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**UNITED STATES**



**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**



**FORM 10-Q**



**(Mark One)**

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

**For the quarterly period ended September 30, 2017**

* **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** |  |  | **(IRS Employer** |
| **incorporation or organization)** |  |  | **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 ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be

submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

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

|  |  |  |  |
| --- | --- | --- | --- |
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☑ (Do not check if a smaller reporting company) | Smaller reporting company | ☐ |
|  |  | Emerging Growth Company | ☑ |

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

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

The registrant had 37,505,996 shares of common stock, $0.01 par value, outstanding as of October 31, 2017.



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**LANTHEUS HOLDINGS, INC.**

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**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Statements (Unaudited)**

**Lantheus Holdings, Inc.**

**Condensed Consolidated Balance Sheets**

**(Unaudited)**

**(in thousands, except par value)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | **September 30,** | |  | **December 31,** |
|  |  | **2017** |  |  | **2016** |
| **Assets** |  |  |  |  |  |
| **Current assets** |  |  |  |  |  |
|  |  |  |  |  |  |
| Cash and cash equivalents | $ | 68,077 |  | $ | 51,178 |
| Accounts receivable, net |  | 41,713 |  |  | 36,818 |
|  |  |  |  |  |  |
| Inventory |  | 23,032 |  |  | 17,640 |
| Other current assets |  | 3,789 |  |  | 5,183 |
|  |  |  |  |  |  |
| Total current assets |  | 136,611 |  |  | 110,819 |
| Property, plant & equipment, net |  | 94,516 |  |  | 94,187 |
|  |  |  |  |  |  |
| Intangibles, net |  | 12,645 |  |  | 15,118 |
| Goodwill |  | 15,714 |  |  | 15,714 |
|  |  |  |  |  |  |
| Other long-term assets |  | 21,535 |  |  | 20,060 |
| Total assets | $ | 281,021 |  | $ | 255,898 |
|  |  |  |  |  |  |
| **Liabilities and Stockholders’ Deficit** |  |  |  |  |  |
| **Current liabilities** |  |  |  |  |  |
|  |  |  |  |  |  |
| Current portion of long-term debt | $ | 2,750 |  | $ | 3,650 |
| Revolving line of credit |  | — | |  | — |
|  |  |  |  |  |  |
| Accounts payable |  | 18,756 |  |  | 18,940 |
| Accrued expenses and other liabilities |  | 24,581 |  |  | 21,249 |
|  |  |  |  |  |  |
| Total current liabilities |  | 46,087 |  |  | 43,839 |
| Asset retirement obligations |  | 10,151 |  |  | 9,370 |
|  |  |  |  |  |  |
| Long-term debt, net |  | 265,523 |  |  | 274,460 |
| Other long-term liabilities |  | 37,176 |  |  | 34,745 |
|  |  |  |  |  |  |
| Total liabilities |  | 358,937 |  |  | 362,414 |
| **Commitments and contingencies (See Note 12)** |  |  |  |  |  |
|  |  |  |  |  |  |
| **Stockholders’ deficit** |  |  |  |  |  |
| 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; 37,498 and 36,756 shares issued and outstanding, |  |  |  |  |  |
| respectively) |  | 375 |  |  | 367 |
| Additional paid-in capital |  | 228,934 |  |  | 226,462 |
|  |  |  |  |  |  |
| Accumulated deficit |  | (306,139) |  |  | (332,398) |
| Accumulated other comprehensive loss |  | (1,086) |  |  | (947) |
|  |  |  |  |  |  |
| Total stockholders’ deficit |  | (77,916) |  |  | (106,516) |
| Total liabilities and stockholders’ deficit | $ | 281,021 |  | $ | 255,898 |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

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** | | | | |  | **Nine Months Ended** | | | |  |
|  |  | **September 30,** | | | | |  | **September 30,** | | | |  |
|  |  | **2017** |  |  | **2016** |  |  | **2017** |  |  | **2016** |  |
| Revenues | $ | 79,941 |  | $ | 73,063 |  | $ | 250,137 |  | $ | 227,503 |  |
| Cost of goods sold |  | 41,414 |  |  | 39,382 |  |  | 125,901 |  |  | 124,370 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Gross profit |  | 38,527 |  |  | 33,681 |  |  | 124,236 |  |  | 103,133 |  |
| Operating expenses |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Sales and marketing |  | 10,075 |  |  | 8,706 |  |  | 31,892 |  |  | 27,856 |  |
| General and administrative |  | 12,076 |  |  | 10,091 |  |  | 35,549 |  |  | 28,842 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Research and development |  | 3,554 |  |  | 2,849 |  |  | 14,149 |  |  | 8,493 |  |
| Total operating expenses |  | 25,705 |  |  | 21,646 |  |  | 81,590 |  |  | 65,191 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Gain on sales of assets |  | — | |  | (560) |  |  | — | |  | (6,505) |  |
| Operating income |  | 12,822 |  |  | 12,595 |  |  | 42,646 |  |  | 44,447 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Interest expense |  | 4,442 |  |  | 6,792 |  |  | 14,147 |  |  | 20,799 |  |
| Debt retirement costs |  | — | |  | 1,415 |  |  | — | |  | 1,415 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Loss on extinguishment of debt |  | — | |  | — | |  | 2,161 |  |  | — |  |
| Other (income) expense |  | (908) |  |  | 148 |  |  | (2,037) |  |  | (317) |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Income before income taxes |  | 9,288 |  |  | 4,240 |  |  | 28,375 |  |  | 22,550 |  |
| Provision for income taxes |  | 762 |  |  | 20 |  |  | 2,116 |  |  | 657 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Net income | $ | 8,526 |  | $ | 4,220 |  | $ | 26,259 |  | $ | 21,893 |  |
| Net income per common share outstanding: |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Basic | $ | 0.23 |  | $ | 0.14 |  | $ | 0.71 |  | $ | 0.71 |  |
| Diluted |  |  |  |  |  |  |  |  |  |  |  |  |
| $ | 0.22 |  | $ | 0.13 |  | $ | 0.67 |  | $ | 0.71 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Weighted-average common shares outstanding: |  |  |  |  |  |  |  |  |  |  |  |  |
| Basic |  | 37,393 |  |  | 31,221 |  |  | 37,174 |  |  | 30,658 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Diluted |  | 39,121 |  |  | 32,402 |  |  | 38,971 |  |  | 31,049 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

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

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Net income

Other comprehensive (loss) income:

**Lantheus Holdings, Inc.**

**Condensed Consolidated Statements of Comprehensive Income**

**(Unaudited)**

**(in thousands)**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Three Months Ended** | | | | |  | **Nine Months Ended** | | | |
|  | **September 30,** | | | | |  | **September 30,** | | | |
|  | **2017** |  |  | **2016** |  |  | **2017** |  |  | **2016** |
| $ | 8,526 |  | $ | 4,220 |  | $ | 26,259 |  | $ | 21,893 |



|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Reclassification adjustment for gains on sales of assets included in net income |  | — | |  | 435 |  |  | — | |  | 435 |
| Foreign currency translation |  | (115) |  |  | 234 |  |  | (139) |  |  | 490 |
|  |  |  |  |  |  |  |  |  |  |  |  |
| Total other comprehensive (loss) income |  | (115) |  |  | 669 |  |  | (139) |  |  | 925 |
| Total comprehensive income | $ | 8,411 |  | $ | 4,889 |  | $ | 26,120 |  | $ | 22,818 |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |

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

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**Lantheus Holdings, Inc.**

**Condensed Consolidated Statements of Cash Flows**

**(Unaudited)**

**(in thousands)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | **Nine Months Ended** | | | |
|  |  | **September 30,** | | | |
|  |  | **2017** |  |  | **2016** |
| **Operating activities** |  |  |  |  |  |
| Net income | $ | 26,259 |  | $ | 21,893 |
|  |  |  |  |  |  |
| Adjustments to reconcile net income to net cash flows from operating activities: |  |  |  |  |  |
| Depreciation, amortization and accretion |  | 15,019 |  |  | 12,664 |
|  |  |  |  |  |  |
| Amortization of debt related costs |  | 1,031 |  |  | 1,235 |
| Provision for excess and obsolete inventory |  | 1,002 |  |  | 982 |
|  |  |  |  |  |  |
| Stock-based compensation |  | 3,764 |  |  | 1,869 |
| Gain on sales of assets |  | — | |  | (6,505) |
|  |  |  |  |  |  |
| Loss on extinguishment of debt and debt retirement costs |  | 2,161 |  |  | 1,415 |
| Other |  | 1,404 |  |  | (254) |
|  |  |  |  |  |  |
| Increases (decreases) in cash from operating assets and liabilities: |  |  |  |  |  |
| Accounts receivable |  | (4,609) |  |  | 1,071 |
|  |  |  |  |  |  |
| Inventory |  | (6,361) |  |  | (1,658) |
| Other current assets |  | 54 |  |  | (1,032) |
|  |  |  |  |  |  |
| Accounts payable |  | (270) |  |  | 2,684 |
| Accrued expenses and other liabilities |  | 2,237 |  |  | 2,497 |
|  |  |  |  |  |  |
| Net cash provided by operating activities |  | 41,691 |  |  | 36,861 |
| **Investing activities** |  |  |  |  |  |
|  |  |  |  |  |  |
| Proceeds from sales of assets |  | 1,234 |  |  | 10,541 |
| Capital expenditures |  | (11,589) |  |  | (4,976) |
|  |  |  |  |  |  |
| Other |  | — | |  | 74 |
| Net cash (used in) provided by investing activities |  | (10,355) |  |  | 5,639 |
|  |  |  |  |  |  |
| **Financing activities** |  |  |  |  |  |
| Payments on long-term debt |  | (285,979) |  |  | (57,790) |
|  |  |  |  |  |  |
| Proceeds from issuance of long-term debt |  | 274,313 |  |  | — |
| Proceeds from issuance of common stock |  | 187 |  |  | 41,600 |
|  |  |  |  |  |  |
| Payments for public offering costs |  | — | |  | (1,266) |
| Proceeds from stock option exercises |  | 1,210 |  |  | 61 |
|  |  |  |  |  |  |
| Payments for minimum statutory tax withholding related to net share settlement of equity awards |  | (2,681) |  |  | (552) |
| Deferred financing costs |  | (1,576) |  |  | (11) |
|  |  |  |  |  |  |
| Other |  | (74) |  |  | — |
| Net cash used in financing activities |  | (14,600) |  |  | (17,958) |
|  |  |  |  |  |  |
| Effect of foreign exchange rates on cash and cash equivalents |  | 163 |  |  | 57 |
| Net increase in cash and cash equivalents |  | 16,899 |  |  | 24,599 |
|  |  |  |  |  |  |
| Cash and cash equivalents, beginning of period |  | 51,178 |  |  | 28,596 |
| Cash and cash equivalents, end of period | $ | 68,077 |  | $ | 53,195 |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

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

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**Lantheus Holdings, Inc.**

**Notes to Condensed Consolidated Financial Statements**

**(Unaudited)**

**Note Regarding Company References and Trademarks**

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

**1. Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements include the accounts of Lantheus Holdings, Inc. and its direct and indirect wholly-owned subsidiaries and have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these condensed consolidated financial statements do not include all of the information and notes required by generally accepted accounting principles in the United States of America (“U.S. GAAP”) for complete financial statements. In the opinion of management, all adjustments (consisting of normal and recurring adjustments) considered necessary for a fair statement have been included. The results of operations for the three and nine months ended September 30, 2017 are not necessarily indicative of the results that may be expected for the year ended December 31, 2017 or any future period.

The condensed consolidated balance sheet at December 31, 2016 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, 2016 filed with the Securities Exchange Commission (“SEC”) on February 23, 2017. Certain immaterial amounts in the prior period have been reclassified to conform to the current period financial statement presentation.

