

---

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

---

**FORM 10-K**

---

(Mark One)

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

For the fiscal year ended December 31, 2014

**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 333-169785

---

**LANTHEUS MEDICAL IMAGING, INC.**

(Exact name of registrant as specified in its charter)

---

Delaware  
(State of incorporation)  
331 Treble Cove Road, North Billerica, MA  
(Address of principal executive offices)

51-0396366  
(IRS Employer Identification No.)  
01862  
(Zip Code)

(978) 671-8001  
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: None

---

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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 if disclosure of delinquent filers pursuant to item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this form 10-K or any amendment to this form 10-K

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>

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

The registrant is a privately-held corporation, and accordingly, as of June 30, 2014, there is no public market for its common stock. The registrant had one thousand shares of common stock, \$0.01 par value per share, issued and outstanding as of March 4, 2015.

---

---

---

[Table of Contents](#)

**EXPLANATORY NOTE**

The registrant has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, during the preceding 12 months but is not subject to such filing requirements.

---

[Table of Contents](#)

TABLE OF CONTENTS

	<u>Page</u>
<b>PART I</b>	
Item 1. <a href="#">Business</a>	3
Item 1A. <a href="#">Risk Factors</a>	26
Item 1B. <a href="#">Unresolved Staff Comments</a>	51
Item 2. <a href="#">Properties</a>	51
Item 3. <a href="#">Legal Proceedings</a>	52
Item 4. <a href="#">Mine Safety Disclosures</a>	52
<b>PART II</b>	
Item 5. <a href="#">Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</a>	53
Item 6. <a href="#">Selected Financial Data</a>	53
Item 7. <a href="#">Management’s Discussion and Analysis of Financial Condition and Results of Operations</a>	56
Item 7A. <a href="#">Quantitative and Qualitative Disclosures About Market Risk</a>	83
Item 8. <a href="#">Financial Statements and Supplementary Data</a>	85
Item 9. <a href="#">Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</a>	129
Item 9A. <a href="#">Controls and Procedures</a>	129
Item 9B. <a href="#">Other Information</a>	129
<b>PART III</b>	
Item 10. <a href="#">Directors, Executive Officers and Corporate Governance</a>	130
Item 11. <a href="#">Executive Compensation</a>	135
Item 12. <a href="#">Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</a>	150
Item 13. <a href="#">Certain Relationships and Related Transactions, and Director Independence</a>	150
Item 14. <a href="#">Principal Accountant Fees and Services</a>	152
<b>PART IV</b>	
Item 15. <a href="#">Exhibits and Financial Statement Schedules</a>	153

## PART I

### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements contained in this annual report are forward-looking statements. These forward-looking statements, including, in particular, statements about our plans, strategies, prospects and industry estimates are subject to risks and uncertainties. These statements identify prospective information and include words such as “anticipates,” “intends,” “plans,” “seeks,” “believes,” “estimates,” “expects,” “should,” “could,” “predicts,” “hopes” and similar expressions. Examples of forward-looking statements include, but are not limited to, statements we make regarding: (i) outlook and expectations related to products manufactured at Jubilant HollisterStier, or JHS, and Pharmedica and global isotope supply; (ii) our outlook and expectations including, without limitation, in connection with continued market expansion and penetration for our commercial products, particularly DEFINITY in the face of increased competition; (iii) our outlook and expectations related to our intention to seek to engage strategic partners to assist in developing and potentially commercializing development candidates; and (iv) our liquidity, including our belief that our existing cash, cash equivalents, anticipated revenues and availability under our revolving credit facility are sufficient to fund our existing operating expenses, capital expenditures and liquidity requirements for at least the next twelve months. Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. The matters referred to in the forward-looking statements contained in this annual report 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 dependence upon third parties for the manufacture and supply of a substantial portion of our products;
- risks associated with the technology transfer programs to secure production of our products at alternate contract manufacturer sites;
- risks associated with the manufacturing and distribution of our products and the regulatory requirements related thereto;
- the instability of the global Molybdenum-99, or Moly, supply;
- our ability to continue to increase segment penetration for DEFINITY in suboptimal echocardiograms and the increased segment competition from other echocardiography contrast agents, including Optison from GE Healthcare and the newly approved Lumason (known as SonoVue outside of the U.S.) from Bracco Diagnostics, Inc., or Bracco;
- risks associated with supply and demand for Xenon;
- our dependence on key customers and group purchasing organization arrangements for our medical imaging products, and our ability to maintain and profitably renew our contracts and relationships with those key customers and group purchasing organizations including our relationship with Cardinal Health, or Cardinal;
- our ability to compete effectively, including in connection with pricing pressures and new market entrants;
- the dependence of certain of our customers upon third party healthcare payors and the uncertainty of third party coverage and reimbursement rates;
- uncertainties regarding the impact of U.S. healthcare reform on our business, including related reimbursements for our current and potential future products;

---

## [Table of Contents](#)

- our being subject to extensive government regulation and our potential inability to comply with those regulations;
- potential liability associated with our marketing and sales practices;
- the occurrence of any side effects with our products;
- our exposure to potential product liability claims and environmental liability;
- risks associated with our lead agent in development, flupiridaz F 18, including our ability to:
  - attract strategic partners to successfully complete the Phase 3 clinical program and possibly commercialize the agent;
  - obtain U.S. Food and Drug Administration, or FDA, approval; and
  - gain post-approval market acceptance and adequate reimbursement;
- risks associated with being able to negotiate in a timely manner relationships with potential strategic partners to advance our other development programs on acceptable terms, or at all;
- the extensive costs, time and uncertainty associated with new product development, including further product development relying on external development partners;
- our inability to introduce new products and adapt to an evolving technology and diagnostic landscape;
- our inability to protect our intellectual property and the risk of claims that we have infringed on the intellectual property of others;
- risks related to our outstanding indebtedness and our ability to satisfy those obligations;
- risks associated with prevailing economic conditions and financial, business and other factors beyond our control;
- risks associated with our international operations;
- our inability to adequately protect our facilities, equipment and technology infrastructure;
- our inability to hire or retain skilled employees and key personnel;
- costs and other risks associated with the Sarbanes-Oxley Act and the Dodd-Frank Act; and
- other factors that are described in “Risk Factors,” beginning on page 22.

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

### **Trademarks**

We own or have the rights to various trademarks, service marks and trade names, including, among others, the following: DEFINITY®, TechneLite®, Cardiolite®, Neurolite®, Ablavar®, Vialmix®, Quadramet® (United States only) and Lantheus Medical Imaging® referred to in this annual report. Solely for convenience, we refer to trademarks, service marks and trade names in this annual report without the TM, SM and ® symbols. Those references are not intended to indicate, in any way, that we will not assert, to the fullest extent permitted under applicable law, our rights to our trademarks, service marks and trade names. Each trademark, trade name or service mark of any other company appearing in this annual report, such as Lumason®, Myoview®, Optison® and SonoVue® are, to our knowledge, owned by that other company.

---

## [Table of Contents](#)

### **Item 1. Business**

*Unless the context requires otherwise, references to the “Company,” “Lantheus,” “LMI,” “our company,” “we,” “us” and “our” refer to Lantheus Medical Imaging, Inc. and its direct and indirect subsidiaries, references to “Lantheus Intermediate” refer to only Lantheus MI Intermediate, Inc., the parent of Lantheus, and references to “Holdings” refer only to Lantheus Holdings, Inc., the parent of Lantheus Intermediate.*

#### **Overview**

We are a global leader in developing, manufacturing, selling and distributing innovative diagnostic medical imaging agents and products that assist clinicians in the diagnosis of cardiovascular and other diseases. Our agents are routinely used to diagnose coronary artery disease, congestive heart failure, stroke, peripheral vascular disease and other diseases. Clinicians use our imaging agents and products across a range of imaging modalities, including nuclear imaging, echocardiography and magnetic resonance imaging, or MRI. We believe that the resulting improved diagnostic information enables healthcare providers to better detect and characterize, or rule out, disease, potentially achieving improved patient outcomes, reducing patient risk and limiting overall costs for payers and the entire healthcare system.

Our commercial products are used by nuclear physicians, cardiologists, radiologists, internal medicine physicians, technologists and sonographers working in a variety of clinical settings. We sell our products to radiopharmacies, hospitals, clinics, group practices, integrated delivery networks, group purchasing organizations and, in certain circumstances, wholesalers. We sell our products globally and have operations in the United States, Puerto Rico, Canada and Australia and distribution relationships in Europe, Asia Pacific and Latin America.

#### **Our Products**

Our portfolio of 10 commercial products is diversified across a range of imaging modalities. Our products include medical radiopharmaceuticals (including technetium generators) and contrast agents. Radiopharmaceuticals, or nuclear imaging agents, are radiolabeled compounds that are used by clinicians to perform nuclear imaging procedures, such as Single Photon Emission Computed Tomography, or SPECT, and positron emission tomography, or PET. Technetium generators are used to prepare the radioactive Technetium (Tc99m) isotope that is combined with organ-localizing pharmaceuticals to create the most commonly used radiopharmaceuticals in diagnostic medicine. Contrast agents are typically non-radiolabeled compounds used by physicians to improve the clarity of the diagnostic image in diagnostic procedures such as echocardiograms or MRIs.

#### ***DEFINITY***

DEFINITY is the leading ultrasound contrast imaging agent based on revenue and usage and, in the United States, is indicated for use in patients with suboptimal echocardiograms. Numerous patient conditions can decrease the quality of images of the left ventricle, the primary pumping chamber of the heart. Of the approximately 30 million echocardiograms performed each year in the United States, a third party source estimates that approximately 20%, or approximately 6.0 million echocardiograms, produce suboptimal images. The use of DEFINITY during echocardiography allows physicians to significantly improve their assessment of the function of the left ventricle.

DEFINITY is a clear, colorless, sterile liquid, which, upon activation in the Vialmix apparatus, a medical device specifically designed for DEFINITY, becomes a homogenous, opaque, milky white injectable suspension of perflutren-containing lipid microspheres. After activation and intravenous injection, DEFINITY improves the ultrasound delineation of the left ventricular endocardial border, or innermost layer of tissue that lines the chamber of the left ventricle. Better visualization of the ventricle wall allows clinicians to see wall motion abnormalities, namely that the heart muscle is not expanding and contracting in a normal, consistent and predictable way. We believe this allows clinicians to make more informed decisions about disease status.

---

## [Table of Contents](#)

DEFINITY offers flexible dosing and administration through an IV bolus injection or continuous IV infusion. We believe DEFINITY's synthetic lipid-cased coating gives the compound a distinct competitive advantage, because it provides a strong ultrasound signal without using human albumin.

Since its launch in 2001, DEFINITY has been used in imaging procedures in approximately five million patients throughout the world. In 2014, DEFINITY was the leading ultrasound imaging agent based on revenue and usage, used by echocardiologists and sonographers. We estimate that DEFINITY had approximately 78% share of the market for contrast agents in the United States as of December 2014. DEFINITY currently competes with Optison, a GE Healthcare product, Lumason, a newly-approved Bracco product (known as SonoVue outside the U.S.) as well as other non-echocardiography imaging modalities. DEFINITY, Optison and Lumason all carry an FDA-required boxed warning, which has been modified over time, to notify physicians and patients about potentially serious safety concerns or risks posed by the products. See "Risk Factors—Ultrasound contrast agents may cause side effects which could limit our ability to sell DEFINITY."

DEFINITY is currently patent protected in the United States until 2021 and in numerous foreign jurisdictions with patent or regulatory protection until 2019, and we have an active life cycle management program for this agent. DEFINITY generated revenues of \$95.8 million, \$78.1 million and \$51.4 million for the years ended December 31, 2014, 2013 and 2012, respectively. DEFINITY represented approximately 32%, 28% and 18% of our revenues in 2014, 2013 and 2012, respectively.

### *TechneLite*

TechneLite is a self-contained system or generator of Technetium (Tc99m), a radioactive isotope with a six hour half-life, used by radiopharmacies to prepare various nuclear imaging agents. Technetium results from the radioactive decay of Moly, itself a radioisotope with a 66-hour half-life produced in nuclear research reactors around the world from enriched uranium. The TechneLite generator is a little larger than a coffee can in size and the self-contained system houses a vertical glass column at its core that contains Moly. During our manufacturing process, Moly is added to the column within the generator where it is adsorbed onto alumina powder. The column is sterilized, enclosed in a lead shield and further sealed in a cylindrical plastic container, which is then immediately shipped to our radiopharmacy customers. Because of the short half-lives of Moly and technetium, radiopharmacies typically purchase TechneLite generators on a weekly basis pursuant to standing orders.

The technetium produced by our TechneLite generator is the medical radioisotope that can be attached to a number of imaging agents, including our own Cardiolite products and Neurolite, during the labeling process. To radiolabel a technetium-based radiopharmaceutical, a vial of sterile saline and a vacuum vial are each affixed to the top of a TechneLite generator. The sterile saline is pulled through the generator where it attracts technetium resulting from the radioactive decay of Moly within the generator column. The technetium-containing radioactive saline is then pulled into the vacuum vial and subsequently combined by a radiopharmacist with the applicable imaging agent, and individual patient-specific radiolabeled imaging agent doses are then prepared. When administered, the imaging agent binds to specific tissues or organs for a period of time, enabling the technetium to illustrate the functional health of the imaged tissues or organs in a diagnostic image. Our ability to produce and market TechneLite is highly dependent on our supply of Moly. See "—Raw Materials and Supply Relationships—Molybdenum-99."

TechneLite is produced in thirteen sizes and is currently marketed in North America, Latin America and Australia, largely to radiopharmacies that prepare unit doses of radiopharmaceutical imaging agents and that ship these preparations directly to hospitals for administration to patients. In the United States, we have supply contracts with significant radiopharmacy chains, including United Pharmacy Partners, or UPPI, and GE Healthcare. We also supply generators on a purchase order basis with other customers. In 2014, we believe TechneLite had approximately 43% of the U.S. generator market share, competing primarily with technetium-based generators produced by Mallinckrodt Pharmaceuticals, or Mallinckrodt. In Canada and Puerto Rico, we also supply TechneLite to our Company-owned radiopharmacies to prepare radiopharmaceutical imaging agent unit doses.

---

## [Table of Contents](#)

The Moly used in our TechneLite generators can be produced using targets made of either highly-enriched uranium, or HEU, or low-enriched uranium, or LEU. LEU consists of uranium that contains less than 20% of the uranium-235 isotope. HEU is often considered weapons grade material, with 20% or more of uranium-235. On January 2, 2013, President Obama signed into law the American Medical Isotopes Production Act of 2011, or AMIPA, as part of the 2013 National Defense Authorization Act. AMIPA encourages the domestic production of LEU Moly and provides for the eventual prohibition of the export of HEU from the United States. Although Medicare generally does not provide separate payment to hospitals for the use of diagnostic radiopharmaceuticals administered in an outpatient setting, since January 1, 2013, the Centers for Medicare and Medicaid Services, or CMS, the federal agency responsible for administering the Medicare program, has provided an add-on payment under the hospital outpatient prospective payment system for every technetium diagnostic dose produced from non-HEU sourced Moly, to cover the marginal cost for radioisotopes produced from non-HEU sources. Our LEU TechneLite generator satisfies the new reimbursement requirements under the applicable CMS rules.

TechneLite has patent protection in the United States and various foreign countries on certain component technology currently expiring in 2029. In addition, given the significant know-how and trade secrets associated with the methods of manufacturing and assembling the TechneLite generator, we believe we have a substantial amount of valuable and defensible proprietary intellectual property associated with the product. We believe that our substantial capital investments in our highly automated TechneLite production line and our extensive experience in complying with the stringent regulatory requirements for the handling of nuclear materials create significant and sustainable competitive advantages for us in generator manufacturing and distribution. TechneLite generated revenues of \$93.6 million, \$92.2 million and \$114.2 million for the years ended December 31, 2014, 2013 and 2012, respectively. TechneLite represented approximately 31%, 33% and 40% of our revenues in 2014, 2013 and 2012, respectively.

### *Xenon Xe 133 Gas*

Xenon is a radiopharmaceutical gas that is inhaled and used to assess pulmonary function and also to image blood flow. Our Xenon is manufactured by a third party as part of the Moly production process and packaged by us. We are currently the leading provider of Xenon in the United States. In 2014, 2013 and 2012, Xenon Xe 133 Gas represented approximately 12%, 11% and 10%, respectively, of our revenues.

### **Other Commercial Products**

In addition to the products listed above, our portfolio of commercial products also includes important imaging agents in specific segments, which provide a stable base of recurring revenue. Most of these products have a favorable industry position as a result of our substantial infrastructure investment, our specialized workforce, our technical know-how and our supplier and customer relationships.

- **Cardiolite**, also known by its generic name sestamibi, is an injectable, technetium-labeled imaging agent used in myocardial perfusion imaging, or MPI, procedures to assess blood flow to the muscle of the heart using SPECT. Cardiolite was approved by the FDA in 1990 and its market exclusivity expired in July 2008. With the advent of generic competition in September 2008, we have faced significant pricing and unit volume pressures on Cardiolite. We also sell Cardiolite in the form of a generic sestamibi at a lower price than branded Cardiolite. Cardiolite represented approximately 6%, 9% and 12% of our revenues in 2014, 2013 and 2012, respectively. Included in Cardiolite revenues are branded Cardiolite and generic sestamibi revenues, some of which we produce and some of which we procure from third parties from time to time.
- **Neurolite** is an injectable, technetium-labeled imaging agent used with SPECT technology to identify the area within the brain where blood flow has been blocked or reduced due to stroke. We launched Neurolite in 1995.
- **Thallium Tl 201** is an injectable radiopharmaceutical imaging agent used in MPI studies to detect coronary artery disease. We have marketed Thallium since 1977 and manufacture the agent using cyclotron technology.



## Table of Contents

- **Gallium Ga 67** is an injectable radiopharmaceutical imaging agent used to detect certain infections and cancerous tumors, especially lymphoma. We manufacture Gallium using cyclotron technology.
- **Gludéf** is an injectable, fluorine-18-radiolabeled imaging agent used with PET technology to identify and characterize tumors in patients undergoing oncologic diagnostic procedures. Gludéf is our branded version of fluorodeoxyglucose, or FDG.
- **Quadramet**, our only therapeutic product, is an injectable radiopharmaceutical used to treat severe bone pain associated with certain kinds of cancer. Previously, we served as a contract manufacturer of Samarium 153, the radioisotope used to prepare Quadramet. Effective December 13, 2013, we purchased the rights to Quadramet in the United States and now serve as the direct manufacturer and supplier of Quadramet in the United States.
- **Ablavar** is an injectable, gadolinium-based contrast agent used with magnetic resonance angiography, or MRA, a type of MRI scan, to image the iliac arteries that start at the aorta and go through the pelvis into the legs, in order to diagnose narrowing or blockage of these arteries in known or suspected peripheral vascular disease. We launched Ablavar in January 2010.

For revenue and other financial information for our U.S. and International segments, see Note 18, “Segment Information” to our consolidated financial statements.

### Distribution, Marketing and Sales

The following table sets forth certain key market information for each of our commercial products:

Product	Currently Marketed	Regulatory Approval, but Not Currently Marketed
DEFINITY	United States, Canada, Australia, New Zealand, Mexico	EU, Israel, India, South Korea, Singapore <sup>(1)</sup>
TechneLite	United States, Canada, Caribbean Islands, Colombia, Costa Rica, Taiwan	Korea, Mexico, Panama, Australia
Xenon Xe 133 Gas	United States, Taiwan	Mexico, New Zealand, Australia, Panama
Cardiolite	United States, Canada, Certain EU countries <sup>(2)</sup> , Brazil, Israel, Japan, South Korea, Mexico, Taiwan, Thailand, Japan, Australia, New Zealand, Slovenia, Hong Kong, Philippines	Denmark, Malta
Neurolite	United States, Canada, Japan, Hong Kong, Mexico, Philippines, Australia, New Zealand, Thailand	South Korea, Europe <sup>(3)</sup> , Slovenia, Taiwan
Thallium Tl 201	United States, Canada, Australia, South Korea, Pakistan, Panama, Taiwan	Mexico, New Zealand
Gallium Ga67	United States, Canada, Australia, Costa Rica, South Korea, Panama, Taiwan, New Zealand	Mexico
Gludéf	Puerto Rico, Canada (Gludéf)	None
Quadramet	United States	None
Ablavar	United States, Canada	Australia

---

## [Table of Contents](#)

- (1) In addition, we have applied for regulatory approval in China, and JHS is pending approval in India and South Korea.
- (2) Cardiolite is currently marketed in Austria, Belgium, Finland, France, Germany, Italy, Luxembourg, Norway, Slovenia, Spain, Sweden and the United Kingdom.
- (3) JHS has regulatory approval pending for Neurolite in Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Italy, Luxembourg, Norway, Slovenia, Spain and Sweden.

In the United States, we sell DEFINITY through our sales team of approximately 80 employees that call on healthcare providers in the echocardiography space, as well as group purchasing organizations and integrated delivery networks. In 2013, we transitioned the sales and marketing efforts for Ablavar from our sales team to our customer service team in order to allow our sales team to focus exclusively on driving our DEFINITY sales growth. For the year ended December 31, 2014, DEFINITY sales represented approximately 32% of our revenues.

Our radiopharmaceutical products are sold in the United States through a small nuclear products sales team, primarily to radiopharmacies. We sell a majority of our radiopharmaceutical products in the United States to radiopharmacies that are controlled by or associated with UPPI, GE Healthcare and Cardinal. Our contractual distribution and other arrangements with these radiopharmacy groups are as follows:

- UPPI is a cooperative purchasing group (roughly analogous to a group purchasing organization) of approximately 77 independently owned or smaller chain radiopharmacies located in the United States. UPPI's radiopharmacies are typically broadly dispersed geographically, with some urban presence and a substantial number of radiopharmacies located in suburban and rural areas of the country. We estimate that these independent radiopharmacies, together with an additional 36 unofficial, independent radiopharmacies, distributed more than 25% of the aggregate U.S. SPECT doses sold in the first half of 2014. We currently have an agreement with UPPI for the distribution of both Cardiolite and TechnoLite products to radiopharmacies or families of radiopharmacies within the UPPI cooperative purchasing group. The agreement contains specified pricing levels based upon specified purchase amounts for UPPI. We are entitled to terminate the UPPI agreement upon 60 days' written notice. The UPPI agreement expires on December 31, 2016.
- GE Healthcare maintains 31 radiopharmacies in the United States that purchase our TechnoLite generators. These radiopharmacies primarily distribute GE Healthcare's Myoview, a technetium-labeled MPI agent. We estimate that GE Healthcare distributed approximately 15% of the aggregate U.S. SPECT doses sold in the first half of 2014. We currently have one agreement with GE Healthcare for the distribution of TechnoLite and other products. The agreement provides that GE Healthcare will purchase a minimum percentage of TechnoLite generators as well as certain other products in the United States or Canada from us. Our agreement, which expires on December 31, 2017, may be terminated by either party on (i) two years' written notice relating to TechnoLite and (ii) six months' written notice relating to the other products. Our agreement also allows for termination upon the occurrence of specified events including a material breach by either party, bankruptcy by either party and force majeure events.
- Cardinal maintains approximately 132 radiopharmacies that are typically located in large, densely populated urban areas in the United States. We estimate that Cardinal's radiopharmacies distributed approximately 44% of the aggregate U.S. SPECT doses sold in the first half of 2014 (the latest information currently available to us). Our written supply agreements with Cardinal relating to TechnoLite, Xenon, Neurolite, Cardiolite and certain other products expired in accordance with their terms on December 31, 2014. Following extended discussions with Cardinal that have not yet resulted in one or more new written supply agreements, we are currently accepting and fulfilling product orders from Cardinal on a purchase order basis at list price. We cannot predict the volumes or product mix Cardinal will continue to order and purchase, and such volumes and product mix may vary over time. In the absence of written supply agreements with Cardinal, unit sales volumes in early 2015 have

---

## [Table of Contents](#)

decreased from levels experienced throughout 2014, but such sales have been at substantially higher prices. However, ultimate future levels of net revenue and operating profit associated with Cardinal cannot be predicted at this time because such amounts depend on future unit sales volumes, product mix and pricing to Cardinal.

In addition to the distribution arrangements for our radiopharmaceutical products described above, we also sell certain of our radiopharmaceutical products to Triad, independent radiopharmacies and directly to hospitals and clinics that maintain in-house radiopharmaceutical capabilities and operations. In the latter case, this represents a small percentage of overall sales because the majority of hospitals and clinics do not maintain these in-house capabilities.

