

Lantheus Holdings, Inc.  
Form 10-Q  
May 03, 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 March 31, 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.

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 32,724,407 of common stock, \$0.01 par value per share, issued and outstanding as of May 3, 2016.

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

	<b>Page</b>
<b>PART I. FINANCIAL INFORMATION</b>	
Item 1. <u>Financial Statements (Unaudited)</u>	1
<u>Condensed Consolidated Statements of Operations for the Three Months Ended March 31, 2016 and 2015</u>	1
<u>Condensed Consolidated Statements of Comprehensive Income for the Three Months Ended March 31, 2016 and 2015</u>	2
<u>Condensed Consolidated Balance Sheets as of March 31, 2016 and December 31, 2015</u>	3
<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2016 and 2015</u>	4
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	5
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>	30
Item 4. <u>Controls and Procedures</u>	31
<b>PART II. OTHER INFORMATION</b>	
Item 1. <u>Legal Proceedings</u>	32
Item 1A. <u>Risk Factors</u>	32
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	33
Item 4. <u>Mine Safety Disclosures</u>	33
Item 6. <u>Exhibits</u>	34
<u>Signatures</u>	35
<u>Exhibit Index</u>	36

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

	<b>For the Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
Revenues	\$ 76,474	\$ 74,823
Cost of goods sold	42,773	39,054
Gross profit	33,701	35,769
Operating expenses		
Sales and marketing expenses	9,307	9,072
General and administrative expenses	9,513	9,123
Research and development expenses	3,036	6,196
Total operating expenses	21,856	24,391
Gain on sale of assets	5,828	
Operating income	17,673	11,378
Interest expense, net	(7,018)	(10,623)
Other income (expense), net	58	(383)
Income before income taxes	10,713	372
Provision (benefit) for income taxes	390	(3)
Net income	\$ 10,323	\$ 375
Net income per common share:		
Basic and diluted	\$ 0.34	\$ 0.02
Common shares:		
Basic	30,368,240	18,080,944
Diluted	30,372,691	18,404,393

See notes to unaudited condensed consolidated financial statements.

**Table of Contents**

**Lantheus Holdings, Inc. and subsidiaries**  
**Condensed Consolidated Statements of Comprehensive Income**  
**(unaudited, in thousands)**

	<b>For the Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
Net income	\$ 10,323	\$ 375
Foreign currency translation	340	(358)
Total comprehensive income	\$ 10,663	\$ 17

See notes to unaudited condensed consolidated financial statements.

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

	<b>March 31, 2016</b>	<b>December 31, 2015</b>
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 38,880	\$ 28,596
Accounts receivable, net of allowance of \$1,051 and \$881	39,896	37,293
Inventory	15,541	15,622
Other current assets	5,721	3,851
Assets held for sale		4,644
Total current assets	100,038	90,006
Property, plant and equipment, net	85,324	86,517
Capitalized software development costs, net	8,615	9,137
Intangibles, net	19,235	20,496
Goodwill	15,714	15,714
Other long-term assets	20,337	20,509
Total assets	\$ 249,263	\$ 242,379
<b>Liabilities and Stockholders' Deficit</b>		
Current liabilities		
Current portion of long-term debt	\$ 3,650	\$ 3,650
Line of credit		
Accounts payable	12,984	11,657
Accrued expenses and other liabilities	14,845	18,502
Liabilities held for sale		1,715
Total current liabilities	31,479	35,524
Asset retirement obligation	8,417	8,145
Long-term debt, net	349,349	349,858
Other long-term liabilities	34,237	34,141
Total liabilities	423,482	427,668
<b>Commitments and contingencies (See Note 16)</b>		
Stockholders' deficit		
Preferred stock (\$0.01 par value, 25,000,000 shares authorized; no shares issued and outstanding)		
Common stock (\$0.01 par value, 250,000,000 shares authorized; 30,377,104 and 30,364,501 shares issued and outstanding)	303	303

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

Additional paid-in capital	175,960	175,553
Accumulated deficit	(348,837)	(359,160)
Accumulated other comprehensive loss	(1,645)	(1,985)
Total stockholders' deficit	(174,219)	(185,289)
Total liabilities and stockholders' deficit	\$ 249,263	\$ 242,379

See notes to unaudited condensed consolidated financial statements.

**Table of Contents**

**Lantheus Holdings, Inc. and subsidiaries**  
**Condensed Consolidated Statements of Cash Flows**  
**(unaudited, in thousands)**

	<b>For the Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
<b>Cash flows from operating activities</b>		
Net income	\$ 10,323	\$ 375
Adjustments to reconcile net income to cash flow from operating activities		
Depreciation, amortization and accretion	4,586	8,120
Provision for excess and obsolete inventory	497	180
Stock-based compensation	407	277
Gain on sale of assets	(5,828)	
Other	513	853
Increase (decrease) in cash from operating assets and liabilities		
Accounts receivable	(2,634)	2,761
Inventory	(304)	(953)
Other current assets	(1,042)	(1,021)
Income taxes	(235)	87
Accounts payable	2,070	(771)
Accrued expenses and other liabilities	(4,573)	5,249
Cash provided by operating activities	3,780	15,157
<b>Cash flows from investing activities</b>		
Proceeds from sale of assets	9,000	
Capital expenditures	(1,652)	(3,498)
Redemption of certificate of deposit - restricted	74	
Cash provided by (used in) investing activities	7,422	(3,498)
<b>Cash flows from financing activities</b>		
Payments on long-term debt	(933)	(18)
Payments for offering costs		(441)
Other	(11)	
Cash used in financing activities	(944)	(459)
Effect of foreign exchange rate on cash	26	(196)
Increase in cash and cash equivalents	10,284	11,004
Cash and cash equivalents, beginning of period	28,596	19,739



Cash and cash equivalents, end of period	\$ 38,880	\$ 30,743
--	-----------	-----------

**Supplemental disclosure of cash flow information**

Interest paid	\$ 6,422	\$ 59
Income taxes paid/(refunded), net	\$ 199	\$ (59)

See notes to unaudited condensed consolidated financial statements.

**Table of Contents**

**Lantheus Holdings, Inc. and subsidiaries**

**Notes to Unaudited Condensed Consolidated Financial Statements**

Unless the context otherwise requires, references to the Company and Lantheus refer to Lantheus Holdings, Inc. and its direct and indirect 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 TM, SM and ® symbols. Those references are not intended to indicate, in any way, that the Company will not assert, to the fullest extent permitted under applicable law, its rights to its trademarks, service marks and trade names.

