Lantheus Holdings, Inc.
Form 10-Q
April 30, 2019
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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 March 31, 2019
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 38,820,101 shares of common stock, $0.01 par value, outstanding as of April 24, 2019.

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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)

	March 31, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$112,061	$ 113,401
Accounts receivable, net	45,021	43,753
Inventory	32,044	33,019
Other current assets	6,372	5,242
Total current assets	195,498	195,415
Property, plant and equipment, net	112,211	107,888
Intangibles, net	8,686	9,133
Goodwill	15,714	15,714
Deferred tax assets, net	79,755	81,449
Other long-term assets	32,044	30,232
Total assets	$443,908	$ 439,831
Liabilities and stockholders' equity		
Current liabilities		
Current portion of long-term debt and other borrowings	$2,854	$ 2,750
Revolving line of credit	—	—
Accounts payable	15,323	17,955
Accrued expenses and other liabilities	24,591	32,050
Total current liabilities	42,768	52,755
Asset retirement obligations	11,895	11,572
Long-term debt, net and other borrowings	263,293	263,709
Other long-term liabilities	42,739	40,793
Total liabilities	360,695	368,829
Commitments and contingencies (See Note 14)		
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; 38,818 and 38,466 shares issued and outstanding, respectively)	388	385
Additional paid-in capital	242,068	239,865
Accumulated deficit	(158,191)	(168,140)
Accumulated other comprehensive loss	(1,052)	(1,108)
Total stockholders' equity	83,213	71,002
Total liabilities and stockholders' equity	$443,908	$ 439,831

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 March 31,	
	2019	2018
Revenues	$86,510	$82,630
Cost of goods sold	42,426	40,321
Gross profit	44,084	42,309
Operating expenses		
Sales and marketing	10,397	10,640
General and administrative	12,589	12,543
Research and development	4,929	3,989
Total operating expenses	27,915	27,172
Operating income	16,169	15,137
Interest expense	4,592	4,050
Other income	(1,187)	(920)
Income before income taxes	12,764	12,007
Income tax expense	2,815	3,796
Net income	$9,949	$8,211
Net income per common share:		
Basic	$0.26	$0.22
Diluted	$0.25	$0.21
Weighted-average common shares outstanding:		
Basic	38,603	37,886
Diluted	39,787	39,493

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 March 31,	
	2019	2018
Net income	$9,949	$8,211
Other comprehensive income:		
Foreign currency translation	56	—
Total other comprehensive income	56	—
Comprehensive income	$10,005	$8,211

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance, January 1, 2018	37,765	$ 378	$232,960	$(209,013)	$ (1,034)	$ 23,291
Net income	—	—	—	8,211	—	8,211
Forfeiture of dividend equivalent right	—	—	—	355	—	355
Other comprehensive income	—	—	—	—	—	—
Stock option exercises and employee stock plan purchases	94	1	719	—	—	720
Vesting of restricted stock awards and units	174	2	(2)	—	—	—
Shares withheld to cover taxes	(36)	(1)	(708)	—	—	(709)
Stock-based compensation	—	—	1,796	—	—	1,796
Balance, March 31, 2018	37,997	$ 380	$234,765	$(200,447)	$ (1,034)	$ 33,664
Balance, January 1, 2019	38,466	$ 385	$239,865	$(168,140)	$ (1,108)	$ 71,002
Net income	—	—	—	9,949	—	9,949
Other comprehensive income	—	—	—	—	56	56
Stock option exercises and employee stock plan purchases	37	—	606	—	—	606
Vesting of restricted stock awards and units	365	4	(4)	—	—	—
Shares withheld to cover taxes	(50)	(1)	(1,119)	—	—	(1,120)
Stock-based compensation	—	—	2,720	—	—	2,720
Balance, March 31, 2019	38,818	$ 388	$242,068	$(158,191)	$ (1,052)	$ 83,213

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)

	Three Months Ended March 31,	
	2019	2018
Operating activities		
Net income	$9,949	$8,211
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation, amortization and accretion	3,323	3,596
Amortization of debt related costs	320	320
Provision for bad debt	(190)	195
Provision for excess and obsolete inventory	511	1,220
Stock-based compensation	2,720	1,796
Deferred taxes	1,741	2,923
Long-term income tax receivable	(802)	(841)
Long-term income tax payable and other long-term liabilities	1,018	854
Other	(6)	(46)
Increases (decreases) in cash from operating assets and liabilities:		
Accounts receivable	(1,040)	(7,816)
Inventory	465	(6,579)
Other current assets	(1,152)	(1,003)
Accounts payable	1,458	2,160
Accrued expenses and other liabilities	(7,847)	(5,656)
Net cash provided by (used in) operating activities	10,468	(666)
Investing activities		
Capital expenditures	(10,550)	(2,135)
Proceeds from sale of assets	—	1,000
Net cash used in investing activities	(10,550)	(1,135)
Financing activities		
Payments on long-term debt and other borrowings	(717)	(715)
Proceeds from stock option exercises	324	514
Proceeds from issuance of common stock	282	206
Payments for minimum statutory tax withholding related to net share settlement of equity awards	(1,120)	(709)
Net cash used in financing activities	(1,231)	(704)
Effect of foreign exchange rates on cash and cash equivalents	(27)	(46)
Net decrease in cash and cash equivalents	(1,340)	(2,551)
Cash and cash equivalents, beginning of period	113,401	76,290
Cash and cash equivalents, end of period	$112,061	$73,739

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 TM, SM and ® symbols. Those references are not intended to indicate, in any way, that the Company will not assert, to the fullest extent permitted under applicable law, its rights to its trademarks, service marks and trade names.