***Manufacturing Concentrations***

The Company currently relies on Jubilant HollisterStier (“JHS”) as its sole source manufacturer of DEFINITY, Neurolite, Cardiolite and evacuation vials for TechneLite. The Company has on-going development and technology transfer activities for a next generation DEFINITY product with Samsung BioLogics (“SBL”) located in Songdo, South Korea, approximately 20 miles southwest of Seoul, but can give no assurances as to when those technology transfer activities will be completed and when the Company will begin to receive supply of a next generation DEFINITY product from SBL. In addition, those activities could be adversely affected by on-going political and military tensions on the Korean peninsula.

**2. Summary of Significant Accounting Policies**

***Collaboration and License Agreement with GE Healthcare Limited***

On April 25, 2017, the Company announced that it entered into a definitive, exclusive Collaboration and License Agreement (the “License Agreement”) with GE Healthcare Limited (“GE Healthcare”) for the continued Phase III development and worldwide commercialization of flurpiridaz F 18, an investigational positron emission tomography myocardial perfusion imaging agent that may improve the diagnosis of coronary artery disease. Under the License Agreement, GE Healthcare will complete the worldwide development of flurpiridaz F 18, pursue worldwide regulatory approvals and, if successful, lead a worldwide launch and commercialization of the agent, with LMI collaborating on both development and commercialization through a joint steering committee. LMI has an option to co-promote the agent in the U.S. GE Healthcare’s development plan will initially focus on obtaining regulatory approval for flurpiridaz F 18 in the U.S., Japan, Europe and Canada.

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Under the terms of the License Agreement, the Company received an up-front payment of $5.0 million. In addition, the Company is eligible to receive, from GE Healthcare, up to $60 million in regulatory and sales-based milestones and tiered double-digit royalties on U.S. sales and mid-single digit royalties on sales outside the U.S. Because the Company concluded there was only one significant deliverable under the License Agreement, consisting of the license of the product which occurred upon the signing of the License Agreement, the Company recognized $5.0 million associated with entering into the license as revenue during the nine months ended September 30, 2017. In addition, because the Company concluded that the regulatory and sales-based milestones are solely dependent on GE Healthcare’s performance and there are no continuing performance obligations from the Company, all development and sales milestones under the License Agreement are considered non-substantive. As of September 30, 2017, the Company has not recognized revenue for those milestones under the License Agreement and will recognize such revenue in the periods in which the milestones are achieved. Similarly, the Company will recognize royalty revenues in the periods of the sale of the related products, provided that the reported sales are reliably measurable, collectability is reasonably assured and the Company has no further performance obligations.

***Recent Accounting Pronouncements***

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

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Standard** |  | **Description** |  | **Effective Date** |  | **Effect on the Condensed Consolidated** |  |  |
|  |  |  | **for Company** |  | **Financial Statements** |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  | **Recently Issued Accounting Standards Not Yet Adopted** | | |  |  |  |  |  |  |
|  | ASU 2017-09, |  | This ASU clarifies when to account for a change to the terms or |  | January 1, 2018 |  | The Company does not expect that the adoption of |  |  |
|  |  |  |  |  |  |
|  | *Compensation—Stock* |  | conditions of a share–based payment award as a modification. Under |  |  |  | this standard will have a material impact on the |  |  |
|  | *Compensation (Topic 718):* |  | the new guidance, modification accounting is required only if the fair |  |  |  | Company’s condensed consolidated financial |  |  |
|  | *Scope of Modification* |  | value, vesting conditions or classification of the award (as equity or |  |  |  | statements. |  |  |
|  | *Accounting* |  | liability) changes as a result of the change in terms or conditions. |  |  |  |  |  |  |
|  |  |  | The new guidance will be applied prospectively to awards modified |  |  |  |  |  |  |
|  |  |  | on or after the adoption date. The guidance is effective for annual |  |  |  |  |  |  |
|  |  |  | periods, and interim periods within those annual periods, beginning |  |  |  |  |  |  |
|  |  |  | after December 15, 2017 for all entities. Early adoption is permitted, |  |  |  |  |  |  |
|  |  |  | including adoption in any interim period for which financial |  |  |  |  |  |  |
|  |  |  | statements have not yet been issued or made available for issuance. |  |  |  |  |  |  |
|  | ASU 2014-09, *Revenue* |  | This ASU and related amendments affect any entity that either enters |  | January 1, 2018 |  | The Company has established an implementation |  |  |
|  |  |  |  |  |  |
|  | *from Contracts with* |  | into contracts with customers to transfer goods or services or enters |  |  |  | team which includes third-party specialists to assist |  |  |
|  | *Customers (Topic 606) and* |  | into contracts for the transfer of nonfinancial assets, unless those |  |  |  | in the evaluation and implementation of the new |  |  |
|  | *related additional* |  | contracts are within the scope of other standards. The guidance in this |  |  |  | standard. The Company has completed its |  |  |
|  | *amendments ASU 2015-14,* |  | ASU supersedes the revenue recognition requirements in Topic 605, |  |  |  | assessment of the impact of the standards on its |  |  |
|  | *ASU 2016-08, ASU 2016-* |  | Revenue Recognition and most industry-specific guidance. The core |  |  |  | contract portfolio by reviewing the Company’s |  |  |
|  | *10, ASU 2016-11, ASU* |  | principle of the guidance is that an entity should recognize revenue |  |  |  | current accounting policies and practices and |  |  |
|  | *2016-12, ASU 2016-20,* |  | upon the transfer of promised goods or services to customers in an |  |  |  | identifying potential differences that would result |  |  |
|  | *ASU 2017-05, ASU 2017-10* |  | amount that reflects the consideration to which the entity expects to be |  |  |  | from applying the requirements of the new |  |  |
|  |  |  | entitled in exchange for those goods or services. The new guidance |  |  |  | standard to its revenue contracts. The Company |  |  |
|  |  |  | also includes a set of disclosure requirements that will provide users |  |  |  | has categorized its customers into multiple |  |  |
|  |  |  | of financial statements with comprehensive information about the |  |  |  | customer types and assessed significant customer |  |  |
|  |  |  | nature, amount, timing, and uncertainty of revenue and cash flows |  |  |  | arrangements within those customer types. The |  |  |
|  |  |  | arising from a reporting organization’s contracts with customers. In |  |  |  | Company is currently in the process of formalizing |  |  |
|  |  |  | August 2015, the Financial Accounting Standards Board issued ASU |  |  |  | its conclusion. At this time, the Company does not |  |  |
|  |  |  | No. 2015-14, “Revenue from Contracts with Customers (Topic 606): |  |  |  | anticipate a significant impact to its revenue upon |  |  |
|  |  |  | Deferral of the Effective Date,” which defers the effective date of |  |  |  | adoption of the new standard. The Company, in |  |  |
|  |  |  | ASU 2014-09 by one year. |  |  |  | part due to the limited anticipated impact, will |  |  |
|  |  |  |  |  |  |  | utilize the modified retrospective approach of |  |  |
|  |  |  | The standard is effective for annual reporting periods beginning after |  |  |  | adopting the ASU. In addition, during 2017 the |  |  |
|  |  |  | December 15, 2017, and interim periods therein, using either of the |  |  |  | Company has begun to identify and implement, if |  |  |
|  |  |  | following transition methods: |  |  |  | necessary, appropriate changes to its business |  |  |
|  |  |  |  |  |  |  | processes, systems and controls to support |  |  |
|  |  |  | • A full retrospective approach reflecting the application of the |  |  |  | recognition and disclosure under the new standard. |  |  |
|  |  |  | standard in each prior reporting period with the option to elect |  |  |  |  |  |  |
|  |  |  | certain practical expedients, or |  |  |  |  |  |  |
|  |  |  | • A modified retrospective approach with the cumulative effect of |  |  |  |  |  |  |
|  |  |  | initially adopting ASU 2014-09 recognized at the date of adoption |  |  |  |  |  |  |
|  |  |  | (which includes additional footnote disclosures). |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

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|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Standard** | **Description** | **Effective Date** | **Effect on the Condensed Consolidated** |  |
| **for Company** | **Financial Statements** |  |
|  |  |  |
|  |  |  |  |  |
| **Accounting Standards Adopted During the Nine Months Ended September 30, 2017** | |  |  |  |
|  |  |  |  |  |
| ASU 2016- | ASU 2016-09 simplifies several aspects of the stock compensation | January 1, 2017 | The adoption of this standard did not have a |  |
| 09, *Compensation - Stock* | guidance in Topic 718 and other related guidance providing the |  | material impact on the Company’s condensed |  |
| *Compensation (Topic 718):* | following amendments: |  | consolidated financial statements. |  |
| *Improvements to Employee* |  |  |  |  |
| *Share-Based Payment* | • Accounting for income taxes upon vesting or exercise of share- |  |  |  |
| *Accounting* | based payments and related EPS effects |  |  |  |
|  | • Classification of excess tax benefits on the statement of cash |  |  |  |
|  | flows |  |  |  |
|  | • Accounting for forfeitures |  |  |  |
|  | • Liability classification exception for statutory tax withholding |  |  |  |
|  | requirements |  |  |  |
|  | • Cash flow presentation of employee taxes paid when an |  |  |  |
|  | employer withholds shares for tax-withholding purposes |  |  |  |
|  | • Elimination of the indefinite deferral in Topic 718 |  |  |  |
|  | For public business entities, the amendments are effective for annual |  |  |  |
|  | periods beginning after December 15, 2016, and interim periods |  |  |  |
|  | within those annual periods. |  |  |  |

**3. 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.

At September 30, 2017 and December 31, 2016, the Company’s financial assets measured at fair value on a recurring basis consist of money market funds. The Company invests excess cash from its operating cash accounts in overnight investments and reflects these amounts in cash and cash equivalents in the condensed consolidated balance sheets at fair value using quoted prices in active markets for identical assets.

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **Total Fair** | |  | **Level 1** | |  | **Level 2** | |  | **Level 3** |  |
|  |  |  | **Value** | |  |  |  |  |
| **September 30, 2017** |  |  |  |  |  | **(in thousands)** | | | | |  |  |  |
| Money market funds |  | $ | 6,565 |  | $ | 6,565 |  | $ | — | | $ | — |  |
|  |  | $ | 6,565 |  | $ | 6,565 |  | $ | — |  | $ | — |  |
| **December 31, 2016** |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Money market funds |  | $ | 3,565 |  | $ | 3,565 |  | $ | — | | $ | — |  |
|  |  | $ | 3,565 |  | $ | 3,565 |  | $ | — |  | $ | — |  |
|  | 7 |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

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**4. Income Taxes**

The Company provides for income taxes at the end of each interim period based on the estimated effective tax rate for the full year in addition to discrete events which impact the interim period. The Company’s effective tax rate differs from the U.S. statutory rate principally due to the change in valuation allowance and the rate impact of uncertain tax positions. 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 tax provision was $0.8 million and $20,000 for the three months ended September 30, 2017 and 2016, respectively, and $2.1 million and $0.7 million for the nine months ended September 30, 2017 and 2016, respectively.

The Company regularly assesses its ability to realize its deferred tax assets. Assessing the realizability of deferred tax assets requires significant management judgment. In determining whether its deferred tax assets are more-likely-than-not realizable, the Company evaluated all available positive and negative evidence, and weighed the objective evidence and expected impact. Evidence the Company considered included its history of net operating losses, which resulted in the Company recording a full valuation allowance against its domestic net deferred tax assets beginning in 2011, and in each year thereafter. The Company was profitable on a cumulative basis for the three-year period ended September 30, 2017, but substantially all of that profitability was achieved during 2016 and the nine months ended September 30, 2017.

