Lantheus Holdings, Inc.
Form 10-Q
October 30, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)
þ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2018
TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission File Number 001-36569

LANTHEUS HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	35-2318913
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
331 Treble Cove Road, North Billerica, MA	01862
(Address of principal executive offices)	(Zip Code)
(978) 671-8001	

(Registrant's telephone number, including area code)

Not Applicable

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

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 þ 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 þ No
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.
Large accelerated filer Accelerated filer þ

Non-accelerated filer Smaller reporting company

Emerging Growth Company þ

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

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

The registrant had 38,464,976 shares of common stock, $0.01 par value, outstanding as of October 26, 2018.

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PART I. FINANCIAL INFORMATION
Item 1. Financial Statements (Unaudited)
Lantheus Holdings, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands, except par value)

	September 30, 2018	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 104,584	$ 76,290
Accounts receivable, net	47,135	40,259
Inventory	34,572	26,080
Other current assets	4,669	5,221
Total current assets	190,960	147,850
Property, plant & equipment, net	99,407	92,999
Intangibles, net	9,727	11,798
Goodwill	15,714	15,714
Deferred tax assets, net	79,358	87,010
Other long-term assets	29,652	28,487
Total assets	$ 424,818	$ 383,858
Liabilities and stockholders' equity		
Current liabilities		
Current portion of long-term debt	$ 2,750	$ 2,750
Revolving line of credit	—	—
Accounts payable	20,363	17,464
Accrued expenses and other liabilities	31,464	26,536
Total current liabilities	54,577	46,750
Asset retirement obligations	11,282	10,412
Long-term debt, net	264,130	265,393
Other long-term liabilities	39,321	38,012
Total liabilities	369,310	360,567
Commitments and contingencies (See Note 13)		
Stockholders' equity		
Preferred stock ($0.01 par value, 25,000 shares authorized; no shares issued and outstanding)	—	—
Common stock ($0.01 par value, 250,000 shares authorized; 38,463 and 37,765 shares issued and outstanding, respectively)	385	378
Additional paid-in capital	237,587	232,960
Accumulated deficit	(181,432)	(209,013)
Accumulated other comprehensive loss	(1,032)	(1,034)
Total stockholders' equity	55,508	23,291
Total liabilities and stockholders' equity	$ 424,818	$ 383,858

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues	$88,900	$79,941	$257,103	$250,137
Cost of goods sold	44,015	41,414	126,063	125,901
Gross profit	44,885	38,527	131,040	124,236
Operating expenses				
Sales and marketing	10,478	10,075	33,248	31,892
General and administrative	13,609	12,076	37,727	35,549
Research and development	4,316	3,554	12,520	14,149
Total operating expenses	28,403	25,705	83,495	81,590
Operating income	16,482	12,822	47,545	42,646
Interest expense	4,446	4,442	12,794	14,147
Loss on extinguishment of debt	—	—	—	2,161
Other income	(799)	(908)	(2,055)	(2,037)
Income before income taxes	12,835	9,288	36,806	28,375
Income tax expense	3,566	762	9,581	2,116
Net income	$9,269	$8,526	$27,225	$26,259
Net income per common share:				
Basic	$0.24	$0.23	$0.71	$0.71
Diluted	$0.24	$0.22	$0.69	$0.67
Weighted-average common shares outstanding:				
Basic	38,342	37,393	38,155	37,174
Diluted	39,402	39,121	39,467	38,971

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net income	$9,269	$8,526	$27,225	$26,259
Other comprehensive (loss) income:				
Foreign currency translation	(2)	(115)	2	(139)
Total other comprehensive (loss) income	(2)	(115)	2	(139)
Comprehensive income	$9,267	$8,411	$27,227	$26,120

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

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

	Nine Months Ended September 30,	
	2018	2017
Operating activities		
Net income	$27,225	$26,259
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation, amortization and accretion	10,544	15,019
Amortization of debt related costs	959	1,031
Provision for bad debt	288	2
Provision for excess and obsolete inventory	2,470	1,002
Stock-based compensation	6,419	3,764
Loss on extinguishment of debt and debt retirement costs	—	2,161
Deferred taxes	7,220	—
Long-term income tax receivable	(2,220)	(1,345)
Long-term income tax payable and other long-term liabilities	2,397	2,120
Other	1,001	627
Increases (decreases) in cash from operating assets and liabilities:		
Accounts receivable	(7,205)	(4,609)
Inventory	(9,832)	(6,361)
Other current assets	(49)	54
Accounts payable	2,200	(270)
Accrued expenses and other liabilities	2,470	2,237
Net cash provided by operating activities	43,887	41,691
Investing activities		
Capital expenditures	(12,766)	(11,589)
Proceeds from sale of assets	1,000	1,234
Net cash used in investing activities	(11,766)	(10,355)
Financing activities		
Proceeds from issuance of long-term debt	—	274,313
Payments on long-term debt	(2,146)	(285,979)
Deferred financing costs	—	(1,576)
Payments for public offering costs	—	(74)
Proceeds from stock option exercises	1,152	1,210
Proceeds from issuance of common stock	428	187
Payments for minimum statutory tax withholding related to net share settlement of equity awards	(3,168)	(2,681)
Net cash used in financing activities	(3,734)	(14,600)
Effect of foreign exchange rates on cash and cash equivalents	(93)	163
Net increase in cash and cash equivalents	28,294	16,899
Cash and cash equivalents, beginning of period	76,290	51,178
Cash and cash equivalents, end of period	$104,584	$68,077

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

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

Note Regarding Company References and Trademarks

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

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of Lantheus Holdings, Inc. and its direct and indirect wholly-owned subsidiaries and have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these condensed consolidated financial statements do not include all of the information and notes required by generally accepted accounting principles in the United States of America ("U.S. GAAP") for complete financial statements. In the opinion of management, all adjustments (consisting of normal and recurring adjustments) considered necessary for a fair statement have been included. The results of operations for the three and nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the year ended December 31, 2018 or any future period.

The condensed consolidated balance sheet at December 31, 2017 has been derived from the audited consolidated financial statements at that date but does not include all of the information and notes required by U.S. GAAP for complete financial statements. These condensed consolidated financial statements and accompanying notes should be read in conjunction with the consolidated financial statements and notes thereto included in Item 8 of the Company's most recent Annual Report on Form 10-K for the year ended December 31, 2017 filed with the Securities Exchange Commission ("SEC") on February 26, 2018. Certain immaterial amounts in the prior period condensed consolidated statement of cash flows have been reclassified to conform to the current period financial statement presentation.

2. Summary of Significant Accounting Policies

Recent Accounting Pronouncements

The following table provides a description of recent accounting pronouncements that may have a material effect on the Company's condensed consolidated financial statements:

Standard	Description	Effective Date for Company	Effect on the Condensed Consolidated Financial Statements
Recently Issued Accounting Standards Not Yet Adopted			
ASU 2016-02, Leases (Topic 842)	This ASU supersedes existing guidance on accounting for leases in "Leases (Topic 840)" and generally requires all leases to be recognized on the balance sheet. The provisions of ASU 2016-02 are effective for annual reporting periods beginning after December 15, 2018; early adoption is permitted. In July 2018, an amendment was made that allows companies the option of	January 1, 2019	The Company is currently in the process of performing an assessment on the impact of the standard, including optional practical expedients and transition methods that the Company may elect upon adoption and is progressing with an implementation plan. The implementation plan includes identifying the Company's lease population, assessing significant leases under the new guidance and identifying changes to processes and controls. The Company is more than halfway through its assessment and implementation plan. At this time, the Company does not anticipate a significant impact to its balance sheet upon adoption of this standard. The Company, in part due to the limited anticipated impact, plans to utilize the prospective approach of adopting

using the effective date of the new standard as the initial application date (at the beginning of the period in which it is adopted, rather than at the beginning of the earliest comparative period).	the standard.

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Standard	Description	Effective Date for Company	Effect on the Condensed Consolidated Financial Statements
Accounting Standards Adopted During the Nine Months Ended September 30, 2018			
ASU 2017-09, Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting	This ASU clarifies when to account for a change to the terms or conditions of a share–based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, vesting conditions or classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The new guidance will be applied prospectively to awards modified on or after the adoption date. The guidance is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017 for all entities.	January 1, 2018	The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.
ASU 2014-09, Revenue from Contracts with Customers (Topic 606) and related amendments	This ASU and related amendments affect any entity that either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets, unless those contracts are within the scope of other standards. The guidance in this ASU supersedes the revenue recognition requirements in Topic 605, Revenue Recognition and most industry-specific guidance. The core principle of the guidance is that an entity should recognize revenue upon the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.	January 1, 2018	See Note 3, "Revenue from Contracts with Customers" for the required disclosures related to the impact of adopting this standard. The adoption of this standard did not have a material impact on the Company's condensed consolidated balance sheets and statements of operations.

3. Revenue from Contracts with Customers

Adoption of ASC Topic 606, "Revenue from Contracts with Customers"

The Company adopted ASC 606 on January 1, 2018 using the modified retrospective method for all contracts not completed as of the date of adoption. The reported results for 2018 reflect the application of ASC 606 guidance while the reported results for 2017 were prepared under the guidance of ASC 605, Revenue Recognition ("ASC 605"). For the Company's accounting policy for revenue recognition under ASC 605, refer to Item 8 of the Annual Report on Form

10-K for the year ended December 31, 2017. The adoption of ASC 606 did not have a material impact on the Company's consolidated balance sheet, results of operations, equity or cash flows as of the adoption date or for the periods presented.

Revenue Recognition

In accordance with ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled to receive in exchange for these goods or services. To achieve this core principle, the Company applies the following five steps: (1) identify the contracts with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the Company satisfies a performance obligation.

Disaggregation of Revenue

The following table summarizes revenue by revenue source and reportable segment as follows:

	Three Months Ended September 30, 2018			Nine Months Ended September 30, 2018		
Major Products/Service Lines (in thousands)	U.S.	International	Total	U.S.	International	Total
Product revenue, net[(1)]	$70,255	$ 18,069	$88,324	$215,829	$ 39,567	$255,396
License and royalty revenues	—	576	576	—	1,707	1,707
Total revenues	$70,255	$ 18,645	$88,900	$215,829	$ 41,274	$257,103

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

Product Revenue, Net

The Company sells its products principally to distributors, radiopharmacies and directly to hospitals and clinics. The Company considers customer purchase orders, which in some cases are governed by master sales or group purchasing organization agreements, to be the contracts with a customer.

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For each contract, the Company considers the promise to transfer products, each of which is distinct, to be the identified performance obligations. In determining the transaction price, the Company evaluates whether the price is subject to refund or adjustment to determine the net consideration to which the Company expects to be entitled.

The Company typically invoices customers upon satisfaction of identified performance obligations. As the Company's standard payment terms are 30 to 60 days from invoicing, the Company has elected to use the significant financing component practical expedient under ASC 606-10-32-18.

The Company allocates the transaction price to each distinct product based on their relative standalone selling price. The product price as specified on the purchase order is considered the standalone selling price as it is an observable input which depicts the price as if sold to a similar customer in similar circumstances.