In Europe, Asia Pacific and Latin America, we utilize third party distributor relationships to market, sell and distribute our products, either on a country-by-country basis or on a multicountry regional basis. In October 2013, we entered into a new supply and distribution agreement for Cardiolite and Neurolite in certain European countries with Mallinckrodt AG. In March 2015, we terminated that agreement. In March 2012, we entered into a new development and distribution arrangement for DEFINITY in China, Hong Kong S.A.R. and Macau S.A.R. with Double-Crane Pharmaceutical Company, or Double-Crane. Double-Crane is currently pursuing the Chinese regulatory approval required to commence the necessary confirmatory clinical trials. There are three milestones in the regulatory approval process to commercialize DEFINITY in China:

- First, submission of a Clinical Trial Application which seeks Import Drug License approval. Double-Crane submitted the Clinical Trial Application to the Chinese Food and Drug Administration, or CFDA, in June 2013. The CFDA accepted the Clinical Trial Application for review in July 2013.
- Second, approval of the Clinical Trial Application, at which point Double-Crane would conduct two small confirmatory clinical trials—one for abdominal (liver and kidney) and one for cardiac.
- Third, approval of the Import Drug License. If the regulatory and clinical trial processes are both successful, we currently estimate the timing for approval of DEFINITY in China could be as soon as 2017.

We believe that international markets, particularly China, represent significant growth opportunities for our products. The Mallinckrodt and Double-Crane distribution agreements did not have a significant impact on our revenue during 2014.

We sell our products (and others) directly to end users through the four radiopharmacies we own in Canada, the two radiopharmacies we own in Australia and the two radiopharmacies we own in Puerto Rico. We also maintain our own direct sales forces in these markets so we can control the marketing, distribution and sale of our imaging agents in these regions.

### **Customers**

For the year ended December 31, 2014, our largest customers were Cardinal, UPPI and GE Healthcare, accounting for 18.0%, 11.1% and 8.8%, respectively, of our revenues.

### **Competition**

We believe that our key product characteristics, such as proven efficacy, reliability and safety, coupled with our core competencies, such as our efficient manufacturing processes, our established distribution network, our experienced field sales organization and our customer service focus, are important factors that distinguish us from our competitors.

The market for diagnostic medical imaging agents is highly competitive and continually evolving. Our principal competitors in existing diagnostic modalities include large, global companies that are more diversified

---

## [Table of Contents](#)

than we are and that have substantial financial, manufacturing, sales and marketing, distribution and other resources. These competitors include Mallinckrodt, GE Healthcare, Bayer, Bracco and Draxis, as well as other competitors. We cannot anticipate their competitive actions in the same or competing diagnostic modalities, such as significant price reductions on products that are comparable to our own, development of new products that are more cost-effective or have superior performance than our current products or the introduction of generic versions after our proprietary products lose their current patent protection. In addition, distributors of our products could attempt to shift end-users to competing diagnostic modalities and products. Our current or future products could be rendered obsolete or uneconomical as a result of these activities.

Generic competition has substantially eroded our market share for Cardiolite, beginning in September 2008 when the first generic product was launched. We are currently aware of four separate, third party generic offerings of sestamibi. We also sell our own generic version of sestamibi. See “Item 1A—Risk Factors—Generic competition has significantly eroded our market share of the MPI segment for Cardiolite products and will continue to do so.”

### **Raw Materials and Supply Relationships**

We rely on certain raw materials and supplies to produce our products. Due to the specialized nature of our products and the limited, and sometimes intermittent, supply of raw materials available in the market, we have established relationships with several key suppliers. Our most important and widely used raw material is Moly. For the year ended December 31, 2014, our largest supplier of raw materials and supplies was Nordion, accounting for approximately 16% of our total purchases.

#### ***Molybdenum-99***

Our TechnoLite, Cardiolite and Neurolite products all rely on Moly, the radioisotope which is produced by bombarding Uranium-235 with neutrons in research reactors. Moly is the most common radioisotope used for medical diagnostic imaging purposes. With a 66-hour half-life, Moly decays into among other things technetium-99m, (Tc-99m), another radioisotope with a half-life of six hours. Tc-99m is the isotope that is attached to radiopharmaceuticals, including our own Cardiolite and Neurolite, during the labeling process.

We currently purchase finished Moly from four of the five main processing sites in the world, namely, ANSTO in Australia; Institute for Radioelements or IRE, in Belgium; Nordion, formerly known as MDS Nordion, in Canada; and NTP Radioisotopes, or NTP, in South Africa. These processing sites are, in turn, supplied by seven of the eight main Moly-producing reactors in the world, namely, OPAL in Australia; BR2 in Belgium; OSIRIS in France; LVR-10 in the Czech Republic; High Flux Reactor, or HFR, in The Netherlands; NRU in Canada; and SAFARI in South Africa.

Historically, our largest supplier of Moly has been Nordion, which relies on the NRU reactor for its supply of Moly. Our agreement with Nordion contains minimum percentage purchase requirements for Moly. The agreement allows for termination upon the occurrence of certain events. Nordion can terminate if we fail to purchase a minimum percentage of Moly or if Nordion incurs certain cost increases. Either party may terminate if the other party fails to comply with material obligations, is bankrupt or experiences a force majeure event subject to a waiting period. The current agreement expires on December 31, 2015, and the NRU reactor has announced a transition in 2016 from providing regular supply of medical isotopes to providing only emergency back-up supply of medical isotopes through March 2018.

Our agreement with NTP includes their consortium partner, ANSTO. ANSTO has under construction, in cooperation with NTP, a new Moly processing facility that ANSTO believes will expand its production capacity by approximately 2.5 times, with expanded commercial production planned to start in mid-2016. This new ANSTO production capacity is expected to replace the NRU’s current routine production. The NTP/ANSTO agreement contains minimum percentage volume requirements and provides for the increased supply of Moly

---

## [Table of Contents](#)

derived from LEU targets from NTP and ANSTO. The agreement allows for termination upon the occurrence of certain events, including failure by NTP to provide our required amount of Moly, material breach of any provision by either party, bankruptcy by either party and force majeure events. Additionally, we have the ability to terminate the agreement with six months' written notice prior to the expiration of the agreement. The agreement expires on December 31, 2017.

In March 2013, we entered into a similar agreement with IRE, or the IRE Agreement. IRE previously supplied us as a subcontractor under the agreement with NTP. Similar to the agreement with NTP, the IRE Agreement contains minimum percentage volume requirements. The IRE Agreement also requires IRE to provide certain increased quantities of Moly during periods of supply shortage or failure. The IRE Agreement also provides for an increased supply of Moly derived from LEU targets upon IRE's completion of its ongoing conversion program to modify its facilities and processes in accordance with Belgian nuclear security commitments. The IRE Agreement allows for termination upon the occurrence of certain events, including failure by IRE to provide our required amount of Moly, material breach of any provision by either party, bankruptcy by either party and force majeure events. The IRE Agreement expires on December 31, 2017.

To further augment and diversify our current supply, we are pursuing additional sources of Moly from potential new producers around the world that seek to produce Moly with existing or new reactors or technologies. For example, in November 2014, we announced entering into a new strategic agreement with SHINE Medical Technologies, Inc., a Wisconsin-based company, or 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 currently estimates will occur in 2018. See "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, with the required timeframe, or at all, which could result in order cancellations and decreased revenues."

### ***Xenon***

Currently, Nordion is our sole supplier of Xenon, and we believe it is currently the principal supplier of Xenon in the world. Xenon is captured by the NRU reactor as a by-product of the Moly production process. Our agreement with Nordion is on a purchase order basis. As a result of this transaction, our supplier could change the terms on which we obtain Xenon. In January 2015, we announced entering into a new strategic agreement with IRE for the future supply of Xenon. Under the terms of the agreement, IRE will provide bulk Xenon to us for processing and finishing once development work has been completed and all necessary regulatory approvals have been obtained. We currently estimate commercial production will occur in 2016. If we are not able to begin providing commercial quantities of Xenon prior to the NRU reactor's announced medical isotope supply transition in October 2016, there may be a period of time during which we are not able to offer Xenon in our portfolio of commercial products. See "Item 1A—Risk Factors—We face potential supply and demand challenges for Xenon."

### ***Other Materials***

We have additional supply arrangements for APIs, excipients, packaging materials and other materials and components, none of which are exclusive, but a number of which are sole source, and all of which we currently believe are either in good standing or replaceable without any material disruption to our business.

### **Manufacturing**

We maintain manufacturing operations at our North Billerica, Massachusetts facility. We manufacture TechneLite on a highly automated production line and also manufacture Thallium and Gallium at this site using

---

## [Table of Contents](#)

our cyclotron infrastructure. We manufacture, finish and distribute our radiopharmaceutical products on a just-in-time basis, and supply our customers with these products either by next day delivery services or by either ground or air custom logistics. We believe that our substantial capital investments in our highly automated generator production line, our cyclotrons and our extensive experience in complying with the stringent regulatory requirements for the handling of nuclear materials and operations in the FDA regulated environment create significant and sustainable competitive advantages for us.

In addition to our in-house manufacturing capabilities, a substantial portion of our products are manufactured by third party contract manufacturing organizations, and in certain instances, we rely on them for sole source manufacturing. To ensure the quality of the products that are manufactured by third parties, the key raw materials used in those products are first sent to our North Billerica facility, where we test them prior to the third party manufacturing of the final product. After the final products are manufactured, they are sent back to us for final quality control testing and then we ship them to our customers. We have expertise in the design, development and validation of complex manufacturing systems and processes, and our strong execution and quality control culture supports the just-in-time manufacturing model at our North Billerica facility.

### ***BVL, JHS and Pharmalucence***

Historically, we relied on Ben Venue Laboratories, or BVL, as our sole manufacturer of DEFINITY, NeuroLite and evacuation vials, an ancillary component for our TechnoLite generators, and as one of our two manufacturers of Cardiolite. Following extended operational and regulatory challenges at BVL's Bedford, Ohio facility, in March 2012, we entered into a settlement arrangement with BVL, resulting in an aggregate payment to us of \$35.0 million, a broad mutual waiver and a covenant by us not to sue. Later in 2012 and in 2013, BVL continued to attempt to manufacture our products for us, and in October 2013 announced that it would cease to manufacture new batches of our products at its Bedford, Ohio facility. In November 2013, we entered into a second settlement arrangement with BVL, resulting in an additional aggregate payment to us of \$8.9 million, a broad mutual waiver and a covenant by us not to sue. At this time, we have a very limited amount of BVL-manufactured products in our finished goods inventory.

Contemporaneous with the BVL supply challenges, we expedited a number of technology transfer programs to secure and qualify production of our BVL-manufactured products from alternate contract manufacturer sites.

- *DEFINITY*—We entered into a Manufacturing and Supply Agreement, effective as of February 1, 2012, with JHS, for the manufacture of DEFINITY. Under the agreement, JHS manufactures DEFINITY for us for an initial term of five years. We have the right to extend the agreement for an additional five-year period, with automatic renewals for additional one year periods thereafter. The agreement allows for termination upon the occurrence of certain events such as a material breach or default by either party, or bankruptcy by either party. The agreement also requires us to place orders for a minimum percentage of our requirements for DEFINITY with JHS.

On November 12, 2013, we entered into a Manufacturing and Supply Agreement with Pharmalucence to manufacture and supply DEFINITY and we are currently in the technology transfer process with Pharmalucence in order to diversify our supply. We currently believe that Pharmalucence will file for FDA approval to manufacture DEFINITY in 2015. There are no minimum purchase requirements under this agreement, which has an initial term of five years from the effective date and is renewable at our option for an additional five years. The Manufacturing Agreement allows for termination upon the occurrence of certain events, including material breach or bankruptcy by either party. During the optional five year term, either party may terminate upon thirty months advance notice. Based on our current projections, we believe that we will have sufficient supply of DEFINITY from JHS to meet expected demand.

- *Cardiolite*—We currently have one manufacturer for our Cardiolite supply. We also entered into a Manufacturing and Supply Agreement, effective as of May 3, 2012, with JHS for the manufacture of

---

## [Table of Contents](#)

Cardiolite products, and we are currently in the technology transfer process. Under the agreement, JHS has agreed to manufacture product for an initial term of five years. We have the right to extend the agreement for an additional five-year period, with automatic renewals for additional one year periods thereafter. The agreement allows for termination upon the occurrence of specified events, including material breach or bankruptcy by either party. The agreement requires us to place orders for a minimum percentage of our requirements for Cardiolite with JHS during such term. Based on our current projections, we believe that we will have sufficient Cardiolite product supply from our current supplier and JHS when it has completed the technology transfer process and we have obtained regulatory approval for this manufacturing site to meet expected demand.

- *Neurolite*—We entered into a Manufacturing and Supply Agreement, effective as of May 3, 2012, with JHS for the manufacture of Neurolite, and in January 2015 the FDA granted approval to JHS to be a new manufacturing site for this product. Under the agreement, JHS has agreed to manufacture product for an initial term of five years. We have the right to extend the agreement for an additional five-year period, with automatic renewals for additional one year periods thereafter. The agreement allows for termination upon the occurrence of specified events, including material breach or bankruptcy by either party. The agreement also requires us to place orders for a minimum percentage of our requirements for Neurolite with JHS during such term. Based on our current projections, we believe that we will have sufficient supply of Neurolite from JHS to meet expected demand.

Although we are pursuing new manufacturing relationships to establish and secure additional long-term or alternative suppliers as described above, we are uncertain of the timing as to when these arrangements could provide meaningful quantities of product. See “Item 1A—Risk Factors—Risks Relating to Our Business and Industry—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 timeframes, or at all, which could result in order cancellations and decreased revenues,” “Item 1A—Risk Factors—with product quality or product performance, including defects, caused by us or our suppliers could result in a decrease in customers and sales, unexpected expenses and loss of market share” and “Item 1A—Risk Factors—Our business and industry are subject to complex and costly regulations. If government regulations are interpreted or enforced in a manner adverse to us or our business, we may be subject to enforcement actions, penalties, exclusion and other material limitations on our operations.”

### ***PET Manufacturing Facilities***

If flurpiridaz F 18 is ultimately successful in clinical trials, a new manufacturing model will have to be implemented where chemical ingredients of the imaging agent are provided to PET radiopharmacies that have fluorine-18 radioisotope-producing cyclotrons on premises. The radiopharmacies will combine these chemical ingredients with fluorine-18 they manufactured in specially designed chemistry synthesis boxes to generate the final radiopharmaceutical imaging agent, flurpiridaz F 18. Radiopharmacists will be able to prepare and dispense patient-specific doses from the final product. However, because each of these PET radiopharmacies will be deemed by the FDA to be a separate manufacturing site for flurpiridaz F 18, each of the radiopharmacies will have to be included in the agent’s NDA and subsequent FDA filings. As a result, there will be quality and oversight responsibilities of the PET radiopharmacies associated with the NDA, unlike the current relationship we have with our nuclear imaging agent distributors that operate radiopharmacies. See “—Research and Development—Flurpiridaz F 18 Phase 3 Program.”

### **Research and Development**

For the years ended December 31, 2014, 2013 and 2012, we invested \$13.7 million, \$30.5 million and \$40.6 million, respectively, in R&D. Our R&D team includes our medical affairs and medical information functions, which educate physicians on the scientific aspects of our commercial products and the approved indications, labeling and the receipt of reports relating to product quality or adverse events. We have developed a

---

## [Table of Contents](#)

pipeline of three potential cardiovascular imaging agents which were discovered and developed in-house and which are protected by patents and patent applications we own in the United States and numerous foreign jurisdictions.

In March 2013, we began to implement a strategic shift in how we will fund our important R&D programs. We have reduced our internal R&D resources while at the same time we seek to engage strategic partners to assist us in the further development and commercialization of these agents, including flurpiridaz F 18, 18F LMI 1195 and LMI 1174. See “Item 1A—Risk Factors—Risks Relating to our Business and Industry—We will not be able to further develop or commercialize our agents in development without successful strategic partners.”

### ***Flurpiridaz F 18—PET Perfusion Agent—Myocardial Perfusion***

We have developed flurpiridaz F 18, an internally discovered small molecule radiolabeled with fluorine-18, as an imaging agent used in PET MPI to assess blood flow to the heart.

Today, most MPI procedures use SPECT technology. Although this imaging modality provides substantial clinical value, there is growing interest in the medical community to utilize technology such as PET that can provide meaningful advantages. PET is an imaging technology that when used in combination with an appropriate radiopharmaceutical imaging agent can provide important insights into physiologic and metabolic processes in the body and be useful in evaluating a variety of conditions including neurological disease, heart disease and cancer. PET imaging has demonstrated broad utility for diagnosis, prognosis, disease staging and therapeutic response. Images generated with PET technology typically exhibit very high image resolution because of substantially higher signal-to-noise efficiency, a measure of the efficiency by which energy can be captured to create an image.

Although SPECT imaging used in conjunction with a radiopharmaceutical imaging agent, such as Cardiolite, is most commonly used for MPI studies, PET imaging has gained considerable support in the field of cardiovascular imaging as it offers many advantages to SPECT imaging, including: higher image quality, increased diagnostic certainty, more accurate risk stratification and reduced patient radiation exposure. In addition, PET MPI imaging could be particularly useful in difficult to image patients, including women and obese patients. The use of PET technology in MPI tests represents a broad emerging application for a technology more commonly associated with oncology and neurology. We anticipate that the adoption of PET technology in MPI tests will increase significantly in the future.

### ***Flurpiridaz F 18 Clinical Overview***

We submitted an Investigational New Drug Application, or IND, for flurpiridaz F 18 to the FDA in August 2006. Our clinical program to date has consisted of three Phase 1 studies, a Phase 2 clinical trial, conducted from 2007 to 2010, involving a total of 208 subjects who received PET MPI performed with flurpiridaz F 18 and a Phase 3 clinical trial conducted from 2011 to 2013 involving 920 subjects who received PET MPI procedures with flurpiridaz F 18.

### ***Flurpiridaz F 18 Phase 2 Trial***

We evaluated flurpiridaz F 18 in a Phase 2 trial consisting of 176 subjects from 21 centers. These subjects underwent both SPECT and PET MPI with flurpiridaz at rest and at stress and were evaluated for safety. Of these subjects, 86 underwent coronary angiography, the current standard clinical method for diagnosing coronary artery disease. Coronary angiography is an invasive procedure using fluoroscopy performed in a cardiac catheterization lab while the subject is under mild sedation. These 86 subjects formed the population for evaluating diagnostic performance.



---

## [Table of Contents](#)

The PET MPI that was performed with flurpiridaz F 18 at stress utilized either pharmacological coronary vasodilation or treadmill exercise. Unlike currently available PET imaging agents for MPI with half-lives measured in seconds, flurpiridaz F 18 can be used in conjunction with treadmill exercise given its substantially longer 110 minute half-life.

The Phase 2 trial results showed the following:

- a significantly higher percentage of images were rated as either excellent or good quality with PET imaging, compared to SPECT imaging for stress images (98.8% vs. 84.9%,  $p < 0.01$ ) and rest images (95.3% vs. 69.8%,  $p < 0.01$ );
- diagnostic certainty of interpretation, the percentage of cases with definitely abnormal or definitely normal interpretation, was significantly higher for flurpiridaz F 18 compared to SPECT (90.7% vs. 75.6%,  $p < 0.01$ );
- the area under the ROC curve (the relative operating characteristic curve comparing the true positive rate to the false positive rate for coronary artery disease diagnosis) was significantly higher for flurpiridaz F 18 than SPECT ( $0.82 \pm 0.05$  vs.  $0.70 \pm 0.05$ ,  $p < 0.05$ ), indicating higher diagnostic performance;
- superiority for sensitivity (that is, the ability to identify disease) with flurpiridaz F 18 imaging was significantly higher than SPECT (78.8% vs. 61.5%,  $p = 0.02$ );
- a trend toward higher specificity (that is, the ability to rule out disease) was noted, although the advantage was not statistically significant in the study; and
- no drug-related serious adverse events were observed, demonstrating a positive safety profile for PET MPI imaging with flurpiridaz F 18.

### ***Flurpiridaz F 18 Phase 3 Program***

To date, our Phase 3 program for flurpiridaz F 18 has included a phase 3 trial (study 301), which was an open-label, multicenter, international trial to assess the diagnostic efficacy of flurpiridaz F 18 PET MPI, as compared with SPECT MPI, in the detection of significant coronary artery disease. Coronary angiography was used as the truth standard for all subjects. The clinical development program included hypotheses for superiority for sensitivity (identifying disease) and non-inferiority for specificity (ruling out disease) with SPECT.

In March 2011, we obtained agreement from the FDA on a Special Protocol Assessment, or SPA, for our 301 trial. See “Business—Regulatory Matters—Food and Drug Laws.”

During the third quarter of 2013, we completed patient enrollment in the 301 trial. In the fourth quarter of 2013, we announced preliminary results from the 301 trial. Flurpiridaz F 18 appeared to be well-tolerated from a safety perspective and outperformed SPECT in a highly statistically significant manner in the co-primary endpoint of sensitivity. In addition, flurpiridaz F 18 showed statistically significant improvements in the secondary endpoints of image quality and diagnostic certainty in comparison to SPECT. However, flurpiridaz F 18 did not meet its other co-primary endpoint of non-inferiority for identifying subjects without disease.

In the fourth quarter of 2014, we completed a re-read of the 301 trial results, which confirmed the consistency and reproducibility of the flurpiridaz F 18 results when compared to coronary angiography, the truth standard. For the overall population, the re-read results comparing flurpiridaz F 18 against SPECT for sensitivity and specificity were similar to the results in the initial read. However, in certain populations of special clinical interest, the re-read results improved versus the initial read. Flurpiridaz F 18 outperformed SPECT in women and in subjects with high body mass index, or BMI, in a statistically and clinically significant manner. In addition, flurpiridaz F 18 showed statistical superiority versus SPECT in accuracy, diagnostic certainty and image quality in the overall population and in those of clinical interest. Importantly, flurpiridaz studies exposed patients to approximately 50% of the radiation exposure of SPECT.

---

## [Table of Contents](#)

In agreement with FDA, we are currently finalizing the study design of a second phase 3 trial (study 303) with new primary and secondary endpoints and have submitted an SPA to the Agency in February 2015. At the same time, we are seeking strategic partners to further develop and, if approved, commercialize flurpiridaz F 18. See “Item 1A—Risk Factors—The process of developing new drugs and obtaining regulatory approval is complex, time-consuming and costly, and the outcome is not certain.”

### ***18F LMI 1195—Cardiac Neuronal Activity Imaging Agent***

We have developed 18F LMI 1195, also an internally discovered small molecule that is a fluorine-18-based radiopharmaceutical imaging agent, designed to assess cardiac sympathetic nerve function with PET. Sympathetic nerve activation increases the heart rate, constricts blood vessels and raises blood pressure by releasing a neurotransmitter called norepinephrine throughout the heart. Changes in the cardiac sympathetic nervous system have been associated with heart failure progression and fatal arrhythmias.

Heart failure is a major public health problem in North America, associated with high morbidity and mortality, frequent hospitalizations and a major cost burden on the community. In the United States alone, there are over five million patients living with congestive heart failure, and over a half million new diagnoses each year. Mortality for this condition is around 50% within five years of diagnosis. Expensive therapies for heart failure are often utilized without effective predictors of patient response. Costly device therapies (for example, implantable cardiac defibrillators, or ICDs, and cardiac resynchronization therapy) are often used, although they sometimes do not provide any benefits or are activated in only a minority of recipients. Conversely, heart failure clinical practice guidelines currently preclude the use of device therapy in many patients who might benefit. Thus, a key opportunity is to better match patients to treatment based on the identification of the underlying molecular status of disease progression.

18F LMI 1195 is taken up by the transporter that regulates norepinephrine released by the sympathetic nervous system at multiple nerve endings of the heart. PET imaging using 18F LMI 1195 could allow for the identification of patients at risk of sudden death, potentially improving clinical decision-making, including identifying which patients could benefit from certain drug therapies or the implantation of certain anti-arrhythmia devices such as ICDs.

We have completed a Phase 1 study of 18F LMI 1195 using PET imaging. 12 normal subjects were injected intravenously with approximately six millicuries of 18F LMI 1195, imaged sequentially for a period of approximately five hours and monitored closely to observe any potential adverse events. Excellent quality images were obtained, and the radiation dose to the subjects was found to be well within acceptable limits. Blood radioactivity cleared quickly and lung activity was low throughout the study. The agent appeared to have a favorable safety profile. We are seeking to engage strategic partners to assist us with the ongoing development activities relating to this agent.