**1. Business Overview**

**Overview**

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, technologists and sonographers 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, Canada, Puerto Rico and Australia and distribution relationships in Europe, Asia Pacific and Latin America.

The Company's portfolio of 10 commercial products is diversified across a range of imaging modalities. 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, or 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 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 Single Photon Emission Computed Tomography, or SPECT, technology in myocardial perfusion imaging, or 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 commercial radiopharmacies owned or controlled by third parties. In Puerto Rico and Australia, the Company owns three radiopharmacies and sells its own radiopharmaceuticals, as well as others, directly to end users. In Canada, Europe, Asia Pacific and Latin America, the Company utilizes distributor relationships to market, sell and distribute its products.

***Basis of Consolidation and Presentation***

The financial statements have been prepared in United States dollars, in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

In the opinion of the Company's management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the Company's financial statements for interim periods in accordance with U.S. GAAP. Certain information and footnote disclosures normally included in

---

**Table of Contents**

financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission, or the SEC. The information included in this quarterly report should be read in conjunction with the Company's consolidated financial statements and the accompanying notes for the year ended December 31, 2015 included in the Company's Form 10-K filed with the SEC on March 2, 2016. The Company's accounting policies are described in the Notes to Consolidated Financial Statements in the Form 10-K and updated, as necessary, in this quarterly report. There were no changes to the Company's accounting policies since December 31, 2015. The year-end condensed consolidated balance sheet data presented for comparative purposes was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. The results of operations for the three months ended March 31, 2016 are not necessarily indicative of the operating results for the full year or for any other subsequent interim period.

The Company currently relies on Jubilant HollisterStier, or JHS, as its sole source manufacturer of DEFINITY, Neurolite and evacuation vials for TechneLite. The Company has additional ongoing technology transfer activities at JHS for its Cardiolite product supply, which is currently approved for manufacture by a single manufacturer. While the Company has ongoing technology transfer activities at Pharmalucence for the manufacture and supply of DEFINITY, such activities have been delayed and the Company cannot project when 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 \$50.0 million revolving credit facility, or 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, or 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 March 31, 2016, the aggregate Borrowing Base was approximately \$48.3 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 \$39.4 million. The Company's \$365.0 million senior secured term loan facility, or 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.

***Recent Accounting Standards***

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 tax assets and liabilities, and any related valuation allowances, to be classified as non-current on the balance sheet. Adoption of this standard has 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 both March 31, 2016 and December 31, 2015.

---

**Table of Contents**

In February 2016, the Financial Accounting Standards Board, or the FASB, issued ASU No. 2016-02, *Leases (Topic 842)*, or ASU 2016-02. 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 supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under existing U.S. GAAP including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. 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, the FASB issued ASU 2016-08, *Revenue from Contracts with Customers (Topic 606), Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, which further clarifies the implementation guidance on principal versus agent considerations. The new guidance requires either a retrospective or a modified retrospective approach to adoption. The Company is currently evaluating the impact these ASUs will have on our financial position, results of operations, cash flows and disclosures.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-4): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* or ASU 2014-15. ASU 2014-15 to provide guidance on management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosures. The amendments in ASU 2014-15 are effective for annual reporting periods ending after December 15, 2016. Early adoption is permitted. The Company does not anticipate this ASU will have a material impact to the Company's financial position, results of operations, cash flows and disclosures.

## **2. Summary of Significant Accounting Policies**

### **Revenue Recognition**

The Company recognizes revenue when evidence of an arrangement exists, title has passed, the risks and rewards of ownership have transferred to the customer, the selling price is fixed and determinable, and collectability is reasonably assured. For transactions for which revenue recognition criteria have not yet been met, the respective amounts are recorded as deferred revenue until such point in time the criteria are met and revenue can be recognized. Revenue is recognized net of reserves, which consist of allowances for returns and rebates.

Revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer. The arrangement's consideration is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value; (ii) third-party evidence of selling price; and (iii) best estimate of selling price. The best estimate of selling price reflects the Company's best estimate of what the selling price would be if the deliverable was regularly sold by the Company on a stand-alone basis. The consideration allocated to each unit of accounting is then recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. Supply or service transactions may involve the charge of a nonrefundable initial fee with subsequent periodic payments for future products or services. The up-front fees, even if nonrefundable, are recognized as revenue as the products and/or services are delivered and performed over the term of the arrangement.

### **Inventory**

Inventory costs associated with product that has not yet received regulatory approval are capitalized if the Company believes there is probable future commercial use of the product and future economic benefits of the asset. If future commercial use of the product is not probable, then inventory costs associated with such product are expensed during the period the costs are incurred. There was no significant product expensed for the three months ended March 31, 2016 and 2015. At March 31, 2016 and December 31, 2015, the Company had no capitalized inventories associated with product that did not have regulatory approval.

**Table of Contents****Goodwill**

Goodwill is not amortized, but is instead tested for impairment at least annually and whenever events or circumstances indicate that it is more likely than not that it may be impaired. The Company has elected to perform the annual test for goodwill impairment as of October 31 of each year. During the quarter ended March 31, 2016, there were no events that triggered an interim impairment test of goodwill.

**3. 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 March 31, 2016 and December 31, 2015, and indicate 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.

(in thousands)	Total fair value at March 31, 2016	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Money market	\$ 2,577	\$ 2,577	\$	\$
	\$ 2,577	\$ 2,577	\$	\$

  

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

At December 31, 2015, the Company had a \$0.1 million certificate of deposit, which was collateral for a long-term lease and was included in other long-term assets on the condensed consolidated balance sheet. In January 2016, the certificate of deposit was redeemed. Certificates of deposit are classified within Level 2 of the fair value hierarchy, as these are not traded on the open market.

At March 31, 2016, the Company had total cash and cash equivalents of \$38.9 million, which included approximately \$2.6 million of money market funds and \$36.3 million of cash on-hand. At December 31, 2015, the Company had total cash and cash equivalents of \$28.6 million, which included approximately \$1.6 million of money market funds



and \$27.0 million of cash on-hand.

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 March 31, 2016 and December 31, 2015, approximated the carrying value because the interest rate is subject to change with market interest rates.

#### **4. 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 \$0.4 million for the three months ended March 31, 2016, compared to a tax benefit of \$3,000 for the three months ended March 31, 2015.