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of 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 months ended March 31, 2019 are not necessarily indicative of the results that may be expected for the year ended December 31, 2019 or any future period.

The condensed consolidated balance sheet at December 31, 2018 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, 2018 filed with the Securities Exchange Commission (“SEC”) on February 20, 2019.

2. Summary of Significant Accounting Policies

Recent Accounting Pronouncements

Standard	Description	Effective Date for Company	Effect on the Condensed Consolidated Financial Statements
Accounting Standards Adopted During the Three Months Ended March 31, 2019			
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. In July 2018, an amendment was made that allows companies the option of 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).	January 1, 2019	See Note 11, "Leases" for the required disclosures related to the impact of adopting this standard. The adoption of this standard resulted in the recording of an additional lease asset and lease liability of approximately $1.1 million as of January 1, 2019. The standard did not have a material impact on the Company’s condensed consolidated statements of operations, equity or cash flows.

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3. Revenue from Contracts with Customers

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

	Three Months Ended March 31, 2019			Three Months Ended March 31, 2018		
Major Products/Service Lines (in thousands)	U.S.	International	Total	U.S.	International	Total
Product revenue, net[(1)]	$75,434	$ 10,549	$85,983	$71,488	$ 10,580	$82,068
License and royalty revenues	—	527	527	—	562	562
Total revenues	$75,434	$ 11,076	$86,510	$71,488	$ 11,142	$82,630

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

The Company recognized certain revenues as follows:

(in thousands)	Three Months Ended March 31, 2019	Three Months Ended March 31, 2018
Amounts included in the contract liability at the beginning of the period	$ 8	$ 8
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 tables below present information about the Company's assets and liabilities measured at fair value on a recurring basis:

	March 31, 2019			
(in thousands)	Total Fair Value	Level 1	Level 2	Level 3
Money market	$55,730	$55,730	$ —	$ —

Total	$55,730	$55,730	$ —	$ —

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(in thousands)	December 31, 2018 Total Fair Value	Level 1	Level 2	Level 3
Money market	$61,391	$61,391	$ —	$ —
Total	$61,391	$61,391	$ —	$ —

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 2019 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. Cumulative adjustments to the tax provision are recorded in the interim period in which a change in the estimated annual effective tax rate is determined. The Company's income tax expense is presented below:

(in thousands)	Three Months Ended March 31, 2019	2018
Income tax expense	$2,815	$3,796

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 evaluates all available positive and negative evidence, and weighs the objective evidence and expected impact. The Company continues to record a valuation allowance against certain foreign 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. A long-term receivable is recorded to account for the expected value to the Company of future indemnification payments, net of actual tax benefits received. The tax indemnification receivable is recognized within other long-term assets. 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, 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 no effect on net income and no net cash outflows related to these liabilities.

6. Inventory

Inventory consisted of the following:

(in thousands)	March 31, 2019	December 31, 2018
Raw materials	$ 11,521	$ 11,100
Work in process	9,007	4,261
Finished goods	11,516	17,658
Total inventory	$ 32,044	$ 33,019

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7. Property, Plant and Equipment, Net

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

(in thousands)	March 31, 2019	December 31, 2018
Land	$13,450	$ 13,450
Buildings	64,957	64,444
Machinery, equipment and fixtures	70,133	69,298
Computer software	19,846	19,266
Construction in progress	29,034	24,169
	197,420	190,627
Less: accumulated depreciation and amortization	(85,209)	(82,739)
Total property, plant and equipment, net	$112,211	$ 107,888

Depreciation and amortization expense related to property, plant and equipment, net, was $2.5 million and $2.6 million for the three months ended March 31, 2019 and 2018, respectively.

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 March 31, 2019, 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, 2019	$11,572
Accretion expense	323
Balance at March 31, 2019	$11,895

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9. Long-term debt, net and other borrowings

As of March 31, 2019, the Company's maturities of principal obligations under its long-term debt and other borrowings are as follows:

(in thousands)	Amount
Remainder of 2019	$2,063
2020	2,750
2021	2,750
2022	261,937
Total principal outstanding	269,500
Unamortized debt discount	(1,471)
Unamortized debt issuance costs	(1,992)
Finance lease liabilities	110
Total	266,147
Less: current portion	(2,854)
Total long-term debt, net and other borrowings	$263,293

At March 31, 2019, the Company's interest rate under its long-term debt was 6.2%.

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 March 31,	
(in thousands)	2019	2018
Cost of goods sold	$440	$229
Sales and marketing	451	302
General and administrative	1,574	980
Research and development	255	285
Total stock-based compensation expense	$2,720	$1,796

11. Leases

Adoption of ASC Topic 842, "Leases"

The Company adopted ASC 842 on January 1, 2019, using the prospective approach which provides a method for recording existing leases at adoption using the effective date of the standard as its initial application date. ASC 842 generally requires all leases to be recognized on the balance sheet. In addition, the Company elected the relief package of practical expedients permitted under the transition guidance within the new standard, which, among other things, allowed the Company not to reassess whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for any existing leases. The reported results for 2019 reflect the application of ASC 842 guidance while the reported results for 2018 were prepared under the guidance of ASC 840, Leases. The adoption of ASC 842 resulted in the recording of an additional lease asset and lease liability of approximately $1.1 million as of January 1, 2019. ASC 842 did not materially impact the Company's condensed consolidated results of operations, equity or cash flows as of the adoption date or for the periods presented.

Leases

The Company determines if an arrangement is a lease at inception. The Company has operating and finance leases for vehicles, corporate offices and certain equipment.