### ***LMI 1174—Vascular Remodeling Imaging Agent***

We have developed LMI 1174, an internally discovered gadolinium-based MRI agent targeted to elastin in the arterial walls and atherosclerotic plaque. We believe that this agent could allow assessment of plaque location, burden, type of arterial wall remodeling and, as a result, the potential for a vascular event, which, in turn, could lead to heart attack or stroke.

Atherosclerosis is the leading cause of heart attacks, strokes and peripheral vascular disease. Elastin plays a key role in the structure of the arterial wall and in biological signaling functions. Several pathological stimuli may be responsible for triggering elastogenesis in atherosclerosis, leading to a marked increase in elastin content during plaque development. In addition to the increase in elastin seen in autopsy samples from patients with carotid atherosclerosis, there is also an increase of elastin in aortic aneurysm samples. As a result, an elastin-specific imaging agent may facilitate detection of remodeling of the arterial walls.

---

## [Table of Contents](#)

The majority of the assessments of atherosclerosis are currently obtained using angiography or MPI. MRI using LMI 1174 could allow for the identification, on a minimally-invasive basis without radiation exposure, of the presence and characteristics of atherosclerosis, potentially improving clinical decision-making to reduce the risks of cardiovascular events.

In our preclinical work, we have identified a series of low molecular weight molecules that bind to elastin and final optimization is ongoing. Our lead molecule, LMI 1174, has been used to demonstrate utility in a number of different animal models. We are seeking to engage strategic partners to assist us with the ongoing development activities relating to this agent.

### **Intellectual Property**

Patents, trademarks and other intellectual property rights, both in the United States and foreign countries, are very important to our business. We also rely on trade secrets, manufacturing know-how, technological innovations and licensing agreements to maintain and improve our competitive position. We review third party proprietary rights, including patents and patent applications, as available, in an effort to develop an effective intellectual property strategy, avoid infringement of third party proprietary rights, identify licensing opportunities and monitor the intellectual property owned by others. Our ability to enforce and protect our intellectual property rights may be limited in certain countries outside the United States, which could make it easier for competitors to capture market position in those countries by utilizing technologies that are similar to those developed or licensed by us. Competitors also may harm our sales by designing products that mirror the capabilities of our products or technology without infringing our intellectual property rights. If we do not obtain sufficient protection for our intellectual property, or if we are unable to effectively enforce our intellectual property rights, our competitiveness could be impaired, which would limit our growth and future revenue.

#### ***Trademarks, Service Marks and Trade Names***

We own various trademarks, service marks and trade names, including DEFINITY, TechneLite, Cardiolite, Neurolite, Ablavar, Vialmix, Quadramet (U.S. only) and Lantheus Medical Imaging. We have registered these trademarks, as well as others, in the United States and numerous foreign jurisdictions.

#### ***Patents***

We actively seek to protect the proprietary technology that we consider important to our business, including chemical species, compositions and formulations, their methods of use and processes for their manufacture, as new intellectual property is developed. In addition to seeking patent protection in the United States, we file patent applications in numerous foreign countries in order to further protect the inventions that we consider important to the development of our international business. We also rely upon trade secrets and contracts to protect our proprietary information. As of January 31, 2015, our patent portfolio included a total of 44 issued U.S. patents, 194 issued foreign patents, 19 pending patent applications in the United States and 148 pending foreign applications. These patents include claims covering the composition of matter and methods of use for all of our preclinical and clinical stage agents.

Our patents cover many of our commercial products, and our current patent protection is generally in the United States, Canada, Mexico, most of Western Europe and Scandinavia (including Austria, Belgium, Denmark, Finland, France, Germany, Great Britain, Italy, Luxembourg, Netherlands, Norway, Spain, Switzerland and Sweden), and markets in Asia (including China, Hong Kong, Japan, Singapore and South Korea) and Latin America (including Chile and Brazil). For DEFINITY, we hold a number of different compositions of matter, use, formulation and manufacturing patents, with U.S. patent protection until 2021 and patent or regulatory extension protection in Canada, Europe and parts of Asia until 2019, and we have an active life cycle management program for this agent. TechneLite currently has patent protection in the United States and various foreign countries on certain component technology expiring in 2029. In addition, given the significant know-how

---

## [Table of Contents](#)

and trade secrets associated with the methods of manufacturing and assembling the TechnoLite generator, we believe we have a substantial amount of valuable and defensible proprietary intellectual property associated with the product. Neither Cardiolite nor Neurolite is covered any longer by patent protection in either the United States or the rest of the world. For Ablavar, we hold a number of different compositions of matter, use, formulation and manufacturing patents, with the last U.S. patent not expiring until 2020 with regulatory extension and a manufacturing patent application, which if granted, will expire in 2034 in the absence of any patent term adjustment or regulatory extension. Thallium, Gallium and Xenon are all generic radiopharmaceuticals.

We have numerous patents and patent applications relating to our clinical development pipeline. We have patents in numerous jurisdictions covering composition, use, formulation and manufacturing of flurpiridaz F 18, including in the United States a composition patent expiring in 2026 and a method of use patent expiring in 2028 in the absence of any regulatory extension, and various patent applications, one of which, if granted, will expire in 2033. We also have patents and patent applications in numerous jurisdictions covering composition, use, and synthesis of 18F LMI 1195, our cardiac neuronal imaging agent, some of which, if granted, will expire in 2027 and some in 2031 in the absence of any patent term adjustment or regulatory extensions, in the United States a composition patent expiring in 2030 in the absence of any regulatory extension, and in Europe a composition patent expiring in 2027 in the absence of any regulatory extension. Additionally, we have patent applications in numerous jurisdictions covering composition, use and synthesis of LMI 1174, our vascular remodeling imaging agent, some of which if granted, will expire in 2029 and some in 2030 in the absence of any patent term adjustment or regulatory extensions and in the United States a composition and method of use patent expiring in 2031 in the absence of any regulatory extension.

In addition to patents, we rely where necessary upon unpatented trade secrets and know-how, proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our collaborators, employees, consultants and other third parties and invention assignment agreements with our employees. These confidentiality agreements may not prevent unauthorized disclosure of trade secrets and other proprietary information, and we cannot assure you that an employee or an outside party will not make an unauthorized disclosure of our trade secrets, other technical know-how or proprietary information. We may not have adequate monitoring abilities to discover, or adequate remedies for, any unauthorized disclosure. This might happen intentionally or inadvertently. It is possible that a competitor will make use of such information, and that our competitive position will be compromised, in spite of any legal action we might take against persons making such unauthorized disclosures. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

In addition, we license a limited number of third party technologies and other intellectual property rights that are incorporated into some elements of our drug discovery and development efforts. These licenses are not material to our business, and the technologies can be obtained from multiple sources. We are currently party to separate royalty-free, non-exclusive, cross-licenses with each of Bracco, GE Healthcare and Imcor Pharmaceutical Company. These cross-licenses give us freedom to operate in connection with contrast enhanced ultrasound imaging technology. We also in-license certain freedom to operate rights for Ablavar from, among others, Bayer.

---

## [Table of Contents](#)

### **Regulatory Matters**

#### *Food and Drug Laws*

The development, manufacture, sale and distribution of our products are subject to comprehensive governmental regulation both within and outside the United States. A number of factors substantially increase the time, difficulty and costs incurred in obtaining and maintaining the approval to market newly developed and existing products. These factors include governmental regulation, such as detailed inspection of and controls over research and laboratory procedures, clinical investigations, manufacturing, marketing, sampling, distribution, import and export, record keeping and storage and disposal practices, together with various post-marketing requirements. Governmental regulatory actions can result in the seizure or recall of products, suspension or revocation of the authority necessary for their production and sale as well as other civil or criminal sanctions.

Our activities in the development, manufacture, packaging or repackaging of our pharmaceutical and medical device products subjects us to a wide variety of laws and regulations. We are required to register for permits and/or licenses with, seek approvals from and comply with operating and security standards of the FDA, the U.S. Nuclear Regulatory Commission, or the NRC, the U.S. Department of Health and Human Services, or the HHS, Health Canada, the European Medicines Agency, or the EMA, the U.K. Medicines and Healthcare Products Regulatory Agency, or MHRA, the CFDA and various state and provincial boards of pharmacy, state and provincial controlled substance agencies, state and provincial health departments and/or comparable state and provincial agencies, as well as foreign agencies, and certain accrediting bodies depending upon the type of operations and location of product distribution, manufacturing and sale.

The FDA and various state regulatory authorities regulate the research, testing, manufacture, safety, labeling, storage, recordkeeping, premarket approval, marketing, advertising and promotion, import and export and sales and distribution of pharmaceutical products in the United States. Prior to marketing a pharmaceutical product, we must first receive FDA approval. Specifically, in the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the Public Health Service Act, and implementing regulations. The process of obtaining regulatory approvals and compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Currently, the process required by the FDA before a drug product may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices regulations;
- submission to the FDA of an IND which must become effective before human clinical studies may begin;
- performance of adequate and well-controlled human clinical studies according to Good Clinical Practices and other requirements, to establish the safety and efficacy of the proposed drug product for its intended use;
- submission to the FDA of a New Drug Application, or NDA, for a new drug;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug product is produced to assess compliance with current Good Manufacturing Practices, or cGMPs, regulations; and
- FDA review and approval of the NDA.

The testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approvals for our agents in development will be granted on a timely basis, if at all. Once a pharmaceutical agent is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity, formulation, and stability, as well as animal studies to assess its potential safety and efficacy. This testing culminates in the submission of the IND to the FDA.

---

## [Table of Contents](#)

Once the IND becomes effective, the clinical trial program may begin. Each new clinical trial protocol must be submitted to the FDA before the study may begin. Human clinical studies are typically conducted in three sequential phases that may overlap or be combined:

Phase 1. The agent is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the agent may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with those diseases.

Phase 2. Involves studies in a limited patient population to identify possible adverse effects and safety risks, to evaluate preliminarily the efficacy of the agent for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.

Phase 3. Clinical studies are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to collect sufficient safety and effectiveness data to support the NDA for FDA approval.

Clinical trial sponsors may request an SPA from the FDA. The FDA's SPA process creates a written agreement between the sponsoring company and the FDA regarding the clinical trial design and other clinical trial issues that can be used to support approval of an agent. The SPA is intended to provide assurance that, if the agreed-upon clinical trial protocols are followed and the trial endpoints are achieved, then the data may serve as the primary basis for an efficacy claim in support of an NDA. However, the SPA agreement is not a guarantee of an approval of an agent or any permissible claims about the agent. In particular, the SPA is not binding on the FDA if public health concerns become evident that are unrecognized at the time that the SPA agreement is entered into, other new scientific concerns regarding product safety or efficacy arise, or if the clinical trial sponsor fails to comply with the agreed upon clinical trial protocols.

Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. Submissions must also be made to inform the FDA of certain changes to the clinical trial protocol. Federal law also requires the sponsor to register the trials on public databases when they are initiated, and to disclose the results of the trials on public databases upon completion. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the clinical trial sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, any institutional review board, or IRB, serving any of the institutions participating in the clinical trial can suspend or terminate approval of a clinical study at a relevant institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the agent has been associated with unexpected serious harm to patients. Failure to register a clinical trial or disclose study results within the required time periods could result in penalties, including civil monetary penalties.

Concurrent with clinical studies, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the agent and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the agent does not undergo unacceptable deterioration over its shelf life.

The results of product development, preclinical studies and clinical studies, along with descriptions of the manufacturing process, analytical tests conducted on the drug product, proposed labeling, and other relevant information, are submitted to the FDA as part of an NDA for a new drug, requesting approval to market the agent. The submission of an NDA is subject to the payment of a substantial user fee, pursuant to the Prescription

---

## [Table of Contents](#)

Drug User Fee Act, or PDUFA, which was first enacted in 1992 to provide the FDA with additional resources to speed the review of important new medicines. A waiver of that fee may be obtained under certain limited circumstances. PDUFA expires every five years and must be reauthorized by Congress. PDUFA IV expired on September 30, 2012, and was renewed as Title I of the FDA Safety and Innovation Act, or PDUFA V, in 2012 and is scheduled to expire in 2017. PDUFA V focuses on improving the efficiency and predictability of the review process, strengthening the agency regulatory science base and enhancing benefit-risk assessment and post-approval safety surveillance.

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied. The FDA has substantial discretion in the product approval process, and it is impossible to predict with any certainty whether and when the FDA will grant marketing approval. The FDA may on occasion require the sponsor of an NDA to conduct additional clinical studies or to provide other scientific or technical information about the product, and these additional requirements may lead to unanticipated delay or expense. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical studies are not always conclusive, and the FDA may interpret data differently than we interpret the same data.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing which involves clinical studies designed to further assess a drug product's safety and effectiveness after NDA approval. The FDA also may impose a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of a product outweigh its risks. A REMS could add training requirements for healthcare professionals, safety communications efforts and limits on channels of distribution, among other things. The sponsor would be required to evaluate and monitor the various REMS activities and adjust them if need be. Whether a REMS would be imposed on any of our products and any resulting financial impact is uncertain at this time.

Any drug products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label and promotional claims must be appropriately balanced with important safety information and otherwise be adequately substantiated. Further, manufacturers of drugs must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Drug product manufacturers and other entities involved in the manufacturing and distribution of approved drugs products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain other agencies for compliance with cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the drug product. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards, and test each product batch or lot prior to its release. In addition, manufacturers of commercial PET products, including radiopharmacies, hospitals and academic medical centers, are required to submit either an NDA or Abbreviated New Drug Application, or ANDA, in order to produce PET drugs for clinical use, or produce the drugs under an IND.

---

## [Table of Contents](#)

The FDA also regulates the preclinical and clinical testing, design, manufacture, safety, efficacy, labeling, storage, record keeping, sales and distribution, postmarket adverse event reporting, import/export and advertising and promotion of any medical devices that we distribute pursuant to the FDCA and FDA's implementing regulations. The Federal Trade Commission shares jurisdiction with the FDA over the promotion and advertising of certain medical devices. The FDA can also impose restrictions on the sale, distribution or use of medical devices at the time of their clearance or approval, or subsequent to marketing. Currently, two medical devices, both of which are manufactured by third parties which hold the product clearances, comprise only a small portion of our revenues.

The FDA may withdraw marketing authorization a pharmaceutical or medical device product if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, warning letters, holds on clinical studies, product recalls or seizures, product detention or refusal to permit the import or export of pharmaceuticals or medical device products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions, or civil or criminal penalties.

Because our operations include nuclear pharmacies and related businesses, such as cyclotron facilities used to produce PET products used in diagnostic medical imaging, we are subject to regulation by the NRC or the departments of health of each state in which we operate and the applicable state boards of pharmacy. In addition, the FDA is also involved in the regulation of cyclotron facilities where PET products are produced and compliance with cGMP requirements and United States Pharmacopeia requirements for PET drug compounding.

Drug laws also are in effect in many of the non-U.S. markets in which we conduct business. These laws range from comprehensive drug approval requirements to requests for product data or certifications. In addition, inspection of and controls over manufacturing, as well as monitoring of adverse events, are components of most of these regulatory systems. Most of our business is subject to varying degrees of governmental regulation in the countries in which we operate, and the general trend is toward increasingly stringent regulation. The exercise of broad regulatory powers by the FDA continues to result in increases in the amount of testing and documentation required for approval or clearance of new drugs and devices, all of which add to the expense of product introduction. Similar trends also are evident in major non-U.S. markets, including Canada, the European Union, Australia and Japan.

To assess and facilitate compliance with applicable FDA, NRC and other state, federal and foreign regulatory requirements, we regularly review our quality systems to assess their effectiveness and identify areas for improvement. As part of our quality review, we perform assessments of our suppliers of the raw materials that are incorporated into products and conduct quality management reviews designed to inform management of key issues that may affect the quality of our products. From time to time, we may determine that products we manufactured or marketed do not meet our specifications, published standards, such as those issued by the International Standards Organization, or regulatory requirements. When a quality or regulatory issue is identified, we investigate the issue and take appropriate corrective action, such as withdrawal of the product from the market, correction of the product at the customer location, notice to the customer of revised labeling and other actions.

### ***Drug Price Competition and Patent Term Restoration Act of 1984***

The Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, added two pathways for FDA drug approval. First, the Hatch-Waxman Act permits the FDA to approve ANDAs for generic versions of drugs if the ANDA applicant demonstrates, among other things, that its product is bioequivalent to the innovator product and provides relevant chemistry, manufacturing and product data. Second, the Hatch-Waxman Act created what is known as a Section 505(b)(2) NDA, which requires the same information



---

## [Table of Contents](#)

as a full NDA (known as a Section 505(b)(1) NDA), including full reports of clinical and preclinical studies but allows some of the information from the reports required for marketing approval to come from studies which the applicant does not own or have a legal right of reference. A Section 505(b)(2) NDA permits a manufacturer to obtain marketing approval for a drug without needing to conduct or obtain a right of reference for all of the required studies. The Hatch-Waxman Act also provides for: (1) restoration of a portion of a product's patent term that was lost during clinical development and application review by the FDA; and (2) statutory protection, known as exclusivity, against the FDA's acceptance or approval of certain competitor applications.

Patent term extension can compensate for time lost during product development and the regulatory review process by returning up to five years of patent life for a patent that covers a new product or its use. This period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Patent term extensions, however, are subject to a maximum extension of five years, and the patent term extension cannot extend the remaining term of a patent beyond a total of 14 years. The application for patent term extension is subject to approval by the U.S. Patent and Trademark Office in conjunction with the FDA.

The Hatch-Waxman Act also provides for a period of statutory protection for new drugs that receive NDA approval from the FDA. If the FDA approves a Section 505(b)(1) NDA for a new drug that is a new chemical entity, meaning that the FDA has not previously approved any other new drug containing any same active moiety, then the Hatch-Waxman Act prohibits the submission or approval of an ANDA or a Section 505(b)(2) NDA for a period of five years from the date of approval of the NDA, except that the FDA may accept an application for review after four years under certain circumstances. The Hatch-Waxman Act will not prevent the filing or approval of a full NDA, as opposed to an ANDA or Section 505(b)(2) NDA, for any drug, but the competitor would be required to conduct its own clinical trials, and any use of the drug for which marketing approval is sought could not violate another NDA holder's patent claims. The Hatch-Waxman Act provides for a three-year period of exclusivity for an NDA for a new drug containing an active moiety that was previously approved by the FDA, but also includes new clinical data (other than bioavailability and bioequivalence studies) to support an innovation over the previously approved drug and those studies were conducted or sponsored by the applicant and were essential to approval of the application. This three-year exclusivity period does not prohibit the FDA from accepting an application from a third party for a drug with that same innovation, but it does prohibit the FDA from approving that application for the three year period. The three year exclusivity does not prohibit the FDA, with limited exceptions, from approving generic drugs containing the same active ingredient but without the new innovation.

### ***Healthcare Reform Act and Related Laws***

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Healthcare Reform Act substantially changes the way in which healthcare is financed by both governmental and private insurers and has a significant impact on the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that affect coverage and reimbursement of drug products and the medical imaging procedures in which our drug products are used. Key provisions, include the following:

- increasing the presumed utilization rate from 50% to 75% for imaging equipment costing \$1 million or more in the physician office and free-standing imaging facility setting for dates of service on or after January 1, 2011. Under the American Taxpayer Relief Act of 2012, or ATRA, the presumed utilization rate was further increased to 90%, effective January 1, 2014, which reduces the Medicare per procedure medical imaging reimbursement;
- increasing the minimum rebate percentage of the average manufacturer price for Medicaid rebates payable by manufacturers of brand-name drugs (such as us) from 15.1% to the higher of 23.1% of the average manufacturer price or the difference between the average manufacturer price and the best price, as adjusted by the Consumer Price Index-Urban;

---

## [Table of Contents](#)

- extending Medicaid rebates payable by manufacturers of brand-name drugs to drugs paid by Medicaid managed care organizations;
- expanding eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage generally to individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanding access to commercial health insurance coverage through new state-based health insurance marketplaces, or exchanges;
- imposing a non-deductible annual fee on pharmaceutical manufacturers or importers who sell brand name prescription drugs to specified federal government programs; and
- imposing an excise tax on the sale of taxable medical device, to be paid by the entity that manufactures or imports the device.

The Healthcare Reform Act also establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB is mandated to propose changes in Medicare payments if it is determined that the rate of growth of Medicare expenditures exceeds target growth rates or the projected percentage increase for the medical expenditures portion of the Consumer Price Index is greater than the projected percentage increase in the Consumer Price Index for all items. A proposal made by the IPAB must be implemented by CMS, unless Congress adopts a proposal that achieves the necessary savings. Although under the Healthcare Reform Act, the IPAB proposals may impact payments for physician and free-standing imaging services beginning in 2015 and for hospital services beginning in 2020, the threshold for triggering IPAB proposals has not been reached, so no adjustments will be made under the IPAB in 2017 (at the earliest).

The Healthcare Reform Act also amended the federal self-referral laws, requiring referring physicians to inform patients under certain circumstances that the patients may obtain services, including MRI, computed tomography or CT, PET and certain other diagnostic imaging services, from a provider other than that physician, another physician in his or her group practice, or another individual under direct supervision of the physician or another physician in the group practice. The referring physician must provide each patient with a written list of other suppliers who furnish those services in the area in which the patient resides. These new requirements could have the effect of shifting where certain diagnostic medical imaging procedures are performed.

In addition, the Budget Control Act of 2011, as amended by the ATRA imposed across-the-board cuts, or sequestrations, to mandatory and discretionary spending. Medicare (but not Medicaid) reimbursement rates were reduced by 2% beginning in April 2013. The Bipartisan Budget Act of 2013 applied reductions to Medicare reimbursement rates through 2023, with two pieces of additional legislation extending these cuts through 2024 and front-loading the cuts in 2024 to the first half of the year, respectively. The ATRA also, among other things, further reduced Medicare payments to several providers, including hospitals and imaging centers.

The Healthcare Reform Act has been subject to political and judicial challenges. In 2012, the Supreme Court considered the constitutionality of certain provisions of the law. The Court upheld as constitutional the mandate for individuals to obtain health insurance, but held the provision allowing the federal government to withhold certain Medicaid funds to states that do not expand state Medicaid programs unconstitutional. Therefore, not all states have expanded their Medicaid programs under the Healthcare Reform Act. Political and judicial challenges to the law may continue in the wake of the Court's ruling. Perhaps of most significance is the case challenging the Internal Revenue Service's application of the premium tax credits to individuals in all states, regardless of whether their state established a state-run exchange or allowed the federal government to facilitate an exchange on its behalf. The Court is scheduled to hear the challenge in March of 2015.

### ***Healthcare Fraud and Abuse Laws***

We are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry, including anti-kickback and false claims laws. Anti-kickback laws generally prohibit a pharmaceutical

---

## [Table of Contents](#)

manufacturer from soliciting, offering, receiving, or paying any remuneration in order to generate business, including the purchase or prescription of a particular drug. Although the specific provisions of these laws vary, their scope is generally broad and there may not be regulations, guidance or court decisions that apply the laws to particular industry practices. There is therefore a possibility that our practices might be challenged under the anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third party payors (including Medicare and Medicaid) claims for drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including fines and civil monetary penalties, and/or exclusion from federal health care programs (including Medicare and Medicaid). Federal and state authorities are paying increased attention to enforcement of these laws within the pharmaceutical industry and private individuals have been active in alleging violations of the laws and bringing suits on behalf of the government under the false claims act. Violations of international fraud and abuse laws could result in similar penalties, including exclusion from participation in health programs outside the United States. If we were subject to allegations concerning, or were convicted of violating, these laws, our business could be harmed.

Laws and regulations have also been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and health care providers; require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government; and/or require disclosure to the government and/or public of financial interactions (so-called "sunshine laws"). State laws may also require disclosure of pharmaceutical pricing information and marketing expenditures. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

### ***Other Healthcare Laws***

Our operations may be affected by the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, or HITECH, which impose obligations on certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) and certain of their "business associate" contractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Although we believe that we are neither a "covered entity" nor a "business associate" under the legislation, a business associate relationship may be imputed from facts and circumstances even in the absence of an actual business associate agreement. In addition, HIPAA and HITECH may affect our interactions with customers who are covered entities or their business associates.