**Table of Contents**

In connection with the Company's acquisition of the medical imaging business from Bristol-Myers Squibb, or BMS, in 2008, the Company obtained a tax indemnification agreement with BMS related to certain tax obligations arising prior to the acquisition of the Company, for which the Company has the primary legal obligation. The tax indemnification receivable is recognized within other noncurrent assets. The changes in the tax indemnification asset are recognized within other income (expense), net in the condensed consolidated statement of operations. In accordance with the Company's accounting policy, the change in the tax liability and penalties and interest associated with these obligations (net of any offsetting federal or state benefit) is recognized within the tax provision. Accordingly, as these reserves change, adjustments are included in the tax provision while the offsetting adjustment is included in other income (expense), net. Assuming that the receivable from BMS continues to be considered recoverable by the Company, there is no net effect on earnings related to these liabilities and no net cash outflows.

**5. Assets Held for Sale**

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, or the Purchase Agreement, pursuant to which it would sell substantially all of the assets of its Canadian radiopharmacies 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. The 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 Purchase Agreement.

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 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 business 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 December 31, 2015:

<b>(in thousands)</b>	<b>January 12, 2016</b>	<b>December 31, 2015</b>
<b>Current Assets:</b>		
Accounts receivable, net	\$ 2,565	\$ 2,512
Inventory	730	806
Other current assets	14	26

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

Total current assets	3,309	3,344
Non-Current Assets:		
Property, plant and equipment, net	760	791
Intangibles, net	462	480
Other long-term assets	28	29
 Total assets held for sale	 \$ 4,559	 \$ 4,644
Current Liabilities:		
Accounts payable	\$ 435	\$ 430
Accrued expense and other liabilities	858	1,285
 Total liabilities held for sale	 \$ 1,293	 \$ 1,715

The sale resulted in a pre-tax book gain of \$5.8 million, which was recorded within operating income in the condensed consolidated statement of operations in the quarter ended March 31, 2016.

**Table of Contents****6. Inventory**

The Company includes within current assets the amount of inventory that is estimated to be utilized within twelve months. Inventory that will be utilized after twelve months is classified within other long-term assets.

Inventory, classified in inventory or other long-term assets, consisted of the following:

(in thousands)	March 31, 2016	December 31, 2015
Raw materials	\$ 6,801	\$ 7,506
Work in process	4,273	2,407
Finished goods	4,467	5,709
Inventory	15,541	15,622
Other long-term assets	1,156	1,156
Total	\$ 16,697	\$ 16,778

At both March 31, 2016 and December 31, 2015, inventories reported as other long-term assets included \$1.2 million of raw materials.

**7. Property, Plant and Equipment, net**

Property, plant and equipment consisted of the following:

(in thousands)	March 31, 2016	December 31, 2015
Land	\$ 14,950	\$ 14,950
Buildings	69,222	68,941
Machinery, equipment and fixtures	61,927	60,787
Construction in progress	8,242	9,099
Accumulated depreciation	(69,017)	(67,260)
Property, plant and equipment, net	\$ 85,324	\$ 86,517

For the three months ended March 31, 2016 and 2015, depreciation expense related to property, plant and equipment was \$2.0 million and \$5.7 million, respectively.

Fixed assets dedicated to research and development, or R&D, activities, which were impacted by the March 2013 R&D strategic shift, have a carrying value of \$4.0 million as of March 31, 2016. The Company believes these fixed 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 fixed assets, then they could be subject to impairment in the future.

## **8. Asset Retirement Obligations**

The Company considers the legal obligation to remediate its facilities upon a decommissioning of its radioactive related operations 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 March 31, 2016, the liability is measured at the present value of the obligation expected to be incurred, of approximately \$26.7 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 three months ended March 31, 2016:

<b>(in thousands)</b>	
Balance at January 1, 2016	\$ 8,145
Net increase due to changes in estimated future cash flows	39
Accretion expense	233
Balance at March 31, 2016	\$ 8,417

**9. Intangibles, net**

Intangibles, net consisted of the following:

<b>(in thousands)</b>	<b>March 31, 2016</b>			
	<b>Cost</b>	<b>Accumulated amortization</b>	<b>Net</b>	<b>Amortization Method</b>
Trademarks	\$ 13,540	\$ 7,389	\$ 6,151	Straight-line
Customer relationships	100,948	89,429	11,519	Accelerated
Other patents	42,780	41,215	1,565	Straight-line
	\$ 157,268	\$ 138,033	\$ 19,235	

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

For the three months ended March 31, 2016 and 2015, the Company recorded amortization expense for its intangible assets of \$1.3 million and \$1.5 million, respectively.

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

<b>(in thousands)</b>	
Remainder of 2016	\$ 3,879
2017	3,391
2018	2,687

2019	1,835
2020	1,594
2021 and thereafter	5,849
	\$ 19,235

## 10. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities are comprised of the following:

(in thousands)	March 31, 2016	December 31, 2015
Compensation and benefits	\$ 7,061	\$ 10,525
Freight, distribution and operations	2,724	2,962
Accrued rebates, discounts and chargebacks	2,279	2,085
Accrued professional fees	1,029	1,493
Marketing expense	572	490
Research and development services	438	360
Other	742	587
	\$ 14,845	\$ 18,502

**Table of Contents**

**11. 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, or IPO, and cash on hand, were used to refinance in full the aggregate principal amount of the \$400.0 million 9.750% Senior Notes, or 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 March 31, 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, with a premium applicable for the first six months of the Term Facility in connection with a repricing transaction. 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;

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

50% of net payments from any Zurich insurance settlement (as defined therein).

The foregoing mandatory prepayments will be applied to the scheduled installments of principal of the Term Facility 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.



The Company's minimum payments of principal obligations under the Term Facility are as follows as of March 31, 2016:

<b>(in thousands)</b>	
Remainder of 2016	\$ 2,738
2017	3,650
2018	3,650
2019	3,650
2020	3,650
2021 and thereafter	344,925
<b>Total debt</b>	<b>362,263</b>
Unamortized debt discount	(4,035)
Unamortized debt issuance costs	(5,229)
<b>Total</b>	<b>352,999</b>
<b>Less current portion</b>	<b>(3,650)</b>
<b>Total long-term debt</b>	<b>\$ 349,349</b>

**Table of Contents****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>
Q3 2015 to Q1 2016	6.25 to 1.00
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 March 31, 2016, the Company has a Revolving Facility with an aggregate principal amount not to exceed \$50.0 million. The loans under the Revolving Facility bear interest subject to a pricing grid based on average historical excess availability, with pricing based from time to time at the election of LMI at (i) LIBOR plus a spread ranging from 2.00% or (ii) the Reference Rate (as defined in the agreement) plus 1.00%. The Revolving Facility also includes an unused line fee of 0.375% and expires on June 30, 2020.

As of March 31, 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 March 31, 2016, the aggregate Borrowing Base was approximately \$48.3 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 \$39.4 million.

