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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, 2018**

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

**For the transition period from** **to**



**Commission File Number 001-36569**



**LANTHEUS HOLDINGS, INC.**



**(Exact name of registrant as specified in its charter)**



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



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

**Not Applicable**



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



Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ 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 | ☐ | Smaller reporting company | ☐ |
|  |  | Emerging Growth Company | ☑ |

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



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

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

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

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

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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,** |
|  |  |  |  |  |  |  |  |  |  |  |
|  | **2018** |  |  | **2017** |  |  | **2018** |  |  | **2017** |
|  |  |  |  |  |  |  |  |  |  |  |
| $ | 9,269 |  | $ | 8,526 |  | $ | 27,225 |  | $ | 26,259 |



|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Foreign currency translation |  | (2) |  |  | (115) |  |  | 2 |  |  | (139) |
| Total other comprehensive (loss) income |  | (2) |  |  | (115) |  |  | 2 |  |  | (139) |
|  |  |  |  |  |  |  |  |  |  |  |  |
| Comprehensive income | $ | 9,267 |  | $ | 8,411 |  | $ | 27,227 |  | $ | 26,120 |
|  |  |  |  |  |  |  |  |  |  |  |  |

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

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

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

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**Lantheus Holdings, Inc.**

**Notes to Condensed Consolidated Financial Statements**

(Unaudited)

**Note Regarding Company References and Trademarks**

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

**1. Basis of Presentation**

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

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

**2. Summary of Significant Accounting Policies**

***Recent Accounting Pronouncements***

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

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

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

**3. Revenue from Contracts with Customers**

***Adoption of ASC Topic 606, “Revenue from Contracts with Customers”***

The Company adopted ASC 606 on January 1, 2018 using the modified retrospective method for all contracts not completed as of the date of adoption. The reported results for 2018 reflect the application of ASC 606 guidance while the reported results for 2017 were prepared under the guidance of ASC 605, Revenue Recognition (“ASC 605”). For the Company’s accounting policy for revenue recognition under ASC 605, refer to Item 8 of the Annual Report on Form 10-K for the year ended December 31, 2017. The adoption of ASC 606 did not have a material impact on the Company’s consolidated balance sheet, results of operations, equity or cash flows as of the adoption date or for the periods presented.

***Revenue Recognition***

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

***Disaggregation of Revenue***

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

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

***Product Revenue, Net***

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

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

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

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

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

Frequently, the Company receives orders for products to be delivered over multiple dates that may extend across several reporting periods. The

Company invoices for each delivery upon shipment and recognizes revenues for each distinct product delivered, assuming transfer of control has occurred.

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

*Variable Consideration*

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

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

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

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

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

***License and Royalty Revenues***

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

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

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

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

*Royalty Revenues:* For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license isdeemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

***Contract Costs***

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

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The Company recognized certain revenues as follows:

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

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

**4. Fair Value of Financial Instruments**

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

* *Level 1* — Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at themeasurement date.
* *Level 2* — Inputs include quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities inmarkets 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 orliability. The Company develops these inputs based on the best information available, including its own data.

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

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

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  | **September 30, 2018** |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | **Total Fair** |  |  |  |  |  |  |  |  |
| **(in thousands)** |  | **Value** |  | **Level 1** |  | **Level 2** |  | **Level 3** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Money market | $ | 12,605 |  | $ | 12,605 |  | $ | — | $ | — |
|  | Total | $ | 12,605 |  | $ | 12,605 |  | $ | — |  | $ | — |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  | **December 31, 2017** |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | **Total Fair** |  |  |  |  |  |  |  |  |
| **(in thousands)** |  | **Value** |  | **Level 1** |  | **Level 2** |  | **Level 3** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Money market | $ | 8,700 |  | $ | 8,700 |  | $ | — | $ | — |
|  | Total | $ | 8,700 |  | $ | 8,700 |  | $ | — |  | $ | — |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |

***Nonrecurring Fair Value Measurements***

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

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**5. Income Taxes**

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

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

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

The Company is still studying all of the ramifications of the Act, but expects the primary material impact of the Act to be the remeasurement of the Company’s deferred tax assets, which was recorded in fiscal 2017 as a result of the reduction in U.S. corporate tax rates from 35% to 21%. As

of December 31, 2017, the Company determined it had no accumulated unrepatriated foreign earnings, and therefore had recorded no liability for the repatriation transition tax. No changes have been made to these estimates.

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

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

In connection with the Company’s acquisition of the medical imaging business from Bristol Myers Squibb (“BMS”) in 2008, the Company entered into a tax indemnification agreement with BMS related to certain tax obligations arising prior to the acquisition of the Company, for which the Company has the primary legal obligation. A long-term receivable is recorded to account for the expected value to the Company of future indemnification payments, net of actual U.S. federal tax benefits. The tax indemnification receivable is recognized within other long-term assets. The changes in the tax indemnification asset are recognized within other income in the condensed consolidated statement of operations. In accordance with the Company’s accounting policy, the change in the tax liability and penalties and interest associated with these obligations (net of any offsetting federal or state benefit) is recognized within income tax expense. Accordingly, as these reserves change, adjustments are included in income tax expense while the offsetting adjustment is included in other income. Assuming that the receivable from BMS continues to be considered recoverable by the Company, there will be minimal net effect on earnings and net cash outflows related to these liabilities.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **6. Inventory** |  |  |  |  |  |
| Inventory consisted of the following: |  |  |  |  |  |
|  |  |  |  |  | **September 30,** |  | **December 31,** |
|  | **(in thousands)** |  | **2018** |  |  | **2017** |
|  |  |  |  |  |  |  |  |  |
|  | Raw materials | $ | 11,896 |  | $ | 10,447 |
|  | Work in process |  | 7,168 |  |  | 5,509 |
|  |  |  |  |  |  |  |  |  |
|  | Finished goods |  | 15,508 |  |  | 10,124 |
|  |  | Total inventory | $ | 34,572 |  | $ | 26,080 |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

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

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

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

***Long-Lived Assets Held for Sale***

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

**8. Asset Retirement Obligations**

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

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

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

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

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

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**9. Financing Arrangements**

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

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

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

***2017 Term Facility***

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

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

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **(in thousands)** |  |  | **Amount** |  |
|  |  |  |  |  |  |  |
| Remainder of 2018 | $ | 688 |  |
| 2019 |  |  |  | 2,750 |  |
|  |  |  |  |  |  |  |
| 2020 |  |  |  | 2,750 |  |
| 2021 |  |  |  | 2,750 |  |
|  |  |  |  |  |  |  |
| 2022 |  |  |  | 261,937 |  |
|  | Total principal outstanding |  |  | 270,875 |  |
|  |  |  |  |  |  |  |
| Unamortized debt discount |  |  | (1,697) |  |
| Unamortized debt issuance costs |  |  | (2,298) |  |
|  |  |  |  |  |  |  |
|  | Total |  |  | 266,880 |  |
| Less: current portion |  |  | (2,750) |  |
|  |  |  |  |  |  |  |
|  | Total long-term debt | $ | 264,130 |  |
|  |  |  | 12 |  |  |  |
|  |  |  |  |  |  |

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***2017 Revolving Facility***

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

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

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

***2017 Facility Covenants***

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

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

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

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.

**10. Stock-Based Compensation**

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | **Three Months Ended** |  | **Nine Months Ended** |
|  |  |  |  | **September 30,** |  | **September 30,** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | **(in thousands)** |  | **2018** |  |  | **2017** |  |  | **2018** |  |  | **2017** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Cost of goods sold | $ | 322 |  | $ | 198 |  | $ | 812 |  | $ | 514 |
|  | Sales and marketing |  | 193 |  |  | 183 |  |  | 892 |  |  | 474 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | General and administrative |  | 1,540 |  |  | 1,089 |  |  | 3,741 |  |  | 2,315 |
|  | Research and development |  | 352 |  |  | 187 |  |  | 974 |  |  | 461 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Total stock-based compensation expense | $ | 2,407 |  | $ | 1,657 |  | $ | 6,419 |  | $ | 3,764 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | 13 |  |  |  |  |  |  |  |  |  |