### ***Laws Relating to Foreign Trade***

We are subject to various federal and foreign laws that govern our international business practices with respect to payments to government officials. Those laws include the Foreign Corrupt Practices Act, or FCPA, which prohibits U.S. companies and their representatives from paying, offering to pay, promising, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate for the purpose of obtaining or retaining business or to otherwise obtain favorable treatment or influence a person working in an official capacity. In many countries, the healthcare professionals we regularly interact with may meet the FCPA's definition of a foreign government official. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect their transactions and to devise and maintain an adequate system of internal accounting controls.

---

## [Table of Contents](#)

Those laws also include the Bribery Act which proscribes giving and receiving bribes in the public and private sectors, bribing a foreign public official, and failing to have adequate procedures to prevent employees and other agents from giving bribes. U.S. companies that conduct business in the United Kingdom generally will be subject to the Bribery Act. Penalties under the Bribery Act include potentially unlimited fines for companies and criminal sanctions for corporate officers under certain circumstances.

Our policies mandate compliance with these anti-bribery laws. Our operations reach many parts of the world that have experienced governmental corruption to some degree, and in certain circumstances strict compliance with anti-bribery laws may conflict with local customs and practices. Despite our training and compliance programs, our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents.

### **Health and Safety Laws**

We are also subject to various federal, state and local laws, regulations and recommendations, both in the United States and abroad, relating to safe working conditions, laboratory and manufacturing practices and the use, transportation and disposal of hazardous or potentially hazardous substances.

### **Environmental Matters**

We are subject to various federal, state and local laws and regulations relating to the protection of the environment, human health and safety in the United States and in other jurisdictions in which we operate. Our operations, like those of other medical product companies, involve the transport, use, handling, storage, exposure to and disposal of materials and wastes regulated under environmental laws, including hazardous and radioactive materials and wastes. If we violate these laws and regulations, we could be fined, criminally charged or otherwise sanctioned by regulators. We believe that our operations currently comply in all material respects with applicable environmental laws and regulations. See “Item 1A—Risk Factors—We use hazardous materials in our business and must comply with environmental laws and regulations, which can be expensive.”

Certain environmental laws and regulations assess liability on current or previous owners or operators of real property for the cost of investigation, removal or remediation of hazardous materials or wastes at those formerly owned or operated properties or at third party properties at which they have disposed of hazardous materials or wastes. In addition to cleanup actions brought by governmental authorities, private parties could bring personal injury, property damage or other claims due to the presence of, or exposure to, hazardous materials or wastes. We currently are not party to any claims or any obligations to investigate or remediate contamination at any of our facilities.

We are required to maintain a number of environmental permits and nuclear licenses for our North Billerica facility, which is our primary manufacturing, packaging and distribution facility. In particular, we must maintain a nuclear byproducts materials license issued by the Commonwealth of Massachusetts. This license requires that we provide financial assurance demonstrating our ability to cover the cost of decommissioning and decontaminating, or D&D, the Billerica site at the end of its use as a nuclear facility. As of December 31, 2014, we currently estimate the D&D cost at the Billerica site to be approximately \$24.1 million. As of December 31, 2014 and 2013, we have a liability recorded associated with the fair value of the asset retirement obligations of approximately \$7.4 million and \$6.4 million, respectively. We have recorded accretion expense of \$0.8 million, \$0.6 million and \$0.6 million during the years ended December 31, 2014, 2013 and 2012, respectively. We currently provide this financial assurance in the form of surety bonds. We generally contract with third parties for the disposal of wastes generated by our operations. Prior to disposal, we store any low level radioactive waste at our facilities until the materials are no longer considered radioactive, as allowed by our licenses and permits.

Environmental laws and regulations are complex, change frequently and have become more stringent over time. While we have budgeted for future capital and operating expenditures to maintain compliance with these

---

## [Table of Contents](#)

laws and regulations, we cannot assure you that our costs of complying with current or future environmental protection, health and safety laws and regulations will not exceed our estimates or adversely affect our results of operations and financial condition. Further, we cannot assure you that we will not be subject to additional environmental claims for personal injury or cleanup in the future based on our past, present or future business activities. While it is not feasible to predict the future costs of ongoing environmental compliance, it is possible that there will be a need for future provisions for environmental costs that, in management's opinion, are not likely to have a material effect on our financial condition, but could be material to the results of operations in any one accounting period.

### **Employees**

As of December 31, 2014, we had 524 employees, of which 406 were located in the United States and 118 were located internationally, and approximately 84 contractors. None of our employees are represented by a collective bargaining unit, and we believe that our relationship with our employees is good.

### **Corporate History**

Founded in 1956 as New England Nuclear Corporation, our medical imaging diagnostic business was purchased by DuPont in 1981. BMS subsequently acquired our diagnostic medical imaging business as part of its acquisition of DuPont Pharmaceuticals in 2001. Avista acquired our medical imaging business from BMS in January 2008.

### **Our Sponsor**

Avista is a leading private equity firm with over \$5 billion under management and offices in New York, NY, Houston, TX and London, UK. Founded in 2005 as a spin-out from the former DLJ Merchant Banking Partners, or DLJMB, franchise, Avista makes controlling or influential minority investments primarily in growth-oriented energy, healthcare, communications and media, industrial and consumer businesses. Through its team of seasoned investment professionals and industry experts, Avista seeks to partner with exceptional management teams to invest in and add value to well-positioned businesses.

### **Item 1A. Risk Factors**

*You should carefully consider the following risks. These risks could materially affect our business, results of operations or financial condition, cause the trading price of our outstanding notes to decline materially or cause our actual results to differ materially from those expected or those expressed in any forward-looking statements made by us or on our behalf. See "Cautionary Note Regarding Forward-Looking Statements" and the risks of our businesses described elsewhere in this annual report.*

***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.***

We obtain a substantial portion of our products from third party manufacturers and suppliers. Historically, we relied on BVL in Bedford, Ohio as our sole manufacturer of DEFINITY, Neurolite and evacuation vials, an ancillary component for our TechnLite generators, and as one of two manufacturers of Cardiolite. Following extended operational and regulatory challenges at BVL, in March 2012 we entered into a settlement arrangement with BVL, resulting in an aggregate payment to us of \$35.0 million, a broad mutual waiver and a covenant by us not to sue. Later in 2012 and in 2013, BVL continued to attempt to manufacture our products for us, and in October 2013 announced that it would cease to manufacture new batches of our products at its Bedford, Ohio facility. In November 2013, we entered into a second settlement arrangement with BVL, resulting in an additional aggregate payment to us of \$8.9 million, a broad mutual waiver and a covenant by us not to sue. At this time, we have a very limited amount of BVL-manufactured products in our finished goods inventory.

---

## [Table of Contents](#)

Following extensive technology transfer activities, we now rely on JHS as our sole source manufacturer of DEFINITY, Neurolite and evacuation vials. We currently have additional ongoing technology transfer activities at JHS for our Cardiolite products and at Phamalucence for DEFINITY, but we can give no assurances as to when that technology transfer will be completed and when we will actually receive supply of Cardiolite from JHS or DEFINITY from Phamalucence. In the meantime, our DEFINITY, Neurolite, evacuation vial and Cardiolite product supply is currently manufactured by a single manufacturer. In addition, we currently have no manufacturer for Ablavar.

Based on our current estimates, we believe that we will have sufficient supply of DEFINITY, Neurolite and evacuation vials from JHS to meet expected demand, sufficient Cardiolite product supply from our current manufacturer to meet expected demand, and sufficient Ablavar product supply to meet expected demand. However, we can give no assurances that JHS or our other manufacturing partners will be able to manufacture and distribute our products in a high quality and timely manner and in sufficient quantities to allow us to avoid product stock-outs and shortfalls. Currently, the regulatory authorities in certain countries have not yet approved JHS as a manufacturer of our products. Accordingly, until those regulatory approvals have been obtained, our international business, results of operations, financial condition and cash flows will continue to be adversely affected.

Our manufacturing agreement for Ablavar has terminated. We do not have any current plans to initiate technology transfer activities for Ablavar. If we do not engage in Ablavar technology transfer activities in the future with a new manufacturing partner for Ablavar, then our existing Ablavar inventory will expire in 2016 and we will have no further Ablavar inventory that we will be able to sell.

In addition to the products described above, for reasons of quality assurance or cost-effectiveness, we purchase certain components and raw materials from sole suppliers (including, for example, the lead casing for our TechneLite generators, the evacuation vials for our TechneLite generators manufactured by JHS and the lipid blend material used in the processing of DEFINITY). Because we do not control the actual production of many of the products we sell and many of the raw materials and components that make up the products we sell, we may be subject to delays caused by interruption in production based on events and conditions outside of our control. At our North Billerica, Massachusetts facility, we manufacture TechneLite on a relatively new, highly automated production line, as well as Thallium and Gallium using our older cyclotron technology. As with all manufacturing facilities, equipment and infrastructure age and become subject to increasing maintenance and repair. If we or one of our manufacturing partners experiences an event, including a labor dispute, natural disaster, fire, power outage, machinery breakdown, security problem, failure to meet regulatory requirements, product quality issue, technology transfer issue or other issue, we may be unable to manufacture the relevant products at previous levels or on the forecasted schedule, if at all. Due to the stringent regulations and requirements of the governing regulatory authorities regarding the manufacture of our products, we may not be able to quickly restart manufacturing at a third party or our own facility or establish additional or replacement sources for certain products, components or materials.

In addition to our existing manufacturing relationships, we are also pursuing new manufacturing relationships to establish and secure additional or alternative suppliers for our commercial products. On November 12, 2013, we entered into a Manufacturing and Supply Agreement with Phamalucence to manufacture and supply DEFINITY. We cannot assure you, however, that these supply diversification activities will be successful, or that before those alternate manufacturers or sources of product are fully functional and qualified, that we will be able to avoid or mitigate interim supply shortages. In addition, we cannot assure you that our existing manufacturers or suppliers or any new manufacturers or suppliers can adequately maintain either their financial health or regulatory compliance to allow continued production and supply. A reduction or interruption in manufacturing, or an inability to secure alternative sources of raw materials or components, could eventually have a material adverse effect on our business, results of operations, financial condition and cash flows.

---

## [Table of Contents](#)

***Challenges with product quality or product performance, including defects, caused by us or our suppliers could result in a decrease in customers and sales, unexpected expenses and loss of market share.***

The manufacture of our products is highly exacting and complex and must meet stringent quality requirements, due in part to strict regulatory requirements, including the FDA's current cGMPs. Problems may be identified or arise during manufacturing quality review, packaging or shipment for a variety of reasons including equipment malfunction, failure to follow specific protocols and procedures, defective raw materials and environmental factors. Additionally, manufacturing flaws, component failures, design defects, off-label uses or inadequate disclosure of product-related information could result in an unsafe condition or the injury or death of a patient. Those events could lead to a recall of, or issuance of a safety alert relating to, our products. We also may undertake voluntarily to recall products or temporarily shutdown production lines based on internal safety and quality monitoring and testing data.

Quality, regulatory and recall challenges could cause us to incur significant costs, including costs to replace products, lost revenue, damage to customer relationships, time and expense spent investigating the cause and costs of any possible settlements or judgments related thereto and potentially cause similar losses with respect to other products. These challenges could also divert the attention of our management and employees from operational, commercial or other business efforts. If we deliver products with defects, or if there is a perception that our products or the processes related to our products contain errors or defects, we could incur additional recall and product liability costs, and our credibility and the market acceptance and sales of our products could be materially adversely affected. Due to the strong name recognition of our brands, an adverse event involving one of our products could result in reduced market acceptance and demand for all products within that brand, and could harm our reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our applications for new product approvals. These challenges could have a material adverse effect on our business, results of operations, financial condition and cash flows.

***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 TechnoLite, historically our largest product by annual revenues, is Moly. We currently purchase finished Moly from four of the five main processing sites in the world, namely ANSTO in Australia; IRE in Belgium; Nordion, formerly known as MDS Nordion, in Canada; and NTP in South Africa. These processing sites are, in turn, supplied by seven of the eight main Moly-producing reactors in the world, namely, OPAL in Australia; BR2 in Belgium; OSIRIS in France; LVR-10 in the Czech Republic; HFR in The Netherlands; NRU in Canada; and SAFARI in South Africa.

Historically, our largest supplier of Moly has been Nordion, which has relied on the NRU reactor owned and operated by Atomic Energy of Canada Limited, or AECL, a Crown corporation of the Government of Canada, located in Chalk River, Ontario. This reactor was off-line from May 2009 until August 2010 due to a heavy water leak in the reactor vessel. The inability of the NRU reactor to produce Moly and of Nordion to finish Moly during the shutdown period had a detrimental effect on our business, results of operations and cash flows. As a result of the NRU reactor shutdown, we experienced business interruption losses. We estimate the quantity of those losses to be, in the aggregate, more than \$70 million, including increases in the cost of obtaining limited amounts of Moly from alternate, more distant, suppliers and substantial decreases in revenue as a result of significantly curtailed manufacturing of TechnoLite generators and our decreased ability to sell other Moly-based medical imaging products, including Cardiolute, in comparison to our forecasted results. The Government of Canada has stated that it intends to exit the medical isotope business when the NRU reactor's current license transitions in October 2016 and thereafter provide only emergency back-up medical isotope supply through March 2018.

---

## [Table of Contents](#)

As part of the conditions for the relicensing of the NRU reactor, the Canadian government has asked AECL to shut down the reactor for at least four weeks at least once a year for inspection and maintenance. The most recent shutdown period ran from April 13, 2014 until May 13, 2014, and we were able to source sufficient Moly to satisfy all of our standing-order customer demand for our TechneLite generators during this time period from our other suppliers. During this shutdown period, however, because Xenon is a by-product of the Moly production process and is currently captured only by NRU, we were not able to supply all of our standing-order customer demand for Xenon. There can be no assurance that in the future these off-line periods will last for the stated time or that the NRU will not experience other unscheduled shutdowns. Further prolonged scheduled or unscheduled shutdowns would limit the amount of Moly and Xenon available to us and limit the quantity of TechneLite that we could manufacture, sell and distribute and the amount of Xenon that we could sell and distribute, resulting in a further substantial negative effect on our business, results of operations, financial condition and cash flows.

In the face of the NRU reactor operating challenges and licensure issues we entered into Moly supply agreements with NTP, ANSTO and IRE to augment our supply of Moly. ANSTO has under construction, in cooperation with NTP, a new Moly processing facility that ANSTO believes will expand its production capacity by approximately 2.5 times, with expanded commercial production planned to start in mid-2016. This new ANSTO production capacity is expected to replace the NRU's current routine production. While we believe this additional Moly supply now gives us the most balanced and diversified Moly supply chain in the industry, a prolonged disruption of service from only one of our significant Moly suppliers could have a material adverse 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. For example, in November 2014, we announced entering into a new strategic agreement 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 currently estimates will occur in 2018. 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.

Although our agreements with NTP, ANSTO and IRE run until December 31, 2017, our agreement with Nordion runs only until December 31, 2015 and can be terminated by Nordion upon the occurrence of certain events, including if we fail to purchase a minimum percentage of Moly or if Nordion incurs certain cost increases.

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, the Moly produced from these projects will likely not become available until after the NRU reactor's transition in 2016 from providing regular supply of medical isotopes to providing only emergency back-up supply of medical isotopes through March 2018. 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 AREVA Group in France to fabricate uranium targets for research reactors from which Moly is produced. Absent a new supplier, a supply disruption relating to uranium targets could have a substantial negative effect on our business, results of operations, financial condition and cash flows.



---

## [Table of Contents](#)

***The instability of the global supply of Moly, including supply shortages, resulted in increases in the cost of Moly, which has negatively affected our margins, and more restrictive agreements with suppliers, which could further increase our costs.***

With the general instability in the global supply of Moly, including supply shortages during 2009 and 2010, we have faced substantial increases in the cost of Moly in comparison to historical costs. We expect these cost increases to continue in the future as the Moly suppliers move closer to a full cost recovery business model. The Organization of Economic Cooperation and Development, or OECD, defines full cost recovery as the identification of all of the costs of production and recovering these costs from the market. While we are generally able to pass Moly cost increases on to our customers in our customer contracts, if we are not able to do so in the future, our margins may decline further with respect to our TechnoLite generators, which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

***The Moly supply shortage caused by the 2009-10 NRU reactor shutdown has had a negative effect on the demand for some of our products, which will likely continue in the future.***

The Moly supply shortage also had a negative effect on the use of other technetium generator-based diagnostic medical imaging agents, including our Cardiolite products. With less Moly, we manufactured fewer generators for radiopharmacies and hospitals to make up unit doses of Cardiolite products, resulting in decreased market share of Cardiolite products in favor of Thallium, an older medical isotope that does not require Moly, and other diagnostic modalities. With the return to service of the NRU reactor, we have seen increased sales of TechnoLite. However, TechnoLite unit volume has not returned to pre-shortage levels for, we believe, a number of reasons, including: (i) changing staffing and utilization practices in radiopharmacies, which have resulted in an increased number of unit-doses of technetium-based radiopharmaceuticals being made from available amounts of technetium; (ii) shifts to alternative diagnostic imaging modalities during the Moly supply shortage, which have not returned to technetium-based procedures; and (iii) decreased amounts of technetium being used in unit-doses of technetium-based radiopharmaceuticals due to growing concerns about patient radiation dose exposure. We do not know if the staffing and utilization practices in radiopharmacies, the mix between technetium and non-technetium-based diagnostic procedures and the increased concerns about radiation exposure, will allow technetium demand to ever return to pre-shortage levels, which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

***Our just-in-time manufacturing of radiopharmaceutical products relies on the timely receipt of radioactive raw materials and the timely shipment of finished goods, and any disruption of our supply or distribution networks could have a negative effect on our business.***

Because a number of our radiopharmaceutical products, including our TechnoLite generators, rely on radioisotopes with limited half-lives, we must manufacture, finish and distribute these products on a just-in-time basis, because the underlying radioisotope is in a constant state of radio decay. For example, if we receive Moly in the morning of a manufacturing day for TechnoLite generators, then we will generally ship finished generators to customers by the end of that same business day. Shipment of generators may be by next day delivery services or by either ground or air custom logistics. Any delay in us receiving radioisotopes from suppliers or being able to have finished products delivered to customers because of weather or other unforeseen transportation issues could have a negative effect on our business, results of operations, financial condition and cash flows.

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

The growth of our business is substantially dependent on increased market penetration for the appropriate use of DEFINITY in suboptimal echocardiograms. Of the approximately 30 million echocardiograms performed each year in the United States, a third party source estimates that 20%, or approximately six million echocardiograms, produce suboptimal images. We estimate that DEFINITY had approximately 78% share of the market for contrast agents in the United States as of December 2014. If we are not able to continue to grow

---

## [Table of Contents](#)

DEFINITY sales through increased market penetration, we will not be able to grow the revenue and cash flow of the business or continue to fund our other growth initiatives at planned levels, which could have a negative effect on our prospects.

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

Currently, Nordion is our sole supplier, and we believe the principal supplier on a global basis, of Xenon, which is captured by the NRU reactor as a by-product of the Moly production process. In January 2015, we announced entering into a new strategic agreement with IRE for the future supply of Xenon. Under the terms of the agreement, IRE will provide bulk Xenon to us for processing and finishing once development work has been completed and all necessary regulatory approvals have been obtained. We currently estimate commercial production will occur in 2016. If we are not able to begin providing commercial quantities of Xenon prior to the NRU reactor's transition in October 2016 from providing regular supply of medical isotopes to providing only emergency back-up supply of medical isotopes through March 2018, there may be a period of time during which we are not able to offer Xenon in our portfolio of commercial products, which would have a negative effect on our business, results of operations, financial condition and cash flows. For the year ended December 31, 2014, Xenon represented approximately 12% of our revenues.

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

Currently, we are the leading provider of packaged Xenon in the United States. If other providers obtained regulatory approval and began to sell packaged Xenon in the United States without otherwise increasing market penetration for the agent, or if there is an increase in the use of other imaging modalities in place of using packaged Xenon, our current sales volumes would decrease, which could have a negative effect on our business, results of operations, financial condition and cash flows.

Xenon is frequently administered as part of a ventilation scan to evaluate pulmonary function prior to a perfusion scan with microaggregated albumin, or MAA, a technetium-based radiopharmaceutical used to evaluate blood flow to the lungs. Currently, Draxis is the sole supplier of MAA on a global basis. Recently, Draxis encountered supply challenges and announced substantial price increases for MAA. If supply challenges for MAA or the increased price of MAA decreases the frequency that MAA is used for lung perfusion evaluation, which, in turn, decreases the frequency that Xenon is used for pulmonary function evaluation, the MAA supply challenges or price increase would have a negative effect on our business, results of operations, financial condition and cash flows.

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

In the United States, we have historically relied on a limited number of radiopharmacy customers, primarily Cardinal, GE Healthcare, UPPI and Triad, to distribute our current largest volume nuclear imaging products and generate a majority of our revenues. Three customers accounted for approximately 38% of our revenues in the fiscal year ended December 31, 2014, with Cardinal, UPPI and GE Healthcare accounting for approximately 18%, 11% and 9%, respectively. Among the existing radiopharmacies in the United States, continued consolidations, divestitures and reorganizations may have a negative effect on our business, results of operations, financial condition or cash flows. We generally have distribution arrangements with our major radiopharmacy customers pursuant to multi-year contracts, each of which is subject to renewal. If these contracts are terminated prior to expiration of their term, or are not renewed, or are renewed on terms that are less favorable to us, then such an event could have a material adverse effect on our business, results of operations, financial condition and cash flows.

---

## [Table of Contents](#)

Our written supply agreements with Cardinal relating to TechnoLite, Xenon, NeuroLite, Cardiolite and certain other products expired in accordance with their terms on December 31, 2014. Following extended discussions with Cardinal that have not yet resulted in one or more new written supply agreements, we are currently accepting and fulfilling product orders from Cardinal on a purchase order basis at list price. We cannot predict the volumes or product mix Cardinal will continue to order and purchase, and such volumes and product mix may vary over time. In the absence of written supply agreements with Cardinal, unit sales volumes have decreased in early 2015 from levels experienced throughout 2014, but such sales have been at substantially higher prices. However, ultimate future levels of net revenue and operating profit associated with Cardinal cannot be predicted at this time because such amounts depend on future unit sales volumes, product mix and pricing to Cardinal. A significant decrease in the operating profit contribution from sales to Cardinal would have a material adverse effect on our business, results of operations, financial condition and cash flows.

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

Outside of the United States, Canada, Australia and Puerto Rico, we have no radiopharmacies or sales force and, consequently, rely on third party distributors, either on a country-by-country basis or on a multicountry, regional basis, to market, sell and distribute our products. These distributors accounted for approximately 17%, 13% and 16% of non-U.S. revenues for the fiscal years ended December 31, 2014, 2013 and 2012, respectively. In certain circumstances, these distributors may also sell competing products to our own or products for competing diagnostic modalities and may have incentives to shift sales towards those competing products. As a result, we cannot assure you that our international distributors will increase or maintain our current levels of unit sales or increase or maintain our current unit pricing, which, in turn, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

***We have a history of net losses and total stockholder's deficits which may continue and which may negatively impact our ability to achieve or sustain profitability.***

We have a history of net losses and cannot assure you that we will achieve or sustain profitability in the future. We incurred net loss for the years ended December 31, 2014, 2013 and 2012 of \$1.2 million, \$61.7 million and \$42.0 million, respectively, and as of December 31, 2014, we had a total stockholders' deficit of \$241.0 million. We cannot assure you that we will be able to achieve or sustain profitability on a quarterly or annual basis in the future. If we cannot improve our profitability, the value of our enterprise may decline.

***We face significant competition in our business and may not be able to compete effectively.***

The market for diagnostic medical imaging agents is highly competitive and continually evolving. Our principal competitors in existing diagnostic modalities include large, global companies with substantial financial, manufacturing, sales and marketing and logistics resources that are more diversified than ours, such as Mallinckrodt, GE Healthcare, Bayer Schering Pharma AG, or Bayer, Bracco, and DRAXIS Specialty Pharmaceuticals Inc. (an affiliate of JHS), or Draxis, as well as other competitors. We cannot anticipate their actions in the same or competing diagnostic modalities, such as significant price reductions on products that are comparable to our own, development or introduction of new products that are more cost-effective or have superior performance than our current products, the introduction of generic versions when our proprietary products lose their patent protection or the new entry into a generic market in which we are already a participant. In addition, distributors of our products could attempt to shift end-users to competing diagnostic modalities and products. Our current or future products could be rendered obsolete or uneconomical as a result of these activities. Our failure to compete effectively could cause us to lose market share to our competitors and have a material adverse effect on our business, results of operations, financial condition and cash flows.

