional currency. Intercompany transactions between entities that use different functional currencies also expose us to foreign currency risk.

During the nine months ended September 30, 2016 and 2015, the net impact of foreign currency changes on transactions was a loss of \$0.3 million and \$1.0 million, respectively. Historically, we have not used derivative financial instruments or other financial instruments to hedge these economic exposures.

A portion of our earnings is generated by our foreign subsidiaries, whose functional currencies are other than the U.S. Dollar. Our earnings could be materially impacted by movements in foreign currency exchange rates upon the translation of the earnings of those subsidiaries into the U.S. Dollar. The Canadian Dollar presents the primary currency risk on our earnings. If the U.S. Dollar had been uniformly stronger by 10%, compared to the actual average exchange rates, our gross margin would have decreased by \$1.4 million during the nine months ended September 30, 2016 as a result of this translation risk.

The cost of goods for our products that are manufactured in the United States and are sold in currencies other than the U.S. Dollar by our foreign subsidiaries are also affected by foreign currency exchange rate movements. Our gross margin would have decreased by \$1.7 million if the U.S. Dollar had been stronger by 10% when compared to the actual rates used during the nine months ended September 30, 2016 as a result of this risk.

**Item 4. Controls and Procedures**  
**Disclosure Controls and Procedures**

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) or 15d-15(e) promulgated under the Exchange Act. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report.

**Changes in Internal Control Over Financial Reporting**

There have been no changes during the quarter ended September 30, 2016 in our internal control over financial reporting (as defined in Rule 13a-15(f) promulgated under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents**

**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 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. 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 noted above, as of September 30, 2016, the Company had no material ongoing litigation in which the Company was a defendant or any material ongoing regulatory or other proceedings and had no knowledge of any investigations by government or regulatory authorities in which the Company is a target that could have a material adverse effect on its current business.

**Item 1A. Risk Factors**

There have been no material changes in the risk factors set forth in our Form 10-K for the fiscal year ended December 31, 2015 except as set forth below. For further information, refer to Item 1A. Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

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

We obtain a substantial portion of our products from third party manufacturers and suppliers. We rely on JHS as our sole source manufacturer of DEFINITY, Neurolite, Cardiolite and evacuation vials. We currently have additional ongoing technology transfer activities at Pharmeducence for DEFINITY, but we can give no assurances as to when that technology transfer will be completed and when we will actually receive supply of DEFINITY from Pharmeducence. Currently, our DEFINITY, Neurolite, evacuation vial, saline and Cardiolite product supply is approved for manufacture by a single manufacturer. In addition, we have no manufacturer for Ablavar.

Currently, we believe that we will have sufficient supply of DEFINITY, Neurolite, Cardiolite and evacuation vials from JHS to meet expected demand and sufficient supply of saline from our sole manufacturer. However, we can give no assurances that JHS or our other manufacturing partners will be able to manufacture and distribute our products in a high quality and timely manner and in sufficient quantities to allow us to avoid product stock-outs and shortfalls. Currently, regulatory authorities in certain countries have not yet approved JHS as a manufacturer of our products. Accordingly, until those regulatory approvals have been obtained, our international business, results of operations, financial condition and cash flows will continue to be adversely affected.

Our manufacturing agreement for Ablavar has terminated. We have no current plans to initiate technology transfer activities for Ablavar. Our existing Ablavar inventory has expired during the third quarter of 2016, and we have no further Ablavar inventory that we will be able to sell unless and until we engage in Ablavar technology transfer

activities in the future with a new manufacturing partner.

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

---

**Table of Contents**

In addition to our existing manufacturing relationships, we are also pursuing new manufacturing relationships to establish and secure additional or alternative suppliers for our commercial products. Our technology transfer activities are ongoing at Pharmeducence for the manufacture and supply of DEFINITY, but such activities have been further delayed and we cannot predict when or if Pharmeducence will be able to manufacture and supply DEFINITY. We cannot assure you that any of our additional supply activities will be successful, or that before those new manufacturers or sources of product are fully functional and qualified, that we will be able to avoid or mitigate interim supply shortages. In addition, we cannot assure you that our existing manufacturers or suppliers or any new manufacturers or suppliers can adequately maintain either their financial health or regulatory compliance to allow continued production and supply. A reduction or interruption in manufacturing, or an inability to secure alternative sources of raw materials or components, could eventually have a material adverse effect on our business, results of operations, financial condition and cash flows.