**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.

## **12. Stockholders Equity**

As of March 31, 2016, the authorized capital stock of the Company consisted of 250,000,000 shares of common stock, par value \$0.01 per share, and 25,000,000 shares of preferred stock, par value \$0.01 per share. The common stockholders are entitled to one vote per share and will share equally on a per share basis in any dividend declared by the Board of Directors, subject to any preferential rights of the holders of any outstanding preferred stock.

**Table of Contents**

The following table presents the changes in stockholders' deficit for the three months ended March 31, 2016:

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Deficit
	Shares	Amount				
Balance at January 1, 2016	30,364,501	\$ 303	\$ 175,553	\$ (359,160)	\$ (1,985)	\$ (185,289)
Net income				10,323		10,323
Other comprehensive income					340	340
Vesting of restricted stock awards	12,603					
Stock-based compensation			407			407
Balance at March 31, 2016	30,377,104	\$ 303	\$ 175,960	\$ (348,837)	\$ (1,645)	\$ (174,219)

**13. Stock-Based Compensation**

As of June 24, 2015, the Company adopted the 2015 Equity Incentive Plan, or 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, or 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 DER is treated as a separate award. The number of shares authorized for issuance under the 2015 Plan increased from 2,190,320 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.

Stock-based compensation expense for both time based and performance based stock options, restricted stock awards and common stock grants were recognized in the condensed consolidated statements of operations as follows:

(in thousands)

**Three Months  
Ended  
March 31,  
2016 2015**

Cost of goods sold	\$ 67	\$ (1)
Sales and marketing	48	37
General and administrative	233	213
Research and development	59	28
Total stock-based compensation expense	\$ 407	\$ 277

#### 14. Net Income Per 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 March 31,	
	2016	2015
Net income	\$ 10,323	\$ 375
Basic weighted average common shares outstanding	30,368,240	18,080,944
Effect of dilutive restricted stock awards	4,451	
Effect of dilutive stock options		323,449
Diluted weighted average common shares outstanding	30,372,691	18,404,393
Basic and diluted income per common share	\$ 0.34	\$ 0.02

The weighted average number of common shares for the three months ended March 31, 2016 and 2015, did not include 2,221,940 and 751,964 options and unvested restricted stock, respectively, because of their antidilutive effect.

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

Other income (expense), net consisted of the following:

(in thousands)	Three Months Ended March 31,	
	2016	2015
Foreign currency losses	\$ (237)	\$ (378)
Tax indemnification income (expense)	296	(4)
Other expense	(1)	(1)
Total other income (expense), net	\$ 58	\$ (383)

**16. 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 March 31, 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.

On December 16, 2010, LMI filed suit against one of its insurance carriers seeking to recover business interruption losses associated with the NRU reactor shutdown and the ensuing global Moly supply shortage. The claim is the result

of the shutdown of the NRU reactor in Chalk River, Ontario. The NRU reactor was off-line from May 2009 until August 2010. The defendant answered the complaint on January 21, 2011, denying substantially all of the allegations, presenting certain defenses and requesting dismissal of the case with costs and disbursements. Discovery, including international discovery and related motion practice, has been on-going for more than three years. The defendant filed a motion for summary judgment on July 14, 2014. The Company filed a memorandum of law in opposition to defendant's motion for summary judgment on August 25, 2014. The defendant filed a reply memorandum of law in further support of its motion for summary judgment on September 15, 2014. Expert witness discovery was completed on October 31, 2014. On March 25, 2015, the United States District Court for the Southern District of New York granted defendant's motion for summary judgment. On September 4, 2015, the Company filed an appeal of the District Court decision with the United States Court of Appeals for the Second Circuit. On December 4, 2015, the defendant filed an answer brief to the Company's appeal, and on December 18, 2015, the Company filed a reply brief to the defendant's answer. On April 21, 2016, the United States Court of Appeals for the Second Circuit heard oral arguments of the Company and the defendant in connection with the Company's appeal. The Company cannot be certain what amount, if any, or when, if ever, it will be able to recover for business interruption losses related to this matter.

**Table of Contents****17. Related Party Transactions**

Avista, the Company's majority 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. During the three months ended March 31, 2016, the Company did not incur any costs associated with this agreement as compared to \$0.3 million for the prior year comparative period. At both March 31, 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, or 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 months ended March 31, 2016, the Company incurred costs associated with this agreement of approximately \$0.2 million. At March 31, 2016, \$0.2 million was included in accrued expenses and other liabilities.

The Company purchases inventory supplies from VWR Scientific, or VWR. Avista and certain of its affiliates are principal owners of both VWR and the Company. During the three months ended March 31, 2016 and 2015, the Company made purchases of \$103,000 and \$71,000, respectively. At March 31, 2016 and December 31, 2015, \$1,000 and \$10,000, respectively, was included in accounts payable and accrued expenses and other liabilities.

**18. Segment Information**

The Company reports two operating segments, U.S. and International, based on geographic customer base. The results of these operating segments are regularly reviewed by the Company's chief operating decision maker, the President and Chief Executive Officer. The Company's segments derive revenues through the manufacturing, marketing, selling and distribution of medical imaging products, focused primarily on cardiovascular diagnostic imaging. The U.S. segment comprises 84.9% and 81.1% of consolidated revenues for the three months ended March 31, 2016 and 2015, respectively and 93.2% and 92.0% of consolidated assets at March 31, 2016 and December 31, 2015, respectively. All goodwill has been allocated to the U.S. operating segment.

Selected information for each business segment are as follows (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
<b><i>Revenues</i></b>		
U.S.	\$ 70,770	\$ 65,788
International	11,541	14,156
Total revenue, including inter-segment	82,311	79,944
Less inter-segment revenue	(5,837)	(5,121)



	\$ 76,474	\$ 74,823
<b><i>Revenues from external customers</i></b>		
U.S.	\$ 64,933	\$ 60,667
International	11,541	14,156
	\$ 76,474	\$ 74,823
<b><i>Operating income</i></b>		
U.S.	\$ 13,403	\$ 12,679
International	4,135	(1,474)
Total operating income, including inter-segment	17,538	11,205
Inter-segment operating income	135	173
Operating income	17,673	11,378
Interest expense, net	(7,018)	(10,623)
Other income (expense), net	58	(383)
Income before income taxes	\$ 10,713	\$ 372

**Table of Contents**

In the table below, the Company has revised its previous presentation of U.S. and International total assets as of December 31, 2015, to correctly reflect the allocation of total assets between U.S. and International segments. This revision resulted in a decrease to total International assets of \$12.7 million with a corresponding increase to total U.S. assets in the same amount. This revision had no impact on the balance sheet, statement of operations or statement of cash flows for the year ended December 31, 2015.