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

**11. Net Income Per Common Share**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  | **Three Months Ended** |  |  | **Nine Months Ended** |  |
|  |  |  |  |  |  |  |  |  |  |  | **September 30,** |  |  | **September 30,** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **(in thousands, except per share amounts)** |  |  |  |  |  | **2018** |  |  |  |  | **2017** |  |  |  |  | **2018** |  |  | **2017** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Net income |  |  |  | $ | 9,269 |  | $ | 8,526 |  |  | $ | 27,225 |  | $ | 26,259 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Basic weighted-average common shares outstanding |  |  |  |  |  | 38,342 |  |  |  |  | 37,393 |  |  |  |  | 38,155 |  |  | 37,174 |  |
|  | Effect of dilutive stock options |  |  |  |  |  | 31 |  |  |  |  | 318 |  |  |  |  | 70 |  |  | 371 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Effect of dilutive restricted stock |  |  |  |  |  | 1,029 |  |  |  |  | 1,410 |  |  |  |  | 1,242 |  |  | 1,426 |  |
| Diluted weighted-average common shares outstanding |  |  |  |  |  | 39,402 |  |  |  |  | 39,121 |  |  |  |  | 39,467 |  |  | 38,971 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Basic income per common share |  |  |  | $ | 0.24 |  | $ | 0.23 |  |  | $ | 0.71 |  | $ | 0.71 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Diluted income per common share |  |  |  | $ | 0.24 |  | $ | 0.22 |  |  | $ | 0.69 |  | $ | 0.67 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Antidilutive securities excluded from diluted net income per common share |  |  |  |  | 355 |  |  |  |  | 322 |  |  |  |  | 346 |  |  | 378 |  |
| **12. Other Income** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Other income consisted of the following: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  | **Three Months Ended** |  |  |  | **Nine Months Ended** |  |  |  |
|  |  |  |  |  |  |  | **September 30,** |  |  |  | **September 30,** |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | **(in thousands)** |  | **2018** |  |  |  | **2017** |  |  |  |  | **2018** |  |  |  |  | **2017** |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | Foreign currency gains (losses) | $ | 89 |  | $ | 414 |  | $ | (198) |  | $ | 554 |  |  |  |
|  |  | Tax indemnification income |  | 692 |  |  |  | 489 |  |  |  |  | 2,220 |  |  |  |  | 1,469 |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | Other |  | 18 |  |  |  | 5 |  |  |  |  | 33 |  |  |  |  | 14 |  |  |  |
|  |  |  | Total other income | $ | 799 |  | $ | 908 |  |  | $ | 2,055 |  |  |  | $ | 2,037 |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**13. Legal Proceedings and Contingencies**

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

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

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

**14. Segment Information**

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

Selected information regarding the Company’s segments is provided as follows:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | **Three Months Ended** |  | **Nine Months Ended** |
|  |  |  |  | **September 30,** |  | **September 30,** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **(in thousands)** |  | **2018** |  |  | **2017** |  |  | **2018** |  |  | **2017** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Revenues from external customers** |  |  |  |  |  |  |  |  |  |  |  |
| U.S. | $ | 70,255 |  | $ | 69,579 |  | $ | 215,829 |  | $ | 218,706 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| International |  | 18,645 |  |  | 10,362 |  |  | 41,274 |  |  | 31,431 |
|  | Total revenues from external customers | $ | 88,900 |  | $ | 79,941 |  | $ | 257,103 |  | $ | 250,137 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Operating income** |  |  |  |  |  |  |  |  |  |  |  |
| U.S. | $ | 12,897 |  | $ | 12,243 |  | $ | 41,345 |  | $ | 40,306 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| International |  | 3,585 |  |  | 579 |  |  | 6,200 |  |  | 2,340 |
|  | Total operating income |  | 16,482 |  |  | 12,822 |  |  | 47,545 |  |  | 42,646 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Interest expense |  | 4,446 |  |  | 4,442 |  |  | 12,794 |  |  | 14,147 |
| Loss on extinguishment of debt |  | — |  | — |  | — |  | 2,161 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Other income |  | (799) |  |  | (908) |  |  | (2,055) |  |  | (2,037) |
|  | Income before income taxes | $ | 12,835 |  | $ | 9,288 |  | $ | 36,806 |  | $ | 28,375 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | 15 |  |  |  |  |  |  |  |  |  |

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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 segment competition and potential generic competition as a result of future patent and regulatory exclusivity expirations; (ii) our outlook and expectations related to the global Molybdenum-99 (“Moly”) supply; (iii) our outlook and expectations in connection with future performance of Xenon in the face of increased competition; and (iv) our outlook and expectations related to products manufactured at Jubilant HollisterStier (“JHS”). Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward-looking statements relate to the future, such statements are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements. Such statements are neither statements of historical fact nor guarantees or assurances of future performance. The matters referred to in the forward-looking statements contained in this Quarterly Report on Form 10-Q may not in fact occur. We caution you, therefore, against relying on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include regional, national or global political, economic, business, competitive, market and regulatory conditions and the following:
	* Our ability to continue to grow the appropriate use of DEFINITY in suboptimal echocardiograms in the face of segment competition from other echocardiography contrast agents, including Optison from GE Healthcare Limited (“GE Healthcare”) and Lumason from Bracco Diagnostics Inc. (“Bracco”), and potential generic competition as a result of future patent and regulatory exclusivity expirations;
	* The instability of the global Moly supply, including outages at the NTP Radioisotopes (“NTP”) processing facility in South Africa from late November 2017 until mid-February 2018 and again from early June 2018 through the present, resulting in our inability to fill all of the demand for our TechneLite generators on certain manufacturing days during those periods;
	* Risks associated with revenues and unit volumes for Xenon in pulmonary studies as a result of increased competition from Curium;
	* Our dependence upon third parties for the manufacture and supply of a substantial portion of our products, raw materials and components, including DEFINITY at JHS;
	* Our dependence on key customers for our medical imaging products, and our ability to maintain and profitably renew our contracts with those key customers, including Cardinal Health (“Cardinal”), United Pharmacy Partners (“UPPI”), GE Healthcare and Jubilant Drax Image Radiopharmaceuticals (“JDI”) d/b/a Triad Isotopes, Inc. (“Triad”);
	* Risks associated with the technology transfer programs to secure production of our products at additional contract manufacturer sites, including an alternative microbubble formulation at Samsung BioLogics (“SBL”) in South Korea;
	* Risks associated with our lead agent in development, flurpiridaz F 18, including:
		+ The ability of GE Healthcare to successfully complete the Phase 3 development program;
		+ The ability to obtain Food and Drug Administration (“FDA”) approval; and
		+ The ability to gain post-approval market acceptance and adequate reimbursement;
	* Risks associated with our two current internal clinical development programs - DEFINITY for a left ventricular ejection fraction (“LVEF”) indication, and LMI 1195 for patient populations that would benefit from molecular imaging of the norepinephrine pathway, including risk stratification of ischemic heart failure patients;
	* Risks associated with the manufacturing and distribution of our products and the regulatory requirements related thereto;
	* Risks associated with our investment in, and construction of, additional specialized manufacturing capabilities at our North Billerica, Massachusetts facility;
	* The dependence of certain of our customers upon third-party healthcare payors and the uncertainty of third-party coverage and reimbursement rates;
	* Uncertainties regarding the impact of on-going U.S. healthcare reform proposals on our business, including related reimbursements for our current and potential future products;

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

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

**Available Information**

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

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

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

**Overview**

***Our Business***

We are a global leader in the development, manufacture and commercialization of innovative diagnostic medical imaging agents and products that assist clinicians in the diagnosis and treatment of cardiovascular and other diseases. Clinicians use our imaging agents and products across a range of imaging modalities, including echocardiography and nuclear imaging. We believe that the resulting improved diagnostic information enables healthcare providers to better detect and characterize, or rule out, disease, potentially achieving improved patient outcomes, reducing patient risk and limiting overall costs for payers and the entire healthcare system.

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

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

***Our Product Portfolio***

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

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

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

We also maintain our own direct sales force in Canada for certain customers so that we can control the importation, marketing, distribution and sale of our imaging agents in Canada in this sales channel. In Europe, Australia, Asia-Pacific and Latin America, we rely on third-party distributors to market, sell and distribute our nuclear imaging and contrast agent products, either on a country-by-country basis or on a multi-country regional basis.

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

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

**Key Factors Affecting Our Results**

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

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

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

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

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

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

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

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

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

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

See Part I, Item 1A. “Risk Factors—The growth of our business is substantially dependent on our ability to continue to grow the appropriate use of DEFINITY in suboptimal echocardiograms in the face of increased segment competition from other existing echocardiography agents and potential generic competitors as a result of future patent and regulatory exclusivity expirations,” and “—If we are unable to protect our intellectual property, our competitors could develop and market products with features similar to our products, and demand for our products may decline,” both in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018. See also Part I, Item 1A. “Risk Factors—Our dependence upon third parties for the manufacture and supply of a substantial portion of our products could prevent us from delivering our products to our customers in the required quantities, within the required timeframes, or at all, which could result in order cancellations and decreased revenues,” and “—Item 1. Business—Our Product Portfolio—DEFINITY and Our Microbubble Franchise Strategy,” both in our Annual Report on Form 10-K for the year ended December 31, 2017.

***Global Moly Supply***

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

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

To expand its current Moly production capacity, ANSTO is currently commissioning a new Mo-99 production facility that also will expand its production capacity from 2,000 to 3,500 curies per week which is expected to be in commercial operation in the first half of 2019. We also have a strategic arrangement with SHINE Medical Technologies, Inc. (“SHINE”), a Wisconsin-based company, for the future supply of Moly. Under the terms of that agreement, SHINE will provide us Moly once SHINE’s facility becomes operational and receives all necessary approvals, which SHINE now estimates will occur in 2021.