The Company continues to evaluate other negative evidence including customer concentration and contractual risk, DEFINITY supplier risk, the risk of Moly supply availability and cost, and certain product development risks, all of which provide for uncertainties around the Company’s future level of profitability. Based on its review of all available evidence, the Company determined that it has not yet attained a sustained level of profitability sufficient to outweigh the objectively verifiable negative evidence, and has recorded a full valuation allowance against its domestic net deferred tax assets at September 30, 2017. The Company will continue to assess the level of the valuation allowance required. If a sufficient weight of positive evidence exists in future periods to support a release of some or all of the valuation allowance recorded against domestic deferred tax assets, such a release would likely have a material impact on the Company’s results of operations in that future period.

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

**5. Inventory**

Inventory consisted of the following:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **(in thousands)** | | |  | **September 30,** | |  | **December 31,** |  |
|  | **2017** |  |  | **2016** |  |
|  |  |  |  |  |  |  |  |  |
| Raw materials | | | $ | 10,699 |  | $ | 9,658 |  |
| Work in process | | |  | 5,571 |  |  | 3,965 |  |
|  |  |  |  |  |  |  |  |  |
| Finished goods | | |  | 6,762 |  |  | 4,017 |  |
|  | Total inventory | | $ | 23,032 |  | $ | 17,640 |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

As of September 30, 2017 and December 31, 2016, the Company had $1.2 million of inventory classified within other long-term assets, which represent raw materials not expected to be used by the Company during the next twelve months.

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

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

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **(in thousands)** | |  | **September 30,** | |  | **December 31,** |  |
|  |  | **2017** |  |  | **2016** |  |
|  |  |  |  |  |  |  |  |  |
|  | Land | | $ | 14,950 |  | $ | 14,950 |  |
|  | Buildings | |  | 74,864 |  |  | 70,628 |  |
|  |  |  |  |  |  |  |  |  |
|  | Machinery, equipment and fixtures | |  | 69,549 |  |  | 65,407 |  |
|  | Computer software | |  | 18,463 |  |  | 18,482 |  |
|  |  |  |  |  |  |  |  |  |
|  | Construction in progress | |  | 10,068 |  |  | 7,224 |  |
|  |  |  |  | 187,894 |  |  | 176,691 |  |
|  |  |  |  |  |  |  |  |  |
|  | Less: accumulated depreciation and amortization | |  | (93,378) |  |  | (82,504) |  |
|  | Total property, plant & equipment, net | | $ | 94,516 |  | $ | 94,187 |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

Depreciation and amortization expense related to property, plant & equipment, net, was $2.7 million for the three months ended September 30, 2017 and 2016 and $11.7 million and $8.1 million for the nine months ended September 30, 2017 and 2016, respectively.

**7. Asset Retirement Obligations**

The Company considers its legal obligation to remediate its facilities upon a decommissioning of its radioactive-related operations as an asset retirement obligation. The Company has production facilities which manufacture and process radioactive materials at its North Billerica, Massachusetts and San Juan, Puerto Rico sites.

The Company is required to provide the U.S. Nuclear Regulatory Commission and Massachusetts Department of Public Health financial assurance demonstrating the Company’s ability to fund the decommissioning of its North Billerica, Massachusetts production facility upon closure, although the Company does not intend to close the facility. The Company has provided this financial assurance in the form of a $28.2 million surety bond.

The fair value of a liability for asset retirement obligations is recognized in the period in which the liability is incurred. As of September 30, 2017, 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, 2017 | | | $ | 9,370 |
|  | Accretion expense | |  | 781 |
|  |  |  |  |  |
| Balance at September 30, 2017 | | | $ | 10,151 |
|  |  |  |  |  |

**8. Financing Arrangements**

On March 30, 2017, the Company refinanced its previous $365 million seven-year term loan agreement (the facility thereunder, the “2015 Term Facility”) with a new five-year $275 million term loan facility (the “2017 Term Facility” and the loans thereunder, the “Term Loans”). In addition, the Company replaced its previous $50.0 million five-year asset based loan facility (the “ABL Facility”) with a new $75.0 million five-year revolving credit facility (the “2017 Revolving Facility” and, together with the 2017 Term Facility, the “2017 Facility”). The terms of the 2017 Facility are set forth in that certain Amended and Restated Credit Agreement, dated as of March 30, 2017 (the “Credit Agreement”), by and among Holdings, the Company, the lenders from time to time party thereto and JPMorgan Chase Bank, N.A., as administrative agent and collateral agent. The 2017 Term Facility was issued net of a $0.7 million discount. The Company has the right to request an increase to the 2017 Term Facility or request the establishment of one or more new incremental term loan facilities, in an aggregate principal amount of up to $75.0 million, plus additional amounts, in certain circumstances.

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

***2017 Term Facility***

The Term Loans under the 2017 Term Facility bear interest, with pricing based from time to time at the Company’s election at (i) LIBOR plus a spread of 4.50% or (ii) the Base Rate (as defined in the Credit Agreement) plus a spread of 3.50%. Interest is payable (i) with respect to LIBOR Term Loans, at the end of each Interest Period (as defined in the Credit Agreement) and (ii) with respect to Base Rate Term Loans, at the end of each quarter. At September 30, 2017, the Company’s interest rate under the 2017 Term Facility was 5.7%.

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

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **(in thousands)** | |  | **Amount** |
|  |  |  |  |  |
|  | Remainder of 2017 | | $ | 688 |
| 2018 | |  |  | 2,750 |
|  |  |  |  |  |
| 2019 | |  |  | 2,750 |
| 2020 | |  |  | 2,750 |
|  |  |  |  |  |
| 2021 | |  |  | 2,750 |
| 2022 | |  |  | 261,937 |
|  |  |  |  |  |
|  | Total principal outstanding | |  | 273,625 |
|  | Unamortized debt discount | |  | (2,273) |
|  |  |  |  |  |
|  | Unamortized debt issuance costs | |  | (3,079) |
|  | Total | |  | 268,273 |
|  |  |  |  |  |
|  | Less: current portion | |  | (2,750) |
|  | Total long-term debt | | $ | 265,523 |
|  |  |  |  |  |
|  |  |  |  |  |

***2017 Revolving Facility***

Under the terms of the 2017 Revolving Facility, the lenders thereunder agreed to extend credit to the Company from time to time until March 30, 2022 (the “Revolving Termination Date”) consisting of revolving loans (the “Revolving Loans” and, together with the Term Loans, the “Loans”) in an aggregate principal amount not to exceed $75.0 million (the “Revolving Commitment”) at any time outstanding. The 2017 Revolving Facility includes a $20.0 million sub-facility for the issuance of letters of credit (the “Letters of Credit”). The Letters of Credit and the borrowings under the 2017 Revolving Facility are expected to be used for working capital and other general corporate purposes.

The Revolving Loans under the 2017 Revolving Facility bear interest, with pricing based from time to time at the Company’s election at (i) LIBOR plus a spread of 3.50% or (ii) the Base Rate (as defined in the Credit Agreement) plus a spread of 2.50%. The 2017 Revolving Facility also includes an unused line fee, which is set at 0.375% while the Company’s secured leverage ratio (as defined in the Credit Agreement) is greater than 3.00 to 1.00 and 0.25% when the Company’s secured leverage ratio is less than or equal to 3.00 to 1.00.

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

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***2017 Facility Covenants***

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

**2017 Facility Financial Covenant**

|  |  |  |
| --- | --- | --- |
| **Period** | **Consolidated** |  |
| **Leverage Ratio** |  |
| Q3 2017 through Q1 2018 | 5.00 to 1.00 |  |
| Q2 2018 through Q1 2019 | 4.75 to 1.00 |  |
|  |  |  |
| Thereafter | 4.50 to 1.00 |  |
|  |  |  |

The 2017 Facility contains usual and customary restrictions on the ability of the Company and its subsidiaries to: (i) incur additional indebtedness

1. create liens; (iii) consolidate, merge, sell or otherwise dispose of all or substantially all of its assets; (iv) sell certain assets; (v) pay dividends on, repurchase or make distributions in respect of capital stock or make other restricted payments; (vi) make certain investments; (vii) repay subordinated indebtedness prior to stated maturity; and (viii) enter into certain transactions with its affiliates.

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

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

**9. 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** | | | | |  | **Nine Months Ended** | | | |
|  |  |  |  | **September 30,** | | | | |  | **September 30,** | | | |
| **(in thousands)** | | |  | **2017** |  |  | **2016** |  |  | **2017** |  |  | **2016** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cost of goods sold | | | $ | 198 |  | $ | 120 |  | $ | 514 |  | $ | 259 |
| Sales and marketing | | |  | 183 |  |  | 123 |  |  | 474 |  |  | 251 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| General and administrative | | |  | 1,089 |  |  | 487 |  |  | 2,315 |  |  | 1,065 |
| Research and development | | |  | 187 |  |  | 147 |  |  | 461 |  |  | 294 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Total stock-based compensation expense | | $ | 1,657 |  | $ | 877 |  | $ | 3,764 |  | $ | 1,869 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |

***Increase in Shares Reserved Under the 2015 Equity Incentive Plan***

At the Company’s annual meeting of stockholders, held on April 27, 2017 (the “Annual Meeting”), the Company’s stockholders approved an amendment to the 2015 Equity Incentive Plan to increase the number of shares of common stock reserved for issuance thereunder by 1,200,000 shares, to an aggregate of 5,755,277 shares.

***Employee Stock Purchase Plan***

At the Annual Meeting, the Company’s stockholders also approved the 2017 Employee Stock Purchase Plan (“2017 ESPP”), which authorized the issuance of up to 250,000 shares of common stock thereunder. Under the terms of the 2017 ESPP, eligible U.S. employees can elect to acquire shares of the Company’s common stock through periodic payroll deductions during a series of six month offering periods, which will generally begin in March and September of each year. Purchases under the 2017 ESPP are effected on the last business day of each offering period at a 15% discount to the closing price on that day. The 2017 ESPP was implemented, subject to stockholder approval, on March 10, 2017, and the first purchases thereunder were made on September 13, 2017.

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**10. Net Income Per Common Share**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  | **Three Months Ended** | | | |  |  | **Nine Months Ended** | | | | |  |
|  |  |  |  |  |  |  |  | **September 30,** | | | |  |  | **September 30,** | | | | |  |
|  | **(in thousands, except per share amounts)** | | |  |  |  |  | **2017** |  | **2016** |  |  |  | **2017** |  |  |  | **2016** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Net income | | |  |  |  | $ | 8,526 | $ | 4,220 |  | $ | | 26,259 | |  | $ | 21,893 |  |
|  | Basic weighted-average common shares outstanding | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  | 37,393 |  | 31,221 |  |  |  | 37,174 | |  |  | 30,658 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Effect of dilutive stock options | | |  |  |  |  | 318 |  | 1,084 |  |  |  | 371 | |  |  | 391 |  |
|  | Effect of dilutive restricted stock awards | | |  |  |  |  | 1,410 |  | 97 |  |  |  | 1,426 | |  |  | — |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Diluted weighted-average common shares outstanding | | |  |  |  |  | 39,121 |  | 32,402 |  |  |  | 38,971 | |  |  | 31,049 |  |
|  | Basic income per common share outstanding | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | $ | 0.23 | $ | 0.14 |  | $ | | 0.71 | |  | $ | 0.71 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Diluted income per common share outstanding | | |  |  |  | $ | 0.22 | $ | 0.13 |  | $ | | 0.67 | |  | $ | 0.71 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Antidilutive securities excluded from diluted income per common share | | |  |  |  |  | 322 |  | 448 |  |  |  | 378 | |  |  | 1,873 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **11. Other (Income) Expense** | | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Other (income) expense consisted of the following: | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  | **Three Months Ended** | | | |  | **Nine Months Ended** | | | | | | |  |  |  |
|  |  |  |  |  | **September 30,** | | | |  | **September 30,** | | | | | | |  |  |  |
|  |  | **(in thousands)** | |  | **2017** |  |  | **2016** |  | **2017** |  |  |  | **2016** |  |  |  |  |  |
|  |  | Foreign currency (gains) losses | | $ | (414) |  | $ | 349 | $ | (554) |  | $ | | 330 |  |  |  |  |  |
|  |  | Tax indemnification income | |  | (489) |  |  | (196) |  | (1,469) |  |  |  | (632) |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | Other income | |  | (5) |  |  | (5) |  | (14) |  |  |  | (15) |  |  |  |  |  |
|  |  | Total other (income) expense | | $ | (908) |  | $ | 148 | $ | (2,037) |  | $ | | (317) |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**12. Legal Proceedings and Contingencies**

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

As of September 30, 2017, the Company has no material ongoing litigation in which the Company was a party or any material ongoing regulatory or other proceedings and had no knowledge of any investigations by government or regulatory authorities in which the Company is a target that could have a material adverse effect on its current business.