	<b>March 31, 2016</b>	<b>December 31, 2015</b>
<b><i>Total assets</i></b>		
U.S.	\$ 232,217	\$ 222,926
International	17,046	19,453
	\$ 249,263	\$ 242,379

**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 Pharmalucence and global isotope supply; (iv) our outlook and expectations related to our intention to seek to engage 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 credit facility, or 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 prospectus 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, including Optison from GE Healthcare and Lumason from Bracco Diagnostics Inc., or Bracco;

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, or 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 lead agent in development, flurpiridaz F 18, including our ability to:

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

obtain Food and Drug Administration, or 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; 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.*

**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, stroke, peripheral vascular disease and other diseases. Clinicians use our imaging agents and products across a range of imaging modalities, including nuclear imaging, echocardiography and magnetic resonance imaging, or MRI. 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 hospitals, clinics, group practices, integrated delivery networks, group purchasing organizations and radiopharmacies.

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

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.

**Table of Contents**

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.

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 TechnoLite, 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 two radiopharmacies in Australia and one 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 and certain force majeure events. We also maintain our own direct sales forces in these markets so we can control the importation, marketing, distribution and sale of our imaging agents in these regions. In Europe, Asia Pacific and Latin America, we 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 multicountry regional basis.

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

(dollars in thousands)	Three Months Ended			
	2016	%	March 31, 2015	%
DEFINITY	\$ 31,422	41.1	\$ 25,666	34.3
TechnoLite	24,836	32.5	20,860	27.9
Xenon	8,174	10.7	13,194	17.6
Other	12,042	15.7	15,103	20.2
Revenues	\$ 76,474	100.0	\$ 74,823	100.0

**Key Factors Affecting Our Results**

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

***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.

Prior to the supply issues with Ben Venue Laboratories in 2012, sales of DEFINITY continually increased year-over-year since June 2008, when the boxed warning on DEFINITY was modified. Unit sales of DEFINITY had decreased substantially in late 2007 and early 2008 as a result of an FDA request in October 2007 that we and GE

Healthcare, which distributes Optison, a competitor to DEFINITY, add a boxed warning to their products to notify physicians and patients about potentially serious safety concerns or risks posed by the products. However, in May 2008, the FDA boxed warning was modified in response to the substantial advocacy efforts of prescribing physicians. In October 2011, we received FDA approval of further modifications to the DEFINITY label, including: further relaxing the boxed warning; eliminating the sentence in the Indication and Use section "The safety and efficacy of DEFINITY with exercise stress or pharmacologic stress testing have not been established" (previously added in October 2007 in connection with the imposition of the box warning); and including summary data from the post-approval CaRES (Contrast echocardiography Registry for Safety Surveillance) safety registry and the post-approval pulmonary hypertension study. Bracco's ultrasound contrast agent, Lumason, has substantially similar safety labeling as DEFINITY and Optison. The future growth of our DEFINITY sales will be 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 Pharmedica, 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 U.S. DEFINITY which as of December 2015 had an approximately 78% segment share, Optison, and Lumason, which was approved by the FDA in October 2014. Lumason



## **Table of Contents**

is known as SonoVue outside of the U.S. 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 U.S. echocardiography segment will help raise awareness around the value that echocardiography contrast brings and potentially increase the overall contrast penetration rate, if Bracco successfully commercializes Lumason in the U.S. 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 U.S., but since 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 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 should result in more 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 and evacuation vials, an ancillary component for our TechnoLite generators, and we have ongoing technology transfer activities at JHS for our Cardiolite product supply. In the meantime, our Cardiolite product supply is approved for manufacture by a single manufacturer. 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. On November 12, 2013, we entered into a Manufacturing and Supply Agreement with Pharmeducence to manufacture and supply DEFINITY. However, these activities have been delayed and we cannot project when 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***

Currently, our largest supplier of Moly and our only supplier of Xenon is Nordion, which relies on the NRU reactor in Chalk River, Ontario. For Moly and Xenon, we have supply agreements with Nordion that expire on October 31, 2016, and for Moly, supply agreements with NTP of South Africa, ANSTO of Australia, and IRE of Belgium, each

running through December 31, 2017. The Canadian government required the NRU reactor to shut down for at least four weeks at least once a year for inspection and maintenance. The 2015 shutdown period ran from April 13, 2015 until May 13, 2015, and we were able to source all of our standing order customer demand for Moly during this time period from our other suppliers. However, because Xenon is a by-product of the Moly production process and is currently captured only by Nordion, during this shutdown period, we were not able to supply all of our standing order customer demand for Xenon during the outage. Because the month-long NRU shutdown was fully anticipated in our 2015 budgeting process, the shutdown did not have a material adverse effect on our 2015 results of operations, financial condition and cash flows.

We believe we are well-positioned with our current supply partners to have a secure supply of Moly, including low-enriched uranium, or LEU, Moly, when the NRU reactor transitions in October 2016 from providing regular supply of medical isotopes to providing only emergency back-up supply of HEU based medical isotopes through March 2018. ANSTO has under construction, in cooperation with NTP, a new Moly processing facility that ANSTO believes will expand its production capacity by approximately 2.5 times, with expanded commercial production planned to start in the latter part of 2016. 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 the NRU's current routine production. In January 2015, we announced entering into a new strategic

---

**Table of Contents**

agreement with IRE for the future supply of Xenon. Under the terms of the agreement, IRE will provide bulk Xenon to us for processing and finishing once development work has been completed and all necessary regulatory approvals have been obtained. We currently estimate commercial production will occur in 2016. If we are not able to begin providing commercial quantities of Xenon prior to the NRU reactor's supply transition in 2016, there may be a period of time during which we are not able to offer Xenon in our portfolio of commercial products. See Part II Item 1A. Risk Factors We face potential supply and demand challenges for Xenon.

***Demand for TechneLite***

Since the global Moly supply shortage in 2009 to 2010, we have experienced reduced demand for TechneLite generators from pre-shortage levels even though volume has increased in absolute terms from levels during the shortage following the return of our normal Moly supply in August 2010. However, we do not know if overall industry demand for technetium will ever return to pre-shortage levels. See Part I Item 1A. Risk Factors The Moly supply shortage caused by the 2009-10 NRU reactor shutdown has had a negative effect on the demand for some of our products, which will likely continue in the future of our annual report on Form 10-K for the fiscal year ended December 31, 2015.

Separate from the Moly supply shortage, we believe there has also 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 2014.