Revenue is recognized when control of the product is transferred to the customer (i.e., when the Company's performance obligation is satisfied), which typically occurs upon delivery to the customer. Further, in determining whether control has transferred, the Company considers if there is a present right to payment and legal title, along with risks and rewards of ownership having transferred to the customer.

Frequently, the Company receives orders for products to be delivered over multiple dates that may extend across several reporting periods. The Company invoices for each delivery upon shipment and recognizes revenues for each distinct product delivered, assuming transfer of control has occurred.

The Company generally does not separately charge customers for shipping and handling costs, but any shipping and handling costs charged to customers are included in product revenue, net. Taxes collected from customers relating to product sales and remitted to governmental authorities are excluded from revenues.

Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established for discounts, returns, rebates and allowances that are offered within contracts between the Company and its customers. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as a current liability. Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contract. The amount of variable consideration which is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company adjusts these estimates, which would affect product revenue and earnings in the period such variances become known.

Rebates and Allowances: The Company provides certain customers with rebates and allowances that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. The Company establishes a liability for such amounts, which is included in accrued expenses in the accompanying condensed consolidated balance sheets. These rebates and allowances result from performance-based offers that are primarily based on attaining contractually specified sales volumes and administrative fees the Company is required to pay to group purchasing organizations. The Company estimates the amount of rebates and allowances that are explicitly stated in the Company's contracts based on a combination of actual purchases and an estimate of the customer's buying patterns.

Product Returns: The Company generally offers customers a limited right of return due to non-conforming product. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company currently estimates product return liabilities using its historical product return information and considers other factors that it believes could significantly impact its expected returns, including product recalls. Reserves for product returns are not significant to the Company due to the nature of its products including radiopharmaceutical products with limited half-lives.

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The following table summarizes activity for reserves relating to rebate and allowances (including group purchasing organization administrative fees and returns) for the nine months ended September 30, 2018:

(in thousands)	Rebates and Allowances
Balance, January 1, 2018	$ 2,860
Provision related to current period revenues	9,609
Adjustments relating to prior period revenues	(291)
Payments or credits made during the period	(7,885)
Balance, September 30, 2018	$ 4,293

License and Royalty Revenues

The Company has entered into licensing agreements, which are within the scope of ASC 606, under which it licenses certain rights to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products. The Company also has distribution licenses which are treated as combined performance obligations with the delivery of its products and are classified as product revenue, net.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the five-step approach stated earlier. The Company uses judgment in determining the number of performance obligations in a license agreement by assessing whether the license is distinct or should be combined with another performance obligation, as well as the nature of the license. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success.

Licenses of intellectual property: If the license to the Company’s intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license and royalty revenues and earnings in the period of adjustment. At September 30, 2018, the Company is constraining variable consideration related to milestone payments requiring regulatory approvals.

Royalty Revenues: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which

some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Contract Costs

The Company recognizes an asset for incremental costs of obtaining a contract with a customer if it expects to recover those costs. The Company's sales incentive compensation plans qualify for capitalization since these plans are directly related to sales achieved during a period of time. However, the Company has elected the practical expedient under ASC 340-40-25-4 to expense the costs as they are incurred within selling and marketing expenses since the amortization period is less than one year.

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The Company recognized certain revenues as follows:

(in thousands)	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2018
Amounts included in the contract liability at the beginning of the period	$ 8	$ 25
Performance obligations satisfied (or partially satisfied) in previous periods	$ —	$ —

The Company's performance obligations are typically part of contracts that have an original expected duration of one year or less. As such, under the optional exemption provided by ASC 606-10-50-14, the Company is not disclosing the aggregate amount of the transaction price allocated to performance obligations that are unsatisfied (or partially satisfied) as of the end of the reporting period.

4. Fair Value of Financial Instruments

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

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

The Company's financial assets measured at fair value on a recurring basis consist of money market funds. The Company invests excess cash from its operating cash accounts in overnight investments and reflects these amounts in cash and cash equivalents in the condensed consolidated balance sheets at fair value using quoted prices in active markets for identical assets.

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

	September 30, 2018			
(in thousands)	Total Fair Value	Level 1	Level 2	Level 3
Money market	$12,605	$12,605	$ —	$ —
Total	$12,605	$12,605	$ —	$ —

	December 31, 2017			
(in thousands)	Total Fair Value	Level 1	Level 2	Level 3
Money market	$8,700	$8,700	$ —	$ —
Total	$8,700	$8,700	$ —	$ —

Nonrecurring Fair Value Measurements

As of December 31, 2017, the Company wrote down the value of land held for sale in the U.S. segment to its fair value, less estimated costs to sell, using level 3 inputs. See Note 7, "Property, Plant & Equipment, Net" for further discussion regarding land held for sale.

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5. Income Taxes

The Company provides for income taxes at the end of each interim period based on the estimated effective tax rate for the full year, adjusted for any discrete events which are recorded in the period they occur. The Company's effective tax rate in fiscal 2018 differs from the U.S. federal statutory rate of 21% principally due to the impact of state taxes and the accrual of interest on uncertain tax positions offset by tax benefits arising from stock compensation deductions. The Company's effective rate in fiscal 2017 was impacted by the valuation allowance the Company had on all its U.S. deferred tax assets until the fourth quarter of fiscal 2017. Cumulative adjustments to the tax provision are recorded in the interim period in which a change in the estimated annual effective tax rate is determined. The Company's income tax expense is presented below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2018	2017	2018	2017
Income tax expense	$3,566	$762	$9,581	$2,116

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act of 2017 (the "Act"). The Act is significant and has wide-ranging effects.

The Company is still studying all of the ramifications of the Act, but expects the primary material impact of the Act to be the remeasurement of the Company's deferred tax assets, which was recorded in fiscal 2017 as a result of the reduction in U.S. corporate tax rates from 35% to 21%. As of December 31, 2017, the Company determined it had no accumulated unrepatriated foreign earnings, and therefore had recorded no liability for the repatriation transition tax. No changes have been made to these estimates.

The Company is continuing to evaluate other changes resulting from the Act, including the impact of Global Intangible Low Tax Income, Base Erosion and Anti-abuse Tax, and revisions to Code Section 162(m). The Company has incorporated estimates of these items in its fiscal 2018 effective tax rate and expects to complete its accounting for these items within the prescribed measurement period.

The Company regularly assesses its ability to realize its deferred tax assets. Assessing the realizability of deferred tax assets requires significant management judgment. In determining whether its deferred tax assets are more-likely-than-not realizable, the Company evaluated all available positive and negative evidence, and weighed the objective evidence and expected impact. The Company released its full valuation allowance recorded against its domestic net deferred tax assets during the year ended December 31, 2017. The Company continues to record a valuation allowance against certain of its foreign net deferred tax assets.

In connection with the Company's acquisition of the medical imaging business from Bristol Myers Squibb ("BMS") in 2008, the Company entered into 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. A long-term receivable is recorded to account for the expected value to the Company of future indemnification payments, net of actual U.S. federal tax benefits. The tax indemnification receivable is recognized within other long-term assets. The changes in the tax indemnification asset are recognized within other income 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 income tax expense. Accordingly, as these reserves change, adjustments are included in income tax expense while the offsetting adjustment is included in other income. Assuming that the receivable from BMS continues to be considered recoverable by the Company, there will be minimal net effect on earnings and net cash outflows related to these liabilities.

6. Inventory

Inventory consisted of the following:

(in thousands)	September 30, 2018	December 31, 2017

Raw materials	$ 11,896	$ 10,447
Work in process	7,168	5,509
Finished goods	15,508	10,124
Total inventory	$ 34,572	$ 26,080

As of December 31, 2017, the Company had $1.1 million of inventory classified within other long-term assets, which represent raw materials not expected to be used by the Company during the next twelve months. As of September 30, 2018, the Company had no inventory classified within other long-term assets.

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7. Property, Plant & Equipment, Net

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

(in thousands)	September 30, 2018	December 31, 2017
Land	$ 13,450	$ 13,450
Buildings	63,647	76,059
Machinery, equipment and fixtures	68,966	71,870
Computer software	18,365	20,271
Construction in progress	15,285	7,622
	179,713	189,272
Less: accumulated depreciation and amortization	(80,306)	(96,273)
Total property, plant & equipment, net	$ 99,407	$ 92,999

Depreciation and amortization expense related to property, plant & equipment, net, was $2.5 million and $2.7 million for the three months ended September 30, 2018 and 2017, respectively, and $7.6 million and $11.7 million for the nine months ended September 30, 2018 and 2017, respectively.

Long-Lived Assets Held for Sale

During the fourth quarter of 2017, the Company committed to a plan to sell a portion of its land in the U.S. segment. This event qualified for held for sale accounting and the land was written down to its fair value, less estimated costs to sell, which is classified in other current assets at December 31, 2017. During the first quarter of 2018, the Company completed the sale of the land for proceeds of $1.0 million.

8. Asset Retirement Obligations

The Company considers its legal obligation to remediate its facilities upon a decommissioning of its radioactive-related operations as an asset retirement obligation. The Company has production facilities which manufacture and process radioactive materials at its North Billerica, Massachusetts and San Juan, Puerto Rico sites. The Company is required to provide the U.S. Nuclear Regulatory Commission and Massachusetts Department of Public Health financial assurance demonstrating the Company’s ability to fund the decommissioning of its North Billerica, Massachusetts production facility upon closure, although the Company does not intend to close the facility. The Company has provided this financial assurance in the form of a $28.2 million surety bond.

The fair value of a liability for asset retirement obligations is recognized in the period in which the liability is incurred. As of September 30, 2018, the liability is measured at the present value of the obligation expected to be incurred, of approximately $26.9 million, and is adjusted in subsequent periods as accretion expense is recorded. The corresponding asset retirement costs are capitalized as part of the carrying values of the related long-lived assets and depreciated over the assets’ useful lives.

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

(in thousands)	Amount
Balance at January 1, 2018	$10,412
Accretion expense	870
Balance at September 30, 2018	$11,282

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9. Financing Arrangements

On March 30, 2017, the Company refinanced its previous $365 million seven-year term loan agreement (the facility thereunder, the "2015 Term Facility") with a new five-year $275 million term loan facility (the "2017 Term Facility" and the loans thereunder, the "Term Loans"). In addition, the Company replaced its previous $50 million five-year asset based loan facility (the "ABL Facility") with a new $75 million five-year revolving credit facility (the "2017 Revolving Facility" and, together with the 2017 Term Facility, the "2017 Facility"). The terms of the 2017 Facility are set forth in that certain Amended and Restated Credit Agreement, dated as of March 30, 2017 (the "Credit Agreement"), by and among Holdings, the Company, the lenders from time to time party thereto and JPMorgan Chase Bank, N.A., as administrative agent and collateral agent. The 2017 Term Facility was issued net of a $0.7 million discount. The Company has the right to request an increase to the 2017 Term Facility or request the establishment of one or more new incremental term loan facilities, in an aggregate principal amount of up to $75.0 million, plus additional amounts, in certain circumstances.