---

## [Table of Contents](#)

In October 2014, Bracco received FDA approval in the United States for its echocardiography agent, Lumason (known as SonoVue outside of the U.S.), which is already approved for sale in Europe and certain Asian markets, including China, Japan and Korea. Bracco now has one of three FDA-approved echocardiography contrast agents in the United States, together with GE Healthcare's Optison and our DEFINITY. Although Bracco has not yet formally launched Lumason in the United States, if Bracco successfully commercializes Lumason in the United States without otherwise increasing the overall usage of ultrasound contrast agents, our current and future sales volume could suffer, which would have a material adverse effect on our business, results of operations, financial condition and cash flows.

***Generic competition has significantly eroded our market share of the MPI segment for Cardiolite products and will continue to do so.***

We are currently aware of four separate, third party generic offerings of sestamibi, the first of which launched in September 2008. Cardiolite products accounted for approximately 6%, 9% and 12% of our revenues in the fiscal years ended December 31, 2014, 2013, and 2012, respectively. Included in Cardiolite is branded Cardiolite and generic sestamibi, some of which we produce and some of which we procure from third parties. With the advent of generic competition in September 2008, we have faced significant pricing and unit volume pressures on Cardiolite. To the extent generic competitors further reduce their prices, we may be forced to further reduce the price of our Cardiolite products as well as lose additional market share, which would have an adverse effect on our business, results of operations, financial condition and cash flows.

In addition, because several of the products we manufacture became less available due to recent supply challenges, certain of our customers may have begun to favor a generic offering or a competing agent or diagnostic modality. If we experience continued pricing and unit volume pressures or that product or modality shift is sustained, it could have a material adverse effect on our business, results of operation, financial condition and cash flows.

***Certain of our customers are highly dependent on payments from third party payors, including government sponsored programs, particularly Medicare, in the United States and other countries in which we operate, and reductions in third party coverage and reimbursement rates for our products (or sources provided with our products) could adversely affect our business and results of operations.***

A substantial portion of our revenue depends, in part, on the extent to which the costs of our products purchased by our customers are reimbursed by third party payors, including Medicare, Medicaid, other U.S. government sponsored programs, non-U.S. governmental payors and private payors. These third party payors exercise significant control over patient access and increasingly use their enhanced bargaining power to secure discounted rates and other requirements that may reduce demand for our products. Our potential customers' ability to obtain appropriate reimbursement for products and services from these third party payors affects the selection of products they purchase and the prices they are willing to pay. If these third party payors do not provide appropriate reimbursement for the costs of our products (or services provided using our products), deny the coverage of the products (or those services), or reduce current levels of reimbursement, healthcare professionals may not prescribe our products and providers and suppliers may not purchase our products. In addition, demand for new products may be limited unless we obtain favorable reimbursement policies (including coverage, coding and payment) from governmental and private third party payors at the time of the product's introduction, which will depend, in part, on our ability to demonstrate that a new agent has a positive impact on clinical outcomes. Third party payors continually review their coverage policies for existing and new therapies and can deny coverage for treatments that include the use of our products or revise payment policies such that payments do not adequately cover the cost of our products. Even if third party payors make coverage and reimbursement available, that reimbursement may not be adequate or these payors' reimbursement policies may have an adverse effect on our business, results of operations, financial condition and cash flows.

---

## [Table of Contents](#)

Over the past several years, Medicare has implemented numerous changes to payment policies for imaging procedures in both the hospital setting and non-hospital settings (which include physician offices and freestanding imaging facilities). Some of these changes have had a negative impact on utilization of imaging services. Examples of these changes include:

- limiting payments for imaging services in physician offices and free-standing imaging facility settings based upon rates paid to hospital outpatient departments;
- reducing payments for certain imaging procedures when performed together with other imaging procedures in the same family of procedures on the same patient on the same day in the physician office and free-standing imaging facility setting;
- making significant revisions to the methodology for determining the practice expense component of the Medicare payment applicable to the physician office and free-standing imaging facility setting which results in a reduction in payment; and
- revising payment policies and reducing payment amounts for imaging procedures performed in the hospital outpatient setting.

We believe that Medicare changes to payment policies for imaging procedures will continue to result in certain physicians practices ceasing to provide these services and a further shifting of where certain medical imaging procedures are performed, from the physician office and free-standing imaging facility settings to the hospital outpatient setting. We believe that these changes and their resulting pressures may incrementally reduce the overall number of diagnostic medical imaging procedures performed. In recent legislation, Congress expanded CMS' authority to review and revalue the codes used for reimbursement under the Medicare Physician Fee Schedule. Changes applicable to Medicare payment in the hospital outpatient setting could influence the decisions by hospital outpatient physicians to perform procedures that involve our products. These changes overall could slow the acceptance and introduction of next-generation imaging equipment into the marketplace, which, in turn, could adversely impact the future market adoption of certain of our imaging agents already in the market or currently in clinical or preclinical development. We expect that there will continue to be proposals to reduce or limit Medicare and Medicaid payment for diagnostic services.

Even within the hospital outpatient setting, CMS has revised its payment policy such that the use of many of our products is not separately payable by Medicare, although other products may be payable as an addition to the procedure. Specifically, in 2013, although Medicare generally does not provide separate payment to hospitals for the use of diagnostic radiopharmaceuticals administered in an outpatient setting, CMS finalized a policy to make an additional payment to hospitals that utilize products with non-HEU, meaning the product is 95% derived from non-HEU sources. This payment policy continues in 2015. Although some of our TechneLite generators are manufactured using non-HEU, not all of our TechneLite generators meet CMS's definition of non-HEU, and therefore this payment will not be available for doses produced by the latter category of TechneLite generators used by our customers. This payment as well as other changes to the Medicare hospital outpatient prospective payment system payment rates could influence the decisions by hospital outpatient physicians to perform procedures that involve our products.

We also expect increased regulation and oversight of advanced diagnostic testing. One provision in the Protecting Access to Medicare Act requires CMS to develop appropriate use criteria, or AUC, that professionals must consult when ordering advanced diagnostic imaging services (which include MRI, CT, nuclear medicine (including PET) and other advanced diagnostic imaging services that the Secretary of the Department of Health and Human Services, or HHS, may specify). Beginning in 2017, payment will be made to the furnishing professional for an applicable advanced diagnostic imaging service only if the claim indicates that the ordering professional consulted a qualified clinical decision support mechanism, as identified by HHS, as to whether the ordered service adheres to the applicable AUC. To the extent that these types of changes have the effect of reducing the aggregate number of diagnostic medical imaging procedures performed in the United States, our business, results of operations, financial condition and cash flows would be adversely affected. See "Business—Regulatory Matters."

---

## [Table of Contents](#)

### ***Reforms to the United States healthcare system may adversely affect our business.***

A significant portion of our patient volume is derived from U.S. government healthcare programs, principally Medicare, which are highly regulated and subject to frequent and substantial changes. For example, in March 2010, the President signed one of the most significant healthcare reform measures in decades, the Healthcare Reform Act. The Healthcare Reform Act contains a number of provisions that affect coverage and reimbursement of drug products and medical imaging procedures in which our drug products are used. See “Business—Regulatory Matters—Healthcare Reform Act and Related Laws.” We cannot assure you that the Healthcare Reform Act, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative, judicial or administrative changes relating to healthcare reform will affect our business.

In addition, other legislative changes have been proposed and adopted since the Healthcare Reform Act was enacted. The Budget Control Act of 2011 includes provisions to reduce the federal deficit. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare payments to providers, which went into effect on April 1, 2013 and will remain in effect through 2024 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us, as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, could have an adverse impact on our results of operations.

In addition, federal spending is also subject to a statutory debt ceiling. If the federal debt reaches the statutory debt ceiling, Congress must enact legislation to suspend enforcement of, or increase, the statutory debt ceiling. If Congress fails to do so before the ceiling is reached and, as a result, is unable to satisfy its financial obligations, including under Medicare, Medicaid and other publicly funded or subsidized health programs, our results of operations could be adversely impacted.

The full impact on our business of the Healthcare Reform Act and the other new laws is uncertain. Nor is it clear whether other legislative changes will be adopted or how those changes would affect our industry generally or our ability to successfully commercialize our products or the development of new products.

Under the statutory Medicare sustainable growth rate formula, payments under the Medicare Physician Fee Schedule could have decreased significantly over the past several years without congressional intervention. In the past, when the application of the statutory formula would have resulted in lower payments, Congress has passed interim legislation to prevent the reductions. In 2014, Congress again prevented the negative update factor from going into effect until March 31, 2015. If Congress fails to intervene to prevent the negative update factor in the future through either another temporary measure or a permanent revision to the statutory formula, payments to physicians may be reduced.

### ***The Healthcare Reform Act could potentially reduce the number of diagnostic medical imaging procedures performed or could reduce the amount of reimbursements paid for those procedures.***

The implementation of the Healthcare Reform Act could potentially reduce the aggregate number of diagnostic medical imaging procedures performed in the United States. Under the Healthcare Reform Act, referring physicians under the federal self-referral law must inform patients that they may obtain certain services, including MRI, CT, PET and certain other diagnostic imaging services from a provider other than that physician, another physician in his or her group practice, or another individual under the direct supervision of the physician or another physician in the group practice. The referring physician must provide each patient with a written list of other suppliers which furnish those services in the area in which the patient resides. These new requirements could have the effect of shifting where certain diagnostic medical imaging procedures are performed. In addition, they could potentially reduce the overall number of diagnostic medical imaging procedures performed. We cannot predict the full impact of the Healthcare Reform Act on our business. The law substantially changed the way healthcare is financed by both governmental and private insurers. Although certain provisions may

---

## [Table of Contents](#)

negatively affect payment rates for certain imaging services, the Healthcare Reform Act is projected to reduce the number of people without health insurance by approximately 25 million by 2016 (based on April 2014 estimates from the Congressional Budget Office), which may result in an increase in the demand for our services, but we cannot be assured of a proportional, or any, increase in the use of our products.

Further, we expect that there will continue to be proposals to reduce or limit Medicare and Medicaid payment for services. Rates paid by some private third party payors are based, in part, on established physician, clinic and hospital charges and are generally higher than Medicare payment rates. Reductions in the amount of reimbursement paid for diagnostic medical imaging procedures and changes in the mix of our patients between non-governmental payors and government sponsored healthcare programs and among different types of non-government payor sources, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

***Our business and industry are subject to complex and costly regulations. If government regulations are interpreted or enforced in a manner adverse to us or our business, we may be subject to enforcement actions, penalties, exclusion and other material limitations on our operations.***

Both before and after the approval of our products and agents in development, we, our products, development agents, operations, facilities, suppliers, distributors, contract manufacturers, contract research organizations and contract testing laboratories are subject to extensive and, in certain circumstances, expanding regulation by federal, state and local government agencies in the United States as well as non-U.S. and transnational laws and regulations, with regulations differing from country to country. In the United States, the FDA regulates, among other things, the pre-clinical testing, clinical trials, manufacturing, safety, efficacy, potency, labeling, storage, record keeping, quality systems, advertising, promotion, sale, distribution, and import and export of drug products. We are required to register our business for permits and/or licenses with, and comply with the stringent requirements of the FDA, the NRC, the HHS, Health Canada, the EMA, the MHRA, the CFDA, state and provincial boards of pharmacy, state and provincial health departments and other federal, state and provincial agencies.

Under U.S. law, for example, we are required to report certain adverse events and production problems, if any, to the FDA. We also have similar adverse event and production reporting obligations outside of the United States, including to the EMA and MHRA. Additionally, we must comply with requirements concerning advertising and promotion for our products, including the prohibition on the promotion of our products for indications that have not been approved by the FDA or a so-called "off-label use." If the FDA determines that our promotional materials constitute the unlawful promotion of an off-label use, it could request that we modify our promotional materials or subject us to regulatory or enforcement actions. Also, quality control and manufacturing procedures at our own facility and at third party suppliers must conform to cGMP regulations and other applicable law after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMPs and other applicable law, and, from time to time, makes those cGMPs more stringent. Accordingly, we and others with whom we work must expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control. For example, we currently rely on JHS as our sole manufacturer of DEFINITY and Neurolite. In 2013, JHS received a warning letter from the FDA in connection with their manufacturing facility in Spokane, Washington where our products are manufactured. If JHS cannot resolve the issues in their facility underlying the warning letter or if the issues become worse, then the FDA could take additional regulatory action which could limit or suspend the ability of JHS to manufacture our products or have any additional products approved at the Spokane facility for manufacture until the issues are resolved and remediated. Such a limitation or suspension could have a material adverse effect on our business, results of operations, financial condition and cash flows.

We are also subject to laws and regulations that govern financial and other arrangements between pharmaceutical manufacturers and healthcare providers, including federal and state anti-kickback statutes, federal and state false claims laws and regulations and other fraud and abuse laws and regulations. For example, in 2010, we entered into a Medicaid Drug Rebate Agreement with the federal government for some but not all of our

---

## [Table of Contents](#)

products, which requires us to report certain price information to the federal government that could subject us to potential liability under the False Claims Act, civil monetary penalties or liability under other laws and regulations in connection with the covered products as well as the products not covered by the agreement. Determination of the rebate amount that we pay to state Medicaid programs for our products, as well as determination of payment amounts under Medicare and certain other third party payers, including government payers, depends upon information reported by us to the government. If we provide customers or government officials with inaccurate information about the products' pricing or eligibility for coverage, or the products fail to satisfy coverage requirements, we could be terminated from the rebate program, be excluded from participation in government healthcare programs, or be subject to potential liability under the False Claims Act or other laws and regulations. See "Business—Regulatory Matters—Healthcare Fraud and Abuse Laws."

Additionally, funds received under all healthcare reimbursement programs are subject to audit with respect to the proper billing by customers. Our customers engage in billing, and retroactive adjustments of revenue received from these programs could occur.

Failure to comply with other requirements and restrictions placed upon us or our third party manufacturers or suppliers by laws and regulations can result in fines, civil and criminal penalties, exclusion from federal healthcare programs and debarment. Possible consequences of those actions could include:

- substantial modifications to our business practices and operations;
- significantly reduced demand for our products (if products become ineligible for reimbursement under federal and state healthcare programs);
- a total or partial shutdown of production in one or more of the facilities where our products are produced while the alleged violation is being remediated;
- delays in or the inability to obtain future pre-market clearances or approvals; and
- withdrawals or suspensions of our current products from the market.

Regulations are subject to change as a result of legislative, administrative or judicial action, which may also increase our costs or reduce sales. Violation of any of these regulatory schemes, individually or collectively, could disrupt our business and have a material adverse effect on our business, results of operations, financial condition and cash flows.

***Our marketing and sales practices may contain risks that could result in significant liability, require us to change our business practices and restrict our operations in the future.***

We are subject to domestic (federal, state and local) and foreign laws addressing fraud and abuse in the healthcare industry, including the False Claims Act and Federal Anti-Kickback Statute, the U.S. Foreign Corrupt Practices Act, or the FCPA, the U.K. Bribery Act, or the Bribery Act, the self-referral laws and restrictions on the promotion of off-label uses of our products. Violations of these laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in healthcare programs such as Medicare and Medicaid as well as health programs outside the United States, and even alleged violations can result in the imposition of corporate integrity agreements that could severely restrict or limit our business practices. These laws and regulations are complex and subject to changing interpretation and application, which could restrict our sales or marketing practices. Even minor and inadvertent irregularities could potentially give rise to a charge that the law has been violated. Although we believe we maintain an appropriate compliance program, we cannot be certain that the program will adequately detect or prevent violations and/or the relevant regulatory authorities may disagree with our interpretation. Additionally, if there is a change in law, regulation or administrative or judicial interpretations, we may have to change one or more of our business practices to be in compliance with these laws. Required changes could be costly and time consuming.



---

## [Table of Contents](#)

The Healthcare Reform Act, through its federal “sunshine” provisions, also imposes new requirements on certain device and drug manufacturers to report certain financial interactions with physicians and teaching hospitals as well as ownership and investment interests held by physicians or their immediate family members. The first report containing aggregate payment data was due by March 31, 2014 (covering August 1, 2013 through December 31, 2013). Manufacturers subject to the reporting requirements were required to report detailed payment data for the same reporting period and submit legal attestation to the completeness and accuracy of such data by June 30, 2014. Thereafter, the manufacturers must submit reports by the 90th day of each subsequent calendar year. A manufacturer may be subject to civil monetary penalties of up to \$150,000 aggregate per year for failures to report required information and up to \$1 million aggregate per year for “knowing” failures to report.

Separately, the Healthcare Reform Act requires manufacturers to submit information on the identity and quantity of drug samples requested and distributed by a manufacturer during each year. The first report (covering 2011) was to be submitted by April 1, 2012, but the FDA indicated that it would exercise enforcement discretion until October 1, 2012, and would issue a notice prior to its decision to begin enforcing this decision. The FDA released a draft guidance document in July 2014 requiring submission of data for 2014 by April 1, 2015. We have not yet submitted reports. State laws may also require disclosure of pharmaceutical pricing information and marketing expenditures, compliance with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and/or the tracking and reporting of gifts, compensation, and other remuneration to physicians and other healthcare providers. We believe we have developed appropriate protocols to implement these state requirements. Any irregularities or mistakes in our reporting, however, could result in a finding that we have been non-compliant with these requirements, which could subject us to the penalty provisions of applicable federal and state laws and regulations.

The Healthcare Reform Act also provides greater financial resources to be allocated to enforcement of the fraud and abuse laws and amends the intent requirements of the Federal Anti-Kickback Statute and the general criminal healthcare fraud statute, which may increase overall compliance costs for industry participants, including us. A person or entity does not need to have actual knowledge of the statutes or a specific intent to violate them. In addition, the Healthcare Reform Act revised the False Claims Act to provide that a claim arising from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. If our operations are found to be in violation of these laws or any other government regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, imprisonment, the curtailment or restructuring of our operations, or exclusion from state and federal healthcare programs including Medicare and Medicaid, any of which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

### ***Ultrasound contrast agents may cause side effects which could limit our ability to sell DEFINITY.***

DEFINITY is an ultrasound contrast agent based on perflutren lipid microspheres. In 2007, the FDA received reports of deaths and serious cardiopulmonary reactions following the administration of ultrasound micro-bubble contrast agents used in echocardiography. Four of the 11 reported deaths were caused by cardiac arrest occurring either during or within 30 minutes following the administration of the contrast agent; most of the serious but non-fatal reactions also occurred in this time frame. As a result, in October 2007, the FDA requested that we and GE Healthcare, which distributes Optison, a competitor to DEFINITY, add a boxed warning to these products emphasizing the risk for serious cardiopulmonary reactions and that the use of these products was contraindicated in certain patients. In a strong reaction by the cardiology community to the FDA’s new position, a letter was sent to the FDA, signed by 161 doctors, stating that the benefit of these ultrasound contrast agents outweighed the risks and urging that the boxed warning be removed. In May 2008, the FDA substantially modified the boxed warning. On May 2, 2011, the FDA held an advisory committee meeting to consider the status of ultrasound micro-bubble contrast agents and the boxed warning. In October 2011, we received FDA approval of further modifications to the DEFINITY label, including: further relaxing the boxed warning; eliminating the sentence in the Indication and Use section “The safety and efficacy of DEFINITY with exercise

---

## [Table of Contents](#)

stress or pharmacologic stress testing have not been established” (previously added in October 2007 in connection with the imposition of the box warning); and including summary data from the post-approval CaRES (Contrast echocardiography Registry for Safety Surveillance) safety registry and the post-approval pulmonary hypertension study. Bracco’s newly approved ultrasound contrast agent, Lumason, has substantially similar safety labeling as DEFINITY and Optison. If additional safety issues arise, this may result in further changes in labeling or result in restrictions on the approval of our product, including removal of the product from the market. Lingering safety concerns about DEFINITY among some healthcare providers or future unanticipated side effects or safety concerns associated with DEFINITY could limit expanded use of DEFINITY and have a material adverse effect on the unit sales of this product and our financial condition and results of operations.

### ***Our business depends on our ability to successfully introduce new products and adapt to a changing technology and diagnostic landscape.***

The healthcare industry is characterized by continuous technological development resulting in changing customer preferences and requirements. The success of new product development depends on many factors, including our ability to fund development of new agents, anticipate and satisfy customer needs, obtain regulatory approval on a timely basis based on performance of our agents in development versus their clinical study comparators, develop and manufacture products in a cost-effective and timely manner, maintain advantageous positions with respect to intellectual property and differentiate our products from our competitors. To compete successfully in the marketplace, we must make substantial investments in new product development whether internally or externally through licensing or acquisitions. Our failure to introduce new and innovative products in a timely manner would have an adverse effect on our business, results of operations, financial condition and cash flows.

Even if we are able to develop, manufacture and obtain regulatory approvals for our new products, the success of these products would depend upon market acceptance and adequate reimbursement. Levels of market acceptance for our new products could be affected by a number of factors, including:

- the availability of alternative products from our competitors, such as, in the case of DEFINITY, GE Healthcare’s Optison, Bracco’s Lumason and other imaging modalities;
- the price of our products relative to those of our competitors;
- the timing of our market entry;
- our ability to market and distribute our products effectively;
- market acceptance of our products; and
- our ability to obtain adequate reimbursement.

The field of diagnostic medical imaging is dynamic, with new products, including equipment and agents, continually being developed and existing products continually being refined. Our own diagnostic imaging agents compete not only with other similarly administered imaging agents but also with imaging agents employed in different and often competing diagnostic modalities. New imaging agents in a given diagnostic modality may be developed that provide benefits superior to the then-dominant agent in that modality, resulting in commercial displacement. Similarly, changing perceptions about comparative efficacy and safety including, among other things, comparative radiation exposure, as well as changing availability of supply may favor one agent over another or one modality over another. In addition, new or revised appropriate use criteria developed by professional societies, to assist physicians and other health care providers in making appropriate imaging decisions for specific clinical conditions, can and have reduced the frequency of and demand for certain imaging modalities and imaging agents. To the extent there is technological obsolescence in any of our products that we manufacture, resulting in lower unit sales or decreased unit sales prices, we will have increased unit overhead allocable to the remaining market share, which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

---

## [Table of Contents](#)

Our current portfolio of commercial products primarily focuses on heart disease and vascular disease. This particular focus, however, may not be in our long-term best interest if the incidence and prevalence of heart disease and vascular disease decrease over time. Despite the aging population in the affluent parts of the world where diagnostic medical imaging is most frequently used, government and private efforts to promote preventative cardiac care through exercise, diet and improved medications could decrease the overall demand for our products, which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

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

We currently have three agents in development, two of which (flurpiridaz F 18 and 18F LMI 1195) are currently in clinical development, while a third (LMI 1174) is in pre-clinical development. To obtain regulatory approval for these agents, we must conduct extensive human tests, which are referred to as clinical trials, as well as meet other rigorous regulatory requirements, as further described in “Business—Regulatory Matters.” Satisfaction of all regulatory requirements typically takes many years and requires the expenditure of substantial resources. A number of other factors may cause significant delays in the completion of our clinical trials, including unexpected delays in the initiation of clinical sites, slower than projected enrollment, competition with ongoing clinical trials and scheduling conflicts with participating clinicians, regulatory requirements, limits on manufacturing capacity and failure of an agent to meet required standards for administration to humans. In addition, it may take longer than we project to achieve study endpoints and complete data analysis for a trial or we may decide to slow down the enrollment in a trial in order to conserve financial resources.

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

In our flurpiridaz F 18 Phase 3 program, in the fourth quarter of 2013 we announced preliminary results from the 301 trial, which is subject to an SPA with the FDA. Although flurpiridaz F 18 appeared to be well-tolerated from a safety perspective and outperformed SPECT in a highly statistically significant manner in the co-primary endpoint of sensitivity and in the secondary endpoints of image quality and diagnostic certainty, the agent did not meet its other co-primary endpoint of non-inferiority for identifying subjects without disease. We can give no assurances that our SPA agreement will be deemed binding on the FDA or will result in any particular outcome from regulatory review of the study or the agent, that any of the data generated in the 301 trial will be sufficient to support an NDA approval, that a strategic partner will have to conduct only one additional clinical trial prior to filing an NDA, or that flurpiridaz F 18 will ever be approved as a PET MPI imaging agent by the FDA. See “Business—Regulatory Matters—Food and Drug Laws.”