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

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***Competition for Xenon***

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

***Inventory Supply***

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

In addition to JHS, we are also currently working to secure additional alternative suppliers for our key products as part of our ongoing supply chain diversification strategy. We have ongoing development and technology transfer activities for an alternative microbubble formulation with SBL, which is located in South Korea, but we cannot give any assurances as to if and when those technology transfer activities will be completed and when we will begin to receive supply of an alternative microbubble formulation from SBL. As described above, we have also commenced an extensive, multi-year effort to add in-house specialized manufacturing capabilities at our North Billerica, Massachusetts facility. This project is part of a larger strategy to create a competitive advantage in specialized manufacturing, which will also allow us to optimize our costs and reduce our supply chain risk. We can give no assurance as to when or if we will be successful in these efforts or that we will be able to successfully manufacture any additional commercial products at our North Billerica, Massachusetts facility. See Part I, Item 1A. “Risk Factors—Our dependence upon third parties for the manufacture and supply of a substantial portion of our products could prevent us from delivering our products to our customers in the required quantities, within the required timeframes, or at all, which could result in order cancellations and decreased revenues” of our Annual Report on Form 10-K for the year ended December 31, 2017.

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

***Research and Development Expenses***

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

***Strategic Activities***

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

***Segments***

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

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***Executive Overview***

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

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

**Results of Operations**

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | **Three Months Ended** |  | **Nine Months Ended** |
|  |  |  |  | **September 30,** |  | **September 30,** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | **(in thousands)** |  | **2018** |  |  | **2017** |  |  | **2018** |  |  | **2017** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Revenues | $ | 88,900 |  | $ | 79,941 |  | $ | 257,103 |  | $ | 250,137 |
|  | Cost of goods sold |  | 44,015 |  |  | 41,414 |  |  | 126,063 |  |  | 125,901 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Gross profit |  | 44,885 |  |  | 38,527 |  |  | 131,040 |  |  | 124,236 |
|  | Operating expenses |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Sales and marketing |  | 10,478 |  |  | 10,075 |  |  | 33,248 |  |  | 31,892 |
|  | General and administrative |  | 13,609 |  |  | 12,076 |  |  | 37,727 |  |  | 35,549 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Research and development |  | 4,316 |  |  | 3,554 |  |  | 12,520 |  |  | 14,149 |
|  | Total operating expenses |  | 28,403 |  |  | 25,705 |  |  | 83,495 |  |  | 81,590 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Operating income |  | 16,482 |  |  | 12,822 |  |  | 47,545 |  |  | 42,646 |
|  | Interest expense |  | 4,446 |  |  | 4,442 |  |  | 12,794 |  |  | 14,147 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Loss on extinguishment of debt |  | — |  | — |  | — |  | 2,161 |
|  | Other income |  | (799) |  |  | (908) |  |  | (2,055) |  |  | (2,037) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Income before income taxes |  | 12,835 |  |  | 9,288 |  |  | 36,806 |  |  | 28,375 |
|  | Income tax expense |  | 3,566 |  |  | 762 |  |  | 9,581 |  |  | 2,116 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Net income | $ | 9,269 |  | $ | 8,526 |  | $ | 27,225 |  | $ | 26,259 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | 22 |  |  |  |  |  |  |  |  |  |

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**Comparison of the Periods Ended September 30, 2018 and 2017**

***Revenues***

Segment revenues are summarized by product as follows:

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

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

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

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

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

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*Rebates and Allowances*

Estimates for rebates and allowances represent our estimated obligations under contractual arrangements with third parties. Rebate accruals and allowances are recorded in the same period the related revenue is recognized, resulting in a reduction to other revenue and the establishment of a liability which is included in accrued expenses. These rebates and allowances result from performance-based offers that are primarily based on attaining contractually specified sales volumes and growth, Medicaid rebate programs for our products, administrative fees of group purchasing organizations, royalties and certain distributor related commissions. The calculation of the accrual for these rebates and allowances is based on an estimate of the third-party’s buying patterns and the resulting applicable contractual rebate or commission rate(s) to be earned over a contractual period.

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | **Rebates and** |  |  |
|  |  | **(in thousands)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | **Allowances** |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | Balance, January 1, 2018 |  |  |  |  |  |  |  |  |  |  |  |  | $ |  |  | 2,860 |  |  |
|  |  |  | Provision related to current period revenues |  |  |  |  |  |  |  |  |  |  |  |  |  | 9,609 |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  | Adjustments relating to prior period revenues |  |  |  |  |  |  |  |  |  |  |  |  |  | (291) |  |  |
|  |  |  | Payments or credits made during the period |  |  |  |  |  |  |  |  |  |  |  |  |  | (7,885) |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | Balance, September 30, 2018 |  |  |  |  |  |  |  |  |  |  |  |  |  | $ |  |  | 4,293 |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ***Gross Profit*** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Gross profit is summarized by segment as follows: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  | **Three Months Ended** |  |  |  |  |  |  | **Nine Months Ended** |  |  |
|  |  |  |  |  |  |  |  |  | **September 30,** |  |  |  |  |  |  |  | **September 30,** |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  | **Change** | **Change** |  |  |  |  |  |  |  |  | **Change** | **Change** |  |
| **(in thousands)** |  | **2018** |  |  | **2017** |  |  | **$** |  | **%** |  |  | **2018** |  |  | **2017** |  |  | **$** |  |  | **%** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| U.S. | $ | 40,193 |  | $ | 36,820 |  | $ | 3,373 |  | 9.2% |  | $ | 121,163 |  | $ | 118,481 | $ | 2,682 |  |  | 2.3% |  |
| International |  | 4,692 |  |  | 1,707 |  |  | 2,985 |  | 174.9% |  |  | 9,877 |  |  | 5,755 |  |  | 4,122 |  |  | 71.6% |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Total gross profit | $ | 44,885 |  | $ | 38,527 |  | $ | 6,358 |  | 16.5% |  | $ | 131,040 |  | $ | 124,236 | $ | 6,804 |  |  | 5.5% |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

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

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

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

***Sales and Marketing***

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

Sales and marketing expense is summarized by segment as follows:

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

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

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

***General and Administrative***

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

General and administrative expense is summarized by segment as follows:

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

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

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

***Research and Development***

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

Research and development expense is summarized by segment as follows:

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

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

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

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

***Interest Expense***

Interest expense decreased by approximately $1.4 million for the nine months ended September 30, 2018 as compared to the prior year period due to comparatively lower outstanding principal balances and effective interest rates on our long-term debt during the period as a result of our March 2017 refinancing.

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***Loss on Extinguishment of Debt***

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

***Income Tax Expense***

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

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

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

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

**Nine Months Ended**

**September 30,**



|  |  |  |  |
| --- | --- | --- | --- |
|  | **2018** |  | **2017** |
|  |  |  |  |
| Effective tax rate | 26.0% |  | 7.5% |
|  |  |  |  |

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

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

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

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Liquidity and Capital Resources** |  |  |  |  |  |  |
| ***Cash Flows*** |  |  |  |  |  |  |
| The following table provides information regarding our cash flows: |  |  |  |  |  |  |
|  |  |  |  |  | **Nine Months Ended** |
|  |  |  |  |  | **September 30,** |
|  |  |  |  |  |  |  |  |  |
|  | **(in thousands)** |  |  | **2018** |  |  | **2017** |
|  |  |  |  |  |  |  |  |  |
|  | Net cash provided by operating activities | $ | 43,887 |  | $ | 41,691 |
|  | Net cash used in investing activities | $ | (11,766) |  | $ | (10,355) |
|  |  |  |  |  |  |  |  |  |
|  | Net cash used in financing activities | $ | (3,734) |  | $ | (14,600) |
|  |  |  | 26 |  |  |  |  |  |

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*Net Cash Provided by Operating Activities*

Net cash provided by operating activities of $43.9 million in the nine months ended September 30, 2018 was driven primarily by net income of

$27.2 million plus $10.5 million of depreciation, amortization and accretion expense, changes in deferred taxes of $7.2 million and $6.4 million of stock-

based compensation expense. These net sources of cash were offset by a net decrease of $12.4 million related to movements in our working capital accounts

during the period. The overall decreases in cash from our working capital accounts were primarily driven by the timing of inventory purchases during the

period as well as higher accounts receivable as a result of temporary incremental demand for TechneLite in our International segment.

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

*Net Cash Used in Investing Activities*

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

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

*Net Cash Used in Financing Activities*

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

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

***External Sources of Liquidity***

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

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

The Term Loans under the 2017 Term Facility bear interest, with pricing based from time to time at our election at (i) LIBOR plus a spread of 3.75% or

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

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

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

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

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

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

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

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

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

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

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

***Funding Requirements***

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

* The pricing environment and the level of product sales of our currently marketed products, particularly DEFINITY and any additional products that we may market in the future;
* Revenue mix shifts and associated volume and selling price changes that could result from contractual status changes with key customers and additional competition;
* Our investment in the further clinical development and commercialization of existing products and development candidates;
* The costs of investing in our facilities, equipment and technology infrastructure;
* The extent to which we acquire or invest in new products, businesses and technologies;

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

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

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

At September 30, 2018, our only current committed external source of funds is our borrowing availability under our 2017 Revolving Facility. We had $104.6 million of cash and cash equivalents at September 30, 2018. Our 2017 Facility contains a number of affirmative, negative, reporting and financial covenants, in each case subject to certain exceptions and materiality thresholds. Incremental borrowings under the 2017 Revolving Facility may affect our ability to comply with the covenants in the 2017 Facility, including the financial covenant restricting consolidated net leverage. Accordingly, we may be limited in utilizing the full amount of our 2017 Revolving Facility as a source of liquidity.