The net proceeds of the 2017 Term Facility, together with approximately $15.3 million of cash on hand, were used to refinance in full the aggregate remaining principal amount of the loans outstanding under the 2015 Term Facility and pay related interest, transaction fees and expenses. No amounts were outstanding under the ABL Facility at that time. The Company accounted for the refinancing as both a debt extinguishment and debt modification by evaluating the refinancing on a creditor by creditor basis. The Company recorded a loss on extinguishment of debt of $2.2 million related to the write-off of unamortized debt issuance costs and incurred general and administrative expenses of $1.7 million related to third-party costs associated with the modified debt. In addition, the Company incurred and capitalized $1.6 million of new debt issuance costs related to the refinancing.

On November 29, 2017, the Company entered into Amendment No. 1 (the "Repricing Amendment") to the 2017 Facility to, among other things, (i) reduce the applicable interest rate margins with respect to the LIBOR and Base Rate Term Loans (as defined in the Credit Agreement) and (ii) reduce the applicable interest rate margins with respect to the LIBOR and Base Rate Revolving Loans (as defined in the Credit Agreement). The Company accounted for the Repricing Amendment as both a debt extinguishment and debt modification by evaluating the refinancing on a creditor by creditor basis.

2017 Term Facility

The Term Loans under the 2017 Term Facility bear interest, with pricing based from time to time at the Company's election at (i) LIBOR plus a spread of 3.75% or (ii) the Base Rate (as defined in the Credit Agreement) plus a spread of 2.75%. Interest is payable (i) with respect to LIBOR Term Loans, at the end of each Interest Period (as defined in the Credit Agreement) and (ii) with respect to Base Rate Term Loans, at the end of each quarter. At September 30, 2018, the Company's interest rate under the 2017 Term Facility was 6.0%.

The Company is permitted to voluntarily prepay the Term Loans, in whole or in part. The 2017 Term Facility requires the Company to make mandatory prepayments of the outstanding Term Loans in certain circumstances. The 2017 Term Facility amortizes at 1.00% per year until its June 30, 2022 maturity date.

The Company's maturities of principal obligations under the 2017 Term Facility are as follows as of September 30, 2018:

(in thousands)	Amount
Remainder of 2018	$688
2019	2,750
2020	2,750
2021	2,750
2022	261,937
Total principal outstanding	270,875
Unamortized debt discount	(1,697)
Unamortized debt issuance costs	(2,298)
Total	266,880
Less: current portion	(2,750)
Total long-term debt	$264,130

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2017 Revolving Facility

Under the terms of the 2017 Revolving Facility, the lenders thereunder agreed to extend credit to the Company from time to time until March 30, 2022 (the "Revolving Termination Date") consisting of revolving loans (the "Revolving Loans" and, together with the Term Loans, the "Loans") in an aggregate principal amount not to exceed $75 million (the "Revolving Commitment") at any time outstanding. The 2017 Revolving Facility includes a $20 million sub-facility for the issuance of letters of credit (the "Letters of Credit"). The Letters of Credit and the borrowings under the 2017 Revolving Facility are expected to be used for working capital and other general corporate purposes.

The Revolving Loans under the 2017 Revolving Facility bear interest, with pricing based from time to time at the Company's election at (i) LIBOR plus a spread of 3.00% or (ii) the Base Rate (as defined in the Credit Agreement) plus a spread of 2.00%. The 2017 Revolving Facility also includes an unused line fee, which is set at 0.38% while the Company's secured leverage ratio (as defined in the Credit Agreement) is greater than 3.00 to 1.00 and 0.25% when the Company's secured leverage ratio is less than or equal to 3.00 to 1.00.

The Company is permitted to voluntarily prepay the Revolving Loans, in whole or in part, or reduce or terminate the Revolving Commitment, in each case, without premium or penalty. On any business day on which the total amount of outstanding Revolving Loans and Letters of Credit exceeds the total Revolving Commitment, the Company must prepay the Revolving Loans in an amount equal to such excess. As of September 30, 2018, there were no outstanding borrowings under the 2017 Revolving Facility.

2017 Facility Covenants

The 2017 Facility contains a number of affirmative, negative, reporting and financial covenants, in each case subject to certain exceptions and materiality thresholds. The 2017 Facility requires the Company to be in quarterly compliance, measured on a trailing four quarter basis, with a financial covenant. The maximum consolidated leverage ratio permitted by the financial covenant is displayed in the table below:

Period	Consolidated Leverage Ratio
Q4 2018 through Q1 2019	4.75 to 1.00
Thereafter	4.50 to 1.00

The 2017 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.

Upon an event of default, the administrative agent under the Credit Agreement will have the right to declare the Loans and other obligations outstanding immediately due and payable and all commitments immediately terminated or reduced.

The 2017 Facility is guaranteed by Holdings and Lantheus MI Real Estate, LLC ("LMI-RE"), and obligations under the 2017 Facility are generally secured by first priority liens over substantially all of the assets of each of LMI, Holdings and LMI-RE (subject to customary exclusions set forth in the transaction documents) owned as of March 30, 2017 or thereafter acquired.

10. Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2018	2017	2018	2017
Cost of goods sold	$322	$198	$812	$514
Sales and marketing	193	183	892	474
General and administrative	1,540	1,089	3,741	2,315
Research and development	352	187	974	461

Total stock-based compensation expense	$2,407	$1,657	$6,419	$3,764

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During the first quarter of 2018, the Company granted approximately 207,000 total stockholder return restricted stock awards ("TSR Awards") that include a three-year market condition where the performance measurement period is three years. Vesting of the TSR Awards is based on the Company's level of attainment of specified TSR targets relative to a specified index of companies for the respective three-year period and is also subject to the continued employment of the grantees. The number of shares that can be earned over the performance period ranges from 0% to 200% of the initial award. The fair value of these awards are based on a Monte Carlo simulation valuation model.

11. Net Income Per Common Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share amounts)	2018	2017	2018	2017
Net income	$9,269	$8,526	$27,225	$26,259
Basic weighted-average common shares outstanding	38,342	37,393	38,155	37,174
Effect of dilutive stock options	31	318	70	371
Effect of dilutive restricted stock	1,029	1,410	1,242	1,426
Diluted weighted-average common shares outstanding	39,402	39,121	39,467	38,971
Basic income per common share	$0.24	$0.23	$0.71	$0.71
Diluted income per common share	$0.24	$0.22	$0.69	$0.67
Antidilutive securities excluded from diluted net income per common share	355	322	346	378

12. Other Income

Other income consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2018	2017	2018	2017
Foreign currency gains (losses)	$89	$414	$(198)	$554
Tax indemnification income	692	489	2,220	1,469
Other	18	5	33	14
Total other income	$799	$908	$2,055	$2,037

13. 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 costs and outcome of litigation, regulatory or other proceedings cannot be predicted with certainty, and some lawsuits, claims, actions or proceedings may be disposed of unfavorably to the Company. 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.

The Company is currently in arbitration with Pharmalucence in connection with a Manufacturing and Supply Agreement, dated November 12, 2013, under which Pharmalucence agreed to manufacture and supply DEFINITY for the Company. The commercial arrangement contemplated by that agreement was repeatedly delayed and ultimately never successfully realized. After extended settlement discussions between Sun Pharma, the ultimate parent of Pharmalucence, and the Company, which did not lead to a mutually acceptable outcome, on November 10, 2017, the

Company filed an arbitration demand (and later an amended arbitration demand) with the American Arbitration Association against Pharmalucence, alleging breach of contract, breach of the covenant of good faith and fair dealing, tortious misrepresentation and violation of the Massachusetts Consumer Protection Law, also known as Chapter 93A. The Company is seeking monetary damages but cannot predict the outcome of this dispute resolution proceeding and whether the Company will be able to obtain any financial recovery as a result of this proceeding.

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As of September 30, 2018, except as disclosed above the Company had no material ongoing litigation in which the Company was a party. In addition, the Company had no material ongoing regulatory or other proceedings and no knowledge of any investigations by government or regulatory authorities in which the Company is a target, in either case that the Company believes could have a material and adverse effect on its current business.

14. Segment Information

The Company reports two operating segments, U.S. and International, based on geographic customer base. The results of these operating segments are regularly reviewed by the Company's chief operating decision maker, the President and Chief Executive Officer. The Company's segments derive revenues through the manufacture, marketing, selling and distribution of medical imaging products, focused primarily on cardiovascular diagnostic imaging. All goodwill has been allocated to the U.S. operating segment. The Company does not identify or allocate assets to its segments. Selected information regarding the Company's segments is provided as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2018	2017	2018	2017
Revenues from external customers				
U.S.	$70,255	$69,579	$215,829	$218,706
International	18,645	10,362	41,274	31,431
Total revenues from external customers	$88,900	$79,941	$257,103	$250,137
Operating income				
U.S.	$12,897	$12,243	$41,345	$40,306
International	3,585	579	6,200	2,340
Total operating income	16,482	12,822	47,545	42,646
Interest expense	4,446	4,442	12,794	14,147
Loss on extinguishment of debt	—	—	—	2,161
Other income	(799)	(908)	(2,055)	(2,037)
Income before income taxes	$12,835	$9,288	$36,806	$28,375

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

Cautionary Note Regarding Forward-Looking Statements

Some of the statements contained in this Quarterly Report on Form 10-Q are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements, including, in particular, statements about our plans, strategies, prospects and industry estimates are subject to risks and uncertainties. These statements identify prospective information and include words such as "anticipates," "intends," "plans," "seeks," "believes," "estimates," "expects "should," "could," "predicts," "hopes" and similar expressions. Examples of forward-looking statements include, 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 segment competition and potential generic competition as a result of future patent and regulatory exclusivity expirations; (ii) our outlook and expectations related to the global Molybdenum-99 ("Moly") supply; (iii) our outlook and expectations in connection with future performance of Xenon in the face of increased competition; and (iv) our outlook and expectations related to products manufactured at Jubilant HollisterStier ("JHS"). Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward-looking statements relate to the future, such statements are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements. Such statements are neither statements of historical fact nor guarantees or assurances of future performance. The matters referred to in the forward-looking statements contained in this Quarterly Report on Form 10-Q may not in fact occur. We caution you, therefore, against relying on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include regional, national or global political, economic, business, competitive, market and regulatory conditions and the following:

- Our ability to continue to grow the appropriate use of DEFINITY in suboptimal echocardiograms in the face of segment competition from other echocardiography contrast agents, including Optison from GE Healthcare Limited ("GE Healthcare") and Lumason from Bracco Diagnostics Inc. ("Bracco"), and potential generic competition as a result of future patent and regulatory exclusivity expirations;
- The instability of the global Moly supply, including outages at the NTP Radioisotopes ("NTP") processing facility in South Africa from late November 2017 until mid-February 2018 and again from early June 2018 through the present, resulting in our inability to fill all of the demand for our TechneLite generators on certain manufacturing days during those periods;
- Risks associated with revenues and unit volumes for Xenon in pulmonary studies as a result of increased competition from Curium;
- Our dependence upon third parties for the manufacture and supply of a substantial portion of our products, raw materials and components, including DEFINITY at JHS;
- Our dependence on key customers for our medical imaging products, and our ability to maintain and profitably renew our contracts with those key customers, including Cardinal Health ("Cardinal"), United Pharmacy Partners ("UPPI"), GE Healthcare and Jubilant Drax Image Radiopharmaceuticals ("JDI") d/b/a Triad Isotopes, Inc. ("Triad");
- Risks associated with the technology transfer programs to secure production of our products at additional contract manufacturer sites, including an alternative microbubble formulation at Samsung BioLogics ("SBL") in South Korea;
- Risks associated with our lead agent in development, flurpiridaz F 18, including:
  - The ability of GE Healthcare to successfully complete the Phase 3 development program;
  - The ability to obtain Food and Drug Administration ("FDA") approval; and
  - The ability to gain post-approval market acceptance and adequate reimbursement;
- Risks associated with our two current internal clinical development programs - DEFINITY for a left ventricular ejection fraction ("LVEF") indication, and LMI 1195 for patient populations that would benefit from molecular imaging of the norepinephrine pathway, including risk stratification of ischemic heart failure patients;