We are not permitted to market our agents in development in the United States or other countries until we have received requisite regulatory approvals. For example, securing FDA approval for a new drug requires the

---

## [Table of Contents](#)

submission of an NDA to the FDA for our agents in development. The NDA must include extensive nonclinical and clinical data and supporting information to establish the agent's safety and effectiveness for each indication. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. The FDA review process can take many years to complete, and approval is never guaranteed. If a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling, impose restricted distribution programs, require expedited reporting of certain adverse events, or require costly ongoing requirements for post-marketing clinical studies and surveillance or other risk management measures to monitor the safety or efficacy of the agent. Markets outside of the United States also have requirements for approval of agents with which we must comply prior to marketing. Obtaining regulatory approval for marketing of an agent in one country does not ensure we will be able to obtain regulatory approval in other countries, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. Also, any regulatory approval of any of our products or agents in development, once obtained, may be withdrawn. Approvals might not be granted on a timely basis, if at all.

Any failure or significant delay in completing clinical trials for our product candidates or in receiving regulatory approval for the sale of our product candidates may severely harm our business and delay or prevent us from being able to generate revenue from product sales.

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

***We will not be able to further develop or commercialize our agents in development without successful strategic partners.***

In March 2013, we began to implement a strategic shift in how we will fund our important R&D programs. We have reduced our internal R&D resources, while at the same time we are seeking to engage strategic partners to further develop and commercialize our important agents in development, including flurpiridaz F 18, 18F LMI 1195 and LMI 1174. However, different strategic partners may have different time horizons, risk profiles, return expectations and amounts of capital to deploy, and we may not be able to negotiate relationships with potential strategic partners on acceptable terms, or at all. If we are unable to establish or maintain these strategic partnerships, we will have to limit the size or scope of, or delay, our development programs.

In addition, our dependence on strategic partnerships is subject to a number of risks, including:

- the inability to control the amount or timing of resources that our partners may devote to developing the agents;
- the possibility that we may be required to relinquish important rights, including economic, intellectual property, marketing and distribution rights;
- the receipt of lower revenues than if we were to commercialize those agents ourselves;
- our failure to receive future milestone payments or royalties if a partner fails to commercialize one of our agents successfully;

---

## Table of Contents

- the possibility that a partner could separately move forward with competing agents developed either independently or in collaboration with others, including our competitors;
- the possibility that our strategic partners may experience financial or operational difficulties;
- business combinations or significant changes in a partner's business strategy that may adversely affect that partner's willingness or ability to complete its obligations under any arrangement with us; and
- the possibility that our partners may operate in countries where their operations could be negatively impacted by changes in the local regulatory environment or by political unrest.

Any of these factors either alone or taken together could have a material adverse effect on our business, results of operations, financial condition and cash flows.

### ***A heightened public or regulatory focus on the radiation risks of diagnostic imaging could have an adverse effect on our business.***

We believe that there has been heightened public and regulatory focus on radiation exposure, including the concern that repeated doses of radiation used in diagnostic imaging procedures pose the potential risk of long-term cell damage, cancer and other diseases. For example, starting in January 2012, the CMS required the accreditation of facilities providing the technical component of advanced imaging services, including CT, MRI, PET and nuclear medicine, in non-hospital free-standing settings. In August 2011, The Joint Commission (an independent, not-for-profit organization that accredits and certifies more than 20,500 healthcare organizations and programs in the United States) issued an alert on the radiation risks of diagnostic imaging and recommended specific actions for providing "the right test and the right dose through effective processes, safe technology and a culture of safety." Revised accreditation standards issued by The Joint Commission for diagnostic imaging will take effect in July 2015.

Heightened regulatory focus on risks caused by the radiation exposure received by diagnostic imaging patients could lead to increased regulation of radiopharmaceutical manufacturers or healthcare providers who perform procedures that use our imaging agents, which could make the procedures more costly, reduce the number of providers who perform procedures and/or decrease the demand for our products. In addition, heightened public focus on or fear of radiation exposure could lead to decreased demand for our products by patients or by healthcare providers who order the procedures in which our agents are used. Although we believe that our diagnostic imaging agents when properly used do not expose patients and healthcare providers to unsafe levels of radiation, any of the foregoing risks could have an adverse effect on our business, results of operations, financial condition and cash flows.

### ***In the ordinary course of business, we may be subject to product liability claims and lawsuits, including potential class actions, alleging that our products have resulted or could result in an unsafe condition or injury.***

Any product liability claim brought against us, with or without merit, could be time consuming and costly to defend and could result in an increase of our insurance premiums. Although we have not had any such claims to date, claims that could be brought against us might not be covered by our insurance policies. Furthermore, although we currently have product liability insurance coverage with policy limits that we believe are customary for pharmaceutical companies in the diagnostic medical imaging industry and adequate to provide us with insurance coverage for foreseeable risks, even where the claim is covered by our insurance, our insurance coverage might be inadequate and we would have to pay the amount of any settlement or judgment that is in excess of our policy limits. We may not be able to obtain insurance on terms acceptable to us or at all, since insurance varies in cost and can be difficult to obtain. Our failure to maintain adequate insurance coverage or successfully defend against product liability claims could have a material adverse effect on our business, results of operations, financial condition and cash flows.

---

## [Table of Contents](#)

### ***We use hazardous materials in our business and must comply with environmental laws and regulations, which can be expensive.***

Our operations use hazardous materials and produce hazardous wastes, including radioactive, chemical and, in certain circumstances, biological materials and wastes. We are subject to a variety of federal, state and local laws and regulations as well as non-U.S. laws and regulations relating to the transport, use, handling, storage, exposure to and disposal of these materials and wastes. Environmental laws and regulations are complex, change frequently and have become more stringent over time. We are required to obtain, maintain and renew various environmental permits and nuclear licenses. Although we believe that our safety procedures for transporting, using, handling, storing and disposing of, and limiting exposure to, these materials and wastes comply in all material respects with the standards prescribed by applicable laws and regulations, the risk of accidental contamination or injury cannot be eliminated. We place a high priority in these safety procedures and seek to limit any inherent risks. We generally contract with third parties for the disposal of wastes generated by our operations. Prior to disposal, we store any low level radioactive waste at our facilities to decay until the materials are no longer considered radioactive. Although we believe we have complied in all material respects with all applicable environmental, health and safety laws and regulations, we cannot assure you that we have been or will be in compliance with all such laws at all times. If we violate these laws, we could be fined, criminally charged or otherwise sanctioned by regulators. We may be required to incur further costs to comply with current or future environmental and safety laws and regulations. In addition, in the event of accidental contamination or injury from these materials, we could be held liable for any damages that result and any such liability could exceed our resources.

While we have budgeted for current and future capital and operating expenditures to maintain compliance with these laws and regulations, we cannot assure you that our costs of complying with current or future environmental, health and safety laws and regulations will not exceed our estimates or adversely affect our results of operations and financial condition. Further, we cannot assure you that we will not be subject to additional environmental claims for personal injury, investigation or cleanup in the future based on our past, present or future business activities.

### ***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 technologies and agents in development as well as successfully defending these patents and trade secrets against third party challenges, both in the United States 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 United States 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;

---

## [Table of Contents](#)

- 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, reexaminations 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 fail 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 United States patents and so our products may not receive the same degree of protection in foreign countries as they would in the United States;
- 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 U.S. Patent and Trademark Office 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 defense and prosecution of intellectual property suits, interferences, oppositions and related legal and administrative proceedings are costly, time consuming to pursue and result in diversion of resources. The outcome of these proceedings is uncertain and could significantly harm our business. If we are not able to 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 adverse effect on our business, results of operations, financial condition and cash flows.

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 and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. We often 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

---

## [Table of Contents](#)

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 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, TechnLite, Neurolite, Ablavar, Quadramet 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 rebrand 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.

***We may be subject to claims that we have infringed, misappropriated or otherwise violated the patent or other intellectual property rights of a third party. The outcome of any of these claims is uncertain and any unfavorable result could adversely affect our business, financial condition and results of operations.***

We may be subject to claims by third parties that we have infringed, misappropriated or otherwise violated their intellectual property rights. While we believe that the products that we currently manufacture using our proprietary technology do not infringe upon or otherwise violate proprietary rights of other parties or that meritorious defenses would exist with respect to any assertions to the contrary, we cannot assure you that we would not be found to infringe on or otherwise violate the proprietary rights of others.

We may be subject to litigation over infringement claims regarding the products we manufacture or distribute. This type of litigation can be costly and time consuming and could divert management's attention and resources, generate significant expenses, damage payments (potentially including treble damages) or restrictions or prohibitions on our use of our technology, which could adversely affect our results of operations. In addition, if we are found to be infringing on proprietary rights of others, we may be required to develop non-infringing technology, obtain a license (which may not be available on reasonable terms, or at all), make substantial one-time or ongoing royalty payments, or cease making, using and/or selling the infringing products, any of which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

***We may be adversely affected by prevailing economic conditions and financial, business and other factors beyond our control.***

Our ability to attract and retain customers, invest in and grow our business and meet our financial obligations depends on our operating and financial performance, which, in turn, is subject to numerous factors, including the prevailing economic conditions and financial, business and other factors beyond our control, such as the rate of unemployment, the number of uninsured persons in the United States and inflationary pressures. We cannot anticipate all the ways in which the current economic climate and financial market conditions could adversely impact our business.

We are exposed to risks associated with reduced profitability and the potential financial instability of our customers, many of which may be adversely affected by volatile conditions in the financial markets. For example, unemployment and underemployment, and the resultant loss of insurance, may decrease the demand for healthcare services and pharmaceuticals. If fewer patients are seeking medical care because they do not have insurance coverage, our customers may experience reductions in revenues, profitability and/or cash flow that could lead them to modify, delay or cancel orders for our products. If customers are not successful in generating sufficient revenue or are precluded from securing financing, they may not be able to pay, or may delay payment of, accounts receivable that are owed to us. This, in turn, could adversely affect our financial condition and liquidity. In addition, widespread and prolonged unemployment, either regionally or on a national basis, prior to the effectiveness of certain provisions of the Healthcare Reform Act, could result in a substantial number of



---

## [Table of Contents](#)

people becoming uninsured or underinsured. In turn, this may lead to fewer individuals pursuing or being able to afford diagnostic medical imaging procedures. To the extent prevailing economic conditions result in fewer procedures being performed, our business, results of operations, financial condition and cash flows could be adversely affected.

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

For the years ended December 31, 2014, 2013 and 2012, 22%, 25% and 27%, respectively, of our revenues were derived from countries outside the United States. We anticipate that revenue from non-U.S. operations will grow in the future. Accordingly, our business is subject to risks associated with doing business internationally, including:

- less stable political and economic environments and changes in a specific country's or region's political or economic conditions;
- entering into or renewing commercial agreements with international governments or provincial authorities or entities directly or indirectly controlled by such governments or authorities, such as our Chinese partner Double-Crane;
- make it more difficult to refinance the outstanding Notes;
- international customers which are agencies or institutions of foreign governments,
- local business practices which may be in conflict with the FCPA and Bribery Act;
- currency fluctuations;
- potential negative consequences from changes in tax laws affecting our ability to repatriate profits;
- unfavorable labor regulations;
- greater difficulties in relying on non-U.S. courts to enforce either local or U.S. laws, particularly with respect to intellectual property;
- greater potential for intellectual property piracy;
- greater difficulties in managing and staffing non-U.S. operations;
- the need to ensure compliance with the numerous in-country and international regulatory and legal requirements applicable to our business in each of these jurisdictions and to maintain an effective compliance program to ensure compliance with these requirements;
- changes in public attitudes about the perceived safety of nuclear facilities;
- changes in trade policies, regulatory requirements and other barriers;
- civil unrest or other catastrophic events; and
- longer payment cycles of non-U.S. customers and difficulty collecting receivables in non-U.S. jurisdictions.

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

***We face currency and other risks associated with international sales.***

We generate significant revenue from export sales, as well as from operations conducted outside the United States. During the years ended December 31, 2014, 2013 and 2012, the net impact of foreign currency changes

---

## [Table of Contents](#)

on transactions was a loss of \$279,000, \$349,000 and \$579,000, respectively. Operations outside the United States expose us to risks including fluctuations in currency values, trade restrictions, tariff and trade regulations, U.S. export controls, non-U.S. tax laws, shipping delays and economic and political instability. For example, violations of U.S. export controls, including those administered by the U.S. Treasury Department's Office of Foreign Assets Control, could result in fines, other civil or criminal penalties and the suspension or loss of export privileges which could have a material adverse effect on our business, results of operations, financial conditions and cash flows.

The functional currency of each of our non-U.S. operations is generally the local currency, although one non-U.S. operation's functional currency is the U.S. Dollar. Exchange rates between some of these currencies and U.S. Dollar have fluctuated significantly in recent years and may do so in the future. Historically, we have not used derivative financial instruments or other financial instruments to hedge those economic exposures. It is possible that fluctuations in exchange rates will have a negative effect on our results of operations.

***U.S. credit markets may impact our ability to obtain financing or increase the cost of future financing, including, in the event we obtain financing with a variable interest rate, interest rate fluctuations based on macroeconomic conditions that are beyond our control.***

As of December 31, 2014, we had approximately \$408.0 million of total principal indebtedness consisting of \$400.0 million of Notes issued May 10, 2010 and March 16, 2011 and due May 15, 2017 and our revolving credit facility, with an outstanding balance of \$8.0 million. In addition to the \$8.0 million outstanding under our revolving credit facility, there is an \$8.8 million unfunded Standby Letter of Credit as of December 31, 2014. As of December 31, 2014, our revolving credit facility had \$33.2 million of remaining availability. In June 2014, we amended our revolving credit facility to increase the size from \$42.5 million to \$50.0 million. During periods of volatility and disruption in the U.S., European, or global credit markets, obtaining additional or replacement financing may be more difficult and the cost of issuing new debt or replacing our revolving credit facility could be higher than under our current revolving credit facility. Higher cost of new debt may limit our ability to have cash on hand for working capital, capital expenditures and acquisitions on terms that are acceptable to us. Additionally, our revolving credit facility has a variable interest rate. By its nature, a variable interest rate will move up or down based on changes in the economy and other factors, all of which are beyond our control. If interest rates increase, our interest expense could increase, affecting earnings and reducing cash flows available for working capital, capital expenditures and acquisitions.

***Many of our customer relationships outside of the United States are, either directly or indirectly, with governmental entities, and we could be adversely affected by violations of the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws outside the United States.***

The FCPA, the Bribery Act and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business.

The FCPA prohibits us from providing anything of value to foreign officials for the purposes of obtaining or retaining business or securing any improper business advantage. It also requires us to keep books and records that accurately and fairly reflect our transactions. Because of the predominance of government-sponsored healthcare systems around the world, many of our customer relationships outside of the United States are, either directly or indirectly, with governmental entities and are therefore subject to the FCPA and similar anti-bribery laws in non-U.S. jurisdictions. In addition, the Bribery Act has been enacted, and its provisions extend beyond bribery of foreign public officials and are more onerous than the FCPA in a number of other respects, including jurisdiction, non-exemption of facilitation payments and penalties.

Our policies mandate compliance with these anti-bribery laws. We operate in many parts of the world that have experienced governmental corruption to some degree, and in certain circumstances strict compliance with anti-bribery laws may conflict with local customs and practices. Despite our training and compliance programs,

---

## [Table of Contents](#)

our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents. Violations of these laws, or allegations of those violations, could disrupt our business and result in a material adverse effect on our results of operations, financial condition and cash flows.

***Our business depends on the continued effectiveness and availability of our information technology infrastructure, and failures of this infrastructure could harm our operations.***

To remain competitive in our industry, we must employ information technologies to support manufacturing processes, quality processes, distribution, R&D and regulatory applications and that capture, manage and analyze the large streams of data generated in our clinical trials in compliance with applicable regulatory requirements. We rely extensively on technology, some of which is managed by third-party service providers, to allow the concurrent conduct of work sharing around the world. As with all information technology, our equipment and infrastructure age and become subject to increasing maintenance and repair and our systems generally are vulnerable to potential damage or interruptions from fires, natural disasters, power outages, blackouts, machinery breakdown, telecommunications failures and other unexpected events, as well as to break-ins, sabotage, increasingly sophisticated intentional acts of vandalism or cyber threats. As these threats continue to evolve, we may be required to expend additional resources to enhance our information security measures or to investigate and remediate any information security vulnerabilities. Given the extensive reliance of our business on technology, any substantial disruption or resulting loss of data that is not avoided or corrected by our backup measures could harm our business, operations and financial condition.

***We may not be able to hire or retain the number of qualified personnel, particularly scientific, medical and sales personnel, required for our business, which would harm the development and sales of our products and limit our ability to grow.***

Competition in our industry for highly skilled scientific, healthcare and sales personnel is intense. Although we have not had any material difficulty in the past in hiring or retaining qualified personnel other than from this intense competition, if we are unable to retain our existing personnel, or attract and train additional qualified personnel, either because of competition in our industry for these personnel or because of insufficient financial resources, then our growth may be limited and it could have a material adverse effect on our business.

***If we lose the services of our key personnel, our business could be adversely affected.***

Our success is substantially dependent upon the performance, contributions and expertise of our chief executive officer, executive leadership and senior management team. Jeffrey Bailey, our Chief Executive Officer and President, and other members of our executive leadership and senior management team play a significant role in generating new business and retaining existing customers. We have employment agreements with Mr. Bailey and a limited number of other individuals on our executive leadership team, although we cannot prevent them from terminating their employment with us. We do not maintain key person life insurance policies on any of our executive officers. While we have experienced both voluntary and involuntary turnover on our executive leadership team, to date we have been able to attract new, qualified individuals to lead our company and key functional areas. Our inability to retain our existing executive leadership and senior management team, maintain an appropriate internal succession program or attract and retain additional qualified personnel could have a material adverse effect on our business.

---

## [Table of Contents](#)

***Our future growth may depend on our ability to identify and in-license or acquire additional products, and if we do not successfully do so, or otherwise fail to integrate any new products into our operations, we may have limited growth opportunities and it could materially adversely affect our relationships with customers and/or result in significant impairment charges.***

We are continuing to seek to acquire or in-license products, businesses or technologies that we believe are a strategic fit with our business strategy. Future in-licenses or acquisitions, however, may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business, customer base and diversion of our management's time and attention to develop acquired products or technologies;
- a reduction of our current financial resources;
- difficulty or inability to secure financing to fund development activities for those acquired or in-licensed technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions; and
- higher than expected acquisition and integration costs.

We may not have sufficient resources to identify and execute the acquisition or in-licensing of third party products, businesses and technologies and integrate them into our current infrastructure. In particular, we may compete with larger pharmaceutical companies and other competitors in our efforts to establish new collaborations and in-licensing opportunities. These competitors likely will have access to greater financial resources than we do and may have greater expertise in identifying and evaluating new opportunities. Furthermore, there may be overlap between our products or customers and the companies which we acquire that may create conflicts in relationships or other commitments detrimental to the integrated businesses. Additionally, the time between our expenditures to in-license or acquire new products, technologies or businesses and the subsequent generation of revenues from those acquired products, technologies or businesses (or the timing of revenue recognition related to licensing agreements and/or strategic collaborations) could cause fluctuations in our financial performance from period to period. Finally, if we devote resources to potential acquisitions or in-licensing opportunities that are never completed, or if we fail to realize the anticipated benefits of those efforts, we could incur significant impairment charges or other adverse financial consequences.

***We have a substantial amount of indebtedness which may limit our financial and operating activities and may adversely affect our ability to incur additional debt to fund future needs.***

As of December 31, 2014, we had approximately \$408.0 million of total principal indebtedness consisting of \$400.0 million of the Notes, which mature on May 15, 2017, and \$8.0 million outstanding under our revolving credit facility. As of December 31, 2014, in addition to the \$8.0 million outstanding under our revolving credit facility, there is an \$8.8 million unfunded Standby Letter of Credit. Our substantial indebtedness and any future indebtedness we incur could:

- require us to dedicate a substantial portion of cash flow from operations to the payment of interest on and principal of our indebtedness, thereby reducing the funds available for other purposes;
- make it more difficult for us to satisfy and comply with our obligations with respect to the Notes, namely the payment of interest and principal;
- make it more difficult to refinance the outstanding Notes;
- subject us to increased sensitivity to interest rate increases;
- make us more vulnerable to economic downturns, adverse industry or company conditions or catastrophic external events;
- limit our ability to withstand competitive pressures;

---

## [Table of Contents](#)

- reduce our flexibility in planning for or responding to changing business, industry and economic conditions; and
- place us at a competitive disadvantage to competitors that have relatively less debt than we have.

In addition, our substantial level of indebtedness could limit our ability to obtain additional financing on acceptable terms, or at all, for working capital, capital expenditures and general corporate purposes. Our liquidity needs could vary significantly and may be affected by general economic conditions, industry trends, performance and many other factors not within our control.

### ***We may not be able to generate sufficient cash flow to meet our debt service obligations.***

Our ability to generate sufficient cash flow from operations to make scheduled payments on our debt obligations, which are currently \$39.0 million of interest per year based on our \$400.0 million in total principal indebtedness as of December 31, 2014 related to the Notes, which principal is due at maturity on May 15, 2017, will depend on our future financial performance, which will be affected by a range of economic, competitive and business factors, many of which are outside of our control. If we do not generate sufficient cash flow from operations to satisfy our debt obligations, including interest payments and the payment of principal at maturity, our credit ratings could be downgraded, and we may have to undertake alternative financing plans, such as refinancing or restructuring our debt, selling assets, entering into additional corporate collaborations or licensing arrangements for one or more of our products or agents in development, reducing or delaying capital investments or seeking to raise additional capital. We cannot assure you that any refinancing would be possible, that any assets could be sold, licensed or partnered, or, if sold, licensed or partnered, of the timing of the transactions and the amount of proceeds realized from those transactions, that additional financing could be obtained on acceptable terms, if at all, or that additional financing would be permitted under the terms of our various debt instruments then in effect. Furthermore, our ability to refinance would depend upon the condition of the financial and credit markets. Our inability to generate sufficient cash flow to satisfy our debt obligations, or to refinance our obligations on commercially reasonable terms or on a timely basis, would have an adverse effect on our business, results of operations and financial condition.

### ***Despite our substantial indebtedness, we may incur more debt, which could exacerbate the risks described above.***

We and our subsidiaries may be able to incur substantial additional indebtedness in the future subject to the limitations contained in the agreements governing our debt, including the Indenture (as defined below) governing the Notes. Although these agreements restrict us and our restricted subsidiaries from incurring additional indebtedness, these restrictions are subject to important exceptions and qualifications. For example, we are generally permitted to incur certain indebtedness, including indebtedness arising in the ordinary course of business, indebtedness among restricted subsidiaries and us and indebtedness relating to hedging obligations. We are also permitted to incur indebtedness under the Indenture governing the Notes so long as we comply with an interest coverage ratio of 2.0 to 1.0, determined on a pro forma basis for the most recently completed four fiscal quarters. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—External Sources of Liquidity.” If we or our subsidiaries incur additional debt, the risks that we and they now face as a result of our high leverage could intensify. In addition, the Indenture governing the Notes and the agreement governing our revolving credit facility will not prevent us from incurring obligations that do not constitute indebtedness under the agreements.

### ***Our debt agreements contain restrictions that will limit our flexibility in operating our business.***

The Indenture governing the Notes and the agreement governing our revolving credit facility contain various covenants that limit our ability to engage in specified types of transactions. These covenants limit our and our restricted subsidiaries’ ability to, among other things:

- incur additional debt;
- pay dividends or make other distributions;

---

## [Table of Contents](#)

- redeem stock;
- issue stock of subsidiaries;
- make certain investments;
- create liens;
- enter into transactions with affiliates; and
- merge, consolidate or transfer all or substantially all of our assets.

A breach of any of these covenants could result in a default under the Indenture governing the Notes and the agreement governing our revolving credit facility. We may also be unable to take advantage of business opportunities that arise because of the limitations imposed on us by the restrictive covenants under our indebtedness.

***We may be limited in our ability to utilize, or may not be able to utilize, net operating loss carryforwards to reduce our future tax liability.***

As of December 31, 2014, we had federal income tax loss carryforwards of \$114.0 million, which will begin to expire in 2031 and will completely expire in 2034. We have had significant financial losses in previous years and as a result we currently maintain a full valuation allowance for our deferred tax assets including our federal and state tax loss carryforwards.

### **Item 1B. Unresolved Staff Comments**

None.