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

**Critical Accounting Policies and Estimates**

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

There have been no other significant changes to our critical accounting policies or in the underlying accounting assumptions and estimates used in such policies in the nine months ended September 30, 2018, except as set forth below. For further information, refer to our summary of significant accounting policies and estimates in our Annual Report on Form 10-K filed for the year ended December 31, 2017.

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***Revenue from Contracts with Customers***

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

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

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

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

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

**Off-Balance Sheet Arrangements**

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

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

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

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

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**Item 4. Controls and Procedures**

**Disclosure Controls and Procedures**

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

**Changes in Internal Controls Over Financial Reporting**

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

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**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

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

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

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

**Item 1A. Risk Factors**

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

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

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

We launched DEFINITY in 2001, and we continue to actively pursue patents in connection with DEFINITY, both in the U.S. and internationally. In the U.S., we now have an Orange Book-listed method of use patent expiring in March 2037 to augment a DEFINITY patent portfolio that includes an Orange Book-listed composition of matter patent expiring in June 2019, and additional manufacturing patents that are not Orange Book-listed expiring in 2021, 2023 and 2037. Outside of the U.S., our DEFINITY patent protection or regulatory exclusivity currently expires in 2019.

Because our Orange Book-listed composition of matter patent expires in June 2019, we may face generic DEFINITY challengers in the near to intermediate term. Under the Hatch-Waxman Act, the FDA can approve ANDAs for generic versions of drugs before the expiration of an Orange Book-listed patent covering the innovator product if the ANDA applicant demonstrates, among other things, that (i) its generic candidate is the same as the innovator product by documenting bioequivalence and providing relevant chemistry, manufacturing and product data, and (ii) the marketing of that generic candidate does not infringe an Orange Book-listed patent or the Orange Book-listed patent is invalid. With respect to any Orange Book-listed patent covering the innovator product that expires after the ANDA applicant intends to begin commercialization, the ANDA applicant must certify that its generic candidate will not infringe the innovator’s Orange Book-listed patents or that the Orange Book-listed patents are invalid. The ANDA applicant must also give Notice to the innovator, which would then enable the innovator to challenge the ANDA applicant in court within 45 days of receiving such Notice. If the innovator challenges the ANDA applicant in court in a timely manner, then FDA approval to commercialize the generic candidate will be stayed (that is, delayed) for up to 30 months while the dispute between the innovator and the ANDA

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

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

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

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

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

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

A critical ingredient of TechneLite is Moly. We currently purchase finished Moly from three of the four main processing sites in the world, namely ANSTO in Australia, IRE in Belgium and NTP in South Africa. These processing sites provide us Moly from five of the six main Moly-producing reactors in the world, namely OPAL in Australia, BR2 in Belgium, LVR-15 in the Czech Republic, HFR in The Netherlands, and SAFARI in South Africa.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Repurchases**

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

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



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* These amounts are not applicable as the Company does not have a share repurchase program in effect.
* Reflects shares withheld to satisfy minimum statutory tax withholding amounts due from employees related to the receipt of stock, which resulted from the exercise or vesting of equity awards.

**Dividend Policy**

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

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

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**Item 6. Exhibits**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  | **INCORPORATED BY REFERENCE** |  |
|  | **EXHIBIT** |  |  |  |  | **DESCRIPTION OF EXHIBITS** |  | **FORM** |  |  | **FILE** | **EXHIBIT** |  | **FILING** |  |
|  | **NUMBER** |  |  |  |  |  |  |  | **NUMBER** |  | **DATE** |  |
|  | 10.1\* |  |  | [Separation Agreement, effective September 20, 2018, by and between Lantheus Medical Imaging, Inc.](#page41) |  |  |  |  |  |  |  |  |  |
|  |  |  |  | [and Timothy Healey](#page41) |  |  |  |  |  |  |  |  |  |  |  |
|  | 10.2\* |  |  | [Separation Agreement, effective September 21, 2018, by and between Lantheus Medical Imaging, Inc.](#page47) |  |  |  |  |  |  |  |  |  |
|  |  |  |  | [and Jack Crowley](#page47) |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 31.1\* |  |  | [Certification of Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a).](#page55) |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 31.2\* |  |  | [Certification of Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a).](#page56) |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 32.1\*\* |  |  | [Certification pursuant to 18 U.S.C. Section 1350.](#page57) |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 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 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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* Filed herewith

\*\* Furnished herewith

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**SIGNATURES**

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

LANTHEUS HOLDINGS, INC.

|  |  |  |
| --- | --- | --- |
| By: | /s/ MARY ANNE HEINO |  |
| Name: |  |  |
| Mary Anne Heino |  |
| Title: | *President and Chief Executive Officer* |  |
|  | *(Principal Executive Officer)* |  |
| Date: | October 30, 2018 |  |
| LANTHEUS HOLDINGS, INC. |  |
| By: | /s/ ROBERT J. MARSHALL, JR. |  |
| Name: |  |  |
| Robert J. Marshall, Jr. |  |
| Title: | *Chief Financial Officer and Treasurer* |  |
|  | *(Principal Financial Officer and Principal* |  |
|  | *Accounting Officer)* |  |
| Date: | October 30, 2018 |  |

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**Exhibit 10.1**

July 25, 2018

VIA HAND DELIVERY

Timothy Healey

c/o Lantheus Medical Imaging, Inc.

331 Treble Cove Road

North Billerica, MA 01862

Dear Tim:

This letter agreement (this “Agreement”) confirms the terms of your separation from Lantheus Medical Imaging, Inc. (the “Company”), effective as of July 25, 2018 (the “Separation Date”).

1. **Resignations.** On the Separation Date, you will be deemed to have resigned from your position as Senior Vice President, Commercial and from anyand all (i) officer positions you hold with the Company or any of its Affiliates (as defined below); (ii) memberships you hold on any boards of directors, boards of managers or other governing boards or bodies of the Company or any of its Affiliates; and (iii) memberships you hold on any of the committees of any of those boards or bodies. For purposes of this Agreement, “Affiliates” means all persons and entities directly or indirectly controlling, controlled by or under common control with the Company, whether control by management authority, equity interest or otherwise.
2. **Final Compensation.** You will receive, on or as soon as reasonably practicable following the Separation Date, in the form of one or more payrollchecks, (i) your base salary for the final, unpaid payroll period(s) of your employment through the Separation Date; (ii) compensation at the rate of your base salary for any vacation time accrued but not used as of the Separation Date; (iii) any contributions that you have made under any employee stock purchase plan of Lantheus Holdings, Inc. (“Parent”) or any of its Affiliates that are refundable to you under its respective terms and conditions; and (iv) reimbursement for business expenses incurred by you but not yet paid to you as of the Separation Date; provided that you submit all expenses and supporting documentation required within thirty (30) days of the Separation Date and that those expenses are reimbursable under Company policies in effect as of the Separation Date.
3. **Employee Benefits.** Except for any right you may have to continue your participation and that of your eligible dependents in the Company’s grouphealth plans under the Consolidated Omnibus Budget Reconciliation Act of 1985 (“COBRA”) or similar state law, your participation in all employee benefit plans and programs of the Company and its Affiliates will end as of the last day of the month in which the Separation Date occurs. You will receive information about your COBRA continuation rights under separate cover.
4. **Equity Awards.** You hold certain equity awards granted to you by Lantheus Holdings, Inc. (“Parent”), an Affiliate of the Company, under its 2008Equity Incentive Plan, 2013 Equity Incentive Plan and/or 2015 Equity Incentive Plan, each as amended, and the equity incentive agreements evidencing those grants entered into between you and Parent under those plans (collectively, the “Equity Agreements” and those equity awards, collectively, the “Equity Awards”). You acknowledge and agree that all Equity Awards that are unvested as of the Separation Date are being forfeited for no consideration due to you in accordance with the Equity Agreements, and all of your then-vested Equity Awards will continue to be subject to the terms and conditions of the applicable Equity Agreements, including the post-termination of employment exercise provisions thereof.
5. **Severance Payments.** Subject to your execution of this Agreement within fifty (50) days following the Separation Date and your not revoking thisAgreement within the seven (7)-day period immediately thereafter, and subject to your meeting in full your obligations under this Agreement and the Continuing Obligations (as defined in Section 8(a) below), the Company will provide you with the following:
6. an amount equal to the sum of (x) $228,589.04, representing a pro rata portion of an amount equal to forty-five percent (45%) of your

annual base salary on the Separation Date, based upon the percentage of the fiscal year elapsed through Separation Date, plus

1. $407,000.00, representing your annual base salary, which amount (i.e., the sum of clauses (x) and (y)) will be paid in substantially equal installments over a period of twelve (12)

months following the Separation Date (the “Severance Period”) in accordance with the Company’s regular payroll practices, with the first payment commencing on the Company’s first payroll date after the sixtieth (60th) day following the Separation Date, and with the first payment including any of those amounts that would otherwise have been paid prior thereto; and