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 percent LEU. In January 2013, we began to offer a TechneLite generator which contains Moly sourced from at least 95 percent 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 F 18. 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 in the three months ended March 31, 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 TechneLite, mainly the result of a contract with a significant customer;

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

\$5.8 million gain on the sale of our Canadian radiopharmacies;

lower international revenues as a result of the sale of our Canadian radiopharmacies 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; and

decreased interest expense due to the refinancing of long-term debt in connection with the IPO.

**Table of Contents****Results of Operations**

<b>(dollars in thousands)</b>	<b>For the Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
Revenues	\$ 76,474	\$ 74,823
Cost of goods sold	42,773	39,054
Gross profit	33,701	35,769
Operating expenses		
Sales and marketing expenses	9,307	9,072
General and administrative expenses	9,513	9,123
Research and development expenses	3,036	6,196
Total operating expenses	21,856	24,391
Gain on sale of assets	5,828	
Operating income	17,673	11,378
Interest expense, net	(7,018)	(10,623)
Other income (expense), net	58	(383)
Income before income taxes	10,713	372
Provision (benefit) for income taxes	390	(3)
Net income	\$ 10,323	\$ 375

**Revenues**

Revenues are summarized as follows:

<b>(dollars in thousands)</b>	<b>Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
United States		
DEFINITY	\$ 30,793	\$ 25,182
TechneLite	21,733	18,173
Xenon	8,172	13,186
Other	4,235	4,126
Total U.S. revenues	64,933	60,667
International		

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

DEFINITY	629	484
TechneLite	3,103	2,687
Xenon	2	8
Other	7,807	10,977
Total International revenues	11,541	14,156
Revenues	\$ 76,474	\$ 74,823

Total revenues increased \$1.7 million, or 2.2%, to \$76.5 million in the three months ended March 31, 2016, as compared to \$74.8 million in the three months ended March 31, 2015. U.S. segment revenue increased \$4.3 million, or 7.0%, to \$65.0 million in the three months ended March 31, 2016, as compared to \$60.7 million in the prior year period. The International segment revenues decreased \$2.6 million, or 18.5%, to \$11.5 million in the three months ended March 31, 2016, as compared to \$14.2 million in the prior year period.

The increase in U.S. segment revenues for the three months ended March 31, 2016, as compared to the prior year period is primarily due to a \$5.6 million increase in DEFINITY revenues as a result of higher unit volumes and a \$3.6 million increase in TechneLite revenues as a result of a contract with a significant customer that increased unit volumes. Offsetting these increases was a \$5.0 million decrease in Xenon revenues over the prior year period primarily as a result of a contract with a significant customer that reduced unit pricing in exchange for committed volume purchases.

**Table of Contents**

The decrease in the International segment revenues for the three months ended March 31, 2016, as compared to the prior year period is primarily a result of the decrease in revenues from third party products in Canada because of the sale of the Canadian radiopharmacies and a \$0.8 million unfavorable foreign exchange.

*Rebates and Allowances*

Estimates for rebates and allowances represent our estimated obligations under contractual arrangements with third parties. Rebate accruals and allowances are recorded in the same period the related revenue is recognized, resulting in a reduction to revenue and the establishment of a liability which is included in accrued expenses. These rebates result from performance-based offers that are primarily based on attaining contractually specified sales volumes and growth, Medicaid rebate programs for certain products, 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>(dollars in thousands)</b>	<b>Rebates</b>	<b>Allowances</b>	<b>Total</b>
Balance, as of January 1, 2016	\$ 2,303	\$ 38	\$ 2,341
Current provisions relating to revenues in current year	1,644	52	1,696
Adjustments relating to prior years' estimate	(39)		(39)
Payments/credits relating to revenues in current year	(582)	(25)	(607)
Payments/credits relating to revenues in prior years	(1,047)	(49)	(1,096)
Balance, as of March 31, 2016	\$ 2,279	\$ 16	\$ 2,295

Accrued sales rebates were approximately \$2.3 million at both March 31, 2016 and December 31, 2015.

**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:

<b>(dollars in thousands)</b>	<b>Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
United States	\$ 33,210	\$ 26,862
International	9,563	12,192
<b>Total Cost of Goods Sold</b>	<b>\$ 42,773</b>	<b>\$ 39,054</b>

Total cost of goods sold increased \$3.7 million, or 9.5%, to \$42.8 million in the three months ended March 31, 2016, as compared to \$39.1 million in the three months ended March 31, 2015. U.S. segment cost of goods sold increased approximately \$6.3 million, or 23.6%, to \$33.2 million in the three months ended March 31, 2016, as compared to \$26.9 million in the prior year period. For the three months ended March 31, 2016, the International segment cost of goods sold decreased \$2.6 million, or 21.6%, to \$9.6 million, as compared to \$12.2 million in the prior year period.

The increase in the U.S. segment cost of goods sold for the three months ended March 31, 2016 over the prior year period is primarily due to a \$4.7 million increase in TechnoLite cost of goods sold and an increase of \$1.3 million in Xenon cost of goods sold due to higher material costs.

The decrease in the International segment cost of goods sold in the three months ended March 31, 2016, as compared to the prior year period, is primarily due to lower manufacturing costs for certain products as a result of the sale of our Canadian radiopharmacies.



**Table of Contents****Gross Profit**

<b>(dollars in thousands)</b>	<b>Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
United States	\$ 31,723	\$ 33,805
International	1,978	1,964
<b>Total Gross Profit</b>	<b>\$ 33,701</b>	<b>\$ 35,769</b>

Total gross profit decreased \$2.1 million, or 5.8%, to \$33.7 million in the three months ended March 31, 2016, as compared to \$35.8 million in the three months ended March 31, 2015. U.S. segment gross profit decreased \$2.1 million, or 6.2%, to \$31.7 million in the three months ended March 31, 2016, as compared to \$33.8 million in the prior year period. For the three months ended March 31, 2016, the International segment gross profit remained consistent.

The decrease in the U.S. segment gross profit for the three months ended March 31, 2016 over the prior year period is primarily due to a decrease in Xenon gross profit due to lower selling prices and a decrease in TechneLite gross profit due to lower selling prices, which was offset by increased volumes. Offsetting these decreases is an increase in DEFINITY gross profit due to higher unit volumes.

The International segment gross profit for the three months ended March 31, 2016 remained consistent as compared to the prior year period despite the decrease in revenue since it fully offset the decrease in cost of goods sold as a result of the sale of our Canadian radiopharmacies.