### **Item 2. Properties**

Our executive offices and primary manufacturing facilities are located at our North Billerica, Massachusetts facility, which we own. In addition, as of December 31, 2014, we lease 5 facilities in Canada, 2 in Australia and 2 in Puerto Rico. Our owned facilities consist of approximately 578,000 square feet of manufacturing, laboratory, mixed use and office space, and our leased facilities consist of approximately 54,019 square feet of manufacturing, laboratory, mixed use and office space. We believe all of these facilities are well-maintained and suitable for the office, radiopharmacy, manufacturing or warehouse operations conducted in them.

The following table summarizes information regarding our significant leased and owned properties, as of December 31, 2014:

<u>Location</u>	<u>Square footage</u>	<u>Owned/Leased</u>
United States		
North Billerica, Massachusetts	578,000	Owned
Canada		
Montreal	8,729	Leased
Dorval	13,079	Leased
Quebec	6,261	Leased
Hamilton*	5,300	Leased
Vancouver	880	Leased
Australia		
Melbourne	4,634	Leased
Adelaide	4,306	Leased
Puerto Rico		
San Juan	9,550	Leased
Ponce	1,280	Leased

\* The Hamilton lease was terminated subsequent to December 31, 2014.

**Item 3. 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 exposes 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 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.

On December 16, 2010, we filed suit against one of our insurance carriers seeking to recover business interruption losses associated with the NRU reactor shutdown and the ensuing global Moly supply shortage (*Lantheus Medical Imaging, Inc., Plaintiff v. Zurich American Insurance Company, Defendant*, United States District Court, Southern District of New York, Case No. 10 Civ 9371). The claim is the result of the shutdown of the NRU reactor in Chalk River, Ontario. The NRU reactor was off-line from May 2009 until August 2010. The defendant answered the complaint on January 21, 2011, denying substantially all of the allegations, presenting certain defenses and requesting dismissal of the case with costs and disbursements. Discovery, including international discovery and related motion practice, has been on-going for more than three years. The defendant filed a motion for summary judgment on July 14, 2014. The Company filed a memorandum of law in opposition to defendant's motion for summary judgment on August 25, 2014. The defendant filed a reply memorandum of law in further support of its motion for summary judgment on September 15, 2014. Expert witness discovery was completed on October 31, 2014. We cannot be certain what amount, if any, or when, if ever, we will be able to recover for business interruption losses related to this matter.

**Item 4. Mine Safety Disclosures**

Not applicable

## PART II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

#### Market and Dividend Information

Our outstanding common stock is privately held and there is no established public trading market for our common stock. There is one stockholder of record of our common stock as of December 31, 2014.

#### Unregistered Sales of Equity Securities

We sold no equity securities during the year ended December 31, 2014.

#### Securities Authorized for Issuance Under Equity Compensation Plans

See "Item 12—Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters—Securities Authorized for Issuance Under Equity Compensation Plans."

### Item 6. Selected Financial Data

#### Basis of Financial Information

Following our purchase of the medical imaging business from Bristol-Myers Squibb Company, or BMS, with the financial sponsorship of Avista on January 8, 2008 (the "Acquisition"), our audited financial statements were prepared at the Lantheus Intermediate level rather than at the Lantheus level due to covenants in our financial arrangements undertaken in connection with the Acquisition.

#### Non-GAAP Financial Measures

Adjusted EBITDA and EBITDA as used in our equity incentive plans, collectively, our Non-GAAP Measures, as presented in this annual report, are supplemental measures of our performance that are not required by, or presented in accordance with GAAP. They are not measurements of our financial performance under GAAP and should not be considered as alternatives to net income (loss) or any other performance measures derived in accordance with GAAP or as alternatives to cash flow from operating activities as measures of our liquidity.

Our presentation of our Non-GAAP Measures may not be comparable to similarly titled measures of other companies. We have included information concerning our Non-GAAP Measures in this annual report because we believe that this information is used by certain investors as measures of a company's historical performance.

Our Non-GAAP Measures have limitations as analytical tools, and you should not consider them in isolation, or as substitutes for analysis of our operating results or cash flows as reported under GAAP. Some of these limitations include:

- they do not reflect our cash expenditures, or future requirements, for capital expenditures or contractual commitments;
- they do not reflect changes in, or cash requirements for, our working capital needs;
- they do not reflect the significant interest expense or the cash requirements necessary to service interest or principal payments, on our debt;
- although depreciation is a non-cash charge, the assets being depreciated will often have to be replaced in the future, and our Non-GAAP Measures do not reflect any cash requirements for those replacements;



## Table of Contents

- they are not adjusted for all non-cash income or expense items that are reflected in our statements of cash flows; and
- other companies in our industry may calculate these measures differently than we do, limiting their usefulness as comparative measures.

Because of these limitations, our Non-GAAP Measures should not be considered as measures of discretionary cash available to us to invest in the growth of our business. We compensate for these limitations by relying primarily on our GAAP results and using our Non-GAAP Measures only for supplemental purposes.

### Selected Financial Data

The following table sets forth certain selected consolidated financial data for Lantheus Intermediate, our parent company and a guarantor of the Notes, as of and for the fiscal years ended December 31, 2014, 2013, 2012, 2011 and 2010, which have been derived from the audited consolidated financial statements of Lantheus Intermediate. See “—Basis of Financial Information.”

The results indicated below and elsewhere in this annual report are not necessarily indicative of our future performance. You should read this information together with “Item 7—Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the consolidated financial statements and related notes included in Item 8 of this annual report.

	Year Ended December 31,				
	2014	2013	2012	2011	2010
	(dollars in thousands)				
<b>Statement of Comprehensive (Loss) Income Data:</b>					
Revenues	\$301,600	\$283,672	\$288,105	\$356,292	\$353,956
Cost of goods sold	176,081	206,311	211,049	255,466	204,006
Loss on firm purchase commitment	—	—	1,859	5,610	—
Sales and marketing expenses	35,116	35,227	37,437	38,689	45,384
General and administrative expenses	34,921	33,159	32,520	32,057	30,042
Research and development expense	13,673	30,459	40,604	40,945	45,130
Proceeds from manufacturer	—	(8,876)	(34,614)	—	—
Impairment on land	—	6,406	—	—	—
Operating income (loss)	41,809	(19,014)	(750)	(16,475)	29,394
Interest expense	(42,288)	(42,915)	(42,014)	(37,658)	(20,395)
Loss on early extinguishment of debt	—	—	—	—	(3,057)
Interest income	27	104	252	333	179
Other income (expense), net	478	1,161	(44)	1,429	1,314
Income (loss) before income taxes	26	(60,664)	(42,556)	(52,371)	7,435
Provision (benefit) for income taxes	1,195	1,014	(555)	84,098	2,465
Net (loss) income	<u>\$ (1,169)</u>	<u>\$ (61,678)</u>	<u>\$ (42,001)</u>	<u>\$ (136,469)</u>	<u>\$ 4,970</u>
<b>Statement of Cash Flows Data:</b>					
Net cash flows provided by (used in):					
Operating activities	\$ 11,573	\$ (15,678)	\$ 523	\$ 22,420	\$ 26,317
Investing activities	(7,682)	(3,483)	(8,145)	(7,694)	(8,550)
Financing activities	(2,293)	5,535	(2,039)	(6,991)	(17,550)
<b>Other Financial Data:</b>					
EBITDA(1)	\$ 60,557	\$ 6,789	\$ 26,815	\$ 16,832	\$ 62,037
Adjusted EBITDA(1)	70,755	38,360	21,598	80,084	85,228
Capital expenditures	8,137	5,010	7,920	7,694	8,335

[Table of Contents](#)

	Year Ended December 31,				
	2014	2013	2012	2011	2010
	(dollars in thousands)				
<b>Balance Sheet Data (at period end):</b>					
Cash and cash equivalents	\$ 17,817	\$ 16,669	\$ 31,595	\$ 40,607	\$ 33,006
Total assets	247,516	259,385	322,926	358,804	495,881
Total liabilities	488,485	496,473	497,279	492,007	342,447
Total long-term debt, net	399,280	399,037	398,822	398,629	250,000
Total stockholder's (deficit) equity	(240,969)	(237,088)	(174,353)	(133,203)	153,434

- (1) EBITDA is defined as net (loss) income plus interest, income taxes, depreciation and amortization. EBITDA is a measure used by management to measure operating performance. Adjusted EBITDA is defined as EBITDA, further adjusted to exclude unusual items and other adjustments required or permitted in calculating Adjusted EBITDA under the indenture governing the Company's notes and the credit agreement for the Company's revolving credit facility. Adjusted EBITDA is also used by management to measure operating performance and by investors to measure a company's ability to service its debt and meet its other cash needs. Management believes that the inclusion of the adjustments to EBITDA applied in presenting Adjusted EBITDA are appropriate to provide additional information to investors about the Company's performance across reporting periods on a consistent basis by excluding items that it does not believe are indicative of its core operating performance. See "—Non-GAAP Financial Measures."

The following table provides a reconciliation of our net (loss) income to EBITDA and Adjusted EBITDA for the periods presented:

	Year Ended December 31,				
	2014	2013(j)	2012(j)	2011	2010
	(dollars in thousands)				
Net (loss) income	\$ (1,169)	\$(61,678)	\$(42,001)	\$(136,469)	\$ 4,970
Interest expense, net	42,261	42,811	41,762	37,325	20,216
Provision for income taxes(a)	441	(127)	(901)	82,718	1,215
Depreciation and amortization	19,024	25,783	27,955	33,258	35,636
EBITDA	60,557	6,789	26,815	16,832	62,037
Non-cash stock-based compensation	1,031	578	1,240	(969)	1,634
Loss on early extinguishment of debt	—	—	—	—	3,057
Legal fees(b)	1,113	660	1,455	2,017	—
Loss on firm purchase commitment(c)	—	—	1,859	5,610	—
Asset write-off(d)	1,257	28,349	13,095	52,973	14,084
Severance and recruiting costs(e)	818	5,239	1,761	1,995	1,001
Sponsor fee and other(f)	1,020	1,457	1,042	1,020	1,090
New manufacturer costs(g)	4,959	4,164	8,945	606	1,816
Ablavar launch costs(h)	—	—	—	—	509
Proceeds from manufacturer	—	(8,876)	(34,614)	—	—
Adjusted EBITDA(i)	<u>\$70,755</u>	<u>\$ 38,360</u>	<u>\$ 21,598</u>	<u>\$ 80,084</u>	<u>\$85,228</u>

- (a) Represents provision for income taxes, less tax indemnification associated with an agreement with BMS, and, in 2011, includes the establishment of a full valuation allowance against the U.S. deferred tax assets.
- (b) Represents legal fees and disbursements incurred in connection with our business interruption claim associated with the NRU reactor shutdown in 2009 to 2010.
- (c) Represents a loss associated with a portion of the committed purchases of Ablavar that we do not believe we will be able to sell prior to expiration.
- (d) Represents non-cash losses incurred associated with the write-down of land, intangible assets, inventory and write-off of long-lived assets. The 2013 amount consists primarily of a \$6.4 million

---

## [Table of Contents](#)

write-down of land, a \$15.4 million impairment charge on the Cardiolite trademark intangible asset, a \$1.7 million impairment charge on a customer relationship intangible asset and a \$1.6 million inventory write-down related to Ablavar. The 2012 amount consists primarily of a \$10.6 million inventory write-down related to Ablavar. The 2011 amount consists primarily of a \$25.8 million inventory write-down related to Ablavar and a \$23.5 million impairment charge to adjust the carrying value of the Ablavar patent portfolio asset to its fair value of zero. The 2010 amount consists primarily of a \$10.9 million inventory write-down related to Ablavar.

- (e) The 2014, 2013, 2012 and 2011 amounts consist of severance and recruitment costs related to employees, executives and directors. The 2010 amount consists of severance costs relating to one of our executive officers and a work force reduction in the fourth quarter.
- (f) Represents annual sponsor monitoring fee and related expenses, and certain non-recurring charges related to a customer relationship.
- (g) Represents internal and external costs associated with establishing new manufacturing sources for our commercial and clinical candidate products.
- (h) Represents costs associated with the launch of Ablavar.
- (i) Does not include run-rate cost savings, operating expense reductions and other expense and cost-savings of \$14.4 million and \$2.9 million, which were realized for the years ended December 31, 2013 and 2012, respectively, primarily relating to our strategic shift from in-house R&D to an external partnering model of R&D.
- (j) Previously presented as excluding Proceeds from manufacturer as an Adjusted EBITDA reconciling item, resulting in 2013 and 2012 Adjusted EBITDA of \$47.2 million and \$56.2 million, respectively. Presentation of 2013 and 2012 Adjusted EBITDA has been modified to allow better go-forward comparability by including Proceeds from manufacturer as an Adjusted EBITDA reconciling item, resulting in 2013 and 2012 Adjusted EBITDA of \$38.4 million and \$21.6 million, respectively.

### **Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*The following discussion and analysis of our financial condition and results of operations should be read together with "Item 6—Selected Financial Data" and the consolidated financial statements and the related notes included in Item 8 of this annual report. This discussion contains forward-looking statements related to future events and our future financial performance that are based on current expectations and subject to risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those set forth under "Item 1A—Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements."*

#### **Overview**

We are a global leader in developing, manufacturing, selling and distributing innovative diagnostic medical imaging agents and products that assist clinicians in the diagnosis of cardiovascular and other diseases. Our agents are routinely used to diagnose coronary artery disease, congestive heart failure, stroke, peripheral vascular disease and other diseases. Clinicians use our imaging agents and products across a range of imaging modalities, including nuclear imaging, echocardiography and MRI. We believe that the resulting improved diagnostic information enables healthcare providers to better detect and characterize, or rule out, disease, potentially achieving improved patient outcomes, reducing patient risk and limiting overall costs for payers and the entire healthcare system.

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

We sell our products globally and have operations in the United States, Puerto Rico, Canada and Australia and distribution relationships in Europe, Asia Pacific and Latin America.

---

[Table of Contents](#)*Our Products*

Our principal products include the following:

DEFINITY is an ultrasound contrast agent used in ultrasound exams of the heart, also known as echocardiography exams. DEFINITY contains perflutren-containing lipid microspheres and is indicated in the United States for use in patients with suboptimal echocardiograms to assist in imaging the left ventricular chamber and left endocardial border of the heart in ultrasound procedures. We launched DEFINITY in 2001, and its last patent in the United States will currently expire in 2021 and in numerous foreign jurisdictions in 2019. We also have an active life cycle management program for this agent.

TechneLite is a technetium generator which provides the essential nuclear material used by radiopharmacies to radiolabel Cardiolite, Neurolite and other technetium-based radiopharmaceuticals used in nuclear medicine procedures. TechneLite uses Molybdenum-99, or Moly, as its main active ingredient.

Xenon is a radiopharmaceutical gas that is inhaled and used to assess pulmonary function and also for imaging blood flow. Xenon is manufactured by a third party and packaged by us.

Cardiolite is a technetium-based radiopharmaceutical imaging agent used in MPI procedures to detect coronary artery disease using SPECT. Cardiolite was approved by the U.S. Food and Drug Administration, or FDA, in 1990, and its market exclusivity expired in July 2008.

Sales of our contrast agent, DEFINITY, are made through our sales team of approximately 80 employees. In the United States, our nuclear imaging products, including TechneLite, Xenon, Cardiolite and Neurolite, are primarily distributed through approximately 350 radiopharmacies that are controlled by or associated with Cardinal Health, or Cardinal, GE Healthcare, United Pharmacy Partners, or UPPI, and Triad. A small portion of our nuclear imaging product sales in the United States are made through our direct sales force to hospitals and clinics that maintain their own in-house radiopharmaceutical capabilities. Outside the United States, we own four radiopharmacies in Canada and two radiopharmacies in each of Puerto Rico and Australia. We also maintain a direct sales force in each of these countries. In Europe, Asia Pacific and Latin America, we rely on third party distributors to market, sell and distribute our nuclear imaging and contrast agent products, either on a country-by-country basis or on a multicountry regional basis.

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

<u>(dollars in thousands)</u>	<u>Year Ended December 31,</u>					
	<u>2014</u>	<u>%</u>	<u>2013</u>	<u>%</u>	<u>2012</u>	<u>%</u>
DEFINITY	\$ 95,760	31.8	\$ 78,094	27.5	\$ 51,431	17.9
TechneLite	93,588	31.0	92,195	32.5	114,249	39.7
Xenon	36,549	12.1	32,125	11.3	30,075	10.4
Cardiolite	18,823	6.2	26,137	9.2	34,995	12.1
Other	56,880	18.9	55,121	19.5	57,355	19.9
Revenues	<u>\$301,600</u>	<u>100.0</u>	<u>\$283,672</u>	<u>100.0</u>	<u>\$288,105</u>	<u>100.0</u>

Included in Cardiolite revenue are sales of branded Cardiolite and generic sestamibi, some of which we produce and some of which we procure from third parties.

---

[Table of Contents](#)

**Key Factors Affecting Our Results**

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

***Growth of DEFINITY***

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

Prior to the supply issues with BVL in 2012, sales of DEFINITY continually increased year-over-year since June 2008, when the boxed warning on DEFINITY was modified. Unit sales of DEFINITY had decreased substantially in late 2007 and early 2008 as a result of an FDA request in October 2007 that we and GE Healthcare, which distributes Optison, a competitor to DEFINITY, add a boxed warning to their products to notify physicians and patients about potentially serious safety concerns or risks posed by the products. However, in May 2008, the FDA boxed warning was modified in response to the substantial advocacy efforts of prescribing physicians. In October 2011, we received FDA approval of further modifications to the DEFINITY label, including: further relaxing the boxed warning; eliminating the sentence in the Indication and Use section "The safety and efficacy of DEFINITY with exercise stress or pharmacologic stress testing have not been established" (previously added in October 2007 in connection with the imposition of the box warning); and including summary data from the post-approval CaRES (Contrast echocardiography Registry for Safety Surveillance) safety registry and the post-approval pulmonary hypertension study. Bracco's newly approved ultrasound contrast agent, Lumason, has substantially similar safety labeling as DEFINITY. As discussed above under "Inventory Supply," the future growth of our DEFINITY sales will be dependent on the ability of JHS and, if approved, Pharamalucence to continue to manufacture and release DEFINITY on a timely and consistent basis and our ability to continue to increase segment penetration for DEFINITY in suboptimal echocardiograms. See "Item 1A—Risk Factors—The growth of our business is substantially dependent on increased market penetration for the appropriate use of DEFINITY in suboptimal echocardiograms."

There are three echocardiography contrast agents approved by the FDA for sale in the U.S. – DEFINITY which as of December 2014 had an approximately 78% segment share, Optison, and Lumason approved by the FDA in October 2014. Lumason is known as SonoVue outside of the U.S. and is already approved for sale in Europe and certain Asian markets, including China, Japan and Korea. While we believe that additional promotion in the U.S. echocardiography segment will help raise awareness around the value that echocardiography contrast brings and potentially increase the overall contrast penetration rate, if Bracco successfully commercializes Lumason in the U.S. without otherwise increasing the overall usage of ultrasound contrast agents, our own growth expectations for DEFINITY revenue, gross profit and gross margin may have to be adjusted.

***Global Isotope Supply***

Currently, our largest supplier of Moly and our only supplier of Xenon is Nordion, which relies on the NRU reactor in Chalk River, Ontario. For Moly, we currently have a supply agreement with Nordion that runs through December 31, 2015, subject to certain early termination provisions and supply agreements with NTP of South Africa, ANSTO of Australia, and IRE of Belgium, each running through December 31, 2017. For Xenon, we have a purchase order relationship with Nordion. The Canadian government requires the NRU reactor to shut down for at least four weeks at least once a year for inspection and maintenance. The 2014 shutdown period ran from April 13, 2014 until May 13, 2014, and we were able to source all of our standing order customer demand for Moly during this time period from our other suppliers. However, because Xenon is a by-product of the Moly

---

## [Table of Contents](#)

production process and is currently captured only by NRU, during this shutdown period, we were not able to supply all of our standing order customer demand for Xenon during the outage. Because the month-long NRU shutdown was fully anticipated in our 2014 budgeting process, the shutdown did not have a material adverse effect on our 2014 results of operations, financial condition and cash flows.

We believe we are well-positioned with our current supply partners to have a secure supply of Moly, including low-enriched uranium, or LEU, Moly, when the NRU reactor transitions in October 2016 from providing regular supply of medical isotopes to providing only emergency back-up supply medical isotopes through March 2018. ANSTO has under construction, in cooperation with NTP, a new Moly processing facility that ANSTO believes will expand its production capacity by approximately 2.5 times, with expanded commercial production planned to start in mid-2016. This new ANSTO production capacity is expected to replace the NRU's current routine production. In January 2015, we announced entering into a new strategic agreement with IRE for the future supply of Xenon. Under the terms of the agreement, IRE will provide bulk Xenon to us for processing and finishing once development work has been completed and all necessary regulatory approvals have been obtained. We currently estimate commercial production will occur in 2016. If we are not able to begin providing commercial quantities of Xenon prior to the NRU reactor's supply transition in 2016, there may be a period of time during which we are not able to offer Xenon in our portfolio of commercial products. See "Item 1A—Risk Factors—We face potential supply and demand challenges for Xenon."

### ***Inventory Supply***

Our products consist of radiopharmaceuticals and other imaging agents. The radiopharmaceuticals are decaying radioisotopes with half-lives ranging from a few hours to several days. These products cannot be kept in inventory because of their limited useful lives and are subject to just-in-time manufacturing, processing and distribution. We obtain a substantial portion of our other imaging agents from third party suppliers. JHS is currently our sole source manufacturer of DEFINITY and Neurolite and we have ongoing technology transfer activities at JHS for our Cardiolite product supply. In the meantime, our Cardiolite product supply is manufactured by a single manufacturer. Until JHS is approved by certain foreign regulatory authorities to manufacture certain of our products, we will face continued limitations on where we can sell those products outside of the U.S.

Historically, we relied on BVL in Bedford, Ohio as our sole manufacturer of DEFINITY, Neurolite and evacuation vials, an ancillary component for our TechnLite generators, and as one of two manufacturers of Cardiolite. Following extended operational and regulatory challenges at BVL, in March 2012 we entered into a settlement arrangement with BVL, resulting in an aggregate payment to us of \$35.0 million, a broad mutual waiver and a covenant by us not to sue. Later in 2012 and in 2013, BVL continued to attempt to manufacture our products for us, and in October 2013 announced that it would cease to manufacture new batches of our products at its Bedford, Ohio facility. In November 2013, we entered into a second settlement arrangement with BVL, resulting in an additional aggregate payment to us of \$8.9 million, a broad mutual waiver and a covenant by us not to sue. At this time, we have a very limited amount of BVL-manufactured products in our finished goods inventory.

In addition to JHS, we are also currently working to secure additional alternative suppliers for our key products as part of our ongoing supply chain diversification strategy. On November 12, 2013, we entered into a Manufacturing and Supply Agreement with Pharmalucence to manufacture and supply DEFINITY. We currently believe that Pharmalucence will file for FDA approval to manufacture DEFINITY in 2015.

### ***Demand for TechnLite***

Since the global Moly supply shortage in 2009 to 2010, we have experienced reduced demand for TechnLite generators from pre-shortage levels even though volume has increased in absolute terms from levels during the shortage following the return of our normal Moly supply in August 2010. However, we do not know if overall industry demand for technetium will ever return to pre-shortage levels.

---

## [Table of Contents](#)

We also believe that there has been an overall decline in the MPI study market because decreased levels of patient studies during the Moly shortage period have not returned to pre-shortage levels and industry-wide cost-containment initiatives that have resulted in a transition of where imaging procedures are performed, from free standing imaging centers to the hospital setting. We expect these factors will continue to affect technetium demand in the future.

In November 2014, CMS announced the 2015 final Medicare payment rules for hospital outpatient settings. Under the final rules, each technetium dose produced from a generator for a diagnostic procedure in a hospital outpatient setting is reimbursed by Medicare at a higher rate if that technetium dose is produced from a generator containing Moly sourced from at least 95 percent LEU. We currently understand that CMS expects to continue this incentive program for the foreseeable future. In January 2013, we began to offer a TechnoLite generator which contains Moly sourced from at least 95 percent LEU and which satisfies the requirements for reimbursement under this incentive program. Although demand for LEU generators appears to be growing, we do not know when, or if, this incremental reimbursement for LEU Moly generators will result in a material increase in our generator sales.