- Risks associated with the manufacturing and distribution of our products and the regulatory requirements related thereto;
- Risks associated with our investment in, and construction of, additional specialized manufacturing capabilities at our North Billerica, Massachusetts facility;
- 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 on-going U.S. healthcare reform proposals on our business, including related reimbursements for our current and potential future products;

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- 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 serious or unanticipated side effects with our products;
- Our exposure to potential product liability claims and environmental liability;
- The extensive costs, time and uncertainty associated with new product development, including further product development relying on external development partners or potentially developed internally;
- Our inability to introduce new products and adapt to an evolving technology and diagnostic landscape;
- Our inability to identify and in-license or acquire additional products to grow our business;
- 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 or political conditions and events and financial, business and other factors beyond our control;
- Risks associated with our international operations;
- Our inability to adequately operate, maintain and protect our facilities, equipment and technology infrastructure;
- Our inability to hire or retain skilled employees and key personnel;
- Our inability to utilize, or limitations in our ability to utilize, net operating loss carryforwards to reduce our future tax liability;
- Risks related to our outstanding indebtedness and our ability to satisfy those obligations;
- Costs and other risks associated with the Sarbanes-Oxley Act and the Dodd-Frank Act, including in connection with potentially becoming a large accelerated filer;
- Risks related to the ownership of our common stock; and
- Other factors that are described in Part I, Item 1A. “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2017.

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 (“SEC”). Any forward-looking statement made by us in this Quarterly Report on Form 10-Q speaks only as of the date on which it is made. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law.

Available Information

Our global Internet site is www.lantheus.com. We routinely make available important information, including copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the SEC, free of charge on our website at www.investor.lantheus.com. We recognize our website as a key channel of distribution to reach public investors and as a means of disclosing material non-public information to comply with our disclosure obligations under SEC Regulation FD. Information contained on our website shall not be deemed incorporated into, or to be part of, this Quarterly Report on Form 10-Q, and any website references are not intended to be made through active hyperlinks.

The public may read and copy any materials we file with the SEC at the SEC’s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Our reports filed with, or furnished to, the SEC are also available on the SEC’s website at www.sec.gov, and for Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q, in an XBRL (Extensible Business Reporting Language) format. XBRL is an electronic coding language used to create interactive financial statement data over the Internet. The information on our website is neither part of nor incorporated by reference into this Quarterly Report on Form 10-Q.

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The following discussion and analysis of our financial condition and results of operations should be read together with the condensed consolidated financial statements and the related notes included in Item 1 of this Quarterly Report on Form 10-Q as well as the other factors described in Part I, Item 1A. “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2017.

Overview

Our Business

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

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

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

Our Product Portfolio

Our product portfolio includes an ultrasound contrast agent and nuclear imaging products. Our principal products include the following:

- DEFINITY is a microbubble contrast agent used in ultrasound exams of the heart, also known as echocardiography exams. DEFINITY contains perflutren-containing lipid microspheres and is indicated in the U.S. for use in patients with suboptimal echocardiograms to assist in imaging the left ventricular chamber and left endocardial border of the heart in ultrasound procedures.
- TechneLite is a Technetium generator that 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 active ingredient.
- Xenon is a radiopharmaceutical gas that is inhaled and used to assess pulmonary function and also for imaging cerebral blood flow. Xenon is manufactured by a third party and is processed and finished by us.

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

We also maintain our own direct sales force in Canada for certain customers so that we can control the importation, marketing, distribution and sale of our imaging agents in Canada in this sales channel. In Europe, Australia, 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 multi-country regional basis.

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
(in thousands)	2018	% of Revenues	2017	% of Revenues	2018	% of Revenues	2017	% of Revenues
DEFINITY	$43,755	49.2 %	$37,729	47.2 %	$134,508	52.3 %	$115,569	46.2 %
TechneLite	30,618	34.4 %	26,356	33.0 %	75,491	29.4 %	79,900	31.9 %
Xenon	7,239	8.2 %	7,726	9.6 %	22,805	8.8 %	23,713	9.5 %
Other	7,288	8.2 %	8,130	10.2 %	24,299	9.5 %	30,955	12.4 %
Total revenues	$88,900	100.0 %	$79,941	100.0 %	$257,103	100.0 %	$250,137	100.0 %

Key Factors Affecting Our Results

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

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

We believe the market opportunity for our ultrasound microbubble contrast agent, DEFINITY, continues to be significant. DEFINITY is our fastest growing and highest margin commercial product. We believe DEFINITY sales will continue to grow and that DEFINITY will constitute a greater share of our overall product mix in 2019 as compared to prior years. As we continue to educate the physician and healthcare provider community about the benefits and risks of DEFINITY, we believe we will be able to continue to grow the appropriate use of DEFINITY in suboptimal echocardiograms. In a U.S. market with three echocardiography contrast agents approved by the FDA, we estimate that DEFINITY had over 80% of the market as of June 30, 2018.

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

- Patents - We continue to actively pursue additional patents in connection with DEFINITY, both in the U.S. and internationally. In the U.S., we now have an Orange Book-listed method of use patent expiring in March 2037. This patent augments an Orange Book-listed composition of matter patent expiring in June 2019, and additional manufacturing patents that are not Orange Book-listed expiring in 2021, 2023 and most recently 2037. Outside of the U.S., our DEFINITY patent protection or regulatory exclusivity currently expires in 2019.

Hatch-Waxman Act - Even though our longest duration Orange Book-listed patent expires in March 2037, because our Orange Book-listed composition of matter patent expires in June 2019, we may face generic DEFINITY challengers in the near to intermediate term. Under the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, the FDA can approve Abbreviated New Drug Applications (“ANDAs”) for generic versions of drugs if the ANDA applicant demonstrates, among other things, that (i) its generic candidate is the same as the innovator product by documenting bioequivalence and providing relevant chemistry, manufacturing and product data, and (ii) the marketing of that generic candidate does not infringe an Orange Book-listed patent. With respect to any Orange Book-listed patent covering the innovator product, the ANDA applicant must give notice to the innovator (a “Notice”) that the ANDA applicant certifies that its generic candidate will not infringe the innovator’s Orange Book-listed patent or that the Orange Book-listed patent is invalid. The innovator can then challenge the ANDA applicant in court within 45 days of receiving such Notice, and FDA approval to commercialize the generic candidate will be stayed (that is, delayed) for up to 30 months while the patent dispute between the innovator and the ANDA applicant is resolved in court. The 30 month stay could potentially expire sooner if the courts determine that no infringement occurs or that the challenged Orange Book-listed patent is invalid or the parties otherwise settle their dispute.

As of the date of filing of this Quarterly Report on Form 10-Q, we have not received any Notice from an ANDA applicant. If we were to (i) receive any such Notice in the future, (ii) bring a patent infringement suit against the ANDA applicant within 45 days of receiving such Notice, and (iii) successfully obtain the full 30 month stay, then the ANDA applicant would be precluded from commercializing a generic candidate prior to the expiration of such 30 month stay period and potentially thereafter depending on how a patent dispute is resolved. Solely by way of example and not based on any knowledge we currently have, if we received a Notice from an ANDA applicant in November 2018 and the full 30 month stay was obtained, then the ANDA applicant would be precluded from commercialization until at least May 2021. If we received a Notice some number of months in the future and the full 30 month stay was

obtained, the commercialization date would roll forward in the future by the same calculation.

- LVEF Indication - We have reached agreement with the FDA on a special protocol assessment, or SPA, for our Phase 3 LVEF clinical program, designed to demonstrate improved accuracy of LVEF measurements with DEFINITY-enhanced echocardiography. We are conducting two well-controlled studies powered to prove superiority in LVEF measurement accuracy with DEFINITY-enhanced versus unenhanced echocardiography. The truth standard in these studies is cardiac

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magnetic resonance imaging. The studies will be at 20 U.S. sites, will include approximately 300 subjects, and enrollment has commenced. We believe DEFINITY could improve the accuracy of LVEF calculations, giving clinicians greater confidence in patient management decisions. An LVEF indication could substantially increase the addressable market for contrast-enhanced echocardiography. We believe that DEFINITY, as the market leader, would benefit from the expanded addressable market.

- Modified Formulation - We are developing at SBL a modified formulation of DEFINITY. We believe this modified formulation will provide an enhanced product profile enabling shipment and storage at room temperature (DEFINITY's current formulation requires refrigerated storage), will give clinicians additional choice, and will allow for greater utility of this formulation in alternative clinical settings. We were recently granted a composition of matter patent on the modified formulation which runs through December 2035. If the modified formulation is approved by the FDA, then this patent would be eligible to be listed in the Orange Book. We currently believe that, if approved by the FDA, the modified formulation could become commercially available in 2020. Given its physical characteristics, the modified formulation may also be better suited for inclusion in kits requiring microbubbles for other indications and applications.
- New Applications - As we continue to look for other opportunities to expand our microbubble franchise, we are evaluating new indications and applications beyond echocardiography and contrast imaging generally.
- In-House Manufacturing - We are currently building specialized in-house manufacturing capabilities at our North Billerica, Massachusetts facility for DEFINITY and, potentially, other sterile vial products. We believe these efforts will allow us to better control DEFINITY manufacturing and inventory, reduce our costs in a potentially more price competitive environment, and provide us with supply chain redundancy. We currently expect to be in a position to use this in-house manufacturing capability by early 2021, although that timing cannot be assured.

See Part I, Item 1A. "Risk Factors—The growth of our business is substantially dependent on our ability to continue to grow the appropriate use of DEFINITY in suboptimal echocardiograms in the face of increased segment competition from other existing echocardiography agents and potential generic competitors as a result of future patent and regulatory exclusivity expirations," and "—If we are unable to protect our intellectual property, our competitors could develop and market products with features similar to our products, and demand for our products may decline," both in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018. See also Part I, Item 1A. "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," and "—Item 1. Business—Our Product Portfolio—DEFINITY and Our Microbubble Franchise Strategy," both in our Annual Report on Form 10-K for the year ended December 31, 2017.

Global Moly Supply

We currently have Moly supply agreements with NTP of South Africa, for itself and on behalf of its subcontractor ANSTO of Australia, running through December 31, 2020, and with IRE running through December 31, 2018, renewable by us on a year-to-year basis thereafter. We also have a Xenon supply agreement with IRE which runs through June 30, 2019, also subject to extensions.