Operating lease right-of-use ("ROU") assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. Lease agreements with lease and non-lease components are accounted for separately. As the Company's leases do not provide an implicit rate, the Company used the incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. The operating lease ROU asset also includes any lease payments

made and excludes lease incentives and initial direct costs incurred. The lease terms

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may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.
Leases with an initial term of 12 months or less are not recorded on the balance sheet as the Company has elected to apply the short term lease exemption. The Company recognizes lease expense for these leases on a straight-line basis over the lease term.
Operating and finance lease assets and liabilities are as follows:

(in thousands)	Classification	March 31, 2019
Assets		
Operating	Other long-term assets	$ 1,062
Finance	Property, plant and equipment, net	107
Total leased assets		$ 1,169
Liabilities		
Current		
Operating	Accrued expenses and other liabilities	$ 180
Finance	Current portion of long-term debt and other borrowings	104
Noncurrent		
Operating	Other long-term liabilities	958
Finance	Long-term debt, net and other borrowings	6
Total leased liabilities		$ 1,248

The components of lease expense were as follows:

(in thousands)	Three Months Ended March 31, 2019
Operating Lease Expense	$ 56
Finance Lease Expense	
Amortization of ROU assets	29
Interest on lease liabilities	2
Short Term Lease Expense	23
Total Lease Expense	$ 110

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Other information related to leases were as follows:

	March 31, 2019
Weighted average remaining lease term (Years):	
Operating leases	5.5
Finance leases	1.0
Weighted average discount rate:	
Operating leases	5.1%
Finance leases	5.9%

(in thousands)	Three Months Ended March 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	57
Operating cash flows from finance leases	2
Financing cash flows from finance leases	30
ROU assets obtained in exchange for lease obligations:	
Operating leases	—
Finance leases	—

Future minimum lease payments under non-cancellable leases as of March 31, 2019 were as follows:

(in thousands)	Operating Leases	Finance Leases
Remainder of 2019	$ 173	$ 93
2020	238	21
2021	238	—
2022	238	—
2023	238	—
Thereafter	178	—
Total future minimum lease payments	1,303	114
Less: interest	165	4
Total	$ 1,138	$ 110

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12. Net Income Per Common Share

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

	Three Months Ended March 31,	
(in thousands, except per share amounts)	2019	2018
Net income	$9,949	$8,211
Basic weighted-average common shares outstanding	38,603	37,886
Effect of dilutive stock options	58	150
Effect of dilutive restricted stock	1,126	1,457
Diluted weighted-average common shares outstanding	39,787	39,493
Basic income per common share	$0.26	$0.22
Diluted income per common share	$0.25	$0.21
Antidilutive securities excluded from diluted net income per common share	222	86

13. Other Income

Other income consisted of the following:

	Three Months Ended March 31,	
(in thousands)	2019	2018
Foreign currency gains	$42	$72
Tax indemnification income	802	841
Interest income	283	7
Other	60	—
Total other income	$1,187	$920

14. Legal Proceedings and Contingencies

From time to time, the Company is a party to various legal proceedings arising in the ordinary course of business. In addition, the Company has in the past been, and may in the future be, subject to investigations by governmental and regulatory authorities, which expose it to greater risks associated with litigation, regulatory or other proceedings, as a result of which the Company could be required to pay significant fines or penalties. The 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.

As of March 31, 2019, 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.

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15. 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 March 31,	
(in thousands)	2019	2018
Revenues from external customers		
U.S.	$75,434	$71,488
International	11,076	11,142
Total revenues from external customers	$86,510	$82,630
Operating income		
U.S.	$14,584	$14,156
International	1,585	981
Total operating income	16,169	15,137
Interest expense	4,592	4,050
Other income	(1,187)	(920)
Income before income taxes	$12,764	$12,007

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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 (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements, including, in particular, statements about our plans, strategies, prospects and industry estimates are subject to risks and uncertainties. These statements identify prospective information and include words such as "anticipates," "intends," "plans," "seeks," "believes," "estimates," "expects," "should," "could," "predicts," "hopes" and similar expressions. Examples of forward-looking statements include, 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. These statements are neither statements of historical fact nor guarantees or assurances of future performance. The matters referred to in the forward-looking statements contained in this Quarterly Report on Form 10-Q may not in fact occur. We caution you, therefore, against relying on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include regional, national or global political, economic, business, competitive, market and regulatory conditions and the following:

- 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 periodic outages at the NTP Radioisotopes ("NTP") processing facility in South Africa in 2017, 2018 and 2019 and the most recent outage commencing in April 2019, 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 DraxImage Radiopharmaceuticals d/b/a Triad Isotopes, Inc. ("Triad");
- Our ability to identify and acquire or in-license additional products, businesses or technologies to drive our future growth;
- Risks associated with the technology transfer programs to secure production of our products at additional contract manufacturer sites, including a modified formulation of DEFINITY at Samsung BioLogics ("SBL") in South Korea;
- Risks associated with our lead agent in development, flurpiridaz F 18, which in 2017 we out-licensed to GE Healthcare, including:
  - The ability 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 on-going internal clinical development of: DEFINITY for a left ventricular ejection fraction ("LVEF") indication;

- Risks associated with our development agent, LMI 1195, for patient populations that would benefit from molecular imaging of the norepinephrine pathway, including: (i) finalizing a Special Protocol Assessment ("SPA") with the FDA in connection with our Phase 3 clinical program in heart failure patients eligible for cardioverter defibrillator implantation, and (ii) designing two Phase 3 clinical trials for the diagnosis and treatment follow-up of neuroendocrine tumors in pediatric and adult populations, respectively, which may qualify for an Orphan Drug designation from the FDA and could allow for a streamlined regulatory process;