* 1. provided that you timely and properly elect to purchase continued healthcare coverage under COBRA, Company-subsidized COBRA benefits (in an amount representing the Company’s contribution level for active employees at the time of payment) for the period ending on the earliest of (i) the expiration of the Severance Period, (ii) the date on which you become covered under another employer’s health plan and (iii) the expiration of the maximum COBRA continuation coverage period for which you are eligible under federal law (for the avoidance of doubt, during this subsidized period, you will be responsible for paying a COBRA premium equal to the active employee contribution rate directly to the Company’s COBRA administrator, and you will be responsible for paying the entirety of the COBRA premium directly to the Company’s COBRA administrator after this period).
1. **Acknowledgement of Full Payment.** You acknowledge and agree that the payments and other benefits provided under this Agreement are incomplete satisfaction of any and all compensation and benefits due to you from the Company or any of its Affiliates, whether for services provided to the Company or otherwise, through the Separation Date. You further acknowledge that, except as expressly provided under this Agreement, no further compensation or benefits are owed or will be provided to you by the Company or any of its Affiliates.
2. **Taxes and Withholding.** All payments made by the Company under this Agreement will be reduced by any tax or other amounts required to bewithheld by the Company under applicable law. This Agreement and the payments and benefits provided under this Agreement are intended to be exempt from the requirements of Section 409A of the Internal Revenue Code of 1986, as amended (“Section 409A”), and this Agreement will be construed consistently with that intent. Without limiting the foregoing, the severance payments set forth in Section 5 of this Agreement are intended to be exempt from Section 409A as “separation pay” within the meaning of Section 1.409A-1(b)(9)(iii) of the Treasury Regulations. Notwithstanding anything to the contrary, in no event will the Company have any liability relating to the failure or alleged failure of any payment or benefit under this Agreement to be exempt from the requirements of Section 409A.
3. **Continuing Obligations.**
	1. You acknowledge and recognize the highly competitive nature of the businesses of the Company and its Affiliates and, accordingly, in consideration of the severance pay and benefits set forth in Section 5 and other valuable consideration, you acknowledge and agree that you will continue to be bound by your obligations relating to confidentiality, non-competition, non-solicitation, no-hire, invention assignment, non-disparagement and/or any other restrictive covenant set forth in any agreement by and between you and the Company or any of its Affiliates, including, without limitation, those set forth in Sections 10-13 of the employment agreement, dated November 16, 2015, between you and the Company (the “Employment Agreement”) (all such obligations, collectively, the “Continuing Obligations”). Each of the Continuing Obligations is an individual right, separately enforceable by the Company and/or its applicable Affiliate(s), notwithstanding any conflict or other inconsistency among any provisions (or any parts of any provisions) of any of the Continuing Obligations, and no such conflict or other inconsistency will have the effect of superseding, restricting or otherwise limiting any of the Continuing Obligations. The obligation of the Company to make payments to you under Section 5, and your right to retain those payments, are expressly conditioned upon your continued full performance of your obligations under this Agreement and of the Continuing Obligations.
	2. You agree not to disclose to any individual or entity any of the terms of, or amounts paid under, this Agreement; provided, however, that you will not be prohibited from making disclosures to your spouse or domestic partner, attorney or tax advisor.
	3. You hereby assign to the Company all right, title and interest that you have in any discovery, invention or innovation conceived or reduced to practice by you in the performance of your employment with the Company (including all intellectual property rights related to any discovery, invention or innovation), which you acknowledge and agree is solely and exclusively owned by the Company. You will cooperate and assist the Company (at the Company’s expense) in obtaining patent protection for any such discovery, invention or innovation, including executing all documents required for such purpose, and you hereby irrevocably appoint the Company as your lawful attorney-in-fact for such purpose. This Agreement will also be deemed a transfer

to the Company of, and you hereby assign to the Company, the copyright of any copyrightable subject matter created by you in the performance of your employment with the Company.

* 1. For the avoidance of doubt, (i) nothing contained in the Employment Agreement or this Agreement, or any of the Continuing Obligations, limits, restricts or in any other way affects your communicating with any governmental agency or entity, or communicating with any official or staff person of any governmental agency or entity, concerning matters relevant to that governmental agency or entity; and (ii) you will not be held criminally or civilly liable under any federal or state trade secret law for disclosing a trade secret (y) in confidence to a federal, state or local government official, either directly or indirectly, or to an attorney, solely for the purpose of reporting or investigating a suspected violation of law, or (z) in a complaint or other document filed under seal in a lawsuit or other proceeding; provided, however, that notwithstanding this immunity from liability, you may be held liable if you unlawfully access trade secrets by unauthorized means or disclose (except as permitted above) or use any trade secrets.
1. **Return of Company Documents and Other Property.** In signing this Agreement, you represent, warrant and covenant that you have returned tothe Company any and all documents, materials and information (whether in hardcopy, on electronic media or otherwise) related to the business of the Company and its Affiliates (whether present or otherwise), and all keys, access cards, credit cards, computer hardware and software, telephones and telephone-related equipment and all other property of the Company or any of its Affiliates in your possession or control. Further, you represent, warrant and covenant that you have not retained any copy or derivation of any documents, materials or information (whether in hardcopy, on electronic media or otherwise) of the Company or any of its Affiliates. Further, you represent, warrant and covenant that you have disclosed to the Company all passwords necessary or desirable to obtain access to, or that would assist in obtaining access to, all information which you have password-protected on any computer equipment, network or system of the Company or any of its Affiliates.
2. **General Release and Waiver of Claims.**
	1. You agree to and do waive any claims you may have for employment by the Company. You, on your own behalf and on behalf of your heirs, estate and beneficiaries, further do hereby release the Company, and in those capacities, any of its Affiliates, and each of their respective past, present and future officers, directors, agents, employees, shareholders, investors, employee benefit plans and their administrators, trustees or fiduciaries, insurers of any of those entities, and its and their successors and assigns and others related to those entities (collectively, the “Released Parties”) from any and all claims made, to be made, or which might have been made of whatever nature, whether known or unknown, from the beginning of time, including those that arose as a consequence of your employment with the Company, or arising out of the termination of your employment with the Company, or any act committed or omitted during or after the existence of that employment relationship, all up through and including the date on which this Agreement is executed, including, but not limited to, those which were, could have been or could be the subject of an administrative or judicial proceeding filed by you or on your behalf under federal, state or local law, whether by statute, regulation, in contract or tort, and including, but not limited to, for front pay, back pay, wages, bonus, fringe benefit, any form of discrimination, wrongful termination, tort, emotional distress, pain and suffering, breach of contract, fraud, defamation, compensatory or punitive damages, interest, attorney’s fees, reinstatement or reemployment, and any rights or claims under the Civil Rights Act of 1866, the Age Discrimination in Employment Act of 1967, 29 U.S.C. sec. 621, *et seq.*, the Older Workers Benefit Protection Act, the Americans with Disabilities Act, the Family and Medical Leave Act, the Civil Rights Act of 1964, Title VII, the Civil Rights Act of 1991, the Employee Retirement Income Security Act of 1974, the Equal Pay Act, the Worker Adjustment and Retraining Notification Act, the Massachusetts Fair Employment Practices Act (M.G.L. c.151B), the Massachusetts Civil Rights Act, the Massachusetts Equal Pay and Maternity Benefits Law, the Massachusetts Equal Rights for Elderly and Disabled Law, the Massachusetts Small Necessities Leave Act, the Massachusetts Age Discrimination Law, the Massachusetts Wage Payment Statutes (M.G.L. c.149, 148, 150), the Massachusetts Earned Sick Tim Law (MGL Ch. 149, Section 148C) and any other federal, state or local law, in each case, as amended, relating to employment, discrimination in employment, termination of employment, wages, benefits or otherwise. You acknowledge and agree that even though claims and facts in addition to those now known or believed by you to exist may subsequently be discovered, it is your intention to fully settle and release all claims you may have against the Company and the Released Parties, whether known, unknown or suspected. The Released Parties who are not party to this Agreement will be third-party beneficiaries of this Section 10(a).
	2. Notwithstanding the generality of the foregoing, you do not waive your right to (i) have a complaint, charge or related lawsuit filed with the Equal Employment Opportunity Commission (“EEOC”) or any similar state or

local governmental agency by you or by anyone on your behalf or to participate in an investigation conducted by the EEOC or any similar state or local governmental agency; however, you expressly waive your right to recover any personal relief, recovery or monies should you or anyone on your behalf pursue any of those complaints, claims or related lawsuits; or (ii) pursue a claim that cannot be waived by law, such as a claim for unemployment benefit rights.