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**13. Related Party Transactions**

Related party expenses consisted of the following:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | **Three Months Ended** | | | | |  | **Nine Months Ended** | | | |
|  |  |  |  |  | **September 30,** | | | | |  | **September 30,** | | | |
| **(in thousands)** | | | **Transaction Type** |  | **2017** |  |  | **2016** |  |  | **2017** |  |  | **2016** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  | Offering costs paid on behalf of Avista pursuant |  |  |  |  |  |  |  |  |  |  |  |
| Avista Capital Partners, L.P. and its affiliates\* | | | to registration rights agreement | $ | — | | $ | — | | $ | 326 |  | $ | — |
| INC Research Holdings, Inc. (“INC”)\*\* | | | Pharmacovigilance services |  | — | |  | 293 |  |  | — | |  | 647 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| VWR Scientific\* | | | Inventory supplies |  | — | |  | 60 |  |  | 297 |  |  | 245 |
|  | Total related party expenses | |  | $ | — |  | $ | 353 |  | $ | 623 |  | $ | 892 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

* During the quarter ended September 30, 2017, Avista Capital Partners, L.P., Avista Capital Partners (Offshore), L.P. and ACP-Lantern Co-Invest, LLC (collectively, “Avista”) distributed approximately 6.3 million shares of common stock of the Company in the aggregate, representing the remainder of their holdings in the Company. The transactions were effected as distributions-in-kind of the Company’s common stock to the investors in those investment funds. As such, Avista and VWR Scientific (an entity in which Avista had an interest) are no longer related parties.
* During the year ended December 31, 2016, investment funds affiliated with Avista disposed of shares of INC common stock held by them. As a result, such investment funds were no longer a principal owner of INC. Related party expenses included in this table represent expenses incurred during the period under which investment funds affiliated with Avista held an investment in INC.

Amounts billed and unbilled for related parties included in accounts payable and accrued expenses are immaterial at December 31, 2016.

**14. Segment Information**

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

Selected information for each operating segment is as follows:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | **Three Months Ended** | | | | |  | **Nine Months Ended** | | | |
|  |  |  |  | **September 30,** | | | | |  | **September 30,** | | | |
|  | **(in thousands)** | |  | **2017** |  |  | **2016** |  |  | **2017** |  |  | **2016** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | **Revenues from external customers** | |  |  |  |  |  |  |  |  |  |  |  |
|  | U.S. | | $ | 69,579 |  | $ | 62,621 |  | $ | 218,706 |  | $ | 192,687 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | International | |  | 10,362 |  |  | 10,442 |  |  | 31,431 |  |  | 34,816 |
|  | Total revenues from external customers | | $ | 79,941 |  | $ | 73,063 |  | $ | 250,137 |  | $ | 227,503 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | **Operating income** | |  |  |  |  |  |  |  |  |  |  |  |
|  | U.S. | | $ | 12,243 |  | $ | 11,649 |  | $ | 40,306 |  | $ | 35,941 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | International | |  | 579 |  |  | 946 |  |  | 2,340 |  |  | 8,506 |
|  | Total operating income | |  | 12,822 |  |  | 12,595 |  |  | 42,646 |  |  | 44,447 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Interest expense | |  | 4,442 |  |  | 6,792 |  |  | 14,147 |  |  | 20,799 |
|  | Debt retirement costs | |  | — | |  | 1,415 |  |  | — | |  | 1,415 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Loss on extinguishment of debt | |  | — | |  | — | |  | 2,161 |  |  | — |
|  | Other (income) expense | |  | (908) |  |  | 148 |  |  | (2,037) |  |  | (317) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Income before income taxes | | $ | 9,288 |  | $ | 4,240 |  | $ | 28,375 |  | $ | 22,550 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |

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**15. Subsequent Events**

On October 30, 2017, LMI entered into a binding commercial supply arrangement pursuant to which LMI will supply Cardinal Health with TechneLite generators, Xenon, Neurolite and other products through 2018. The supply arrangement specifies pricing levels and requires Cardinal Health to purchase minimum volumes of certain products from LMI during certain periods. The supply arrangement will expire on December 31, 2018 and may be terminated upon the occurrence of specified events, including a material breach by the other party and certain force majeure events.

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**Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations Cautionary Note Regarding Forward-Looking Statements**

Some of the statements contained in this Quarterly Report on Form 10-Q are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). These forward-looking statements, including, in particular, statements about our plans, strategies, prospects and industry estimates are subject to risks and uncertainties. These statements identify prospective information and include words such as “anticipates,” “intends,” “plans,” “seeks,” “believes,” “estimates,” “expects,” “should,” “could,” “predicts,” “hopes” and similar expressions. Examples of forward-looking statements include, but are not limited to, statements we make regarding:

1. our outlook and expectations including, without limitation, in connection with continued market expansion and penetration for our commercial products, particularly DEFINITY in the face of increased competition and future patent and regulatory exclusivity expirations; (ii) our outlook and expectations in connection with future performance of Xenon in the face of increased competition; (iii) our outlook and expectations related to our ability to maintain and profitably renew our key customer contracts; and (iv) our outlook and expectations related to products manufactured at Jubilant HollisterStier (“JHS”) and global isotope supply. Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward-looking statements relate to the future, such statements are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements. Such statements are neither statements of historical fact nor guarantees or assurances of future performance. The matters referred to in the forward-looking statements contained in this Quarterly Report on Form 10-Q may not in fact occur. We caution you therefore, against relying on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include regional, national or global political, economic, business, competitive, market and regulatory conditions and the following:
   * Our ability to continue to increase segment penetration for DEFINITY in suboptimal echocardiograms in the face of increased segment competition from other echocardiography contrast agents, including Optison from GE Healthcare Limited (“GE Healthcare”) and Lumason from Bracco Diagnostics Inc. (“Bracco”) and future patent and regulatory exclusivity expirations;
   * Risks associated with revenues and unit volumes for Xenon in pulmonary studies and the potential competition in this generic segment from Curium (formerly known as Mallinckrodt Nuclear Imaging; purchased by IBA Molecular in January 2017 and renamed Curium in April 2017);
   * 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 Triad Isotopes (“Triad”);
   * Our dependence upon third parties for the manufacture and supply of a substantial portion of our products, including DEFINITY at JHS;
   * Risks associated with the technology transfer programs to secure production of our products at alternate contract manufacturer sites, including a next generation DEFINITY product at Samsung BioLogics (“SBL”) in South Korea;
   * Risks associated with the manufacturing and distribution of our products and the regulatory requirements related thereto;
   * The instability of the global Molybdenum-99 (“Moly”) supply;
   * The dependence of certain of our customers upon third-party healthcare payors and the uncertainty of third-party coverage and reimbursement rates;
   * Uncertainties regarding the impact of 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 our potential inability to comply with those regulations;
   * Potential liability associated with our marketing and sales practices;
   * The occurrence of any serious or unanticipated side effects with our products;
   * Our exposure to potential product liability claims and environmental liability;
   * Risks associated with our lead agent in development, flurpiridaz F 18, including:
     + The ability of GE Healthcare to successfully complete the Phase III development program;
     + The ability to obtain Food and Drug Administration (“FDA”) approval; and
     + The ability to gain post-approval market acceptance and adequate reimbursement;

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* The extensive costs, time and uncertainty associated with new product development, including further product development relying on external development partners or potentially developed internally;
* Our inability to introduce new products and adapt to an evolving technology and diagnostic landscape;
* Our inability to identify and in-license or acquire additional products to grow our business;
* Our inability to protect our intellectual property and the risk of claims that we have infringed on the intellectual property of others;
* Risks associated with prevailing economic or political conditions and events and financial, business and other factors beyond our control;
* Risks associated with our international operations;
* Our inability to adequately protect our facilities, equipment and technology infrastructure;
* Our inability to hire or retain skilled employees and key personnel;
* Risks related to our outstanding indebtedness and our ability to satisfy those obligations;
* Costs and other risks associated with the Sarbanes-Oxley Act and the Dodd-Frank Act;
* Our inability to utilize or limitations in our ability to utilize net operating loss carryforwards to reduce our future tax liability;
* 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, 2016 and in Part II—Item 1A. “Risk Factors” of this Quarterly Report on Form 10-Q.

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

**Investor Information**

We routinely make available important information, including copies of our annual, periodic and current reports filed or furnished with the SEC under the Exchange Act, free of charge on our website at http://www.investor.lantheus.com. We recognize our website as a key channel of distribution to reach public investors and as a means of disclosing material non-public information to comply with our disclosure obligations under SEC Regulation FD. Information contained on our website shall not be deemed incorporated into, or to be part of, this Quarterly Report on Form 10-Q, and any website references are not intended to be made through active hyperlinks.

*The 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, 2016 and in Part II— Item 1A. “Risk Factors” of this Quarterly Report on Form 10-Q.*

**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.

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

***Our Product Portfolio***

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

* DEFINITY is an ultrasound contrast agent used in ultrasound exams of the heart, also known as echocardiography exams. DEFINITY contains perflutren-containing lipid microspheres and is indicated in the U.S. for use in patients with suboptimal echocardiograms to assist in imaging the left ventricular chamber and left endocardial border of the heart in ultrasound procedures. We launched DEFINITY in 2001, and in the U.S., its composition of matter patent will expire in 2019, its manufacturing patent will expire in 2021, and a new method of use patent will expire in 2037. In numerous foreign jurisdictions, patent protection or regulatory exclusivity will currently expire in 2019. We also have an active next generation development program for this agent including pursuing additional indications, new patent protection, and new formulations, but we can give no assurance that the program will be successful or that additional patents will protect the agent.
* TechneLite is a technetium generator which provides the essential nuclear material used by radiopharmacies to radiolabel Cardiolite, Neurolite and other technetium-based radiopharmaceuticals used in nuclear medicine procedures. TechneLite uses Moly as its active ingredient.
* Xenon is a radiopharmaceutical gas that is inhaled and used to assess pulmonary function and also for imaging cerebral blood flow. Xenon is manufactured by a third-party and is processed and finished by us.

Sales of our contrast agent, DEFINITY, are made in the U.S. and Canada through our direct sales team of approximately 80 employees. 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 capabilities. Outside the U.S., we own one radiopharmacy in Puerto Rico, where we sell our own products as well as products of third parties to end-users.

In January 2016, we sold our Canadian radiopharmacies to Isologic Innovative Radiopharmaceuticals Ltd. (“Isologic”) and entered into a supply agreement under which we supply Isologic with certain of our products on commercial terms, including certain product purchase commitments by Isologic. In August 2016, we sold our Australian radiopharmacy servicing business to Global Medical Solutions (“GMS”), and entered into a supply agreement under which we supply GMS with certain of our products on commercial terms, including certain minimum product purchase commitments by GMS.

We also maintain our own direct sales force in Canada so that we can control the importation, marketing, distribution and sale of our imaging agents in Canada. 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.