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- 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, including our ability to bring the new capabilities online by 2021;
- 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;
- Our being subject to extensive government regulation and oversight, our potential inability to comply with those regulations and the costs of compliance;
- Potential liability associated with our marketing and sales practices;
- The occurrence of any serious or unanticipated side effects with our products;
- Our exposure to potential product liability claims and environmental, health and safety liability;
- 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 ability to introduce new products and adapt to an evolving technology and medical practice landscape;
- Our ability to protect our intellectual property and the risk of claims that we have infringed on the intellectual property of others;
- Risks associated with prevailing economic or political conditions and events and financial, business and other factors beyond our control;
- Risks associated with our international operations;
- Our ability to adequately qualify, operate, maintain and protect our facilities, equipment and technology infrastructure;
- Our ability to hire or retain skilled employees and key personnel;
- Our ability to utilize, or limitations in our ability to utilize, net operating loss carryforwards to reduce our future tax liability;
- Risks related to our outstanding indebtedness and our ability to satisfy those obligations;
- Costs and other risks associated with the Sarbanes-Oxley Act and the Dodd-Frank Act, including in connection with 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, 2018.

Factors that could cause or contribute to such differences include, but are not limited to, those that are discussed in other documents we file with the SEC. Any forward-looking statement made by us in this Quarterly Report on Form 10-Q speaks only as of the date on which it is made. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law.

Available Information

Our global Internet site is www.lantheus.com. We routinely make available important information, including copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after those reports are electronically filed with, or furnished to, the SEC, free of charge on our website at www.investor.lantheus.com. We recognize our website as a key channel of distribution to reach public investors and as a means of disclosing material non-public information to comply with our disclosure obligations under SEC Regulation FD. Information contained on our website shall not be deemed incorporated into, or to be part of this Quarterly Report on Form 10-Q, and any website references are not intended to be made through active hyperlinks. Our reports filed with, or furnished to, the SEC are also available on the SEC’s website at www.sec.gov, and for Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q, in an 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 in 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, 2018.

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 operate our business in two reportable segments, which are further described below:

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

Our Product Portfolio

Our product portfolio includes an ultrasound contrast agent and nuclear imaging products as well as a nuclear therapeutic product. 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.

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:

	Three Months Ended March 31,					
(in thousands)	2019	% of Revenues		2018	% of Revenues	
DEFINITY	$51,111	59.1	%	$44,655	54.0	%
TechneLite	24,145	27.9	%	21,395	25.9	%
Other nuclear	15,120	17.5	%	19,486	23.6	%
Rebates and allowances	(3,866)	(4.5)	%	(2,906)	(3.5)	%
Total revenues	$86,510	100.0	%	$82,630	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 anticipate 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 December 31, 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 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 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 DEFINITY patent extends until 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 Hatch-Waxman Act, the FDA can approve Abbreviated New Drug Applications (“ANDAs”) for generic versions of drugs if the ANDA applicant demonstrates, among other things, that (i) its generic candidate is the same as the innovator product by establishing bioequivalence and providing relevant chemistry, manufacturing and product data, and (ii) the marketing of that generic candidate does not infringe an Orange Book-listed patent. With respect to any Orange Book-listed patent covering the innovator product, the ANDA applicant must give a notice to the innovator (a “Notice”) that the ANDA applicant certifies that its generic candidate will not infringe the innovator’s Orange Book-listed patent or that the Orange Book-listed patent is invalid. The innovator can then challenge the ANDA applicant in court within 45 days of receiving that Notice, and FDA approval to commercialize the generic candidate will be stayed (that is, delayed) for up to 30 months while the patent dispute between the innovator and the ANDA applicant is resolved in court. The 30 month stay could potentially expire sooner if the courts determine that no infringement had occurred or that the challenged Orange Book-listed patent is invalid or if the parties otherwise settle their dispute.

As of the date of filing of this Quarterly Report on Form 10-Q, we have not received any Notice from an ANDA applicant. If we were to (i) receive any such Notice in the future, (ii) bring a patent infringement suit against the ANDA applicant within 45 days of receiving that Notice, and (iii) successfully obtain the full 30 month stay, then the ANDA applicant would be precluded from commercializing a generic version of DEFINITY prior to the expiration of that 30 month stay period and, potentially, thereafter, depending on how the patent dispute is resolved. Solely by way of example and not based on any knowledge we currently have, if we received a Notice from an ANDA applicant in April 2019 and the full 30 month stay was obtained, then the ANDA applicant would be precluded from commercialization until at least October 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 are currently conducting two well-controlled Phase 3 studies designed to demonstrate improved accuracy of LVEF measurements with DEFINITY-enhanced echocardiography versus unenhanced echocardiography. The truth standard in these studies is cardiac magnetic resonance imaging. The studies will be conducted at 20 U.S. sites and will eventually enroll a total of approximately 300 subjects. We believe DEFINITY could improve the accuracy of LVEF calculations, giving clinicians greater confidence in patient management decisions. An LVEF indication could substantially

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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 storage as well as shipment at room temperature (DEFINITY's current formulation requires refrigerated storage), will give clinicians additional choice, and will allow for greater utility of this formulation in broader clinical settings. We 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, although that timing cannot be assured. Given its physical characteristics, the modified formulation may also be better suited for inclusion in kits requiring microbubbles for other indications and applications.
- New Clinical Applications - As we continue to look for other opportunities to expand our microbubble franchise, we are evaluating new indications and clinical applications beyond echocardiography and contrast imaging generally. For example, we recently announced a strategic development and commercial collaboration with Cerevast Medical, Inc. in which our microbubble will be used in connection with Cerevast's ocular ultrasound device to target improving blood flow in occluded retinal veins in the eye. Retinal vein occlusion is one of the most common causes of vision loss worldwide.
- In-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 the investment in these efforts will allow us to better control DEFINITY manufacturing and inventory, reduce our costs in a potentially more price competitive environment, and provide us with supply chain redundancy. We currently expect to be in a position to use this in-house manufacturing capability 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," "—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 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 the Expansion of Our Ultrasound Microbubble Franchise," of our Annual Report on Form 10-K for the year ended December 31, 2018.