* 1. The Company and you acknowledge and agree that the release contained in Section 10(a) above does not, and will not be construed to, release or limit the scope of any existing obligation of the Company and/or any of its Affiliates (i) if and as applicable, to indemnify you for your acts as an officer or director of the Company and/or its Affiliates in accordance with their respective charters or bylaws or under an indemnification agreement to which you and the Company or any of its Affiliates are parties or under any applicable Directors and Officers insurance policies or under any applicable law; or (ii) to you and your eligible, participating dependents or beneficiaries under the terms of any existing group welfare (excluding severance) or retirement plan of the Company in which you and/or any of those dependents or beneficiaries are participants.
	2. You acknowledge and agree that before entering into this Agreement, you have had the opportunity to consult with any attorney or other advisor of your choice, and you are hereby advised to consult with an attorney. You further acknowledge and agree that by signing this Agreement, you do so of your own free will and act, that it is your intention to be legally bound by its terms, and that no promises or representations have been made to you by any person to induce you to enter into this Agreement other than the express terms set forth herein. You further acknowledge and agree that you have carefully read this Agreement, know and understand its contents and its binding legal effect, including the waiver and release of claims set forth in Section 10(a) above.
1. **Unemployment Benefits.** To the extent permitted by applicable law, the Company will not actively contest any application you make forunemployment benefits. However, the Company will respond truthfully, completely, and timely to any inquiries by the Massachusetts Department of Unemployment Assistance or any other governmental agency or court concerning the termination of your employment.
2. **Cooperation.** Upon reasonable prior request, you agree to cooperate with the Company or its Affiliates in connection with any present or futurelitigation or regulatory proceeding brought against the Company or any of its Affiliates, to the extent the Company or its Affiliate deems your cooperation necessary. This cooperation may include, but will not be limited to, meeting with the Company’s or its Affiliate’s counsel and providing testimony if so requested. The Company or its Affiliate will reimburse you for reasonable pre-approved out-of-pocket expenses incurred by you as a result of this cooperation.
3. **No Admission; Affirmations.** Neither by offering to make nor by making this Agreement does the Company or you admit any failure ofperformance, wrongdoing or violation of law. You also affirm that you have not filed, caused to be filed, nor are you presently a party to any claim against the Company, unless noted below under your signature. You also affirm that you have been paid and/or have received all compensation, wages, bonuses, commissions and/or benefits to which you may be entitled from the Company. You further affirm that you have been granted by the Company any leave to which you were entitled under the Family and Medical Leave Act or related state or local leave or disability accommodation laws. You further affirm that you have no known workplace injuries or occupational diseases regarding your employment at the Company, unless previously reported to the Company in writing. You also affirm that you have not divulged any proprietary or confidential information of the Company and that you have disclosed to the Company any discovery, invention or innovation conceived or reduced to practice by you in the performance of your employment with the Company. You further affirm that you have not been retaliated against for reporting any allegations of wrongdoing by the Company or its officers, including any allegations of corporate fraud. You also affirm by your signature below that you are not aware of any wrongdoing, regulatory violations or corporate fraud committed by the Company, its Affiliates or any employees or independent contractors of any of the foregoing, unless previously reported to the Company in writing.
4. **Miscellaneous.**
	1. This Agreement constitutes the entire agreement between you and the Company or any of its Affiliates, and supersedes all prior and contemporaneous communications, agreements and understandings, whether written or oral, with respect to your employment, its termination and all related matters, excluding only the Continuing Obligations, which will remain in full force and effect in accordance with their terms.

1. This Agreement is a Massachusetts contract, and this Agreement (and all claims, controversies and causes of action arising under or otherwise relating to this Agreement) will be governed and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to any conflict of laws principles that would result in the application of the laws of another jurisdiction. Each party agrees to submit to the exclusive jurisdiction of the courts of the Commonwealth of Massachusetts in connection with any dispute arising out of or otherwise relating to this Agreement.
2. This Agreement may not be modified or amended, and no breach will be deemed to be waived, unless agreed to in writing by you and an expressly authorized representative of the Company. The captions and headings in this Agreement are for convenience only, and in no way define or describe the scope or content of any provision of this Agreement.
3. In the event that any one or more of the provisions of this Agreement is held to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions will not in any way be affected or impaired thereby. Moreover, if any one or more of the provisions contained in this Agreement is held to be excessively broad as to duration, scope or activity or subject, those provisions will be construed by limiting and reducing them so as to be enforceable to the maximum extent compatible with applicable law.
4. This Agreement will inure to the benefit of and be binding upon personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.
5. This Agreement, and all of your rights and duties under this Agreement, will not be assignable or delegable by you. Any purported assignment or delegation by you in violation of the foregoing will be null and void and of no force and effect. This Agreement may be assigned by the Company to an individual or entity which is an Affiliate or a successor in interest to substantially all of the business operations of the Company. Upon any assignment, the rights and obligations of the Company under this Agreement will become the rights and obligations of that Affiliate or successor individual or entity.
6. The Company’s obligation to pay you the amounts set forth under this Agreement and to make the arrangements provided under this agreement are subject to set-off, counterclaim and recoupment of amounts owed by you to the Company or its Affiliates.
7. This Agreement may be executed in separate counterparts (including by electronically delivered .pdf files or copies of manually signed signature pages), each of which will be deemed to be an original and all of which taken together will constitute one and the same agreement.

[*The remainder of page is left blank intentionally.*]

If the terms of this Agreement are acceptable to you, please sign, date and return it to me within fifty (50) days following the date of this Agreement, but in no event prior to the Separation Date. You may revoke this Agreement at any time during the seven (7)-day period immediately following the date of your signing by notifying me in writing of your revocation within that period, and this Agreement will not become effective or enforceable until that seven (7)-day revocation period has expired. If you do not revoke this Agreement, then, on the eighth (8th) day following the date that you signed it, this Agreement will take effect as a legally binding agreement between you and the Company on the basis set forth above.

Sincerely,

Lantheus medical imaging, inc.

/s/ MARY ANNE HEINO



Name: Mary Anne Heino

Title: *President and Chief Executive Officer*

*(Principal Executive Officer)*

Accepted and agreed:

/s/ TIMOTHY HEALEY



Name: Timothy Healey

Date: 9/12/2018

**Exhibit 10.2**

August 20, 2018

VIA HAND DELIVERY

Jack Crowley

c/o Lantheus Medical Imaging, Inc.

331 Treble Cove Road

North Billerica, MA 01862

Dear Jack:

This letter agreement (this “Agreement”) confirms the terms of your separation from Lantheus Medical Imaging, Inc. (the “Company”), effective as of August 20, 2018 (the “Separation Date”).

1. **Resignations.** On the Separation Date, you will be deemed to have resigned from your position as Chief Financial Officer and Treasurer and fromany and all (i) officer positions you hold with the Company or any of its Affiliates (as defined below); (ii) memberships you hold on any boards of directors, boards of managers or other governing boards or bodies of the Company or any of its Affiliates; and (iii) memberships you hold on any of the committees of any of those boards or bodies. For purposes of this Agreement, “Affiliates” means all persons and entities directly or indirectly controlling, controlled by or under common control with the Company, whether control by management authority, equity interest or otherwise.
2. **Advisory Period**. In consideration of the terms of this Agreement, you agree to be engaged by the Company as an employee beginning on theSeparation Date and continuing through September 28, 2018 (the “Advisory Period”)*.* During the Advisory Period, you will provide services on an as-requested basis and will be compensated at the same rate as your salary in effect as of immediately prior to the Separation Date. Such services will be performed at mutually agreeable times. You will not be required to be present at the Company’s offices unless requested by the Company.
3. **Final Compensation.** You will receive, on or as soon as reasonably practicable following the Separation Date, in the form of one or more payrollchecks, (i) your base salary for the final, unpaid payroll period(s) of your employment through the Separation Date; (ii) compensation at the rate of your base salary for any vacation time accrued but not used as of the Separation Date; (iii) any contributions that you have made under the Lantheus Holdings, Inc. 2017 Employee Stock Purchase Plan that are refundable to you under its terms and conditions; and (iv) reimbursement for business expenses incurred by you but not yet paid to you as of the Separation Date; provided that you submit all expenses and supporting documentation required within thirty (30) days of the Separation Date and that those expenses are reimbursable under Company policies in effect as of the Separation Date.
4. **Employee Benefits.** Except for any right you may have to continue your participation and that of your eligible dependents in the Company’s grouphealth plans under the Consolidated Omnibus Budget Reconciliation Act of 1985 (“COBRA”) or similar state law, your participation in all employee benefit plans and programs of the Company and its Affiliates will end as of the Separation Date, except for participation in the Company’s group health plans, which will end as of the last day of the month in which the Separation Date occurs. You will receive information about your COBRA continuation rights under separate cover.
5. **Equity Awards.** You hold certain equity awards granted to you by Lantheus Holdings, Inc. (“Parent”), an Affiliate of the Company, under its 2013Equity Incentive Plan and/or 2015 Equity Incentive Plan, each as amended, and the equity incentive agreements evidencing those grants entered into between you and Parent under those plans (collectively, the “Equity Agreements” and those equity awards, collectively, the “Equity Awards”). Subject to your execution of this Agreement within twenty-one (21) days following the Separation Date and your not revoking this Agreement within the seven (7)-day period immediately thereafter, and subject to your meeting in full your obligations under this Agreement and the Continuing Obligations (as defined in Section 9(a) below), the restricted stock awards set forth on Schedule A attached hereto will remain outstanding as to that number of shares, and will become freely transferable on the dates, in each case, set forth on Schedule A. You acknowledge and agree that all Equity Awards that are unvested as of the Separation Date will be forfeited (with the exception of the restricted stock awards set forth on Schedule A) for no consideration due to you on the Separation Date, and all of your then-vested Equity Awards will continue to be subject

to the terms and conditions of the applicable Equity Agreements, including the post-termination of employment exercise provisions thereof.