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | **Three Months Ended** | | | | |  |  |  |  |  | **Nine Months Ended** | | | | |  |  |
|  |  |  |  | **September 30,** | | | | |  |  |  |  |  | **September 30,** | | | | |  |  |
| **(in thousands)** |  | **2017** |  | **% of** | |  | **2016** |  | **% of** | |  | **2017** |  | **% of** | |  | **2016** |  | **% of** |  |
|  |  | **Revenues** | |  |  | **Revenues** | |  |  | **Revenues** | |  |  | **Revenues** |  |
| DEFINITY | $ | 37,729 |  | 47.2% |  | $ | 32,604 |  | 44.6% |  | $ | 115,569 |  | 46.2% |  | $ | 97,499 |  | 42.9% |  |
| TechneLite |  | 26,356 |  | 33.0% |  |  | 24,533 |  | 33.6% |  |  | 79,900 |  | 31.9% |  |  | 74,621 |  | 32.8% |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Xenon |  | 7,726 |  | 9.6% |  |  | 6,677 |  | 9.1% |  |  | 23,713 |  | 9.5% |  |  | 21,625 |  | 9.5% |  |
| Other |  | 8,130 |  | 10.2% |  |  | 9,249 |  | 12.7% |  |  | 30,955 |  | 12.4% |  |  | 33,758 |  | 14.8% |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Total revenues | $ | 79,941 |  | 100.0% |  | $ | 73,063 |  | 100.0% |  | $ | 250,137 |  | 100.0% |  | $ | 227,503 |  | 100.0% |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  | 17 |  |  |  |  |  |  |  |  |  |  |  |

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**Key Factors Affecting Our Results**

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

***Growth of DEFINITY***

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

The future growth of our DEFINITY sales will be dependent on our ability to continue to increase segment penetration for DEFINITY in suboptimal echocardiograms and, as discussed below in “—Inventory Supply,” on the ability of JHS to continue to manufacture and release DEFINITY on a timely and consistent basis. See “Part II—Item 1A. Risk Factors—The growth of our business is substantially dependent on increased market penetration for the appropriate use of DEFINITY in suboptimal echocardiograms.”

There are three echocardiography contrast agents approved by the FDA for sale in the U.S.—DEFINITY, which we estimated as having approximately

80% of the U.S. market for contrast agents in echocardiography procedures as of December 31, 2016, Optison from GE Healthcare and Lumason from Bracco.

***Competition for Xenon***

Xenon gas for lung ventilation diagnosis is our third largest product by revenues. In order to increase the predictability of our Xenon business, we have entered into Xenon supply agreements with customers at committed volumes and reduced prices. These steps have resulted in more predictable Xenon unit volumes. Historically, several companies, including Mallinckrodt Nuclear Imaging (now known as Curium), sold packaged Xenon as a pulmonary imaging agent in the U.S., but from 2010 through the first quarter of 2016, we were the only supplier of this imaging agent in the U.S. In March 2016, Mallinckrodt Nuclear Imaging received regulatory approval from the FDA to again sell packaged Xenon in the U.S. Depending upon the pricing, extent of availability and market penetration of such offering, we believe we are at risk for volume loss and price erosion for those customers which are not subject to price or volume commitments with us. See Part I, Item 1A. “Risk Factors —We face potential supply and demand challenges for Xenon” of our Annual Report on Form 10-K for the year ended December 31, 2016.

***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 on-going development and technology transfer activities for a next generation DEFINITY product with SBL, which is located in South Korea, but we cannot give any assurances as to if and when those technology transfer activities will be completed and when we will begin to receive supply of a next generation DEFINITY product from SBL. 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, 2016.

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.

***Global Isotope Supply***

We currently have Moly supply agreements with NTP Radioisotopes (“NTP”) of South Africa and ANSTO of Australia, and with Institute for Radioelements (“IRE”) of Belgium, each running through December 31, 2017, and a Xenon supply agreement with IRE which runs through June 30, 2019, subject to extensions.

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We believe we are well-positioned with ANSTO, IRE and NTP to have a secure supply of Moly, including low-enriched uranium-based Moly produced from targets containing less than 20% of Uranium-235 (“LEU Moly”). From November 2016, the NRU reactor transitioned from providing regular supply of medical isotopes to providing only emergency back-up supply of highly-enriched uranium-based Moly through March 2018. ANSTO has already significantly increased its Moly production capacity from its existing facility in August 2016 and has under construction, in cooperation with NTP, a new Moly processing facility that ANSTO believes will expand its production capacity, which is expected to be in commercial operation in the first half of 2018. In addition, IRE received approval from its regulator to expand its production capability by up to 50% of its former capacity. The new ANSTO and IRE production capacity is expected to replace and exceed what was the NRU’s most recent routine production.

We are receiving bulk unprocessed Xenon from IRE, which we are processing and finishing for our customers. We believe we are well-positioned to supply Xenon to our customers. See Part I, Item 1A. “Risk Factors —We face potential supply and demand challenges for Xenon” of our Annual Report on Form 10-K for the year ended December 31, 2016.

***Demand for TechneLite***

We believe that due to industry-wide cost containment initiatives that have resulted in a transition of where imaging procedures are performed, from free-standing imaging centers to the hospital setting, the total MPI market has been essentially flat since 2011. Our 2016 sales of TechneLite generators exceeded our expectations because of opportunistic sales when customers could not obtain sufficient generators from other suppliers. We can give no assurances that such opportunistic sales will be replicated in 2017.

In November 2016, CMS announced the 2017 final Medicare payment rules for hospital outpatient settings. Under the final rules, each technetium dose produced from a generator for a diagnostic procedure in a hospital outpatient setting is reimbursed by Medicare at a higher rate if that technetium dose is produced from a generator containing at least 95% LEU Moly. In January 2013, we began to offer a TechneLite generator which contains at least 95% LEU Moly and which satisfies the requirements for reimbursement under this incentive program. Although demand for LEU generators appears to be growing, we do not know when, or if, this incremental reimbursement for LEU Moly generators will result in a material increase in our generator sales.

***Research and Development Expenses***

To remain a leader in the marketplace, we have historically made substantial investments in new product development. As a result, the positive contributions of those internally funded 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 III development and worldwide commercialization of flurpiridaz F 18. In the future, we may also seek to engage strategic partners for our 18F LMI 1195 and LMI 1174 programs, or we may choose to partially or fully fund one or more development programs ourselves. See Part I, Item 1. “Business—Research and Development— Proposed GE Healthcare Transaction” and Part I, Item 1A. “Risk Factors—We may not be able to further develop or commercialize our agents in development without successful strategic partners” of our Annual Report on Form 10-K for the year ended December 31, 2016.

***Hurricane Maria in Puerto Rico***

In September 2017, Hurricane Maria devastated Puerto Rico, interrupting power and telecommunications services for most of the island and limiting ground and air transportation. We operate a radiopharmacy in San Juan, Puerto Rico; the building that houses our radiopharmacy sustained minimal external physical damage as a result of the hurricane. From and after September 20, 2017, the number of diagnostic imaging procedures performed on the island has severely declined. While we currently believe that the number of diagnostic imaging procedures performed in Puerto Rico will slowly return to prior levels, we can give no assurances of that, and failure of our radiopharmacy to return to such prior levels could have a negative effect on the revenue and cash flow of our business. See Part II, Item 1A. “Risk Factors—In the U.S., we are heavily dependent on a few large customers and group purchasing organization arrangements to generate a majority of our revenues for our medical imaging products. Outside of the U.S., we rely primarily on distributors to generate a substantial portion of our revenue.”

***Segments***

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

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***Executive Overview***

Our results for the three and nine months ended September 30, 2017 as compared to the corresponding periods in 2016 reflect the following:

* increased revenues and segment penetration for DEFINITY in the suboptimal echocardiogram segment as a result of our continued focused sales efforts;
* increased revenues for TechneLite, mainly the result of higher contracted volumes from certain customers;
* increased revenues of $5.0 million from GE Healthcare for the continued Phase III development and worldwide commercialization of flurpiridaz F 18;
* lower international revenues and cost of goods sold as a result of the sales of our Canadian and Australian radiopharmacies in 2016;
* increased depreciation expense as a result of the scheduled decommissioning of certain long-lived assets;
* general and administrative expense of $1.7 million incurred in connection with the refinancing of our debt as well as a related $2.2 million loss on the extinguishment of debt; and
* decreased interest expense due to the refinancing of long-term debt and a lower principal balance on our long-term debt.

**Results of Operations**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | **Three Months Ended** | | | | |  | **Nine Months Ended** | | | |
|  |  |  |  | **September 30,** | | |  |  |  | **September 30,** | | |  |
| **(in thousands)** | | |  | **2017** |  |  | **2016** |  |  | **2017** |  |  | **2016** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Revenues | | | $ | 79,941 |  | $ | 73,063 |  | $ | 250,137 |  | $ | 227,503 |
| Cost of goods sold | | |  | 41,414 |  |  | 39,382 |  |  | 125,901 |  |  | 124,370 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Gross profit | |  | 38,527 |  |  | 33,681 |  |  | 124,236 |  |  | 103,133 |
| Operating expenses | | |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Sales and marketing | |  | 10,075 |  |  | 8,706 |  |  | 31,892 |  |  | 27,856 |
|  | General and administrative | |  | 12,076 |  |  | 10,091 |  |  | 35,549 |  |  | 28,842 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Research and development | |  | 3,554 |  |  | 2,849 |  |  | 14,149 |  |  | 8,493 |
|  | Total operating expenses | |  | 25,705 |  |  | 21,646 |  |  | 81,590 |  |  | 65,191 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Gain on sales of assets | |  | — | |  | (560) |  |  | — | |  | (6,505) |
|  | Operating income | |  | 12,822 |  |  | 12,595 |  |  | 42,646 |  |  | 44,447 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Interest expense | | |  | 4,442 |  |  | 6,792 |  |  | 14,147 |  |  | 20,799 |
| Debt retirement costs | | |  | — | |  | 1,415 |  |  | — | |  | 1,415 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Loss on extinguishment of debt | | |  | — | |  | — | |  | 2,161 |  |  | — |
| Other (income) expense | | |  | (908) |  |  | 148 |  |  | (2,037) |  |  | (317) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Income before income taxes | |  | 9,288 |  |  | 4,240 |  |  | 28,375 |  |  | 22,550 |
| Provision for income taxes | | |  | 762 |  |  | 20 |  |  | 2,116 |  |  | 657 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Net income | | $ | 8,526 |  | $ | 4,220 |  | $ | 26,259 |  | $ | 21,893 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | 20 |  |  |  |  |  |  |  |  |  |

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**Comparison of the Periods Ended September 30, 2017 and 2016**

***Revenues***

Segment revenues are summarized by product as follows:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | **Three Months Ended** | | | | |  |  |  |  |  |  | **Nine Months Ended** | | | | |  |  |
|  |  |  |  |  | **September 30,** | | | | |  |  |  |  |  |  | **September 30,** | | | | |  |  |
| **(in thousands)** |  | **2017** |  |  | **2016** |  |  | **Change** | | **Change** | |  | **2017** |  |  | **2016** |  |  | **Change** | | **Change** |  |
|  |  |  |  |  | **$** |  | **%** |  |  |  |  |  |  | **$** |  | **%** |  |
| U.S. |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| DEFINITY | $ | 36,901 |  | $ | 32,007 |  | $ | 4,894 |  | 15.3 % |  | $ | 113,035 |  | $ | 95,497 |  | $ | 17,538 |  | 18.4 % |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| TechneLite |  | 22,621 |  |  | 20,906 |  |  | 1,715 |  | 8.2 % |  |  | 69,150 |  |  | 64,282 |  |  | 4,868 |  | 7.6 % |  |
| Xenon |  | 7,726 |  |  | 6,675 |  |  | 1,051 |  | 15.7 % |  |  | 23,709 |  |  | 21,620 |  |  | 2,089 |  | 9.7 % |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Other |  | 2,331 |  |  | 3,033 |  |  | (702) |  | (23.1)% |  |  | 12,812 |  |  | 11,288 |  |  | 1,524 |  | 13.5 % |  |
| Total U.S. revenues |  | 69,579 |  |  | 62,621 |  |  | 6,958 |  | 11.1 % |  |  | 218,706 |  |  | 192,687 |  |  | 26,019 |  | 13.5 % |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| International |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| DEFINITY |  | 828 |  |  | 597 |  |  | 231 |  | 38.7 % |  |  | 2,534 |  |  | 2,002 |  |  | 532 |  | 26.6 % |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| TechneLite |  | 3,735 |  |  | 3,627 |  |  | 108 |  | 3.0 % |  |  | 10,750 |  |  | 10,339 |  |  | 411 |  | 4.0 % |  |
| Xenon |  | — | |  | 2 |  |  | (2) |  | (100.0)% |  |  | 4 |  |  | 5 |  |  | (1) |  | (20.0)% |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Other |  | 5,799 |  |  | 6,216 |  |  | (417) |  | (6.7)% |  |  | 18,143 |  |  | 22,470 |  |  | (4,327) |  | (19.3)% |  |
| Total International |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| revenues |  | 10,362 |  |  | 10,442 |  |  | (80) |  | (0.8)% |  |  | 31,431 |  |  | 34,816 |  |  | (3,385) |  | (9.7)% |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Total revenues | $ | 79,941 |  | $ | 73,063 |  | $ | 6,878 |  | 9.4 % |  | $ | 250,137 |  | $ | 227,503 |  | $ | 22,634 |  | 9.9 % |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

The increase in the U.S. segment revenues for the three months ended September 30, 2017, as compared to the prior year period is primarily due to a $4.9 million increase in DEFINITY revenues as a result of higher unit volumes, a $1.7 million increase in TechneLite revenues primarily as a result of increased unit volumes and a $1.1 million increase in Xenon revenues as a result of higher unit volumes. Offsetting these increases was a $0.7 million decrease due to rebate and allowance provisions.