Global Moly Supply

We currently have Moly supply agreements with Institute for Radioelements ("IRE"), running through December 31, 2019, and renewable by us on a year-to-year basis thereafter, and with ANSTO and NTP, running through December 31, 2020. We also have a Xenon supply agreement with IRE which runs through June 30, 2019, also subject to extensions.

Although we believe we are generally well-positioned with IRE, ANSTO and NTP to have a diverse, global Moly supply, including LEU-based Moly, we still face challenges in our Moly supply chain. The NTP processing facility has had periodic outages in 2017, 2018 and 2019, and the most recent outage commenced in April 2019. When NTP has not been producing, we have relied on Moly supply from both IRE and ANSTO to limit the impact of the NTP outages. However, depending on reactor and processor schedules and operations, we have not been able to fill all of the demand for our TechneLite generators on certain manufacturing days.

ANSTO's new Moly processing facility, which will eventually increase ANSTO's production capacity from approximately 2,000 curies per week to 3,500 curies per week, recently received regulatory approval from the Australian nuclear regulatory authority to begin initial production from that new facility. We are currently receiving Moly from ANSTO's older Moly processing facility and will continue to do so in the near future. We recently received notice that the FDA completed its audit of ANSTO's new facility and approved our use of Moly supplied from this

new facility. At full ramp-up capacity, ANSTO's new facility will be able to provide incremental supply to our globally diversified Moly supply chain. We believe the new volumes from ANSTO combined with IRE's Moly production capacity should substantially mitigate any continuing challenges with NTP's Moly production, although we can give no assurances to that effect. In addition, we also have a strategic arrangement with SHINE Medical Technologies, Inc. ("SHINE"), a Wisconsin-based company, for the future supply of 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.

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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 1, Item 1A. “Risk Factors—The instability of the global supply of Moly, including supply shortages, has resulted in increases in the cost of Moly, which has negatively affected our margins, and more restrictive agreements with suppliers, which could further increase our costs” of our Annual Report on Form 10-K for the year ended December 31, 2018.

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 a modified formulation of DEFINITY with SBL, which is located in South Korea. We currently believe that if approved by the FDA, the modified formulation could be commercially available in 2020, although that timing cannot be assured. 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, 2018.

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 are currently conducting two well-controlled Phase 3 studies designed to demonstrate improved accuracy of LVEF measurements with DEFINITY-enhanced echocardiography versus unenhanced echocardiography. For LMI 1195, our PET-based molecular imaging agent for the norepinephrine pathway, we are currently working with the FDA to finalize an SPA in connection with our Phase 3 clinical program to demonstrate improved risk stratification of ischemic heart failure patients eligible for cardioverter defibrillator implantation. We are also currently designing two Phase 3 clinical trials for the use of LMI 1195 for the diagnosis and treatment follow-up of neuroendocrine tumors in pediatric and adult populations, respectively, which may qualify for an Orphan Drug designation from the FDA, and could allow for a streamlined regulatory process. Our investments in these additional clinical activities will increase our operating expenses and impact our results of operations and cash flow.

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Results of Operations

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

	Three Months Ended March 31,	
(in thousands)	2019	2018
Revenues	$86,510	$82,630
Cost of goods sold	42,426	40,321
Gross profit	44,084	42,309
Operating expenses		
Sales and marketing	10,397	10,640
General and administrative	12,589	12,543
Research and development	4,929	3,989
Total operating expenses	27,915	27,172
Operating income	16,169	15,137
Interest expense	4,592	4,050
Other income	(1,187)	(920)
Income before income taxes	12,764	12,007
Income tax expense	2,815	3,796
Net income	$9,949	$8,211

Comparison of the Periods Ended March 31, 2019 and 2018

Revenues

Segment revenues are summarized by product as follows:

	Three Months Ended March 31,			
(in thousands)	2019	2018	Change $	Change %
U.S.				
DEFINITY	$49,716	$43,506	$6,210	14.3 %
TechneLite	20,058	18,063	1,995	11.0 %
Other nuclear	9,524	12,817	(3,293)	(25.7)%
Rebates and allowances	(3,864)	(2,898)	(966)	33.3 %
Total U.S. revenues	75,434	71,488	3,946	5.5 %
International				
DEFINITY	1,395	1,149	246	21.4 %
TechneLite	4,087	3,332	755	22.7 %
Other nuclear	5,596	6,669	(1,073)	(16.1)%
Rebates and allowances	(2)	(8)	6	(75.0)%
Total International revenues	11,076	11,142	(66)	(0.6)%
Total revenues	$86,510	$82,630	$3,880	4.7 %

The increase in the U.S. segment revenues for the three months ended March 31, 2019, as compared to the prior year period is primarily due to a $6.2 million increase in DEFINITY revenue as a result of higher unit volumes and a $2.0 million increase in TechneLite revenue driven by annual pricing adjustments and an increase in volumes as a result of a temporary supplier disruption in the prior year period. These increases were offset in part by decreases primarily associated with lower Xenon volume and an increase in rebate and allowance provisions.

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The International segment revenues were flat for the three months ended March 31, 2019, as compared to the prior year period. The increase of $0.8 million in TechneLite revenue was primarily driven by volume as a result of temporary incremental demand and the increase of $0.2 million in DEFINITY revenue was driven by increased volume. These increases were offset by lower volumes of other products and a negative exchange rate impact of approximately $0.2 million.