We believe we are generally well-positioned with ANSTO, IRE and NTP to have a diverse, global Moly supply, including low-enriched uranium-based Moly produced from targets containing less than 20% of Uranium-235. However, we still face challenges in our Moly supply chain. The NTP processing facility was off-line from late November 2017 until mid-February 2018 and again from early June 2018 through the present. During these periods, we have relied on Moly supply from both IRE and ANSTO to limit the impact of the NTP outage. However, we have been unable to fill all of the demand for our TechneLite generators on certain manufacturing days. We can give no assurances as to when the NTP processing facility will be back on line.

To expand its current Moly production capacity, ANSTO is currently commissioning a new Mo-99 production facility that also will expand its production capacity from 2,000 to 3,500 curies per week which is expected to be in commercial operation in the first half of 2019. We also have a strategic arrangement with SHINE Medical Technologies, Inc. ("SHINE"), a Wisconsin-based company, for the future supply of Moly. Under the terms of that

agreement, SHINE will provide us Moly once SHINE's facility becomes operational and receives all necessary approvals, which SHINE now estimates will occur in 2021.

See Part II, Item 1A. "Risk Factors—The global supply of Moly is fragile and not stable. Our dependence on a limited number of third party suppliers for Moly could prevent us from delivering some of our products to our customers in the required quantities, within the required timeframe, or at all, which could result in order cancellations and decreased revenues" of this Quarterly Report on Form 10-Q and Part I, Item 1A. "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 year ended December 31, 2017.

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Competition for Xenon

Xenon gas for lung ventilation diagnosis is our third largest product by revenues. In order to increase the predictability of our Xenon business, we have entered into Xenon supply agreements with customers at committed volumes and reduced prices. These steps have resulted in more predictable Xenon unit volumes. Historically, several companies, including Curium, sold packaged Xenon as a pulmonary imaging agent in the U.S., but from 2010 through the first quarter of 2016 (when Curium received regulatory approval from FDA to again sell packaged Xenon in the U.S.) we were the only supplier of this imaging agent in the U.S. Curium sold packaged Xenon in the U.S. during parts of 2016 and again began selling packaged Xenon in the U.S. in May 2018. Depending upon the pricing, extent of availability and market penetration of Curium's offering, we believe we are at risk for volume loss and price erosion from those customers that are not subject to price or volume commitments with us. In addition to competition from Curium, other imaging agents and modalities could potentially compete with, or displace, packaged Xenon in pulmonary studies. If there is an increase in the use of other imaging agents or 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. See Part I, Item 1A. "Risk Factors—We face revenue and unit volume risk for Xenon in pulmonary studies as a result of competition from Curium and potentially others" of our Annual Report on Form 10-K for the year ended December 31, 2017.

Inventory Supply

We obtain a substantial portion of our imaging agents from third-party suppliers. JHS is currently our sole source manufacturer of DEFINITY, Neurolite, Cardiolite and evacuation vials, the latter being an ancillary component for our TechneLite generators. We are currently seeking approval from certain foreign regulatory authorities for JHS to manufacture certain of our products. Until we receive these approvals, we will face continued limitations on where we can sell those products outside of the U.S.

In addition to JHS, we are also currently working to secure additional alternative suppliers for our key products as part of our ongoing supply chain diversification strategy. We have ongoing development and technology transfer activities for an alternative microbubble formulation with SBL, which is located in South Korea, but we cannot give any assurances as to if and when those technology transfer activities will be completed and when we will begin to receive supply of an alternative microbubble formulation from SBL. As described above, we have also commenced an extensive, multi-year effort to add in-house specialized manufacturing capabilities at our North Billerica, Massachusetts facility. This project is part of a larger strategy to create a competitive advantage in specialized manufacturing, which will also allow us to optimize our costs and reduce our supply chain risk. We can give no assurance as to when or if we will be successful in these efforts or that we will be able to successfully manufacture any additional commercial products at our North Billerica, Massachusetts facility. See Part I, Item 1A. "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 year ended December 31, 2017.

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

Research and Development Expenses

To remain a leader in the marketplace, we have historically made substantial investments in new product development. As a result, the positive contributions of those internally funded research and development programs have been a key factor in our historical results and success. On April 25, 2017, we announced entering into a definitive, exclusive Collaboration and License Agreement with GE Healthcare for the continued Phase 3 development and worldwide commercialization of flurpiridaz F 18. As part of our microbubble franchise strategy, for our proposed LVEF indication for DEFINITY, we have reached agreement with the FDA on an SPA and have commenced enrollment in our additional clinical trials. For LMI 1195, our PET-based molecular imaging agent for the norepinephrine pathway, we are working with the FDA on a Special Protocol Assessment for a single Phase 3 clinical trial for LMI 1195 to demonstrate improved risk stratification of ischemic heart failure patients. Our investments in

these additional clinical activities will increase our operating expenses and impact our results of operations and cash flow.

Strategic Activities

To further expand and diversify our business, we are pursuing external opportunities that fit our growth and profitability objectives. Our current focus is on the broader imaging agent space and therapeutic adjacencies.

Segments

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

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Executive Overview

Our results for the three and nine months ended September 30, 2018 as compared to the corresponding periods in 2017 reflect the following:

- increased revenues for DEFINITY in the suboptimal echocardiogram segment as a result of our continued focused sales efforts;
- decreased revenues for TechneLite in the U.S. segment primarily as a result of a temporary supplier disruption;
- increased revenues for TechneLite in the International segment primarily driven by increased volume as a result of temporary incremental demand;
- decreased revenues in other revenue due to the recognition of $5.0 million during the prior year from GE Healthcare in exchange for rights to the continued Phase 3 development and worldwide commercialization of flurpiridaz F 18;
- decreased depreciation expense as a result of the decommissioning of certain long-lived assets during the prior year period;
- decreases in general and administrative expense of $1.7 million incurred in connection with the refinancing of our debt, as well as a related $2.2 million loss on the extinguishment of debt during the prior year period; and
- increased tax expense due to the profit generated during the three and nine months ended September 30, 2018 and the fact that we no longer record a valuation allowance against our domestic deferred tax assets.

Results of Operations

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2018	2017	2018	2017
Revenues	$88,900	$79,941	$257,103	$250,137
Cost of goods sold	44,015	41,414	126,063	125,901
Gross profit	44,885	38,527	131,040	124,236
Operating expenses				
Sales and marketing	10,478	10,075	33,248	31,892
General and administrative	13,609	12,076	37,727	35,549
Research and development	4,316	3,554	12,520	14,149
Total operating expenses	28,403	25,705	83,495	81,590
Operating income	16,482	12,822	47,545	42,646
Interest expense	4,446	4,442	12,794	14,147
Loss on extinguishment of debt	—	—	—	2,161
Other income	(799)	(908)	(2,055)	(2,037)
Income before income taxes	12,835	9,288	36,806	28,375
Income tax expense	3,566	762	9,581	2,116
Net income	$9,269	$8,526	$27,225	$26,259

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Comparison of the Periods Ended September 30, 2018 and 2017

Revenues

Segment revenues are summarized by product as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
(in thousands)	2018	2017	Change $	Change %	2018	2017	Change $	Change %
U.S.								
DEFINITY	$42,472	$36,901	$5,571	15.1 %	$131,081	$113,035	$18,046	16.0 %
TechneLite	19,374	22,621	(3,247)	(14.4)%	56,780	69,150	(12,370)	(17.9)%
Xenon	7,239	7,726	(487)	(6.3)%	22,805	23,709	(904)	(3.8)%
Other	1,170	2,331	(1,161)	(49.8)%	5,163	12,812	(7,649)	(59.7)%
Total U.S. revenues	70,255	69,579	676	1.0 %	215,829	218,706	(2,877)	(1.3)%
International								
DEFINITY	1,283	828	455	55.0 %	3,427	2,534	893	35.2 %
TechneLite	11,244	3,735	7,509	201.0 %	18,711	10,750	7,961	74.1 %
Xenon	—	—	—	— %	—	4	(4)	(100.0)%
Other	6,118	5,799	319	5.5 %	19,136	18,143	993	5.5 %
Total International revenues	18,645	10,362	8,283	79.9 %	41,274	31,431	9,843	31.3 %
Total revenues	$88,900	$79,941	$8,959	11.2 %	$257,103	$250,137	$6,966	2.8 %

The increase in the U.S. segment revenues for the three months ended September 30, 2018, as compared to the prior year period is primarily due to an increase of $5.6 million in DEFINITY revenues as a result of higher unit volumes. This was offset by a $3.2 million decrease in TechneLite revenues primarily as a result of lower unit volumes due to a temporary supplier disruption and a change in contracted volumes from certain customers, a $0.5 million decrease in other product revenues due primarily to timing of shipments, a $0.5 million decrease in Xenon revenues due to lower volume and a $0.5 million increase in rebate and allowance provisions.

The decrease in the U.S. segment revenues for the nine months ended September 30, 2018, as compared to the prior year period is primarily due to a $12.4 million decrease in TechneLite revenues primarily as a result of lower unit volumes due to a temporary supplier disruption and a change in contracted volumes from certain customers, a decrease of approximately $5.0 million in other revenue associated with the License Agreement with GE Healthcare in exchange for rights to the continued Phase 3 development and worldwide commercialization of flurpiridaz F 18 which was recorded in the second quarter of the prior year, a $2.0 million increase in rebate and allowance provisions, $0.9 million decrease in Xenon revenues due to lower volume and $0.7 million decrease in other product revenues due primarily to timing of shipments. Offsetting these decreases was an increase of $18.0 million in DEFINITY revenues as a result of higher unit volumes.

The increase in the International segment revenues for the three months ended September 30, 2018, as compared to the prior year period is primarily due to a $7.5 million increase in TechneLite revenues primarily driven by increased volume as a result of temporary incremental demand, a $0.5 million increase in DEFINITY revenues as a result of higher unit volumes and $0.3 million in other product revenue due to timing of shipments.

The increase in the International segment revenues for the nine months ended September 30, 2018, as compared to the prior year period is primarily due to a $8.0 million increase in TechneLite revenues primarily driven by increased volume as a result of temporary incremental demand, a $0.9 million increase in DEFINITY revenues as a result of higher unit volumes, a $0.7 million increase in Thallium revenues as a result of higher volumes and $0.3 million in other product revenue due to timing of shipments.

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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 other revenue and the establishment of a liability which is included in accrued expenses. These rebates and allowances result from performance-based offers that are primarily based on attaining contractually specified sales volumes and growth, Medicaid rebate programs for our products, administrative fees of group purchasing organizations, 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:

(in thousands)	Rebates and Allowances
Balance, January 1, 2018	$ 2,860
Provision related to current period revenues	9,609
Adjustments relating to prior period revenues	(291)
Payments or credits made during the period	(7,885)
Balance, September 30, 2018	$ 4,293

Gross Profit

Gross profit is summarized by segment as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
(in thousands)	2018	2017	Change $	Change %	2018	2017	Change $	Change %
U.S.	$40,193	$36,820	$3,373	9.2 %	$121,163	$118,481	$2,682	2.3 %
International	4,692	1,707	2,985	174.9%	9,877	5,755	4,122	71.6 %
Total gross profit	$44,885	$38,527	$6,358	16.5 %	$131,040	$124,236	$6,804	5.5 %

The increase in the U.S. segment gross profit for the three months ended September 30, 2018 over the prior year period is primarily due to the higher DEFINITY unit volumes.