1. **Severance Payments.** Subject to your execution of this Agreement within twenty-one (21) days following the Separation Date and your notrevoking this Agreement within the seven (7)-day period immediately thereafter, and subject to your meeting in full your obligations under this Agreement and the Continuing Obligations (as defined in Section 9(a) below), the Company will provide you with the following:
	1. an amount equal to the sum of (x) $209,550, representing an amount equal to fifty-five percent (55%) of your annual base salary on the Separation Date, plus (y) $381,000, representing your annual base salary, which amount (i.e., the sum of clauses (x) and (y)) will be paid in substantially equal installments over a period of twelve (12) months following the Separation Date (the “Severance Period”) in accordance with the Company’s regular payroll practices, with the first payment commencing on the Company’s first payroll date after the thirtieth (30th) day following the Separation Date, and with the first payment including any of those amounts that would otherwise have been paid prior thereto; and
	2. an amount equal to $66,000, representing the cash portion of the long-term incentive plan that has been achieved based on performance through the Separation Date, which amount will be payable at the same time it is payable to the other participants in the long-term incentive plan, which is currently expected to be March 31, 2019 but in no event will be later than December 31, 2019; and
	3. provided that you timely and properly elect to purchase continued healthcare coverage under COBRA, reimbursement for COBRA benefits, in an amount representing the Company’s contribution level for active employees at the time of payment, for the period ending on the earliest of (i) the expiration of the Severance Period, (ii) the date on which you become covered under another employer’s health plan and (iii) the expiration of the maximum COBRA continuation coverage period for which you are eligible under federal law; provided that you submit supporting documentation of your payment of COBRA premiums, as provided for below, within thirty (30) days of paying such premiums (for the avoidance of doubt, you will be responsible for paying the applicable COBRA premiums directly to the Company’s COBRA administrator); and
	4. reimbursement for outplacement executive services incurred by you during the twelve (12) months following the Separation Date in an amount up to $25,000; provided that you submit such expenses and supporting documentation required within thirty (30) days of incurring such expenses.
2. **Acknowledgement of Full Payment.** You acknowledge and agree that the payments and other benefits provided under this Agreement are incomplete satisfaction of any and all compensation and benefits due to you from the Company or any of its Affiliates, whether for services provided to the Company or otherwise, through the Separation Date. You further acknowledge that, except as expressly provided under this Agreement, no further compensation or benefits are owed or will be provided to you by the Company or any of its Affiliates.
3. **Taxes and Withholding.** All payments made by the Company under this Agreement will be reduced by any tax or other amounts required to bewithheld by the Company under applicable law. In addition, on the Separation Date, the Company will withhold from the restricted stock awards that remain outstanding as set forth on Schedule A that number of shares of Parent common stock having a fair market value equal to the minimum statutory amount required by law to be withheld to satisfy the Company’s withholding obligations with respect to such restricted stock (it being understood that no such withholding shall relieve you of any tax obligations you may have with respect to such restricted stock awards). This Agreement and the payments and benefits provided under this Agreement are intended to be exempt from the requirements of Section 409A of the Internal Revenue Code of 1986, as amended (“Section 409A”), and this Agreement will be construed consistently with that intent. Without limiting the foregoing, the severance payments set forth in Section 6 of this Agreement are intended to be exempt from Section 409A as “separation pay” within the meaning of Section 1.409A-1(b)(9)(iii) of the Treasury Regulations and/or “short-term deferrals” within the meaning of Section 1.409A-1(b)(4) of the Treasury Regulations. Your right to receive any installments payments pursuant to this Agreement shall be treated as a right to receive a series of separate and distinct payments. Notwithstanding anything to the contrary, in no event will the Company have any liability relating to the failure or alleged failure of any payment or benefit under this Agreement to be exempt from the requirements of Section 409A.

1. **Continuing Obligations.**
	1. You acknowledge and recognize the highly competitive nature of the businesses of the Company and its Affiliates and, accordingly, in consideration of the severance pay and benefits set forth in Section 5 and 6 and other valuable consideration, you acknowledge and agree that you will continue to be bound by your obligations relating to confidentiality, non-competition, non-solicitation, no-hire, invention assignment, non-disparagement and/or any other restrictive covenant set forth in any agreement by and between you and the Company or any of its Affiliates, including, without limitation, those set forth in Sections 9-11 of the employment agreement, effective as of August 12, 2013, between you and the Company (as amended, the “Employment Agreement”) (all such obligations, collectively, the “Continuing Obligations”). Each of the Continuing Obligations is an individual right, separately enforceable by the Company and/or its applicable Affiliate(s), notwithstanding any conflict or other inconsistency among any provisions (or any parts of any provisions) of any of the Continuing Obligations, and no such conflict or other inconsistency will have the effect of superseding, restricting or otherwise limiting any of the Continuing Obligations. The obligation of the Company to make payments and provide the benefits described under Sections 5 and 6, and your right to retain those payments and benefits, are expressly conditioned upon your continued full performance of your obligations under this Agreement and of the Continuing Obligations.
	2. You hereby assign to the Company all right, title and interest that you have in any discovery, invention or innovation conceived or reduced to practice by you in the performance of your employment with the Company (including all intellectual property rights related to any discovery, invention or innovation), which you acknowledge and agree is solely and exclusively owned by the Company. You will cooperate and assist the Company (at the Company’s expense) in obtaining patent protection for any such discovery, invention or innovation, including executing all documents required for such purpose, and you hereby irrevocably appoint the Company as your lawful attorney-in-fact for such purpose. This Agreement will also be deemed a transfer to the Company of, and you hereby assign to the Company, the copyright of any copyrightable subject matter created by you in the performance of your employment with the Company.
	3. For the avoidance of doubt, (i) nothing contained in the Employment Agreement or this Agreement, or any of the Continuing Obligations, limits, restricts or in any other way affects your communicating with any governmental agency or entity, or communicating with any official or staff person of any governmental agency or entity, concerning matters relevant to that governmental agency or entity; and (ii) you will not be held criminally or civilly liable under any federal or state trade secret law for disclosing a trade secret (y) in confidence to a federal, state or local government official, either directly or indirectly, or to an attorney, solely for the purpose of reporting or investigating a suspected violation of law, or (z) in a complaint or other document filed under seal in a lawsuit or other proceeding; provided, however, that notwithstanding this immunity from liability, you may be held liable if you unlawfully access trade secrets by unauthorized means or disclose (except as permitted above) or use any trade secrets.
2. **Return of Company Documents and Other Property.** In signing this Agreement, you represent, warrant and covenant that you have returned tothe Company any and all documents, materials and information (whether in hardcopy, on electronic media or otherwise) related to the business of the Company and its Affiliates (whether present or otherwise), and all keys, access cards, credit cards, computer hardware and software, telephones and telephone-related equipment and all other property of the Company or any of its Affiliates in your possession or control. Further, you represent, warrant and covenant that you have not retained any copy or derivation of any documents, materials or information (whether in hardcopy, on electronic media or otherwise) of the Company or any of its Affiliates. Further, you represent, warrant and covenant that you have disclosed to the Company all passwords necessary or desirable to obtain access to, or that would assist in obtaining access to, all information which you have password-protected on any computer equipment, network or system of the Company or any of its Affiliates.
3. **General Release and Waiver of Claims.**
	1. You agree to and do waive any claims you may have for employment by the Company. You, on your own behalf and on behalf of your heirs, estate and beneficiaries, further do hereby release the Company, and in those capacities, any of its Affiliates, and each of their respective past, present and future officers, directors, agents, employees, shareholders, investors, employee benefit plans and their administrators, trustees or fiduciaries, insurers of any of those entities, and its and their successors and assigns and others related to those entities (collectively, the “Released Parties”) from any and all claims made, to be made, or which might have been made of whatever nature, whether known or unknown, from the beginning of time, including those that arose as a

consequence of your employment with the Company, or arising out of the termination of your employment with the Company, or any act committed or omitted during or after the existence of that employment relationship, all up through and including the date on which this Agreement is executed, including, but not limited to, those which were, could have been or could be the subject of an administrative or judicial proceeding filed by you or on your behalf under federal, state or local law, whether by statute, regulation, in contract or tort, and including, but not limited to, for front pay, back pay, wages, bonus, fringe benefit, any form of discrimination, wrongful termination, tort, emotional distress, pain and suffering, breach of contract, fraud, defamation, compensatory or punitive damages, interest, attorney’s fees, reinstatement or reemployment, and any rights or claims under the Civil Rights Act of 1866, the Age Discrimination in Employment Act of 1967, 29 U.S.C. sec. 621, *et seq.*, the Older Workers Benefit Protection Act, the Americans with Disabilities Act, the Family and Medical Leave Act, the Civil Rights Act of 1964, Title VII, the Civil Rights Act of 1991, the Employee Retirement Income Security Act of 1974, the Equal Pay Act, the Worker Adjustment and Retraining Notification Act, the Massachusetts Fair Employment Practices Act (M.G.L. c.151B), the Massachusetts Civil Rights Act, the Massachusetts Equal Pay and Maternity Benefits Law, the Massachusetts Equal Rights for Elderly and Disabled Law, the Massachusetts Small Necessities Leave Act, the Massachusetts Age Discrimination Law, the Massachusetts Wage Payment Statutes (M.G.L. c.149, 148, 150), the Massachusetts Earned Sick Tim Law (MGL Ch. 149, Section 148C) and any other federal, state or local law, in each case, as amended, relating to employment, discrimination in employment, termination of employment, wages, benefits or otherwise. You acknowledge and agree that even though claims and facts in addition to those now known or believed by you to exist may subsequently be discovered, it is your intention to fully settle and release all claims you may have against the Company and the Released Parties, whether known, unknown or suspected. The Released Parties who are not party to this Agreement will be third-party beneficiaries of this Section 11(a).