Rebates and Allowances

Estimates for rebates and allowances represent our estimated obligations under contractual arrangements with third parties. Rebate accruals and allowances are recorded in the same period the related revenue is recognized, resulting in a reduction to revenue and the establishment of a liability which is included in accrued expenses. These rebates and allowances result from performance-based offers that are primarily based on attaining contractually specified sales volumes and growth, Medicaid rebate programs for our products, administrative fees of group purchasing organizations, 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, 2019	$ 4,654
Provision related to current period revenues	3,818
Adjustments relating to prior period revenues	48
Payments or credits made during the period	(3,972)
Balance, March 31, 2019	$ 4,548

Gross Profit

Gross profit is summarized by segment as follows:

	Three Months Ended March 31,			
(in thousands)	2019	2018	Change $	Change %
U.S.	$41,551	$39,873	$1,678	4.2 %
International	2,533	2,436	97	4.0 %
Total gross profit	$44,084	$42,309	$1,775	4.2 %

The increase in the U.S. segment gross profit for the three months ended March 31, 2019, as compared to the prior year period is primarily due to higher DEFINITY and TechneLite unit volumes. This was offset by lower Xenon unit volumes.

Sales and Marketing

Sales and marketing expenses consist primarily of salaries and other related costs for personnel in field sales, marketing and customer service functions. Other costs in sales and marketing expenses include the development and printing of advertising and promotional material, professional services, market research and sales meetings.

Sales and marketing expense is summarized by segment as follows:

	Three Months Ended March 31,			
(in thousands)	2019	2018	Change $	Change %
U.S.	$9,969	$9,987	$(18)	(0.2)%
International	428	653	(225)	(34.5)%
Total sales and marketing	$10,397	$10,640	$(243)	(2.3)%

The decrease in the International segment sales and marketing expenses for the three months ended March 31, 2019, as compared to the prior year period is primarily due to timing of promotional activities and lower employee-related costs.

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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 March 31,			
(in thousands)	2019	2018	Change $	Change %
U.S.	$12,348	$12,387	$ (39)	(0.3)%
International	241	156	85	54.5 %
Total general and administrative	$12,589	$12,543	$ 46	0.4 %

The U.S. segment general and administrative expenses were flat for the three months ended March 31, 2019, as compared to the prior year period. There was an increase associated with employee-related costs and incremental spend associated with business development activities which was offset by lower information technology costs and campus consolidation costs as a result of prior year efficiency projects, as well as lower bad debt expense.

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 March 31,			
(in thousands)	2019	2018	Change $	Change %
U.S.	$4,650	$3,343	$1,307	39.1 %
International	279	646	(367)	(56.8)%
Total research and development	$4,929	$3,989	$940	23.6 %

The increase in the U.S. segment research and development expenses for the three months ended March 31, 2019, as compared to the prior year period is primarily due to clinical research expenses related to DEFINITY studies and higher employee-related costs.

The decrease in the International segment research and development expenses for the three months ended March 31, 2019, as compared to the prior year period is driven by a European Phase 4 study for one of our products in the prior year.

Interest Expense

Interest expense increased by approximately $0.5 million for the three months ended March 31, 2019, as compared to the prior year period due to higher interest rates on our long-term debt.

Income Tax Expense

Income tax expense is summarized as follows:

	Three Months Ended March 31,			
(in thousands)	2019	2018	Change $	Change %
Income tax expense	$2,815	$3,796	$(981)	(25.8)%

The income tax expense for the three months ended March 31, 2019 and 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.

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

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

	Three Months Ended March 31,	
	2019	2018
Effective tax rate	22.1%	31.6%

Our effective tax rate in fiscal 2019 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 decrease in effective income tax rate for the three months ended March 31, 2019 as compared to the prior year period is primarily due to increased tax benefits arising from stock compensation deductions.

Liquidity and Capital Resources

Cash Flows

The following table provides information regarding our cash flows:

	Three Months Ended March 31,	
(in thousands)	2019	2018
Net cash provided by (used in) operating activities	$10,468	$(666)
Net cash used in investing activities	$(10,550)	$(1,135)
Net cash used in financing activities	$(1,231)	$(704)

Net Cash Provided by (Used in) Operating Activities

Net cash provided by operating activities of $10.5 million in the three months ended March 31, 2019 was driven primarily by net income of $9.9 million plus $3.3 million of depreciation, amortization and accretion expense, stock-based compensation expense of $2.7 million and changes in deferred taxes of $1.7 million. These net sources of cash were offset by a net decrease of $8.1 million related to movements in our working capital accounts during the period. The overall decreases in cash from our working capital accounts were primarily driven by the payment of prior year annual bonuses.

Net cash used in operating activities of $0.7 million in the three months ended March 31, 2018 was driven primarily by net decreases of $18.9 million related to movements in our working capital accounts during the period, which were primarily driven by higher accounts receivable related to increases in revenues to certain major customers, timing of inventory purchases during the period and the payment of prior year annual bonuses. Offsetting these net uses of cash were net income of $8.2 million, depreciation, amortization and accretion expense of $3.6 million, changes in deferred taxes of $2.9 million, stock-based compensation expense of$1.8 million, and provision for excess and obsolete inventory of $1.2 million.

Net Cash Used in Investing Activities

Net cash used in investing activities during the three months ended March 31, 2019 reflected $10.6 million in capital expenditures.

Net cash used in investing activities during the three months ended March 31, 2018 reflected $2.1 million in capital expenditures offset by the cash proceeds of $1.0 million received from the sale of land.

Net Cash Used in Financing Activities

Net cash used in financing activities during the three months ended March 31, 2019 reflected payments for minimum statutory tax withholding related to net share settlement of equity awards of $1.1 million, payments on long-term debt and other borrowings of $0.7 million, offset by proceeds of $0.6 million from the exercise of stock options and the

issuance of common stock. Starting in 2019, we require certain senior executives to cover tax liabilities resulting from the vesting of their equity awards pursuant to sell-to-cover transactions under 10b5-1 plans.