The increase in the U.S. segment gross profit for the nine months ended September 30, 2018 over the prior year period is primarily due to higher DEFINITY unit volumes. This was offset by the recognition of approximately $5.0 million in the prior year period in other revenue associated with the License Agreement with GE Healthcare for the continued Phase 3 development and worldwide commercialization of flurpiridaz F 18 without any associated cost of goods sold, lower TechneLite unit volumes and an increase in excess and obsolete inventory reserve of other materials.

The increase in the International segment gross profit for the three and nine months ended September 30, 2018 over the prior year periods is primarily due to higher TechneLite and other product unit volumes.

Sales and Marketing

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.

Sales and marketing expense is summarized by segment as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
(in thousands)	2018	2017	Change $	Change %	2018	2017	Change $	Change %
U.S.	$9,862	$9,480	$ 382	4.0 %	$31,343	$29,854	$1,489	5.0 %
International	616	595	21	3.5 %	1,905	2,038	(133)	(6.5)%
Total sales and marketing	$10,478	$10,075	$ 403	4.0 %	$33,248	$31,892	$1,356	4.3 %

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The increase in the U.S. segment sales and marketing expenses for the three months ended September 30, 2018 over the prior year period is primarily due to employee-related expenses.

The increase in the U.S. segment sales and marketing expenses for the nine months ended September 30, 2018 over the prior year period is primarily due to employee-related expenses and market research projects.

General and Administrative

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

General and administrative expense is summarized by segment as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
(in thousands)	2018	2017	Change $	Change %	2018	2017	Change $	Change %
U.S.	$13,339	$11,901	$1,438	12.1 %	$37,175	$35,055	$2,120	6.0 %
International	270	175	95	54.3 %	552	494	58	11.7 %
Total general and administrative	$13,609	$12,076	$1,533	12.7 %	$37,727	$35,549	$2,178	6.1 %

The increase in the U.S. segment general and administrative expenses for the three months ended September 30, 2018 over the prior year period is primarily due to higher employee-related expenses and legal fees offset by lower information technology costs.

The increase in the U.S. segment general and administrative expenses for the nine months ended September 30, 2018 over the prior year period is primarily due to higher employee-related expenses and higher legal costs offset by non-recurrence of $1.7 million of debt refinancing costs incurred in the prior year period, lower information technology costs and campus consolidation costs.

Research and Development

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

Research and development expense is summarized by segment as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
(in thousands)	2018	2017	Change $	Change %	2018	2017	Change $	Change %
U.S.	$4,095	$3,196	$ 899	28.1 %	$11,300	$13,265	$(1,965)	(14.8)%
International	221	358	(137)	(38.3)%	1,220	884	336	38.0 %
Total research and development	$4,316	$3,554	$ 762	21.4 %	$12,520	$14,149	$(1,629)	(11.5)%

The increase in the U.S. segment research and development expenses for the three months ended September 30, 2018 over the prior year period is primarily due to clinical research expenses related to DEFINITY studies and higher employee-related expenses.

The decrease in the U.S. segment research and development expenses for the nine months ended September 30, 2018 over the prior year period is primarily due to a decrease in depreciation expense resulting from the decommissioning of certain long-lived assets associated with research and development operations offset by higher employee-related expenses and clinical research expenses related to DEFINITY studies.

The increase in the International segment research and development expenses for the nine months ended September 30, 2018 over the prior year period is driven by a European Phase 4 study for one of our products.

Interest Expense

Interest expense decreased by approximately $1.4 million for the nine months ended September 30, 2018 as compared to the prior year period due to comparatively lower outstanding principal balances and effective interest rates on our

long-term debt during the period as a result of our March 2017 refinancing.

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Loss on Extinguishment of Debt

For the nine months ended September 30, 2017, we incurred a $2.2 million loss on extinguishment of debt in connection with the refinancing of our existing indebtedness with the new term loan and revolving credit facilities, see Note 9, “Financing Arrangements” to our condensed consolidated financial statements.

Income Tax Expense

Income tax expense for the periods presented is summarized as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
(in thousands)	2018	2017	Change $	Change %	2018	2017	Change $	Change %
Income tax expense	$3,566	$762	$2,804	368.0%	$9,581	$2,116	$7,465	352.8%

We provide for income tax expense based on the estimated annual effective tax rate for the full year, adjusted for any discrete events which are recorded in the period they occur.

Our effective tax rate for the periods presented are as follows:

	Nine Months Ended September 30,	
	2018	2017
Effective tax rate	26.0%	7.5%

Our effective tax rate in fiscal 2018 differs from the U.S. statutory rate of 21% principally due to the impact of U.S. state taxes and the accrual of interest on uncertain tax positions offset by tax benefits arising from stock compensation deductions.

The increase in effective income tax rate for the nine months ended September 30, 2018 was due to the fact that we were maintaining a full valuation allowance on our domestic and most of our foreign net deferred tax assets prior to December 31, 2017, at which time the valuation allowance related to our domestic net deferred tax assets was released.

As a result, the income tax expense for the three and nine months ended September 30, 2018 was primarily due to the income generated in the period and the accrual of interest associated with uncertain tax positions offset by tax benefits arising from stock compensation deductions. The income tax expense for the three and nine months ended September 30, 2017 is primarily from the accrual of interest on uncertain tax positions.

We regularly assess our ability to realize our deferred tax assets. Assessing the realizability of deferred tax assets requires significant management judgment. In determining whether our deferred tax assets are more-likely-than-not realizable, we evaluate all available positive and negative evidence, and weigh the objective evidence and expected impact. We released the full valuation allowance recorded against our domestic deferred tax assets during the year ended December 31, 2017. We continue to record a valuation allowance against certain of our foreign net deferred tax assets.

Liquidity and Capital Resources

Cash Flows

The following table provides information regarding our cash flows:

	Nine Months Ended September 30,	
(in thousands)	2018	2017
Net cash provided by operating activities	$43,887	$41,691
Net cash used in investing activities	$(11,766)	$(10,355)
Net cash used in financing activities	$(3,734)	$(14,600)

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Net Cash Provided by Operating Activities

Net cash provided by operating activities of $43.9 million in the nine months ended September 30, 2018 was driven primarily by net income of $27.2 million plus $10.5 million of depreciation, amortization and accretion expense, changes in deferred taxes of $7.2 million and $6.4 million of stock-based compensation expense. These net sources of cash were offset by a net decrease of $12.4 million related to movements in our working capital accounts during the period. The overall decreases in cash from our working capital accounts were primarily driven by the timing of inventory purchases during the period as well as higher accounts receivable as a result of temporary incremental demand for TechneLite in our International segment.

Net cash provided by operating activities of $41.7 million in the nine months ended September 30, 2017 was driven primarily by net income of $26.3 million plus $15.0 million of depreciation, amortization and accretion expense, $3.8 million of stock-based compensation expense and a $2.2 million loss on debt extinguishment. These net sources of cash were offset by a net decrease of $8.9 million related to movements in our working capital accounts during the period. The overall decreases in cash from our working capital accounts were primarily driven by higher accounts receivable related to increases in revenues to certain major customers and timing of inventory purchases during the period.

Net Cash Used in Investing Activities

Net cash used in investing activities during the nine months ended September 30, 2018 reflected $12.8 million in capital expenditures offset by the cash proceeds of $1.0 million received from the sale of land.

Net cash used in investing activities during the nine months ended September 30, 2017 reflected $11.6 million in capital expenditures offset by the cash proceeds of $1.2 million received from the sale of assets from our Australian radiopharmacy business during the third quarter of 2016.

Net Cash Used in Financing Activities

Net cash used in financing activities during the nine months ended September 30, 2018 reflected payments for minimum statutory tax withholding related to net share settlement of equity awards of $3.2 million, payments on long-term debt of $2.1 million, offset by proceeds of $1.2 million from the exercise of stock options.

Net cash used in financing activities during the nine months ended September 30, 2017 was primarily related to the net outflow of $11.9 million in connection with our refinancing of our previous $365.0 million seven-year term loan agreement with a new five-year $275.0 million term loan facility.

External Sources of Liquidity

In March 2017, we refinanced our 2015 $365 million seven-year term loan facility with a new five-year $275 million term loan facility (the “2017 Term Facility” and the loans thereunder, the “Term Loans”). In addition, we replaced our revolving facility with a new $75 million five-year revolving credit facility (the “2017 Revolving Facility” and, together with the 2017 Term Facility, the “2017 Facility”). The terms of the 2017 Facility are set forth in that certain Amended and Restated Credit Agreement, dated as of March 30, 2017 (the “Credit Agreement”), by and among us, the lenders from time to time party thereto and JPMorgan Chase Bank, N.A., as administrative agent and collateral agent. The 2017 Term Facility was issued net of a $0.7 million discount. We have the right to request an increase to the 2017 Term Facility or request the establishment of one or more new incremental term loan facilities, in an aggregate principal amount of up to $75.0 million, plus additional amounts, in certain circumstances.

On November 29, 2017, we entered into Amendment No. 1 (the “Repricing Amendment”) to the 2017 Facility to, among other things, (i) reduce the applicable interest rate margins with respect to the LIBOR and Base Rate Term Loans (as defined in the Credit Agreement) and (ii) reduce the applicable interest rate margins with respect to the LIBOR and Base Rate Revolving Loans (as defined in the Credit Agreement).

The Term Loans under the 2017 Term Facility bear interest, with pricing based from time to time at our election at (i) LIBOR plus a spread of 3.75% or (ii) the Base Rate plus a spread of 2.75%. Interest is payable (i) with respect to LIBOR Term Loans, at the end of each Interest Period (as defined in the Credit Agreement) and (ii) with respect to Base Rate Term Loans, at the end of each quarter. At September 30, 2018, our interest rate under the 2017 Term Facility was 6.0%. As of September 30, 2018, the principal balance outstanding on our 2017 Term Facility was $270.9 million.

We are permitted to voluntarily prepay the Term Loans, in whole or in part. The 2017 Term Facility requires us to make mandatory prepayments of the outstanding Term Loans in certain circumstances. The 2017 Term Facility amortizes at 1.00% per year until its June 30, 2022 maturity date.

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Under the terms of the 2017 Revolving Facility, the lenders thereunder agreed to extend credit to us from time to time until March 30, 2022 (the "Revolving Termination Date") consisting of revolving loans (the "Revolving Loans" and, together with the Term Loans, the "Loans") in an aggregate principal amount not to exceed $75 million (the "Revolving Commitment") at any time outstanding. The 2017 Revolving Facility includes a $20 million sub-facility for the issuance of letters of credit (the "Letters of Credit"). The Letters of Credit and the borrowings under the 2017 Revolving Facility are expected to be used for working capital and other general corporate purposes.