* 1. Notwithstanding the generality of the foregoing, you do not waive your right to (i) have a complaint, charge or related lawsuit filed with the Equal Employment Opportunity Commission (“EEOC”) or any similar state or local governmental agency by you or by anyone on your behalf or to participate in an investigation conducted by the EEOC or any similar state or local governmental agency; however, you expressly waive your right to recover any personal relief, recovery or monies should you or anyone on your behalf pursue any of those complaints, claims or related lawsuits; or (ii) pursue a claim that cannot be waived by law, such as a claim for unemployment benefit rights.
	2. The Company and you acknowledge and agree that the release contained in Section 11(a) above does not, and will not be construed to, release or limit the scope of any existing obligation of the Company and/or any of its Affiliates (i) if and as applicable, to indemnify you for your acts as an officer or director of the Company and/or its Affiliates in accordance with their respective charters or bylaws or under an indemnification agreement to which you and the Company or any of its Affiliates are parties or under any applicable Directors and Officers insurance policies or under any applicable law; or (ii) to you and your eligible, participating dependents or beneficiaries under the terms of any existing group welfare (excluding severance) or retirement plan of the Company in which you and/or any of those dependents or beneficiaries are participants with respect vested benefits under such plans.
	3. You acknowledge and agree that before entering into this Agreement, you have had the opportunity to consult with any attorney or other advisor of your choice, and you are hereby advised to consult with an attorney. You further acknowledge and agree that by signing this Agreement, you do so of your own free will and act, that it is your intention to be legally bound by its terms, and that no promises or representations have been made to you by any person to induce you to enter into this Agreement other than the express terms set forth herein. You further acknowledge and agree that you have carefully read this Agreement, know and understand its contents and its binding legal effect, including the waiver and release of claims set forth in Section 11(a) above.
1. **Unemployment Benefits.** To the extent permitted by applicable law, the Company will not actively contest any application you make forunemployment benefits. However, the Company will respond truthfully, completely, and timely to any inquiries by the Massachusetts Department of Unemployment Assistance or any other governmental agency or court concerning the termination of your employment.
2. **Cooperation.** Upon reasonable prior request, you agree to cooperate with the Company or its Affiliates in connection with any present or futurelitigation or regulatory proceeding brought against the Company or any of its Affiliates, to the extent the Company or its Affiliate deems your cooperation necessary. This cooperation may include, but will not be limited to, meeting with the Company’s or its Affiliate’s counsel and providing testimony if so requested. The Company

or its Affiliate will reimburse you for reasonable pre-approved out-of-pocket expenses incurred by you as a result of this cooperation.

1. **No Admission; Affirmations.** Neither by offering to make nor by making this Agreement does the Company or you admit any failure ofperformance, wrongdoing or violation of law. You also affirm that you have been paid and/or have received all compensation, wages, bonuses, commissions and/or benefits to which you may be entitled from the Company. You further affirm that you have been granted by the Company any leave to which you were entitled under the Family and Medical Leave Act or related state or local leave or disability accommodation laws. You further affirm that you have no known workplace injuries or occupational diseases regarding your employment at the Company, unless previously reported to the Company in writing. You also affirm that you have not divulged any proprietary or confidential information of the Company and that you have disclosed to the Company any discovery, invention or innovation conceived or reduced to practice by you in the performance of your employment with the Company. You further affirm that you have not been retaliated against for reporting any allegations of wrongdoing by the Company or its officers, including any allegations of corporate fraud. You also affirm by your signature below that you are not aware of any wrongdoing, regulatory violations or corporate fraud committed by the Company, its Affiliates or any employees or independent contractors of any of the foregoing, unless previously reported to the Company in writing.
2. **Miscellaneous.**
	1. This Agreement constitutes the entire agreement between you and the Company or any of its Affiliates, and supersedes all prior and contemporaneous communications, agreements and understandings, whether written or oral, with respect to your employment, its termination and all related matters, excluding only the Continuing Obligations, which will remain in full force and effect in accordance with their terms.
	2. This Agreement is a Massachusetts contract, and this Agreement (and all claims, controversies and causes of action arising under or otherwise relating to this Agreement) will be governed and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to any conflict of laws principles that would result in the application of the laws of another jurisdiction. Each party agrees to submit to the exclusive jurisdiction of the courts of the Commonwealth of Massachusetts in connection with any dispute arising out of or otherwise relating to this Agreement.
	3. This Agreement may not be modified or amended, and no breach will be deemed to be waived, unless agreed to in writing by you and an expressly authorized representative of the Company. The captions and headings in this Agreement are for convenience only, and in no way define or describe the scope or content of any provision of this Agreement.
	4. In the event that any one or more of the provisions of this Agreement is held to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions will not in any way be affected or impaired thereby. Moreover, if any one or more of the provisions contained in this Agreement is held to be excessively broad as to duration, scope or activity or subject, those provisions will be construed by limiting and reducing them so as to be enforceable to the maximum extent compatible with applicable law.
	5. This Agreement (including, without limitation, the Company’s obligation to make severance payments and restricted stock awards as specifically provided herein) will remain and inure to the benefit of and be binding upon personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.
	6. This Agreement, and all of your rights and duties under this Agreement, will not be assignable or delegable by you. Any purported assignment or delegation by you in violation of the foregoing will be null and void and of no force and effect. This Agreement may be assigned by the Company to an individual or entity which is an Affiliate or a successor in interest to substantially all of the business operations of the Company. Upon any assignment, the rights and obligations of the Company under this Agreement will become the rights and obligations of that Affiliate or successor individual or entity.
	7. The Company’s obligation to pay you the amounts set forth under this Agreement and to make the arrangements provided under this agreement are subject to set-off, counterclaim and recoupment of amounts owed by you to the Company or its Affiliates.

1. This Agreement may be executed in separate counterparts (including by electronically delivered .pdf files or copies of manually signed signature pages), each of which will be deemed to be an original and all of which taken together will constitute one and the same agreement.

[*The remainder of page is left blank intentionally.*]

If the terms of this Agreement are acceptable to you, please sign, date and return it to me within twenty-one (21) days following the date of this Agreement, but in no event prior to the Separation Date. You may revoke this Agreement at any time during the seven (7)-day period immediately following the date of your signing by notifying me in writing of your revocation within that period, and this Agreement will not become effective or enforceable until that seven

(7)-day revocation period has expired. If you do not revoke this Agreement, then, on the eighth (8th) day following the date that you signed it, this Agreement will take effect as a legally binding agreement between you and the Company on the basis set forth above.

Sincerely,

Lantheus medical imaging, inc.

/s/ MARY ANNE HEINO



Name: Mary Anne Heino

Title: *President and Chief Executive Officer*

*(Principal Executive Officer)*

Accepted and agreed:

/s/ JOHN W. CROWLEY



Name: John W. Crowley

Date: 9/2018

Schedule A

Subject to the terms and conditions of this Agreement, the following restricted stock awards shall remain outstanding after the Separation Date as to that number of shares set forth below and shall become freely transferable by you in accordance with the schedule below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  | **Date on Which** |  |
|  |  |  | **Restrictions on** |  |
| **Equity Award** | **Grant Date** | **Grant ID** | **Transferability Lapse\*** | **Number of Shares** |
| **Unvested restricted stock** | 09/01/2015 | [LRSA15] | 09/01/2018 | 10,000 |
| **Unvested restricted stock** | 09/01/2015 | [LRSA15] | 09/01/2019 | 10,000 |
|  |  |  |  |  |
| **Unvested restricted stock** | 04/06/2015 | [LRSA15] | 01/30/2019 | 5,338 |
| **Unvested restricted stock** | 04/26/2016 | [LRSA15] | 04/26/2019 | 15,500 |
|  |  |  |  |  |

\*Until the date listed above, with respect to the restricted stock listed opposite such date, you may not sell, transfer, pledge, hypothecate or otherwise dispose of such shares of restricted stock; provided, however, that this restriction shall not apply following a Change in Control (as defined in Parent’s 2015 Equity Incentive Plan). The Company shall retain the certificates representing shares of restricted stock (or, with respect to uncertificated shares, impose transfer restrictions thereon) until the applicable date set forth in the table above with respect to the restricted stock listed opposite such date.

**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: October 30, 2018

/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, Robert J. Marshall, Jr., 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: October 30, 2018

/s/ ROBERT J. MARSHALL, JR.



Name: Robert J. Marshall, Jr.

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 Robert J. Marshall, Jr., 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, 2018 (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: October 30, 2018

/s/ MARY ANNE HEINO



Name: Mary Anne Heino

Title: *President and Chief Executive Officer*

*(Principal Executive Officer)*

Date: October 30, 2018

/s/ ROBERT J. MARSHALL, JR.



Name: Robert J. Marshall, Jr.

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.