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Net cash used in financing activities during the three months ended March 31, 2018 reflected payments on long-term debt and other borrowings of $0.7 million, payments for minimum statutory tax withholding related to net share settlement of equity awards of $0.7 million, offset by proceeds of $0.5 million from the exercise of stock options.

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, as amended in connection with a repricing on November 29, 2017 (as amended, 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. 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.

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.

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 consisting of revolving loans in an aggregate principal amount not to exceed $75 million 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.

Please refer to our Form 10-K for fiscal year ended December 31, 2018 for further details on the 2017 Facility.

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 costs of acquiring or in-licensing, developing, obtaining regulatory approval for, and commercializing, new products, businesses or technologies, together with the costs of pursuing opportunities that are not eventually consummated;
- 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 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;

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- The legal costs relating to maintaining, expanding and enforcing our intellectual property portfolio, pursuing insurance or other claims and defending against product liability, regulatory compliance or other claims; and
- The cost of interest on any additional borrowings which we may incur under our financing arrangements.

Until we successfully become dual sourced for our principal products, we are vulnerable to future supply shortages. Disruption in our financial performance could also occur if we experience significant adverse changes in product or customer mix, broad economic downturns, adverse industry or company conditions or catastrophic external events, including 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, debt financings, assets securitizations, sale-leasebacks or other financing or strategic alternatives, to the extent such transactions are permissible under the covenants of our Credit Agreement. Additional equity or debt financing, or other transactions, may not be available on acceptable terms, if at all. If any of these transactions require an amendment or waiver under the covenants in our Credit Agreement, which could result in additional expenses associated with obtaining the amendment or waiver, we will seek to obtain such a waiver to remain in compliance with those covenants. However, we cannot be assured that such an amendment or waiver would be granted, or that additional capital will be available on acceptable terms, if at all.

At March 31, 2019, our only current committed external source of funds is our borrowing availability under our 2017 Revolving Facility. We had $112.1 million of cash and cash equivalents at March 31, 2019. 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 condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these condensed consolidated financial statements require us to make estimates and judgments that affect our reported assets and liabilities, revenues and expenses, and other financial information. Actual results may differ materially from these estimates under different assumptions and conditions. In addition, our reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

There have been no other significant changes to our critical accounting policies or in the underlying accounting assumptions and estimates used in such policies in the three months ended March 31, 2019. 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, 2018.

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, 2018. Our exposures to market risk have not changed materially since December 31, 2018.

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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 March 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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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 March 31, 2019, 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, 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, 2018.

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. The NTP processing facility has had periodic outages in 2017, 2018 and 2019, and the most recent outage commenced in April 2019. When NTP has not been producing, we have relied on Moly supply from both IRE and ANSTO to limit the impact of the NTP outages. However, depending on reactor and processor schedules and operations, we have not been able 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. ANSTO’s new Moly processing facility, which will eventually increase ANSTO’s production capacity from approximately 2,000 curies per week to 3,500 curies per week, recently received regulatory approval from the Australian nuclear regulatory authority to begin initial production from that new facility. We are currently receiving Moly from ANSTO’s older Moly processing facility and will continue to do so in the near future. We recently received notice that the FDA completed its audit of ANSTO’s new facility and approved our use of Moly supplied from this new facility. At full ramp-up capacity, ANSTO’s new facility will be able to provide incremental supply to our globally diversified Moly supply chain. We believe the new volumes from ANSTO, combined with IRE’s Moly production capacity, should substantially mitigate any continuing challenges with NTP’s Moly production, although we can give no assurances to that effect, and a prolonged disruption of service 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

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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.

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.

The process of developing new drugs and obtaining regulatory approval is complex, time-consuming and costly, and the outcome is not certain.

We currently have three active clinical development programs in the U.S. - DEFINITY for LVEF, flurpiridaz F 18 and LMI 1195. To obtain regulatory approval for these agents in the indications being pursued, we must conduct extensive human tests, which are referred to as clinical trials, as well as meet other rigorous regulatory requirements, as further described in Part I, Item 1. “Business-Regulatory Matters.” Satisfaction of all regulatory requirements typically takes many years and requires the expenditure of substantial resources. A number of other factors may cause significant delays in the completion of our clinical trials, including unexpected delays in the initiation of clinical sites, slower than projected enrollment, competition with ongoing clinical trials and scheduling conflicts with participating clinicians, regulatory requirements, limits on manufacturing capacity and failure of an agent to meet required standards for administration to humans. In addition, it may take longer than we project to achieve study endpoints and complete data analysis for a trial or we may decide to slow down the enrollment in a trial in order to conserve financial resources.

Our agents in development are also subject to the risks of failure inherent in drug development and testing. The results of preliminary studies do not necessarily predict clinical success, and larger and later stage clinical trials may not produce the same results as earlier stage trials. Sometimes, agents that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials. Agents in later stage clinical trials may fail to show desired safety and efficacy traits, despite having progressed through initial clinical testing. In addition, the data collected from clinical trials of our agents in development may not be sufficient to support regulatory approval, or regulators could interpret the data differently and less favorably than we do. Further, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts. Regulatory authorities may require us or our partners to conduct additional clinical testing, in which case we would have to expend additional time and resources. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in regulatory policy that occur prior to or during regulatory review. The failure to provide clinical and preclinical data that are adequate to demonstrate to the satisfaction of the regulatory authorities that our agents in development are safe and effective for their proposed use will delay or preclude approval and will prevent us from marketing those products.