The Revolving Loans under the 2017 Revolving Facility bear interest, with pricing based from time to time at our election at (i) LIBOR plus a spread of 3.00% or (ii) the Base Rate (as defined in the Credit Agreement) plus a spread of 2.00%. The 2017 Revolving Facility also includes an unused line fee, which is set at 0.38% while our secured leverage ratio (as defined in the Credit Agreement) is greater than 3.00 to 1.00 and 0.25% when our secured leverage ratio is less than or equal to 3.00 to 1.00.

We are permitted to voluntarily prepay the Revolving Loans, in whole or in part, or reduce or terminate the Revolving Commitment, in each case, without premium or penalty. On any business day on which the total amount of outstanding Revolving Loans and Letters of Credit exceeds the total Revolving Commitment, we must prepay the Revolving Loans in an amount equal to such excess. The 2017 Facility contains a number of affirmative, negative, reporting and financial covenants, in each case subject to certain exceptions and materiality thresholds. The 2017 Facility requires us to be in quarterly compliance, measured on a trailing four quarter basis, with a financial covenant. The maximum consolidated leverage ratio permitted by the financial covenant is displayed in the table below:

Period	Consolidated Leverage Ratio
Q4 2018 through Q1 2019	4.75 to 1.00
Thereafter	4.50 to 1.00

The 2017 Facility contains usual and customary restrictions on our ability and that of 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.

Upon an event of default, the administrative agent under the Credit Agreement will have the right to declare the Loans and other obligations outstanding immediately due and payable and all commitments immediately terminated or reduced.

The 2017 Facility is guaranteed by Holdings and Lantheus MI Real Estate, LLC ("LMI-RE"), and obligations under the 2017 Facility are generally secured by first priority liens over substantially all of the assets of each of LMI, Holdings and LMI-RE (subject to customary exclusions set forth in the transaction documents) owned as of March 30, 2017 or thereafter acquired.

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

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

Funding Requirements

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

- The 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;
-

Our investment in the further clinical development and commercialization of existing products and development candidates;

- The costs of investing in our facilities, equipment and technology infrastructure;
- The extent to which we acquire or invest in new products, businesses and technologies;

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- The costs and timing of establishing manufacturing and supply arrangements for commercial supplies of our products and raw materials and components;
- Our ability to have product manufactured and released from JHS and other manufacturing sites in a timely manner in the future;
- The costs of further commercialization of our existing products, particularly in international markets, including product marketing, sales and distribution and whether we obtain local partners to help share such commercialization costs;
- The extent to which we choose to establish collaboration, co-promotion, distribution or other similar arrangements for our marketed products;
- The legal costs relating to maintaining, expanding and enforcing our intellectual property portfolio, pursuing insurance or other claims and defending against product liability, regulatory compliance or other claims; and
- The cost of interest on any additional borrowings which we may incur under our financing arrangements.

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

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

At September 30, 2018, our only current committed external source of funds is our borrowing availability under our 2017 Revolving Facility. We had $104.6 million of cash and cash equivalents at September 30, 2018. Our 2017 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 2017 Revolving Facility may affect our ability to comply with the covenants in the 2017 Facility, including the financial covenant restricting consolidated net leverage. Accordingly, we may be limited in utilizing the full amount of our 2017 Revolving Facility 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 2017 Revolving Facility will be sufficient to continue to fund our liquidity requirements for the foreseeable future.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial position and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America (“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 other significant changes to our critical accounting policies or in the underlying accounting assumptions and estimates used in such policies in the nine months ended September 30, 2018, except as set forth

below. For further information, refer to our summary of significant accounting policies and estimates in our Annual Report on Form 10-K filed for the year ended December 31, 2017.

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Revenue from Contracts with Customers

On January 1, 2018, we adopted Financial Accounting Standards Board Accounting Standards Codification Topic 606, Revenue from Contracts with Customers ("ASC 606") using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. The provisions of ASC 606 supersedes the revenue recognition requirements in Topic 605 "Revenue Recognition", and requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The adoption of ASC 606 requires us to provide expanded disclosures related to our contracts with customers but did not have a material impact on the Company's consolidated financial position, results of operations, equity or cash flows as of the adoption date or for the periods presented.

Revenue is measured based on a consideration specified in a contract with a customer, and excludes any sales incentives and amounts collected on behalf of third parties. We recognize revenue when we satisfy our performance obligations by transferring control over products or services to our customers. The amount of revenue we recognize reflects the consideration to which we expect to be entitled to receive in exchange for these goods or services. To achieve this core principle, we apply the following five steps: (1) identify the contracts with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) we satisfies performance obligations.

We derive our revenues through arrangements with customers for product sales as well as licensing and royalty arrangements. We sell our products principally to distributors, radiopharmacies and directly to hospitals and clinics and we consider customer purchase orders, which in some cases are governed by master sales or group purchasing organization agreements, to be contracts with our customers. In addition to these arrangements, we also enter into licensing agreements under which we license certain rights to third parties. The terms of these arrangements typically include payment to us of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products. We analyze various factors requiring management judgment when applying the five-step model to our contracts with customers.

Our product revenues are recorded at the net sales price (transaction price), which represents our sales price less estimates related to reserves which are established for items such as discounts, returns, rebates and allowances that may be provided for in certain contracts with our customers. Judgment is used in determining and updating our reserves on an on-going basis, and where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contract. Actual amounts of consideration ultimately received may differ from the Company's estimates.

For our licensing and royalty arrangements, we use judgment in determining the number of performance obligations in a license agreement by assessing whether the license is distinct or should be combined with another performance obligation as well as the nature of the license. As part of the accounting for these arrangements, we develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in a contract. These key assumptions may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success.

Off-Balance Sheet Arrangements

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

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

For quantitative and qualitative disclosures about market risk, see Part II, Item 7A, “Quantitative and Qualitative Disclosures About Market Risk,” of our Annual Report on Form 10-K for the year ended December 31, 2017. Our exposures to market risk have not changed materially since December 31, 2017.

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Item 4. Controls and Procedures

Disclosure Controls and Procedures

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

Changes in Internal Controls Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. There were no significant changes to our internal control over financial reporting due to the adoption of ASC 606.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are a party to various legal proceedings arising in the ordinary course of business. In addition, we have in the past been, and may in the future be, subject to investigations by governmental and regulatory authorities which expose us to greater risks associated with litigation, regulatory or other proceedings, as a result of which we could be required to pay significant fines or penalties. The costs and outcome of litigation, regulatory or other proceedings cannot be predicted with certainty, and some lawsuits, claims, actions or proceedings may be disposed of unfavorably to us. In addition, intellectual property disputes often have a risk of injunctive relief which, if imposed against us, could materially and adversely affect our financial condition or results of operations.

We are currently in arbitration with Pharmalucence in connection with a Manufacturing and Supply Agreement, dated November 12, 2013, under which Pharmalucence agreed to manufacture and supply DEFINITY for us. The commercial arrangement contemplated by that agreement was repeatedly delayed and ultimately never successfully realized. After extended settlement discussions between Sun Pharma, the ultimate parent of Pharmalucence, and us, which did not lead to a mutually acceptable outcome, on November 10, 2017, we filed an arbitration demand (and later an amended arbitration demand) with the American Arbitration Association against Pharmalucence, alleging breach of contract, breach of the covenant of good faith and fair dealing, tortious misrepresentation and violation of the Massachusetts Consumer Protection Law, also known as Chapter 93A. We are seeking monetary damages but cannot predict the outcome of this dispute resolution proceeding and whether we will be able to obtain any financial recovery as a result of this proceeding.

As of September 30, 2018, except as disclosed above we had no material ongoing litigation in which we were a party. In addition, we had no material ongoing regulatory or other proceeding and no knowledge of any investigations by governmental or regulatory authorities in which we are a target, in either case that we believe could have a material and adverse effect on our current business.

Item 1A. Risk Factors

There have been no material changes to the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2017 and in the Quarterly Report on Form 10-Q for the period ended June 30, 2018, except as set forth below. For further information, refer to Part I, Item 1A. “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2017.

The growth of our business is substantially dependent on our ability to continue to grow the appropriate use of DEFINITY in suboptimal echocardiograms in the face of increased segment competition from other existing echocardiography agents and potential generic competitors as a result of future patent and regulatory exclusivity expirations.

The growth of our business is substantially dependent on our ability to continue to grow the appropriate use of DEFINITY in suboptimal echocardiograms. There were approximately 33.1 million echocardiograms in 2017 according to a third-party source. Assuming 20% of echocardiograms produce suboptimal images, as stated in the clinical literature, we estimate that approximately 6.6 million echocardiograms in 2017 produced suboptimal images. We estimate that DEFINITY held over 80% of the U.S. market for contrast agents in echocardiography procedures as of June 30, 2018. DEFINITY currently competes with Optison, a GE Healthcare product, Lumason, a Bracco product (known as SonoVue outside the U.S.), as well as other non-echocardiography agents.

We launched DEFINITY in 2001, and we continue to actively pursue patents in connection with DEFINITY, both in the U.S. and internationally. In the U.S., we now have an Orange Book-listed method of use patent expiring in March 2037 to augment a DEFINITY patent portfolio that includes an Orange Book-listed composition of matter patent expiring in June 2019, and additional manufacturing patents that are not Orange Book-listed expiring in 2021, 2023 and 2037. Outside of the U.S., our DEFINITY patent protection or regulatory exclusivity currently expires in 2019. Because our Orange Book-listed composition of matter patent expires in June 2019, we may face generic DEFINITY challengers in the near to intermediate term. Under the Hatch-Waxman Act, the FDA can approve ANDAs for generic versions of drugs before the expiration of an Orange Book-listed patent covering the innovator product if the ANDA applicant demonstrates, among other things, that (i) its generic candidate is the same as the innovator product by documenting bioequivalence and providing relevant chemistry, manufacturing and product data, and (ii) the marketing

of that generic candidate does not infringe an Orange Book-listed patent or the Orange Book-listed patent is invalid. With respect to any Orange Book-listed patent covering the innovator product that expires after the ANDA applicant intends to begin commercialization, the ANDA applicant must certify that its generic candidate will not infringe the innovator's Orange Book-listed patents or that the Orange Book-listed patents are invalid. The ANDA applicant must also give Notice to the innovator, which would then enable the innovator to challenge the ANDA applicant in court within 45 days of receiving such Notice. If the innovator challenges the ANDA applicant in court in a timely manner, then FDA approval to commercialize the generic candidate will be stayed (that is, delayed) for up to 30 months while the dispute between the innovator and the ANDA

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applicant is resolved in court. The 30 month stay can be shortened if the patent infringement suit is resolved in the ANDA applicant's favor before the 30 month stay expires, and this may involve a successful challenge of the patent's validity in U.S. Patent and Trademark Office, or USPTO, proceedings and appeals process.

As of the date of filing of this Quarterly Report on Form 10-Q, we have not received any such Notice from any ANDA applicant but can give no assurance that we will not receive a Notice in the future. If we were to receive any such Notice in the future, we would review the Notice, evaluate the strength of any potential patent infringement claims, and be prepared to challenge the ANDA applicant in a timely fashion, which would thereby trigger the stay of up to 30 months. We can give no assurance that we would have grounds to file a patent infringement suit, that we would obtain the full 30 month stay, that we would be successful on the merits asserting that a generic candidate infringes our Orange Book-listed patent, or that we would be successful defending the validity of our Orange Book-listed patent in court or in a USPTO adversarial proceeding.