The increase in the U.S. segment revenues for the nine months ended September 30, 2017, as compared to the prior year period is primarily due to a $17.5 million increase in DEFINITY revenues as a result of higher unit volumes, a $4.9 million increase in TechneLite revenues primarily as a result of increased unit volumes and a $2.1 million increase in Xenon as a result of higher unit volumes. In addition, there was an increase of $5.0 million in other revenue associated with the up-front license fee recognized related to the License Agreement with GE Healthcare for the continued Phase III development and worldwide commercialization of flurpiridaz F 18. Offsetting these increases was a $1.9 million decrease due to rebate and allowance provisions, as well as a $1.6 million decrease in Ablavar revenues as the product is no longer sold.

The International segment revenues for the three months ended September 30, 2017, were consistent compared to the prior year period. The decrease in the International segment revenues for the nine months ended September 30, 2017, as compared to the prior year period is primarily the result of the sale of the Australian radiopharmacy business during 2016.

*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.

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **(in thousands)** | | |  | **Rebates and** |  |
|  | **Allowances** |  |
|  |  |  |  |  |  |
| Balance, as of January 1, 2017 | | | $ | 2,297 |  |
|  | Current provisions relating to revenues in current year | |  | 6,864 |  |
|  |  |  |  |  |  |
|  | Adjustments relating to prior years’ estimate | |  | (154) |  |
|  | Payments/credits relating to revenues in current year | |  | (4,658) |  |
|  |  |  |  |  |  |
|  | Payments/credits relating to revenues in prior years | |  | (1,474) |  |
| Balance, as of September 30, 2017 | | | $ | 2,875 |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

***Costs of Goods Sold***

Cost of goods sold consists of manufacturing, distribution, intangible asset amortization, write-offs of excess and obsolete inventory and other costs related to our commercial products.

Cost of goods sold is summarized by segment as follows:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  | **Three Months Ended** | | | | |  |  |  |  |  |  | **Nine Months Ended** | | | | |  |  |
|  |  |  |  |  |  |  | **September 30,** | | | | |  |  |  |  |  |  | **September 30,** | | | | |  |  |
| **(in thousands)** | | |  | **2017** |  |  | **2016** |  |  | **Change** | | **Change** | |  | **2017** |  |  | **2016** |  |  | **Change** | | **Change** |  |
|  |  |  |  |  | **$** |  | **%** |  |  |  |  |  |  | **$** |  | **%** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| U.S. | | | $ | 32,759 |  | $ | 31,133 |  | $ | 1,626 |  | 5.2% |  | $ | 100,225 |  | $ | 96,791 |  | $ | 3,434 |  | 3.5 % |  |
| International | | |  | 8,655 |  |  | 8,249 |  |  | 406 |  | 4.9% |  |  | 25,676 |  |  | 27,579 |  |  | (1,903) |  | (6.9)% |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Total cost of goods sold | | $ | 41,414 |  | $ | 39,382 |  | $ | 2,032 |  | 5.2% |  | $ | 125,901 |  | $ | 124,370 |  | $ | 1,531 |  | 1.2 % |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

The increases in the U.S. segment cost of goods sold for the three and nine months ended September 30, 2017 as compared to the prior year periods are primarily due to costs associated with the increase in sales volume as noted above. We also incurred, increases in technology transfer expense, partially offset by lower amortization expense as a result of a fully amortized intangible asset.

The increase in the International segment cost of goods sold for the three months ended September 30, 2017 as compared to the prior year period is primarily due to higher manufacturing costs for certain products due to higher sales volume, partially offset by lower manufacturing costs as a result of the sale of our Australian radiopharmacy business.

The decrease in the International segment cost of goods sold for the nine months ended September 30, 2017 as compared to the prior year period is primarily due to lower manufacturing costs as a result of the sale of our Australian radiopharmacy business, partially offset by higher manufacturing costs for certain products due to higher sales volume and higher material costs for certain products.

***Gross Profit***

Gross profit is summarized by segment as follows:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | **Three Months Ended** | | | | |  |  |  |  |  |  | **Nine Months Ended** | | | | |  |  |
|  |  |  |  |  | **September 30,** | | | | |  |  |  |  |  |  | **September 30,** | | | | |  |  |
| **(in thousands)** |  | **2017** |  |  | **2016** |  |  | **Change** | | **Change** | |  | **2017** |  |  | **2016** |  |  | **Change** | | **Change** |  |
|  |  |  |  |  | **$** |  | **%** |  |  |  |  |  |  | **$** |  | **%** |  |
| U.S. | $ | 36,820 |  | $ | 31,488 |  | $ | 5,332 |  | 16.9 % |  | $ | 118,481 |  | $ | 95,896 |  | $ | 22,585 |  | 23.6 % |  |
| International |  | 1,707 |  |  | 2,193 |  |  | (486) |  | (22.2)% |  |  | 5,755 |  |  | 7,237 |  |  | (1,482) |  | (20.5)% |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Total gross profit | $ | 38,527 |  | $ | 33,681 |  | $ | 4,846 |  | 14.4 % |  | $ | 124,236 |  | $ | 103,133 |  | $ | 21,103 |  | 20.5 % |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

The increase in the U.S. segment gross profit for the three months ended September 30, 2017 over the prior year period is primarily due to higher DEFINITY unit volumes and higher Xenon unit volumes.

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The increase in the U.S. segment gross profit for the nine months ended September 30, 2017 over the prior year period is primarily due to higher DEFINITY unit volumes, higher Xenon unit volumes and the recognition of $5.0 million in other revenue associated with the License Agreement with GE Healthcare for the continued Phase III development and worldwide commercialization of flurpiridaz F 18 without any associated cost of goods sold.

The decreases in the International segment gross profit for the three and nine months ended September 30, 2017 over the prior year periods are primarily due to higher manufacturing and material costs for certain products.

***Sales and Marketing***

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

Sales and marketing expense is summarized by segment as follows:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  | **Three Months Ended** | | | | |  |  |  |  |  |  | **Nine Months Ended** | | | | |  |  |
|  |  |  |  |  |  |  | **September 30,** | | | | |  |  |  |  |  |  | **September 30,** | | | | |  |  |
| **(in thousands)** | | |  | **2017** |  |  | **2016** |  |  | **Change** | | **Change** | |  | **2017** |  |  | **2016** |  |  | **Change** | | **Change** |  |
|  |  |  |  |  | **$** |  | **%** |  |  |  |  |  |  | **$** |  | **%** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| U.S. | | | $ | 9,480 |  | $ | 8,021 |  | $ | 1,459 |  | 18.2 % |  | $ | 29,854 |  | $ | 24,902 |  | $ | 4,952 |  | 19.9 % |  |
| International | | |  | 595 |  |  | 685 |  |  | (90) |  | (13.1)% |  |  | 2,038 |  |  | 2,954 |  |  | (916) |  | (31.0)% |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Total sales and marketing | | $ | 10,075 |  | $ | 8,706 |  | $ | 1,369 |  | 15.7 % |  | $ | 31,892 |  | $ | 27,856 |  | $ | 4,036 |  | 14.5 % |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

The increases in the U.S. segment sales and marketing expenses for the three and nine months ended September 30, 2017 over the prior year periods are primarily due to employee-related expenses, market research and promotional program expenses.

The decreases in the International segment sales and marketing expenses for the three and nine months ended September 30, 2017 over the prior year periods are primarily due to lower headcount.

***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** | | | | |  |  |  |  |  |  | **Nine Months Ended** | | | | |  |  |
|  |  |  |  |  |  |  | **September 30,** | | | | |  |  |  |  |  |  | **September 30,** | | | | |  |  |
| **(in thousands)** | | |  | **2017** |  |  | **2016** |  |  | **Change** | | **Change** | |  | **2017** |  |  | **2016** |  |  | **Change** | | **Change** |  |
|  |  |  |  |  | **$** |  | **%** |  |  |  |  |  |  | **$** |  | **%** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| U.S. | | | $ | 11,901 |  | $ | 9,693 |  | $ | 2,208 |  | 22.8 % |  | $ | 35,055 |  | $ | 27,629 |  | $ | 7,426 |  | 26.9 % |  |
| International | | |  | 175 |  |  | 398 |  |  | (223) |  | (56.0)% |  |  | 494 |  |  | 1,213 |  |  | (719) |  | (59.3)% |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Total general and administrative | | $ | 12,076 |  | $ | 10,091 |  | $ | 1,985 |  | 19.7 % |  | $ | 35,549 |  | $ | 28,842 |  | $ | 6,707 |  | 23.3 % |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

The increase in the U.S. segment general and administrative expenses for the three months ended September 30, 2017 over the prior year period are primarily due to higher employee-related expenses and campus consolidation costs.

The increase in U.S. segment general and administrative expenses for the nine months ended September 30, 2017 over the prior year period are primarily due to $1.7 million of debt refinancing costs, higher employee-related expenses and campus consolidation costs.

The decreases in the International segment general and administrative expenses for the three and nine months ended September 30, 2017 over the prior year periods are primarily due to lower employee headcount and related expenses.

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***Research and Development***

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

Research and development expense is summarized by segment as follows:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  | **Three Months Ended** | | | | |  |  |  |  |  |  | **Nine Months Ended** | | | | |  |  |
|  |  |  |  |  |  |  | **September 30,** | | | | |  |  |  |  |  |  | **September 30,** | | | | |  |  |
| **(in thousands)** | | |  | **2017** |  |  | **2016** |  |  | **Change** | | **Change** | |  | **2017** |  |  | **2016** |  |  | **Change** | | **Change** |  |
|  |  |  |  |  | **$** |  | **%** |  |  |  |  |  |  | **$** |  | **%** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| U.S. | | | $ | 3,196 |  | $ | 2,685 |  | $ | 511 |  | 19.0% |  | $ | 13,265 |  | $ | 7,985 |  | $ | 5,280 |  | 66.1% |  |
| International | | |  | 358 |  |  | 164 |  |  | 194 |  | 118.3% |  |  | 884 |  |  | 508 |  |  | 376 |  | 74.0% |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Total research and development | | $ | 3,554 |  | $ | 2,849 |  | $ | 705 |  | 24.7% |  | $ | 14,149 |  | $ | 8,493 |  | $ | 5,656 |  | 66.6% |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

The increase in the U.S. segment research and development expenses for the three months ended September 30, 2017 over the prior year period is primarily due to an increase in higher employee-related expenses.