***We face potential supply and demand challenges for Xenon.***

Historically, Nordion has been our sole supplier, and a principal supplier on a global basis, of Xenon, which is captured as a by-product of the Moly production process. In January 2015, we entered into a strategic agreement with IRE for the supply of Xenon. We are now receiving bulk unprocessed Xenon from IRE, which we are processing and finishing for our customers. We believe we will have a sufficient supply of Xenon for our customers after the NRU reactor transitions as of November 1, 2016 from providing regular supply of bulk Xenon to providing only an emergency back-up supply of bulk Xenon through March 2018. However, until we can qualify an additional source of bulk unprocessed Xenon, after the Nordion transition we will rely on IRE as a sole source provider. For the year ended December 31, 2015, Xenon represented approximately 17% of our revenues.

Historically, several companies, including Mallinckrodt, sold packaged Xenon as a pulmonary imaging agent in the U.S., but starting in 2010 we have been the only supplier of this imaging agent in the U.S. In March 2016, Mallinckrodt received regulatory approval from the FDA to again sell packaged Xenon in the U.S. and has begun to do so. Depending upon the pricing, extent of availability and market penetration of Mallinckrodt's offering, we believe we are at risk for volume loss and price erosion from those customers that are not subject to price or volume commitments with us.

In addition to Mallinckrodt again selling packaged Xenon in the U.S., if there is an increase in the use of other imaging modalities in place of packaged Xenon, our current sales volumes would decrease, which could have a negative effect on our business, results of operations, financial condition and cash flows.

Xenon is frequently administered as part of a ventilation scan to evaluate pulmonary function prior to a perfusion scan with microaggregated albumin ( MAA ), a technetium-based radiopharmaceutical used to evaluate blood flow to the lungs. Currently, Draxis is the sole supplier of MAA on a global basis. In 2014, Draxis announced substantial price increases for MAA. The increased price of MAA, or difficulties in obtaining MAA, could decrease the frequency in which MAA is used for lung perfusion evaluation, in turn, decreasing the frequency that Xenon is used for pulmonary function evaluation, resulting in a negative effect on our business, results of operations, financial condition and cash flows.

***We face significant competition in our business and may not be able to compete effectively.***

The market for diagnostic medical imaging agents is highly competitive and continually evolving. Our principal competitors in existing diagnostic modalities include large, global companies with substantial financial, manufacturing, sales and marketing and logistics resources that are more diversified than ours, such as GE Healthcare, Bracco, Mallinckrodt, Bayer and Draxis, as well as other competitors. We cannot anticipate their actions in the same

or competing diagnostic modalities, such as significant price reductions on products that are comparable to our own, development or introduction of new products that are more cost-effective or have superior performance than our current products, the introduction of generic versions when our proprietary products lose their patent protection or the new entry into a generic market in which we are already a participant. In addition, distributors of our products could attempt to shift end-users to competing diagnostic modalities and products. Our current or future products could be rendered obsolete or uneconomical as a result of these activities. Our failure to compete effectively could cause us to lose market share to our competitors and have a material adverse effect on our business, results of operations, financial condition and cash flows.

In October 2014, Bracco received FDA approval in the United States for its echocardiography agent, Lumason (known as SonoVue outside of the U.S.), which is already approved for sale in Europe and certain Asian markets, including China, Japan and Korea. Bracco now has one of three FDA-approved echocardiography contrast agents in the United States, together with GE Healthcare's Optison and our DEFINITY. If Bracco successfully grows the use of Lumason in the United States without otherwise increasing the overall usage of ultrasound contrast agents, our current and future sales volume could suffer, which would have a material adverse effect on our business, results of operations, financial condition and cash flows.

**Table of Contents**

Xenon for lung ventilation diagnosis is our third largest product by revenue. Historically, several companies, including Mallinckrodt, sold packaged Xenon as a pulmonary imaging agent in the U.S., but starting in 2010 we have been the only supplier of this imaging agent in the U.S. In March 2016, Mallinckrodt received regulatory approval from the FDA to again sell packaged Xenon in the U.S. and has begun to do so. Depending upon the pricing, extent of availability and market penetration of Mallinckrodt's offering, we believe we are at risk of volume loss and price erosion from those customers that are not subject to price or volume commitments with us.