As part of our microbubble franchise strategy, (i) we have initiated additional clinical trials to pursue expansion of the current DEFINITY indication to include LVEF, (ii) we are developing a modified formulation of DEFINITY, (iii) we look for other opportunities to expand our microbubble franchise, including new applications beyond echocardiography and contrast imaging generally, and (iv) we continue to build specialized in-house manufacturing capabilities at our North Billerica facility for DEFINITY and, potentially, other products. However, we can give no assurance that our microbubble franchise strategy will be successful or that new manufacturing capabilities, a new indication, a modified formulation, new applications or new manufacturing capabilities will grow our microbubble franchise.

We have on-going development and technology transfer activities for our modified formulation with SBL located in South Korea but can give no assurances as to when or if those development and technology transfer activities will be completed and when we will begin to receive a supply of our modified formulation from SBL.

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

The global supply of Moly is fragile and not stable. Our dependence on a limited number of third party suppliers for Moly could prevent us from delivering some of our products to our customers in the required quantities, within the required timeframe, or at all, which could result in order cancellations and decreased revenues.

A critical ingredient of TechneLite is Moly. We currently purchase finished Moly from three of the four main processing sites in the world, namely ANSTO in Australia, IRE in Belgium and NTP in South Africa. These processing sites provide us Moly from five of the six main Moly-producing reactors in the world, namely OPAL in Australia, BR2 in Belgium, LVR-15 in the Czech Republic, HFR in The Netherlands, and SAFARI in South Africa. ANSTO has under construction, in cooperation with NTP, a new Moly processing facility that ANSTO believes will increase its production capacity from approximately 2,000 curies per week to 3,500 curies per week, with commercial production currently planned to start in the first half of 2019. While we believe this additional Moly supply will give us the most balanced and diversified Moly supply chain in the industry, a prolonged disruption of service from only one of our Moly suppliers could have a material adverse effect on our business, results of operations, financial condition and cash flows. The NTP processing facility was off-line from late November 2017 until mid-February 2018 and again from early June 2018 through the present, and we have been forced to rely on Moly supply from both IRE and ANSTO to limit the impact of the NTP outage. However, we have been unable to fill all of the demand for our TechneLite generators on certain manufacturing days, consequently decreasing revenue and cash flow from this product line during the outage periods as compared to prior periods. In addition, a recent unplanned shutdown of the HFR reactor has reduced the Moly supply available for the IRE processing facility. We can give no assurances as to when the NTP processing facility or the HFR reactor will be back on-line. A longer term outage from one of our three Moly processing sites or one of their main Moly-producing reactors could have a substantial negative effect on our business, results of operations, financial condition and cash flows.

We are also pursuing additional sources of Moly from potential new producers around the world to further augment our current supply. In November 2014, we entered into a strategic arrangement with SHINE for the future supply of Moly. Under the terms of the supply agreement, SHINE will provide Moly produced using its proprietary LEU-solution technology for use in our TechneLite generators once SHINE's facility becomes operational and receives all necessary regulatory approvals, which SHINE now estimates will occur in 2021. However, we cannot assure you that SHINE or any other possible additional sources of Moly will result in commercial quantities of Moly for our business, or that these new suppliers together with our current suppliers will be able to deliver a sufficient quantity of Moly to meet our needs.

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U.S., Canadian and international governments have encouraged the development of a number of alternative Moly production projects with existing reactors and technologies as well as new technologies. However, we cannot say when, or if, the Moly produced from these projects will become available. As a result, there is a limited amount of Moly available which could limit the quantity of TechneLite that we could manufacture, sell and distribute, resulting in a further substantial negative effect on our business, results of operations, financial condition and cash flows.

Most of the global suppliers of Moly rely on Framatone-CERCA in France to fabricate uranium targets and in some cases fuel for research reactors from which Moly is produced. Absent a new supplier, a supply disruption relating to uranium targets or fuel could have a substantial negative effect on our business, results of operations, financial condition and cash flows.

If we are unable to protect our intellectual property, our competitors could develop and market products with features similar to our products, and demand for our products may decline.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our commercial products and technologies and agents in development as well as successfully enforcing and defending these patents and trade secrets against third parties and their challenges, both in the U.S. and in foreign countries. We will only be able to protect our intellectual property from unauthorized use by third parties to the extent that we maintain the secrecy of our trade secrets and can enforce our valid patents and trademarks.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. In addition, changes in either the patent laws or in interpretations of patent laws in the U.S. or other countries may diminish the value of our intellectual property and we may not receive the same degree of protection in every jurisdiction. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third party patents.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- We might not have been the first to make the inventions covered by each of our pending patent applications and issued patents, and we could lose our patent rights as a result;
- We might not have been the first to file patent applications for these inventions or our patent applications may not have been timely filed, and we could lose our patent rights as a result;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies;
- It is possible that none of our pending patent applications will result in any further issued patents;
- Our issued patents may not provide a basis for commercially viable drugs, may not provide us with any protection from unauthorized use of our intellectual property by third parties, and may not provide us with any competitive advantages;
- Our patent applications or patents may be subject to interferences, oppositions, post-grant review, ex-parte re-examinations, inter-partes review or similar administrative proceedings;
- While we generally apply for patents in those countries where we intend to make, have made, use or sell patented products, we may not be able to accurately predict all of the countries where patent protection will ultimately be desirable and may be precluded from doing so at a later date;
- We may choose not to seek patent protection in certain countries where the actual cost outweighs the perceived benefit at a certain time;
- Patents issued in foreign jurisdictions may have different scopes of coverage as our U.S. patents and so our products may not receive the same degree of protection in foreign countries as they would in the U.S.;
- We may not develop additional proprietary technologies that are patentable; or
- The patents of others may have an adverse effect on our business.

Moreover, the issuance of a patent is not conclusive as to its validity or enforceability. A third party may challenge the validity or enforceability of a patent even after its issuance by the USPTO or the applicable foreign patent office. It is also uncertain how much protection, if any, will be afforded by our patents if we attempt to enforce them and they are challenged in court or in other proceedings, which may be brought in U.S. or non-U.S. jurisdictions to challenge the validity of a patent.

The initiation, defense and prosecution of intellectual property suits (including Hatch-Waxman related litigation), interferences, oppositions and related legal and administrative proceedings are costly, time consuming to pursue and result in a diversion of

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resources, including a significant amount of management time. The outcome of these proceedings is uncertain and could significantly harm our business. If we are not able to enforce and defend the patents of our technologies and products, then we will not be able to exclude competitors from marketing products that directly compete with our products, which could have a material and adverse effect on our business, results of operations, financial condition and cash flows.

For DEFINITY, our fastest growing and highest margin commercial product in 2018, we continue to actively pursue patents in both the U.S. and internationally. In the U.S., we now have an Orange Book-listed method of use patent expiring in March 2037 to augment an Orange Book-listed composition of matter patent expiring in June 2019, and additional manufacturing patents that are not Orange Book-listed expiring in 2021, 2023 and 2037. Outside of the U.S., our DEFINITY patent protection or regulatory exclusivity currently expires in 2019. See Item 1A “Risk Factors—The growth of our business is substantially dependent on our ability to continue to grow the appropriate use of DEFINITY in suboptimal echocardiograms in the face of increased segment competition from other existing echocardiography agents and potential generic competitors as a result of future patent and regulatory exclusivity expirations.” in this Quarterly Report on Form 10-Q for the quarter ended September 30, 2018.

We will also rely on trade secrets and other know-how and proprietary information to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We use reasonable efforts to protect our trade secrets, but our employees, consultants, contractors, outside scientific partners and other advisors may unintentionally or willfully disclose our confidential information to competitors or other third parties. Enforcing a claim that a third party improperly obtained and is using our trade secrets is expensive, time consuming and resource intensive, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. We rely on confidentiality agreements with our collaborators, employees, consultants and other third parties and invention assignment agreements with our employees to protect our trade secrets and other know-how and proprietary information concerning our business. These confidentiality agreements may not prevent unauthorized disclosure of trade secrets and other know-how and proprietary information, and there can be no guarantee that an employee or an outside party will not make an unauthorized disclosure of our trade secrets, other technical know-how or proprietary information, or that we can detect such an unauthorized disclosure. We may not have adequate remedies for any unauthorized disclosure. This might happen intentionally or inadvertently. It is possible that a competitor will make use of that information, and that our competitive position will be compromised, in spite of any legal action we might take against persons making those unauthorized disclosures, which could have a material and adverse effect on our business, results of operations, financial condition and cash flows.

We rely on our trademarks, trade names and brand names to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks, including DEFINITY, Cardiolite, TechneLite, Neurolite, Quadramet, Luminity, Miraluma and Lantheus Medical Imaging. We cannot assure you that any pending trademark applications will be approved. Third parties may also oppose our trademark applications, or otherwise challenge our use of the trademarks. If our trademarks are successfully challenged, we could be forced to re-brand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot assure you that competitors will not infringe our trademarks, or that we will have adequate resources to enforce our trademarks.

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

Repurchases

The following table presents information with respect to purchases of common stock we made during the quarter ended September 30, 2018. The Company does not currently have a share repurchase program in effect. The 2015 Equity Incentive Plan, adopted by the Company on June 24, 2015, as amended on April 26, 2016 and as further amended on April 27, 2017 (the "2015 Plan"), provides for the withholding of shares to satisfy minimum statutory tax withholding obligations. It does not specify a maximum number of shares that can be withheld for this purpose. The shares of common stock withheld to satisfy minimum tax withholding obligations may be deemed to be "issuer purchases" of shares that are required to be disclosed pursuant to this Item 2.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Program
July 2018**	—	$ —	*	*
August 2018**	11,283	$ 15.94	*	*
September 2018**	48,954	$ 15.39	*	*
Total	60,237		*	

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

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

Dividend Policy

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

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

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Item 6. Exhibits

EXHIBIT NUMBER	DESCRIPTION OF EXHIBITS	INCORPORATED BY REFERENCE			
		FORM	FILE NUMBER	EXHIBIT	FILING DATE
10.1*	Separation Agreement, effective September 20, 2018, by and between Lantheus Medical Imaging, Inc. and Timothy Healey				
10.2*	Separation Agreement, effective September 21, 2018, by and between Lantheus Medical Imaging, Inc. and Jack Crowley				
31.1*	Certification of Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a).				
31.2*	Certification of Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a).				
32.1**	Certification pursuant to 18 U.S.C. Section 1350.				
101.INS*	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
**Furnished herewith

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SIGNATURES

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

LANTHEUS HOLDINGS, INC.

By:	/s/ MARY ANNE HEINO
Name:	Mary Anne Heino
Title:	President and Chief Executive Officer (Principal Executive Officer)
Date:	October 30, 2018

LANTHEUS HOLDINGS, INC.

By:	/s/ ROBERT J. MARSHALL, JR.
Name:	Robert J. Marshall, Jr.
Title:	Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)
Date:	October 30, 2018