The increase in the U.S. segment research and development expenses for the nine months ended September 30, 2017 over the prior year period is primarily due to an increase in depreciation expense and other charges as a result of the scheduled decommissioning of certain long-lived assets associated with research and development operations as well as higher employee-related expenses, partially offset by lower pharmacovigilance expenses due to the transition to a new vendor in the prior year.

The increases in International segment research and development expenses for the three and nine months ended September 30, 2017 over the prior year periods were driven by a European Phase IV study for one of our products.

***Gain on Sales of Assets***

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

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

***Interest Expense***

Interest expense decreased by approximately $2.4 million and $6.7 million for the three and nine months ended September 30, 2017, respectively, as compared to the prior year periods, due to the March 2017 refinancing of our long-term debt and reductions in the principal balance of our long-term debt related to the 2017 refinancing and the voluntary principal prepayments we made during September and November 2016.

***Loss on Extinguishment of Debt***

For the nine months ended September 30, 2017, we incurred a $2.2 million loss on extinguishment of debt in connection with the refinancing of our existing indebtedness with the new term loan and revolving credit facilities, see Note 8, “Financing Arrangements” to our condensed consolidated financial statements.

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***Provision for Income Taxes***

Provision for income taxes for the periods presented is as follows:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  | **Three Months Ended** | | | | |  |  |  |  |  |  | **Nine Months Ended** | | | |  |  |
|  |  |  |  |  |  |  | **September 30,** | | | | |  |  |  |  |  |  | **September 30,** | | | |  |  |
| **(in thousands)** | | |  | **2017** |  |  | **2016** |  |  | **Change** | | **Change** | | | **2017** |  |  | **2016** |  | **Change** | | **Change** |  |
|  |  |  |  |  | **$** |  | **%** |  |  |  |  |  | **$** |  | **%** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Provision for income taxes | | | $ | 762 |  | $ | 20 |  | $ | 742 |  | >1,000% $ | | | 2,116 |  | $ | 657 |  | $ 1,459 |  | 222.1% |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

Our provision for income taxes results primarily from interest and penalties associated with uncertain tax positions, offset by reversals of those positions as statutes lapse or such positions are settled during the year, as well as taxes due in certain foreign jurisdictions where we generate taxable income. The $0.7 million and $1.5 million increases in the tax provision for the three and nine months ended September 30, 2017, as compared to the same periods in 2016 primarily reflect a reduced amount of statute lapses and consequent liability releases in the current period, when compared with the prior year period.

We regularly assess our ability to realize our deferred tax assets. Assessing the realizability of deferred tax assets requires significant management judgment. In determining whether our deferred tax assets are more likely than not realizable, we evaluated all available positive and negative evidence, and weighed the objective evidence and expected impact. Evidence considered included our history of net operating losses, which resulted in our recording of a full valuation allowance against our domestic net deferred tax assets beginning in 2011, and in each year thereafter. We were profitable on a cumulative basis for the three-year period ended September 30, 2017, but substantially all of that profitability was achieved during 2016 and the nine months ended September 30, 2017.

We continue to evaluate other negative evidence, including customer concentration and contractual risk, the risk of Moly supply availability and cost, DEFINITY supplier risk, and certain product development risks, all of which provide for uncertainties around our future level of profitability. Based on our review of all available evidence, we determined that we have not yet attained a sustained level of profitability sufficient to outweigh the objectively verifiable negative evidence, and have recorded a full valuation allowance against our domestic net deferred tax assets at September 30, 2017. We will continue to assess the level of the valuation allowance required. If a sufficient weight of positive evidence exists in future periods to support a release of some or all of the valuation allowance recorded against domestic deferred tax assets, such a release would likely have a material impact on our results of operations in that future period.

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

**Nine Months Ended**

**September 30,**



|  |  |  |  |
| --- | --- | --- | --- |
|  | **2017** |  | **2016** |
| Effective tax rate | 7.5% |  | 2.9% |
|  |  |  |  |

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**Liquidity and Capital Resources**

***Cash Flows***

The following table provides information regarding our cash flows:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | **Nine Months Ended** | | | |
|  |  | **September 30,** | | | |
| **(in thousands)** |  | **2017** |  |  | **2016** |
| Net cash provided by operating activities | $ | 41,691 |  | $ | 36,861 |
| Net cash (used in) provided by investing activities | $ | (10,355) |  | $ | 5,639 |
|  |  |  |  |  |  |
| Net cash used in financing activities | $ | (14,600) |  | $ | (17,958) |
|  |  |  |  |  |  |

***Net Cash Provided by Operating Activities***

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

Cash provided by operating activities of $36.9 million in the nine months ended September 30, 2016 was driven primarily by net income of $21.9 million plus $12.7 million of depreciation, amortization and accretion expense, $1.9 million of stock-based compensation expense and $1.4 million of debt retirement costs. These net sources of cash were offset by the gain on sales of assets of $6.5 million. In addition, we had a $3.6 million net increase related to movements in our working capital during the period. The overall increases in cash from our working capital accounts were primarily driven by the timing of payment runs, timing of payroll and accrued bonuses, and improved collections, which were offset by an increase in inventory due to the timing of production and receipt of inventory and an increase in prepaid expenses due to insurance renewals.

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

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

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

***Net Cash Used in Financing Activities***

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

Net cash used in financing activities during the nine months ended September 30, 2016 was primarily used to repay $55.0 million of the principal balance of our $365.0 million Term Facility with net proceeds of $39.9 million, which were raised upon completion of a follow-on underwritten primary offering, and $15.1 million from cash on hand.

**External Sources of Liquidity**

On June 30, 2015, we completed our initial public offering, entered into a $365.0 million seven-year term facility (the “2015 Term Facility”) and amended and restated our revolving facility (the “2015 Revolving Facility”) that had a borrowing capacity of $50.0 million.

In September 2016, we completed a follow-on underwritten offering of 5,200,000 shares of common stock and utilized the net proceeds to us from this offering, combined with cash on hand, to prepay $55.0 million of the principal balance of our 2015 Term Facility. In November 2016, we completed a second follow-on underwritten offering that included 1,000,000 shares of common stock

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offered by us and utilized the net proceeds to us from this offering, combined with cash on hand, to prepay $20.0 million of the principal balance of our 2015 Term Facility. As of December 31, 2016, the principal balance outstanding on our 2015 Term Facility was $284.5 million.

In March 2017, we refinanced the 2015 Term Facility with a new five-year $275.0 million term loan facility (the “2017 Term Facility” and the loans thereunder, the “Term Loans”). In addition, we replaced our 2015 Revolving Facility with a new $75.0 million five-year revolving credit facility (the “2017 Revolving Facility” and, together with the 2017 Term Facility, the “2017 Facility”, the terms of which are set forth in the Credit Agreement). The 2017 Term Facility was issued net of a $0.7 million discount. We have the right to request an increase to the 2017 Term Facility or request the establishment of one or more new incremental term loan facilities, in an aggregate principal amount of up to $75.0 million, plus additional amounts, in certain circumstances.

We used the net proceeds of the 2017 Term Facility, together with approximately $15.3 million of cash on hand, to refinance in full the aggregate remaining principal amount of the loans outstanding under the 2015 Term Facility and pay related interest, transaction fees and expenses. No amounts were outstanding under the 2015 Revolving Facility at that time.

The Term Loans under the 2017 Term Facility bear interest, with pricing based from time to time at our election at (i) LIBOR plus a spread of 4.50% or

1. the Base Rate (as defined in the Credit Agreement) plus a spread of 3.50%. Interest is payable (i) with respect to LIBOR Term Loans, at the end of each Interest Period (as defined in the Credit Agreement) and (ii) with respect to Base Rate Term Loans, at the end of each quarter. At September 30, 2017, our interest rate under the 2017 Term Facility was 5.7%.

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 (the “Revolving Termination Date”) consisting of revolving loans (the “Revolving Loans” and, together with the Term Loans, the “Loans”) in an aggregate principal amount not to exceed $75.0 million (the “Revolving Commitment”) at any time outstanding. The 2017 Revolving Facility includes a $20.0 million sub-facility for the issuance of letters of credit (the “Letters of Credit”). The Letters of Credit and the borrowings under the 2017 Revolving Facility are expected to be used for working capital and other general corporate purposes.

The Revolving Loans under the 2017 Revolving Facility bear interest, with pricing based from time to time at our election at (i) LIBOR plus a spread of 3.50% or (ii) the Base Rate (as defined in the Credit Agreement) plus a spread of 2.50%. The 2017 Revolving Facility also includes an unused line fee, which is set at 0.375% while our secured leverage ratio (as defined in the Credit Agreement) is greater than 3.00 to 1.00 and 0.25% when our secured leverage ratio is less than or equal to 3.00 to 1.00.

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

**2017 Facility Financial Covenant**

|  |  |
| --- | --- |
|  | **Consolidated** |
| **Period** | **Leverage Ratio** |
|  |  |
| Q3 2017 through Q1 2018 | 5.00 to 1.00 |
| Q2 2018 through Q1 2019 | 4.75 to 1.00 |
|  |  |
| Thereafter | 4.50 to 1.00 |
|  |  |

The 2017 Facility contains usual and customary restrictions on our ability and that of our subsidiaries to: (i) incur additional indebtedness (ii) create liens; (iii) consolidate, merge, sell or otherwise dispose of all or substantially all of its assets; (iv) sell certain assets; (v) pay dividends on, repurchase or make distributions in respect of capital stock or make other restricted payments; (vi) make certain investments; (vii) repay subordinated indebtedness prior to stated maturity; and (viii) enter into certain transactions with its affiliates.

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

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

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

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

**Funding Requirements**

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

* Our ability to have product manufactured and released from JHS and other manufacturing sites in a timely manner in the future;
* The pricing environment and the level of product sales of our currently marketed products, particularly DEFINITY and any additional products that we may market in the future;
* Revenue mix shifts and associated volume and selling price changes that could result from contractual status changes with key customers and additional competition;
* The costs of further commercialization of our existing products, particularly in international markets, including product marketing, sales and distribution and whether we obtain local partners to help share such commercialization costs;
* The costs of investing in our facilities, equipment and technology infrastructure;
* The costs and timing of establishing manufacturing and supply arrangements for commercial supplies of our products;
* The extent to which we acquire or invest in (i) new products, businesses and technologies, or (ii) the further clinical development or commercialization of existing development candidates or products;
* The extent to which we choose to establish collaboration, co-promotion, distribution or other similar arrangements for our marketed products;
* The legal costs relating to maintaining, expanding and enforcing our intellectual property portfolio, pursuing insurance or other claims and defending against product liability, regulatory compliance or other claims; and
* The cost of interest on any additional borrowings which we may incur under our financing arrangements.

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

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

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At September 30, 2017, our only current committed external source of funds is our borrowing availability under our 2017 Revolving Facility. We had $68.1 million of cash and cash equivalents at September 30, 2017. 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 total net leverage. Accordingly, we may be limited in utilizing the full amount of our 2017 Revolving Facility as a source of liquidity.

Based on our current operating plans, we believe that our existing cash and cash equivalents, results of operations and availability under our 2017 Revolving Facility will be sufficient to continue to fund our liquidity requirements for the foreseeable future.

**Critical Accounting Policies and Estimates**

The discussion and analysis of our financial position and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these condensed consolidated financial statements in accordance with U.S. GAAP requires us to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition and related allowances, inventory, impairments of long-lived assets including intangible assets, impairments of goodwill, income taxes including the valuation allowance for deferred tax assets. Actual results may differ materially from these estimates under different assumptions and conditions. In addition, our reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

There have been no material changes to our critical accounting policies or in the underlying accounting assumptions and estimates used in such policies in the nine months ended September 30, 2017. 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, 2016.