*We may be limited in our ability to utilize, or may not be able to utilize, net operating loss carryforwards to reduce our future tax liability.*

As of December 31, 2015, we had federal income tax loss carryforwards of \$175.5 million, which will begin to expire in 2031 and will completely expire in 2034. We have had significant financial losses in previous years and as a result we currently maintain a full valuation allowance for our net deferred tax assets including our federal and state tax loss carryforwards. We may be limited in our ability to use these tax loss carryforwards to reduce our future U.S. federal income tax liabilities if we were to experience an ownership change as specified in Section 382 of the Internal Revenue Code including if we were to issue a certain amount of equity securities, certain of our Stockholders were to sell shares of our common stock, or we were to enter into certain strategic transactions.

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

The following table presents information with respect to purchases of common stock we made during the quarter ending September 30, 2016. The Company does not have a share repurchase program in effect. The 2015 Equity Incentive Plan, or the 2015 Plan, adopted by the Company on June 24, 2015, and further amended April 26, 2016, provides for the withholding of shares to satisfy tax 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.

Period	Total Number of Shares Purchased	Share Price Paid Per Share	Total Number of Shares	
			Announced Programs	Under the Program
July 2016		\$	*	*
August 2016	20,434	\$ 9.52	*	*
September 2016	37,643	\$ 9.50	*	*
Total	58,077		*	

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

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.



**Table of Contents****Item 6. Exhibits**

<b>EXHIBIT NUMBER</b>	<b>DESCRIPTION OF EXHIBITS</b>	<b>INCORPORATED BY REFERENCE</b>	
		<b>FILE FORMNUMBER</b>	<b>EXHIBIT FILING DATE</b>
10.1 *	Share Purchase Agreement, effective August 11, 2016, by and between Lantheus Medical Imaging, Inc. and Global Medical Solutions, Ltd.		
10.2 *	Second Amendment, effective September 2, 2016, to the Manufacturing and Supply Agreement, dated as of February 1, 2012 and amended on May 3, 2012, by and between Lantheus Medical Imaging, Inc. and Jubilant HollisterSteir LLC.		
31.1*	Certification of the Chief Executive Officer Pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as amended, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.		
31.2*	Certification of the Chief Financial Officer Pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as amended, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.		
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002.		
101.INS*	XBRL Instance Document		
101.SCH*	XBRL Taxonomy Extension Schema Document		
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document		
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document		
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document		
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document		

Confidential treatment requested as to certain portions of this exhibit, which portions have been filed separately with the Securities and Exchange Commission.

\* Filed herewith

Table of Contents

**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*  
Date: November 1, 2016

LANTHEUS HOLDINGS, INC.

By: /s/ JOHN CROWLEY  
Name: John Crowley  
Title: *Chief Financial Officer*  
Date: November 1, 2016

**Table of Contents****EXHIBIT INDEX**

<b>EXHIBIT NUMBER</b>	<b>DESCRIPTION OF EXHIBITS</b>	<b>INCORPORATED BY REFERENCE</b>	
		<b>FILE FORMNUMBER</b>	<b>EXHIBIT FILING DATE</b>
10.1 *	Share Purchase Agreement, effective August 11, 2016, by and between Lantheus Medical Imaging, Inc. and Global Medical Solutions, Ltd.		
10.2 *	Second Amendment, effective September 2, 2016, to the Manufacturing and Supply Agreement, dated as of February 1, 2012 and amended on May 3, 2012, by and between Lantheus Medical Imaging, Inc. and Jubilant HollisterSteir LLC.		
31.1*	Certification of the Chief Executive Officer Pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as amended, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.		
31.2*	Certification of the Chief Financial Officer Pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as amended, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.		
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002.		
101.INS*	XBRL Instance Document		
101.SCH*	XBRL Taxonomy Extension Schema Document		
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document		
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document		
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document		
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document		

Confidential treatment requested as to certain portions of this exhibit, which portions have been filed separately with the Securities and Exchange Commission.

\* Filed herewith