**Sales and Marketing**

<b>(dollars in thousands)</b>	<b>Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
United States	\$ 8,305	\$ 8,068
International	1,002	1,004
<b>Total Sales and Marketing</b>	<b>\$ 9,307</b>	<b>\$ 9,072</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.

Total sales and marketing expenses increased \$0.2 million, or 2.6%, to \$9.3 million in the three months ended March 31, 2016, as compared to \$9.1 million in the three months ended March 31, 2015. In the U.S. segment, sales and marketing expense increased \$0.2 million, or 2.9%, to \$8.3 million in the three months ended March 31, 2016, as compared to \$8.1 million in the prior year period. In the International segment, sales and marketing expense remained

consistent.

The increase in the U.S. segment sales and marketing expenses for the three months ended March 31, 2016 over the prior year period is primarily due to higher salary and benefits expenses mainly driven by higher sales incentive compensation due to the increased DEFINITY revenue.

### General and Administrative

(dollars in thousands)	Three Months Ended March 31,	
	2016	2015
United States	\$ 9,154	\$ 8,740
International	359	383
<b>Total General and Administrative</b>	<b>\$ 9,513</b>	<b>\$ 9,123</b>

**Table of Contents**

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.

Total general and administrative expenses increased \$0.4 million, or 4.3%, to \$9.5 million in the three months ended March 31, 2016, as compared to \$9.1 million in the three months ended March 31, 2015. In the U.S. segment, general and administrative expense increased \$0.4 million, or 4.7%, to \$9.2 million in the three months ended March 31, 2016, as compared to \$8.7 million in the prior year period. In the International segment, general and administrative expense remained consistent.

The increase in the U.S. segment general and administrative expenses for the three months ended March 31, 2016 over the prior year period is primarily due to higher software amortization expense, increased severance and related expenses, increased insurance associated with being an equity public company and an increase in our provision for bad debt. These increases were partially offset by decreases in facility costs and by costs incurred in the prior year period not incurred in the current year period, including a \$0.3 million write-off of deferred initial public offering costs and \$0.3 million Avista sponsor fees.

**Research and Development**

(dollars in thousands)	Three Months Ended March 31,	
	2016	2015
United States	\$ 2,867	\$ 6,015
International	169	181
<b>Total Research and Development</b>	<b>\$ 3,036</b>	<b>\$ 6,196</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.

Total research and development expenses decreased \$3.2 million, or 51.0%, to \$3.0 million in the three months ended March 31, 2016, as compared to \$6.2 million in the three months ended March 31, 2015. In the U.S. segment, research and development expense decreased \$3.1 million, or 52.3%, to \$2.9 million in the three months ended March 31, 2016, as compared to \$6.0 million in the prior year period. In the International segment, research and development expense remained.

The decrease in the U.S. segment research and development expenses for the three months ended March 31, 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 pharmacovigilance expenses due to the transition to a new vendor.

**Gain on Sale of Assets**

Effective January 7, 2016, our Canadian subsidiary entered into an asset purchase agreement, pursuant to which it would sell substantially all of the assets of our Canadian radiopharmacies and Gludef manufacturing and distribution business to one of our existing Canadian radiopharmacy customers. The purchase price for the asset sale was \$9.0 million in cash, which resulted in a pre-tax book gain of \$5.8 million, which was recorded within operating income in the quarter ended March 31, 2016.

**Other Expense, Net**

(dollars in thousands)	Three Months Ended March 31,	
	2016	2015
Interest expense	\$ (7,024)	\$ (10,630)
Interest income	6	7
Other income (expense), net	58	(383)
Total other expense, net	\$ (6,960)	\$ (11,006)

**Table of Contents***Interest Expense*

For the three months ended March 31, 2016, compared to the same period in 2015, interest expense decreased by \$3.6 million as a result of the June 2015 refinancing of our long-term debt with a lower interest rate.

*Interest Income*

For the three months ended March 31, 2016, compared to the same period in 2015, interest income remained consistent.

*Other Income (Expense), net*

For the three months ended March 31, 2016, compared to the same period in 2015, other income increased by \$0.4 million primarily due to \$0.3 million increase in tax indemnification income and a \$0.1 million decrease in foreign currency losses.

**Provision (Benefit) for Income Taxes**

(dollars in thousands)	Three Months Ended March 31,	
	2016	2015
Provision (benefit) for income taxes	\$ 390	\$ (3)

For the three months ended March 31, 2016 and 2015, our effective tax rate was 3.6% and 0.8%, respectively. The \$0.4 million increase in the tax provision for the three months ended March 31, 2016, as compared to the same period in 2015, was impacted primarily by changes in uncertain tax positions. Considering our history of losses, we continue to maintain a valuation allowance against substantially all of our net deferred tax assets and therefore our provision (benefit) for income taxes results primarily from taxes due in certain foreign jurisdictions where we generate taxable income, as well as interest and penalties associated with uncertain tax positions offset by reversals of uncertain tax positions as statutes lapse or are settled during the year.

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

The following table provides information regarding our cash flows:

(dollars in thousands)	Three Months Ended March 31,		
	2016	2015	\$ Change
Cash provided by (used in):			
Operating activities	\$ 3,780	\$ 15,157	\$ (11,377)
Investing activities	\$ 7,422	\$ (3,498)	\$ 10,920
Financing activities	\$ (944)	\$ (459)	\$ (485)

*Net Cash Provided by Operating Activities*

Cash provided by operating activities is primarily driven by our earnings and changes in working capital. The \$11.4 million decrease in cash provided by operating activities for the three months ended March 31, 2016 as compared to 2015 was primarily driven by a \$12.1 million increase in cash used for net working capital requirements. The \$12.1 million increase in cash used for net working capital requirements was due to the timing of interest payments on long-term debt which resulted in a \$9.7 million decrease in net working capital as compared to the prior year period. In addition, the increase was further driven by increases in accounts receivable as a result of increases in certain major customer balances. These increases in cash used for net working capital requirements were partially offset by an increase in accounts payable as a result of the timing of payments.

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

The increase in net cash used in investing activities in the three months ended March 31, 2016 as compared to 2015 primarily reflects the \$9.0 million gross proceeds from the sale of assets and a \$1.8 million decrease in capital expenditures.

**Table of Contents***Net Cash Used in Financing Activities*

Net cash used in financing activities during the three months ended March 31, 2016 was primarily for our quarterly Term Facility payment.

Net cash used in financing activities during the three months ended March 31, 2015 was due to payments of audit and legal fees in connection with the IPO.

Historically, our primary source of cash flows from financing activities is draws against our outstanding Revolving Facility. Going forward, we expect our primary source of cash flows from financing activities to be similar draws against our Revolving Facility. Our primary historical uses of cash in financing activities are principal payments on our term loan and Revolving Facility as well as dividends to our shareholders. See External Sources of Liquidity.