**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, 2016. Our exposures to market risk have not changed materially since December 31, 2016.

**Item 4. Controls and Procedures**

**Disclosure Controls and Procedures**

The Company’s management, with the participation of the Company’s Chief Executive Officer and Chief Financial Officer (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 as of September 30, 2017. Based on that evaluation, the Company’s Chief Executive Officer and Chief Financial Officer 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 September 30, 2017.

**Changes in Internal Controls Over Financial Reporting**

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2017, 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, the Company is a party to various legal proceedings arising in the ordinary course of business. In addition, the Company has in the past been, and may in the future be, subject to investigations by governmental and regulatory authorities, which expose it to greater risks associated with litigation, regulatory or other proceedings, as a result of which the Company could be required to pay significant fines or penalties. The outcome of litigation, regulatory or other proceedings cannot be predicted with certainty, and some lawsuits, claims, actions or proceedings may be disposed of unfavorably to the Company. In addition, intellectual property disputes often have a risk of injunctive relief which, if imposed against the Company, could materially and adversely affect its financial condition or results of operations.

As of September 30, 2017, the Company has no material ongoing litigation in which the Company was a party or any material ongoing regulatory or other proceedings and had no knowledge of any investigations by government or regulatory authorities in which the Company is a target that could have a material adverse effect on its current business.

**Item 1A. Risk Factors**

There have been no material changes to the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2016, 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, 2016.

***The growth of our business is substantially dependent on increased market penetration for the appropriate use of DEFINITY in suboptimal echocardiograms.***

The growth of our business is substantially dependent on increased market penetration for the appropriate use of DEFINITY in suboptimal echocardiograms. Of the total number of echocardiograms performed each year in the U.S., over 31.8 million in 2016, based on medical literature, a third-party source estimates that 20%, or approximately 6.4 million echocardiograms in 2016, produced suboptimal images. We estimate that DEFINITY had an approximately 80% share of the U.S. market for contrast agents in echocardiography procedures as of December 2016. We launched DEFINITY in 2001, and in the U.S., its composition of matter patent will expire in 2019, its manufacturing patent will expire in 2021, and a new method of use patent will expire in 2037. In numerous foreign jurisdictions, patent protection or regulatory exclusivity will currently expire in 2019. We have an active next generation development program for this agent, including pursuing additional indications, new patent protection, and new formulations, but there can be no assurance that this program will be successful or that new patents will protect the agent.

We have on-going development and technology transfer activities for a next generation DEFINITY product with SBL located in Songdo, South Korea, approximately 20 miles southwest of Seoul, but can give no assurances as to when those technology transfer activities will be completed and when we will begin to receive a supply of a next generation DEFINITY product from SBL. In addition, those activities could be adversely affected by on-going political and military tensions on the Korean peninsula.

If we are not able to continue to grow DEFINITY sales through increased market penetration, we will not be able to grow the revenue and cash flow of the business or leverage the substantial overhead of the balance of our business, which could have a negative effect on our prospects.

***In the U.S., we are heavily dependent on a few large customers and group purchasing organization arrangements to generate a majority of our revenues for our nuclear medical imaging products and our other products. Outside of the U.S., we rely primarily on distributors to generate a substantial portion of our revenue.***

In the U.S., we have historically relied on a limited number of radiopharmacy customers, primarily Cardinal, UPPI, GE Healthcare and Triad, to distribute our current largest volume nuclear imaging products and generate a majority of our revenues. Three customers accounted for approximately 30% of our revenues in the year ended December 31, 2016, with UPPI, Cardinal, and GE Healthcare accounting for approximately 11%, 10% and 9%, respectively. Among the existing radiopharmacies in the U.S., continued consolidations, divestitures and reorganizations may have a negative effect on our business, results of operations, financial condition or cash flows. We generally have distribution arrangements with our major radiopharmacy customers pursuant to multi-year contracts, each of which is subject to renewal. If these contracts are terminated prior to expiration of their term, or are not renewed, or are renewed on terms that are less favorable to us, then such an event could have a material adverse effect on our business, results of operations, financial condition and cash flows.

In Puerto Rico, we own and operate one of two radiopharmacies on the island and sell our own products as well as products of third parties to end users. In September 2017, Hurricane Maria devastated the island, interrupting power and telecommunications services for most of the island and limiting ground and air transportation. The building that houses our radiopharmacy sustained

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minimal external physical damage as a result of the hurricane. From and after September 20, 2017, the number of diagnostic imaging procedures performed on the island has severely declined. While we currently believe that the number of diagnostic imaging procedures performed in Puerto Rico will slowly return to prior levels, we can give no assurances of that, and failure of our radiopharmacy to return to such prior levels could have a negative effect on the revenue and cash flow of our business.

For all of our medical imaging products, we continue to experience significant pricing pressures from our competitors, large customers and group purchasing organizations, and any significant, additional pricing pressures could lead to a reduction in revenue which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Outside of the U.S., Canada and Puerto Rico, we have no sales force and, consequently, rely on third-party distributors, either on a country-by-country basis or on a multi-country, regional basis, to market, sell and distribute our products. This is the case in both Canada and Australia, where we formerly owned or operated radiopharmacies and are now distributing products under the Isologic Agreement and the GMS Agreement, respectively. Distributors accounted for approximately 34%, 15% and 17% of International segment revenues for the years ended December 31, 2016, 2015 and 2014, respectively. In certain circumstances, distributors may also sell competing products to our own or products for competing diagnostic modalities and may have incentives to shift sales towards those competing products. As a result, we cannot assure you that our international distributors will increase or maintain current levels of unit sales or that we will be able to increase or maintain our current unit pricing, which, in turn, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

***Our business is subject to international economic, political and other risks that could negatively affect our results of operations or financial***

***position.***

For the years ended December 31, 2016, 2015 and 2014, we derived approximately 15%, 20% and 22% of our revenues from outside the fifty United States, respectively. Accordingly, our business is subject to risks associated with doing business internationally, including:

* Less stable political and economic environments and changes in a specific country’s or region’s political or economic conditions, including on-going political and military tensions on the Korean peninsula which could adversely affect our next generation DEFINITY program at SBL;
* Entering into or renewing commercial agreements with international governments or provincial authorities or entities directly or indirectly controlled by such governments or authorities, such as our Chinese partner Double-Crane Pharmaceutical Company;
* International customers which are agencies or institutions of foreign governments;
* Local business practices which may be in conflict with the U.S. Foreign Corrupt Practices Act and U.K. Bribery Act;
* Currency fluctuations;
* Potential negative consequences from changes in tax laws affecting our ability to repatriate profits;
* Unfavorable labor regulations;
* Greater difficulties in relying on non-U.S. courts to enforce either local or U.S. laws, particularly with respect to intellectual property;
* Greater potential for intellectual property piracy;
* Greater difficulties in managing and staffing non-U.S. operations;
* The need to ensure compliance with the numerous in-country and international regulatory and legal requirements applicable to our business in each of these jurisdictions and to maintain an effective compliance program to ensure compliance with these requirements;
* Changes in public attitudes about the perceived safety of nuclear facilities;
* Changes in trade policies, regulatory requirements and other barriers;
* Civil unrest or other catastrophic events, including Hurricane Maria in Puerto Rico; and
* Longer payment cycles of non-U.S. customers and difficulty collecting receivables in non-U.S. jurisdictions.

These factors are beyond our control. The realization of any of these or other risks associated with operating outside the fifty United States could have a material adverse effect on our business, results of operations, financial condition and cash flows. As our international exposure increases and as we execute our strategy of international expansion, these risks may intensify.

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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 ending September 30, 2017. The Company does not have a share repurchase program in effect. The 2015 Equity Incentive Plan, adopted by the Company on June 24, 2015, and amended April 26, 2016 and as further amended on April 27, 2017, provides for the withholding of shares held by employees to satisfy tax obligations. It does not specify a maximum number of shares that can be withheld for this purpose. The shares of common stock withheld to satisfy minimum tax withholding obligations may be deemed to be “issuer purchases” of shares that are required to be disclosed pursuant to this Item.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  | **Total Number of** |  | **Approximate Dollar** |  |
|  |  |  |  |  |  |  |  | **Value of Shares that** |  |
|  |  | **Total Number of** |  |  | **Average Price Paid** | | **Shares Purchased as** |  | **May Yet Be Purchased** |  |
| **Period** |  |  |  | **Part of Publicly** |  | **Under** |  |
| **Shares Purchased** |  |  | **per Share** |  | **Announced Programs** |  | **the Program** |  |
| July 2017\*\* | | — | $ | | — | | \* | \* | |  |
| August 2017\*\* | | 27,918 | $ | | 17.48 |  | \* | \* | |  |
|  |  |  |  |  |  |  |  |  |  |  |
| September 2017\*\* | | 37,860 | $ | | 16.80 |  | \* | \* | |  |
| Total | | 65,778 |  |  |  |  | \* |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

\* 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 vesting of restricted shares from equity-based 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 are 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**

On October 30, 2017, we entered into a binding commercial supply arrangement pursuant to which we will supply Cardinal Health with TechneLite generators, Xenon, Neurolite and other products through 2018. The supply arrangement specifies pricing levels and requires Cardinal Health to purchase minimum volumes of certain products from us during certain periods. The supply arrangement will expire on December 31, 2018 and may be terminated upon the occurrence of specified events, including a material breach by the other party and certain force majeure events.

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**Item 6. Exhibits**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **EXHIBIT** | |  |  | **DESCRIPTION OF EXHIBITS** | | | | | |  |
| **NUMBER** | |  |  |  |
| 31.1\* |  |  | [Certification of Chief Executive Officer pursuant to Section 302 of the](#page38) | | | |  | | |  |
|  |  |  | [Sarbanes-Oxley Act of 2002.](#page38) | | | | | | |  |
|  |  |  |  |  |  |  | |  |  |  |
| 31.2\* |  |  | [Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-](#page39) | | | | | |  |  |
|  |  |  | [Oxley Act of 2002.](#page39) |  | | | | | |  |
| 32.1\* |  |  | [Certification Pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section](#page40) | | | | | | |  |
|  |  |  | [906 of the Sarbanes-Oxley Act of 2002.](#page40) | | | | |  | |  |
| 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

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**INCORPORATED BY REFERENCE**



|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **FORM** |  | **FILE** | | **EXHIBIT** |  | **FILING** |  |
| **NUMBER** |  | **DATE** |  |

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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: | November 2, 2017 |  |
| LANTHEUS HOLDINGS, INC. | |  |
| By: | /s/ JOHN W. CROWLEY |  |
| Name: |  |  |
| John W. Crowley |  |
| Title: | *Chief Financial Officer and Treasurer* |  |
|  | *(Principal Financial Officer and Principal* |  |
|  | *Accounting Officer)* |  |
| Date: | November 2, 2017 |  |

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**Exhibit 31.1**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO**

**SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Mary Anne Heino, certify that:

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

Date: November 2, 2017

/s/ MARY ANNE HEINO



Name: Mary Anne Heino

Title: *President and Chief Executive Officer*

*(Principal Executive Officer)*

**Exhibit 31.2**

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO**

**SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, John W. Crowley, certify that:

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

Date: November 2, 2017

/s/ JOHN W. CROWLEY



Name: John W. Crowley

Title: *Chief Financial Officer and Treasurer*

*(Principal Financial Officer and Principal Accounting Officer)*

**Exhibit 32.1**

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350**

**AS ADOPTED PURSUANT TO**

**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

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

1. The Quarterly Report on Form 10-Q for the period ended September 30, 2017 (the “Report”) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 2, 2017

/s/ MARY ANNE HEINO



Name: Mary Anne Heino

Title: *President and Chief Executive Officer*

*(Principal Executive Officer)*

Date: November 2, 2017

/s/ JOHN W. CROWLEY



Name: John W. Crowley

Title: *Chief Financial Officer and Treasurer*

*(Principal Financial Officer and Principal Accounting Officer)*

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.