We are not permitted to market our agents in development in the U.S. or other countries until we have received requisite regulatory approvals. For example, securing FDA approval for a new drug requires the submission of an NDA to the FDA for our agents in development. The NDA must include extensive nonclinical and clinical data and supporting information to establish the agent’s safety and effectiveness for each indication. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. The FDA review process can take many years to complete, and approval is never guaranteed. If a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling, impose restricted distribution programs, require expedited reporting of certain adverse events, or require costly

ongoing requirements for post-marketing clinical studies and surveillance or other risk management measures to monitor the safety or efficacy of the agent.

Markets outside of the U.S. also have requirements for approval of agents with which we must comply prior to marketing. Obtaining regulatory approval for marketing of an agent in one country does not ensure we will be able to obtain regulatory approval in other countries, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. Also, any regulatory approval of any of our products or agents in development, once obtained, may be withdrawn. Approvals might not be granted on a timely basis, if at all. In March 2012, we entered into a development and distribution arrangement for DEFINITY in China, Hong Kong and Macau with Double-Crane Pharmaceutical

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Company ("Double-Crane"). With Double-Crane's support, we are currently pursuing the Chinese regulatory approval required to commercialize DEFINITY. In July 2013, we submitted a clinical trial application to the Chinese Food and Drug Administration ("CFDA") seeking an Import Drug License. After a very extensive waiting period caused by a large number of drugs seeking CFDA regulatory approval, in February 2016, the CFDA approved our clinical trial application. Double-Crane is conducting on our behalf three confirmatory clinical trials in pursuit of cardiac, liver and kidney imaging indications, as well as one small pharmacokinetic study, and enrollment has been completed for all the studies. In the first quarter of 2019, Double-Crane informed us that they anticipate a delay in the DEFINITY regulatory approval process as they work through certain issues relating to CFDA approval of our packaging components as well as the completion of clinical data assessment from our liver and kidney trials. These further delays in our China program could have an adverse effect on the attractiveness of and economic benefits that we could ultimately gain from commercializing DEFINITY in China.

In our flurpiridaz F 18 Phase 3 program, in May 2015, we announced complete results from the 301 trial. Although flurpiridaz F 18 appeared to be well-tolerated from a safety perspective and outperformed SPECT in a highly statistically significant manner in the co-primary endpoint of sensitivity and in the secondary endpoints of image quality and diagnostic certainty, the agent did not meet its other co-primary endpoint of non-inferiority for identifying subjects without disease. In April 2017, we entered into the License Agreement with GE Healthcare for the continued Phase 3 development and worldwide commercialization of flurpiridaz F 18. Under the License Agreement, GE Healthcare will, among other things, complete the worldwide development of flurpiridaz F 18 by conducting a second Phase 3 trial and pursue worldwide regulatory approvals. We cannot assure any particular outcome from GE Healthcare's continued Phase 3 development of the agent or from regulatory review of either our or their Phase 3 study of the agent, that any of the data generated in either our or their sponsored Phase 3 study will be sufficient to support an NDA approval, that GE Healthcare will only have to conduct the one additional Phase 3 clinical study prior to filing an NDA, or that flurpiridaz F 18 will ever be approved as a PET MPI imaging agent by the FDA. Similarly, we can give no assurance that we will be successful in either of our two internal clinical development programs - DEFINITY for an LVEF indication and LMI 1195 for ischemic heart failure patients risk stratification. See Part I, Item 1. "Business-Regulatory Matters-Food and Drug Laws." Any failure or significant delay in completing clinical trials for our product candidates or in receiving regulatory approval for the sale of our product candidates may severely harm our business and delay or prevent us from being able to generate revenue from product sales.

Even if our agents in development proceed successfully through clinical trials and receive regulatory approval, there is no guarantee that an approved product can be manufactured in commercial quantities at a reasonable cost or that such a product will be successfully marketed or distributed. The burden associated with the marketing and distribution of products like ours is substantial. For example, rather than being manufactured at our own facilities, both flurpiridaz F 18 and LMI 1195 would require the creation of a complex, field-based network involving PET cyclotrons located at radiopharmacies where the agent would need to be manufactured and distributed rapidly to end-users, given the agent's 110-minute half-life. In addition, in the case of both flurpiridaz F 18 and LMI 1195, obtaining adequate reimbursement is critical, including not only coverage from Medicare, Medicaid, other government payors as well as private payors but also appropriate payment levels which adequately cover the substantially higher manufacturing and distribution costs associated with a PET agent in comparison to a Technetium-based agent. We can give no assurance even if either flurpiridaz F 18 or LMI 1195 obtains regulatory approval that a network of PET cyclotrons can be established or that adequate reimbursement can be secured to allow the approved agent or agents to become commercially successful.

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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 March 31, 2019. The Company does not currently have a share repurchase program in effect. The 2015 Equity Incentive Plan, adopted by the Company on June 24, 2015, as amended on April 26, 2016 and as further amended on April 27, 2017 and April 24, 2019 (the "2015 Plan"), provides for the withholding of shares to satisfy minimum statutory tax withholding obligations. It does not specify a maximum number of shares that can be withheld for this purpose. The shares of common stock withheld to satisfy minimum tax withholding obligations may be deemed to be "issuer purchases" of shares that are required to be disclosed pursuant to this Item 2.

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
January 2019**	9,274	$ 16.61	*	*
February 2019**	13,737	$ 23.90	*	*
March 2019**	27,464	$ 23.44	*	*
Total	50,475		*	

* 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*+	Third Amendment to Lantheus Holdings, Inc. 2015 Equity Incentive Plan				
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.
+Indicates management contract or compensatory plan or arrangement.

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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:	April 30, 2019

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:	April 30, 2019