*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.

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 March 31, 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**

<b>Period</b>	<b>Total Net Leverage Ratio</b>
Q3 2015 to Q1 2016	6.25 to 1.00
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 March 31, 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 determined by reference to a borrowing base, or 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 March 31, 2016, the aggregate Borrowing Base was approximately \$48.3 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 \$39.4 million.



## **Table of Contents**

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) EBITDA (as defined in the agreement) minus capital expenditures minus certain restricted payments divided by (ii) interest 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. 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.

## **Table of Contents**

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 March 31, 2016, our only current committed external source of funds is our borrowing availability under our Revolving Facility. We had \$38.9 million of cash and cash equivalents at March 31, 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.

There have been no material changes to our critical accounting policies or in the underlying accounting assumptions and estimates used in such policies in the three months ended March 31, 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, or 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.

**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.

## **Table of Contents**

### **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 March 31, 2016, we had \$362.3 million in principal 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 March 31, 2016, there was an \$8.8 million unfunded Standby Letter of Credit and \$0.1 million accrued interest, which reduced availability to \$39.4 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 \$0.9 million in the quarter ended March 31, 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 three months ended March 31, 2016 and 2015, the net impact of foreign currency changes on transactions was a loss of \$0.2 million and \$0.4 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. 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 cost of goods would have increased by \$0.5 million if the U.S. Dollar had been stronger by 10% when compared to the actual rates used during the three months ended March 31, 2016.

If the U.S. Dollar had been uniformly stronger by 10%, compared to the actual average exchange rates, our revenues would have decreased by \$0.7 million and our net income would have decreased by \$1.0 million for the three months ended March 31, 2016.

## **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 March 31, 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.

On December 16, 2010, LMI filed suit against one of its insurance carriers seeking to recover business interruption losses associated with the NRU reactor shutdown and the ensuing global Moly supply shortage. The claim is the result of the shutdown of the NRU reactor in Chalk River, Ontario. The NRU reactor was off-line from May 2009 until August 2010. The defendant answered the complaint on January 21, 2011, denying substantially all of the allegations, presenting certain defenses and requesting dismissal of the case with costs and disbursements. Discovery, including international discovery and related motion practice, has been on-going for more than three years. The defendant filed a motion for summary judgment on July 14, 2014. The Company filed a memorandum of law in opposition to defendant's motion for summary judgment on August 25, 2014. The defendant filed a reply memorandum of law in further support of its motion for summary judgment on September 15, 2014. Expert witness discovery was completed on October 31, 2014. On March 25, 2015, the United States District Court for the Southern District of New York granted defendant's motion for summary judgment. On September 4, 2015, the Company filed an appeal of the District Court decision with the United States Court of Appeals for the Second Circuit. On December 4, 2015, the defendant filed an answer brief to the Company's appeal, and on December 18, 2015, the Company filed a reply brief to the defendant's answer. On April 21, 2016, the United States Court of Appeals for the Second Circuit heard oral arguments of the Company and defendant in connection with the Company's appeal. The Company cannot be certain what amount, if any, or when, if ever, it will be able to recover for business interruption losses related to this matter.

Except as noted above, as of March 31, 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.

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

Currently, Nordion is our sole supplier, and we believe the principal supplier on a global basis, of Xenon, which is captured by Nordion as a by-product of the Moly production process. In January 2015, we entered into a new strategic agreement with IRE for the future supply of Xenon. Under the terms of the agreement, IRE will provide bulk Xenon to us for processing and finishing once development work has been completed and all necessary regulatory approvals have been obtained. We currently estimate commercial production will occur in 2016. If we are not able to begin

providing commercial quantities of Xenon prior to the NRU reactor's transition in October 2016 from providing regular supply of medical isotopes to providing only emergency back-up supply of medical isotopes through March 2018, there may be a period of time during which we are not able to offer Xenon in our portfolio of commercial products, which would have a negative effect on our business, results of operations, financial condition and cash flows. For the year ended December 31, 2015, Xenon represented approximately 17% of our revenues.

Currently, we obtain Xenon from Nordion on a purchase order basis. If we are not able to pass along to our customers any change of terms from our supplier, there could be a negative effect on our business, results of operations, financial condition and cash flows.

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.



---

## **Table of Contents**

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, or 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 commercializes 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.

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 for volume loss and price erosion from those customers that are not subject to price or volume commitments with us.

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

None.

### **Issuer Purchase of Equity Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

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

<b>EXHIBIT NUMBER</b>	<b>DESCRIPTION OF EXHIBITS</b>	<b>INCORPORATED BY REFERENCE</b>			
		<b>FORM</b>	<b>FILE NUMBER</b>	<b>EXHIBIT</b>	<b>FILING DATE</b>
2.1*	Amended and Restated Asset Purchase Agreement, effective January 7, 2016, by and between Lantheus MI Canada, Inc. and Isologic Innovative Radiopharmaceuticals Ltd.				
10.1*	Employment Agreement, effective August 12, 2013, by and between Lantheus Medical Imaging, Inc. and John Crowley.				
10.2*	Amendment to Employment Agreement, effective June 22, 2015, by and between Lantheus Medical Imaging, Inc. and John Crowley.				
10.3*	Amendment to Employment Agreement, effective March 25, 2016, by and between Lantheus Medical Imaging, Inc. and John Crowley.				
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

\* 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: May 3, 2016

LANTHEUS HOLDINGS, INC.

By: /s/ JOHN CROWLEY  
Name: John Crowley  
Title: *Chief Financial Officer*  
Date: May 3, 2016

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

<b>EXHIBIT NUMBER</b>	<b>DESCRIPTION OF EXHIBITS</b>	<b>INCORPORATED BY REFERENCE</b>			
		<b>FORM</b>	<b>FILE NUMBER</b>	<b>EXHIBIT</b>	<b>FILING DATE</b>
2.1*	Amended and Restated Asset Purchase Agreement, effective January 7, 2016, by and between Lantheus MI Canada, Inc. and Isologic Innovative Radiopharmaceuticals Ltd.				
10.1*	Employment Agreement, effective August 12, 2013, by and between Lantheus Medical Imaging, Inc. and John Crowley.				
10.2*	Amendment to Employment Agreement, effective June 22, 2015, by and between Lantheus Medical Imaging, Inc. and John Crowley.				
10.3*	Amendment to Employment Agreement, effective March 25, 2016, by and between Lantheus Medical Imaging, Inc. and John Crowley.				
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

\* Filed herewith