### ***Cardinal Supply Agreements***

Our written supply agreements with Cardinal relating to TechnoLite, Xenon, NeuroLite, Cardiolite and certain other products expired in accordance with their terms on December 31, 2014. Following extended discussions with Cardinal that have not yet resulted in one or more new written supply agreements, we are currently accepting and fulfilling product orders from Cardinal on a purchase order basis at list price. We cannot predict the volumes or product mix Cardinal will continue to order and purchase, and such volumes and product mix may vary over time. In the absence of written supply agreements with Cardinal, unit sales volumes have decreased in early 2015 from levels experienced throughout 2014, but such sales have been at substantially higher prices. However, ultimate future levels of net revenue and operating profit associated with Cardinal cannot be predicted at this time because such amounts depend on future unit sales volumes, product mix and pricing to Cardinal. See “Item 1A—Risk Factors—In the United States, we are heavily dependent on a few large customers and group purchasing organization arrangements to generate a majority of our revenues for our medical imaging products. Outside of the United States, we rely on distributors to generate a substantial portion of our revenues.”

### ***Cardiolite Competitive Pressures***

Cardiolite’s market exclusivity expired in July 2008. In September 2008, the first of several competing generic products to Cardiolite was launched. With continued pricing and unit volume pressures from generic competitors, we also sell our Cardiolite product in the form of a generic sestamibi at the same time as we continue to sell branded Cardiolite throughout the MPI segment. We believe this strategy of selling branded as well as generic sestamibi has slowed our market share loss by having multiple sestamibi offerings that are attractive in terms of brand, as well as price.

In addition to pressures due to generics, our Cardiolite products have also faced a volume decline in the MPI segment due to a change in professional society appropriate use criteria, ongoing reimbursement pressures, the limited availability of Moly during the NRU reactor shutdown, the limited availability of Cardiolite products to us during the BVL outage, and the increase in use of other diagnostic modalities as a result of a shift to more available imaging agents and modalities. We believe the continuing effects from the BVL outage and continued generic competition will result in further market share and margin erosion for our Cardiolite products.

These factors have impacted the carrying value of our Cardiolite trademark intangible asset as further described in “Gross Profit.”

---

[Table of Contents](#)

***Research and Development Expenses***

To remain a leader in the marketplace, we have historically made substantial investments in new product development. As a result, the positive contributions of those internally funded R&D programs have been a key factor in our historical results and success. In March 2013, we began to implement a strategic shift in how we will fund our important R&D programs. We have reduced our internal R&D resources while at the same time we are seeking to engage strategic partners to assist us in the further development and commercialization of our important agents in development, including flurpiridaz F 18, 18F LMI 1195 and LMI 1174. As a result of this shift, we are seeking strategic partners to assist us with the further development and possible commercialization of flurpiridaz F 18. For our other two important agents in development, 18F LMI 1195 and LMI 1174, we will also seek to engage strategic partners to assist us with the ongoing development activities relating to these agents.

**Segments**

We report our results of operations in two operating segments: United States and International. We generate a greater proportion of our revenue and net income in the United States segment, which consists of all regions of the United States with the exception of Puerto Rico. We expect our percentage of revenue and net income derived from our International segment to continue to increase in future periods as we continue to expand globally.

**Operating Results**

The following have been included in our results as of and for the year ended December 31, 2014:

- increased revenues and segment penetration for DEFINITY in the suboptimal echocardiogram segment as a result of our sales efforts and sustained availability of product supply;
- increased revenues for Xenon, mainly the result of higher selling prices, offset in part by mix shift among certain sales channels;
- increased revenues resulting from the return of Neurolite product supply in the third quarter of 2013;
- decreased revenues from our Cardiolite products resulting from continued generic competition;
- the impact of certain cost savings actions taken in March 2013 as we finish implementing the strategic shift in how we fund our research and development, or R&D, programs;
- lower material costs incurred for the production of TechnoLite; and
- lower international revenues across product lines because of unfavorable foreign exchange and competitive pressures.



[Table of Contents](#)

Years Ended December 31, 2014, 2013 and 2012

(dollars in thousands)	December 31,			2014 compared to 2013		2013 compared to 2012	
	2014	2013	2012	Change \$	Change %	Change \$	Change %
Revenues	\$301,600	\$283,672	\$288,105	\$ 17,928	6.3%	\$ (4,433)	(1.5)%
Cost of goods sold	176,081	206,311	211,049	(30,230)	(14.7)	(4,738)	(2.2)
Loss on firm purchase commitment	—	—	1,859	—	—	(1,859)	(100.0)
Total cost of goods sold	<u>176,081</u>	<u>206,311</u>	<u>212,908</u>	<u>(30,230)</u>	<u>(14.7)</u>	<u>(6,597)</u>	<u>(3.1)</u>
Gross profit	<u>125,519</u>	<u>77,361</u>	<u>75,197</u>	<u>48,158</u>	<u>62.3</u>	<u>2,164</u>	<u>2.9</u>
Operating expenses							
Sales and marketing expenses	35,116	35,227	37,437	(111)	(0.3)	(2,210)	(5.9)
General and administrative expenses	34,921	33,159	32,520	1,762	5.3	639	2.0
Research and development expenses	13,673	30,459	40,604	(16,786)	(55.1)	(10,145)	(25.0)
Proceeds from manufacturer	—	(8,876)	(34,614)	8,876	(100.0)	25,738	(74.4)
Impairment on land	—	6,406	—	(6,406)	(100.0)	6,406	100.0
Total operating expenses	<u>83,710</u>	<u>96,375</u>	<u>75,947</u>	<u>(12,665)</u>	<u>(13.1)</u>	<u>20,428</u>	<u>26.9</u>
Operating income (loss)	<u>41,809</u>	<u>(19,014)</u>	<u>(750)</u>	<u>60,823</u>	<u>319.9</u>	<u>(18,264)</u>	<u>2,435.2</u>
Interest expense	(42,288)	(42,915)	(42,014)	627	(1.5)	(901)	2.1
Interest income	27	104	252	(77)	(74.0)	(148)	(58.7)
Other income (expense), net	478	1,161	(44)	(683)	(58.8)	1,205	2,738.6
Income (loss) before income taxes	26	(60,664)	(42,556)	60,690	(100.0)	(18,108)	42.6
Provision (benefit) for income taxes	1,195	1,014	(555)	181	17.9	1,569	282.7
Net loss	<u>(1,169)</u>	<u>(61,678)</u>	<u>(42,001)</u>	<u>60,509</u>	<u>(98.1)</u>	<u>(19,677)</u>	<u>46.8</u>
Foreign currency translation	(1,236)	(1,729)	964	493	(28.5)	(2,693)	(279.4)
Total comprehensive loss	<u>\$ (2,405)</u>	<u>\$ (63,407)</u>	<u>\$ (41,037)</u>	<u>\$ 61,002</u>	<u>(96.2)%</u>	<u>\$ (22,370)</u>	<u>54.5%</u>

[Table of Contents](#)

*Comparison of the Years Ended December 31, 2014, 2013, and 2012*

**Revenues**

Revenues are summarized as follows:

	Year ended December 31,			2014 compared to 2013		2013 compared to 2012	
	2014	2013	2012	Change \$	Change %	Change \$	Change %
(dollars in thousands)							
<b>United States</b>							
DEFINITY	\$ 93,848	\$ 76,539	\$ 50,377	\$17,309	22.6%	\$ 26,162	51.9%
TechneLite	82,321	80,609	101,049	1,712	2.1	(20,440)	(20.2)
Xenon	36,542	32,086	30,048	4,456	13.9	2,038	6.8
Cardiolite	3,268	8,612	13,851	(5,344)	(62.1)	(5,239)	(37.8)
Other	20,541	15,793	14,686	4,748	30.1	1,107	7.5
Total U.S. revenues	<u>\$236,520</u>	<u>\$213,639</u>	<u>\$210,011</u>	<u>\$22,881</u>	10.7%	<u>\$ 3,628</u>	1.7%
<b>International</b>							
DEFINITY	\$ 1,912	\$ 1,555	\$ 1,054	\$ 357	23.0%	\$ 501	47.5%
TechneLite	11,267	11,586	13,200	(319)	(2.8)	(1,614)	(12.2)
Xenon	7	39	27	(32)	(82.1)	12	44.4
Cardiolite	15,555	17,525	21,144	(1,970)	(11.2)	(3,619)	(17.1)
Other	36,339	39,328	42,669	(2,989)	(7.6)	(3,341)	(7.8)
Total International revenues	<u>\$ 65,080</u>	<u>\$ 70,033</u>	<u>\$ 78,094</u>	<u>\$ (4,953)</u>	(7.1)	<u>\$ (8,061)</u>	(10.3)
Revenues	<u>\$301,600</u>	<u>\$283,672</u>	<u>\$288,105</u>	<u>\$17,928</u>	6.3%	<u>\$ (4,433)</u>	(1.5)%

**2014 v. 2013**

Total revenues increased \$17.9 million, or 6.3%, to \$301.6 million in the year ended December 31, 2014, as compared to \$283.7 million in the year ended December 31, 2013. U.S. segment revenue increased \$22.9 million, or 10.7%, to \$236.5 million in the same period, as compared to \$213.6 million in the prior year. The U.S. segment increase is primarily due to a \$17.3 million increase in DEFINITY as a result of higher unit volumes, a \$6.8 million increase in NeuroLite as the product returned to market in September 2013, a \$4.5 million increase in Xenon primarily due to higher selling prices, a \$1.9 million increase in Thallium driven by higher unit volumes with significant customer and \$1.7 million TechneLite increase as a result of higher unit volumes. Offsetting these increases was a decrease in Cardiolite revenues of \$5.3 million over the prior year period as a result of a contract with a significant customer that reduced unit pricing and volume commitments and a \$3.4 million decrease in Quadramet revenues due to lower unit volume as a result of increased competitive pressures since we transitioned to being the direct manufacturer at the end of 2013.

International segment revenues decreased \$5.0 million, or 7.1%, to \$65.1 million in the year ended December 31, 2014, as compared to \$70.0 million in the year ended December 31, 2013. The decrease in the International segment revenue during the year ended December 31, 2014, as compared to the prior year period, is primarily due to \$3.5 million unfavorable foreign exchange, combined with a \$2.3 million decrease in third party product revenues and a \$1.1 million decrease in Cardiolite revenues as a result of competitive pressures in our international markets. Offsetting these decreases were a \$1.0 million increase in NeuroLite revenues driven by the return of finished product to the market, \$0.4 million increase in TechneLite revenues primarily in the Latin America market and \$0.5 million increase in DEFINITY revenues as a result of sales volume growth in certain international markets.

**2013 v. 2012**

Revenues decreased \$4.4 million, or 1.5%, to \$283.7 million in the year ended December 31, 2013, as compared to \$288.1 million in the year ended December 31, 2012. U.S. segment revenue increased \$3.6 million,

---

## [Table of Contents](#)

or 1.7%, to \$213.6 million in the same period, as compared to \$210.0 million in the prior year. The increase of \$3.6 million in U.S. segment revenue during the year ended December 31, 2013, as compared to the prior year period is primarily driven by a \$26.2 million increase in DEFINITY revenue given product supply shortages that impacted the prior year period. Offsetting this increase was a decrease in TechneLite revenues of \$20.4 million over the prior year period as a result of: (i) a contract that took effect at the beginning of 2013 with a significant customer that reduced unit pricing, resulting in lower revenues of \$16.9 million as compared to the prior year period; (ii) a decline in a significant customer's market share which lowered its share of product purchases from us and decreased revenues by \$5.7 million; and (iii) loss of a customer resulting in lower revenue of \$1.3 million. Offsetting these decreases in TechneLite revenues was a higher share volume with a group of customers resulting in a \$3.3 million increase in sales over the prior year period. Additionally, Cardiolite revenues were \$5.2 million lower than the prior year period as a result of a contract with a significant customer that reduced unit pricing and volume commitments.

International segment revenues decreased \$8.1 million, or 10.3%, to \$70.0 million in the year ended December 31, 2013, as compared to \$78.1 million in the year ended December 31, 2012. The decrease of \$8.1 million in the International segment revenue during the year ended December 31, 2013, as compared to the prior year period, is due in part to a \$3.3 million decrease in other revenue. This decrease is the result of a new contract with an existing customer, which altered the timing of shipments and reflected a lower selling price, as well as an unfavorable foreign exchange impact in the amount \$1.9 million for the year ended December 31, 2013 versus the prior year. In addition, Cardiolite sales decreased by \$3.6 million mainly due to competitive pressures in international markets, as well as \$0.7 million in unfavorable foreign exchange. TechneLite sales decreased by \$1.6 million due to reduced selling prices in Canada, lower sales volume in the Latin America and Asia Pacific markets as well as \$0.3 million in unfavorable foreign exchange. Overall, total unfavorable foreign exchange totaled \$2.9 million when compared to the prior period.

### *Rebates and Allowances*

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

## Table of Contents

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

(in thousands)	Rebates	Allowances	Total
Balance, as of January 1, 2012	\$ 1,356	\$ 33	\$ 1,389
Current provisions relating to revenues in current year	3,224	291	3,515
Adjustments relating to prior years' estimate	(145)	—	(145)
Payments/credits relating to revenues in current year	(2,232)	(223)	(2,455)
Payments/credits relating to revenues in prior years	(661)	(35)	(696)
Balance, as of December 31, 2012	1,542	66	1,608
Current provisions relating to revenues in current year	4,696	243	4,939
Adjustments relating to prior years' estimate	(21)	—	(21)
Payments/credits relating to revenues in current year	(3,438)	(220)	(3,658)
Payments/credits relating to revenues in prior years	(1,040)	(69)	(1,109)
Balance, as of December 31, 2013	1,739	20	1,759
Current provisions relating to revenues in current year	5,773	310	6,083
Adjustments relating to prior years' estimate	(18)	—	(18)
Payments/credits relating to revenues in current year	(4,264)	(284)	(4,548)
Payments/credits relating to revenues in prior years	(1,066)	(20)	(1,086)
Balance, as of December 31, 2014	<u>\$ 2,164</u>	<u>\$ 26</u>	<u>\$ 2,190</u>

Sales rebates accrued were approximately \$2.2 million and \$1.7 million at December 31, 2014 and 2013, respectively. The \$0.5 million increase in accrued sales rebates is primarily associated with a new rebate program associated with the Quadramet product as well as royalties incurred associated with the net revenues generated by Quadramet. In addition, accrued sales rebates increased due to the timing of certain rebates.

### Cost of Goods Sold

Cost of goods sold consists of manufacturing, distribution, intangible asset amortization and other costs related to our commercial products. In addition, it includes the write-off of excess and obsolete inventory.

Cost of goods sold is summarized as follows:

(dollars in thousands)	December 31,			2014 compared to 2013		2013 compared to 2012	
	2014	2013	2012	Change \$	Change %	Change \$	Change %
United States	\$127,237	\$149,018	\$156,098	\$(21,781)	(14.6)%	\$(7,080)	(4.5)%
International	48,844	57,293	56,810	(8,449)	(14.7)	483	0.9
Total Cost of Goods Sold	<u>\$176,081</u>	<u>\$206,311</u>	<u>\$212,908</u>	<u>\$(30,230)</u>	(14.7)%	<u>\$(6,597)</u>	(3.1)%

### 2014 v. 2013

Total cost of goods sold decreased \$30.2 million, or 14.7%, to \$176.1 million in the year ended December 31, 2014, as compared to \$206.3 million in the year ended December 31, 2013. U.S. segment cost of goods sold decreased approximately \$21.8 million, or 14.6%, to \$127.2 million in same period, as compared to \$149.0 million in the prior year period. The decrease in the U.S. segment cost of goods sold for the year ended December 31, 2014 over the prior year period is primarily due to a \$22.0 million decrease in Cardiolite cost of goods as a result of a \$15.4 million write-down in the Cardiolite trademark intangible asset in the fourth quarter of 2013 and lower amortization expense in 2014 as compared to 2013 as a result of the impairment. In addition, there was a \$2.8 million decrease in Technelite cost of goods sold primarily due to lower material costs for 2014.

## Table of Contents

We also incurred \$2.1 million of lower write-off expense as compared to the prior year related to the Ablavar product line. Offsetting these decreases was a \$5.9 million increase in DEFINITY and Thallium cost of goods sold due to higher sales unit volumes and higher DEFINITY technology transfer costs.

For the year ended December 31, 2014, the International segment cost of goods sold decreased \$8.5 million, or 14.7%, to \$48.8 million, as compared to \$57.3 million in the prior year period. The decrease in the International segment cost of goods sold during the year ended December 31, 2014, as compared to the prior year period, is primarily due to a \$4.5 million decrease as a result of reduced costs associated with operating efficiencies as well as lower cost of goods sold for certain products. We also incurred an impairment charge of \$1.7 million in the prior year relating to customer relationship intangible assets in Europe, lower amortization expense in the current year and incurred a favorable foreign exchange impact of \$1.7 million in the current year.

### 2013 v. 2012

Total cost of goods sold decreased \$6.6 million, or 3.1%, to \$206.3 million in the year ended December 31, 2013, as compared to \$212.9 million in the year ended December 31, 2012. U.S. segment cost of goods sold decreased approximately \$7.1 million, or 4.5%, to \$149.0 million in same period, as compared to \$156.1 million in the prior year period. The decrease in the U.S. segment cost of goods sold for the year ended December 31, 2013 over the prior year is primarily due to \$10.9 million of lower write-off expense as compared to the prior year related to the Ablavar product line. We also incurred lower cost of goods sold of \$9.3 million for TechnLite over the prior period primarily due to lower material cost and lower unit volumes. Technology transfer costs decreased by \$4.0 million related to JHS becoming an approved manufacturing site for DEFINITY by the FDA in the first quarter of 2013. Lower sales volume of Cardiolite contributed to lower cost of goods sold by \$2.6 million. Offsetting these decreases was an increase in DEFINITY cost of goods sold of approximately \$4.7 million primarily driven by an increase in units sold, an impairment charge of \$15.4 million related to the Cardiolite trademark intangible asset and an increase of \$2.1 million related to NeuroLite technology transfer.

For the year ended December 31, 2013, the International segment cost of goods sold increased \$0.5 million, or 0.9%, to \$57.3 million, as compared to \$56.8 million in the prior year period. The increase in the International segment was primarily due to an impairment charge on customer relationship intangible assets in Europe totaling \$1.7 million, which was partially offset by favorable foreign exchange impact of \$1.0 million, lower volume and lower cost of goods sold for certain products.

### Gross Profit

(dollars in thousands)	December 31,			2014 compared to 2013		2013 compared to 2012	
	2014	2013	2012	Change \$	Change %	Change \$	Change %
United States	\$109,283	\$64,621	\$53,913	44,662	69.1%	\$10,708	19.9%
International	16,236	12,740	21,284	3,496	27.4	(8,544)	(40.1)
Total Gross Profit	<u>\$125,519</u>	<u>\$77,361</u>	<u>\$75,197</u>	<u>48,158</u>	62.3%	<u>\$ 2,164</u>	2.9%

### 2014 v. 2013

Total gross profit increased \$48.2 million, or 62.3%, to \$125.5 million, or 41.6% of revenues in the year ended December 31, 2014, as compared to \$77.4 million or 27.3% of revenues in the year ended December 31, 2013. U.S. segment gross profit increased \$44.7 million, or 69.1%, to \$109.3 million, as compared to \$64.6 million in the prior year period. The increase in the U.S. segment gross profit for the year ended December 31, 2014 over the prior year period is primarily due to a \$16.6 million increase in Cardiolite gross profit due to a write-down in the Cardiolite trademark intangible asset in the fourth quarter of 2013 and a \$25.1 million aggregate increase in DEFINITY, TechnLite and NeuroLite gross profit due to higher unit volumes and

## Table of Contents

lower material costs for TechneLite. In addition, Xenon gross profit increased by \$4.1 million due to higher selling price. Offsetting these increases was a \$3.8 million decrease in Quadramet gross profit due to less unit volume since we transitioned as the direct manufacturer at the end of 2013.

For the year ended December 31, 2014, the International segment gross profit increased \$3.5 million, or 27.4%, to \$16.2 million, as compared to \$12.7 million in the prior year period. The increase in the International segment gross profit during the year ended December 31, 2014, as compared to the prior year period is primarily due to a \$1.7 million impairment charge on customer relationship intangible assets in the prior year and lower amortization as compared to the prior year. The increase is also driven by reduced costs associated with increased operating efficiencies, the return of NeuroLite finished product to the market and lower volume of more expensive substitute products sold in the current period as a result of the return of supply. These increases were partially offset by an unfavorable foreign exchange impact of \$1.8 million.

### 2013 v. 2012

Total gross profit increased \$2.2 million, or 2.9%, to \$77.4 million in the year ended December 31, 2013, as compared to \$75.2 million in the year ended December 31, 2012. U.S. segment gross profit increased \$10.7 million, or 19.9%, to \$64.6 million, as compared to \$53.9 million in the prior year period. The increase in the U.S. segment gross profit for the year ended December 31, 2013 over the prior year period is primarily due to an ongoing shift in mix among products, specifically a higher DEFINITY gross profit of approximately \$25.3 million primarily due to an increase in sales volume and \$4.0 million due to lower technology transfer cost related to JHS becoming an approved manufacturing site for DEFINITY by the FDA. In addition, gross profit improved due to a \$10.9 million decrease in write-offs related to Ablavar. Offsetting these increases was a decrease in TechneLite gross margin of approximately \$11.1 million over the prior period driven primarily by lower selling price and lower gross profit on Cardiolite due to an impairment charge of \$15.4 million related to the Cardiolite trademark intangible asset and lower selling prices.

For the year ended December 31, 2013, the International segment gross profit decreased \$8.5 million, or 40.1%, to \$12.7 million, as compared to \$21.3 million in the prior year period. Gross profit in our International segment decreased due to a new contract with an existing customer, which altered the timing of shipments and reflected a lower selling price, unfavorable changes in foreign exchange rates, lower sales due to competitive pressures in all markets and a \$1.7 million impairment charge on customer relationship intangible assets.

### Sales and Marketing

(dollars in thousands)	December 31,			2014 compared to 2013		2013 compared to 2012	
	2014	2013	2012	Change \$	Change %	Change \$	Change %
United States	\$30,815	\$31,024	\$33,638	\$ (209)	(0.7)%	\$(2,614)	(7.8)%
International	4,301	4,203	3,799	98	2.3	404	10.6
Total Sales and Marketing	<u>\$35,116</u>	<u>\$35,227</u>	<u>\$37,437</u>	<u>\$ (111)</u>	<u>(0.3)%</u>	<u>\$(2,210)</u>	<u>(5.9)%</u>

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.

### 2014 v. 2013

Total sales and marketing expenses decreased \$0.1 million, or 0.3%, to \$35.1 million in the year ended December 31, 2014, as compared to \$35.2 million in the year ended December 31, 2013. In the U.S. segment,

## [Table of Contents](#)

sales and marketing expense decreased \$0.2 million, or 0.7%, to \$30.8 million in the same period, as compared to \$31.0 million in the prior year. The decrease in the U.S. segment sales and marketing expenses for the year ended December 31, 2014 over the prior year period is primarily due to decreases in headcount and employee related expenses. Offsetting these decreases are increases in support of DEFINITY including marketing, research and travel expenses. As a percentage of total U.S. revenues, sales and marketing expenses in the U.S. segment were 13.0%, 14.5% and 16.0% for the years ended December 31, 2014, 2013 and 2012, respectively.

For the year ended December 31, 2014, the International segment sales and marketing expense increased \$0.1 million or 2.3%, to \$4.3 million as compared to \$4.2 million in the prior year period. The increase in the International segment sales and marketing expenses for the year ended December 31, 2014 over the prior year period is primarily due to increased external advertising and marketing expenses and external professional services which were offset by a favorable foreign exchange impact. As a percentage of total International revenues, sales and marketing expenses in the International segment were 6.6%, 6.0% and 4.9% for the years ended December 31, 2014, 2013 and 2012, respectively.

### **2013 v. 2012**

Total sales and marketing expenses decreased \$2.2 million, or 5.9%, to \$35.2 million in the year ended December 31, 2013, as compared to \$37.4 million in the year ended December 31, 2012. In the U.S. segment, sales and marketing expense decreased \$2.6 million, or 7.8%, to \$31.0 million in the same period, as compared to \$33.6 million in the prior year. The decrease in the U.S. segment was primarily due to lower headcount and employee related expenses, including contractors, due to a reduction in workforce and reduced marketing expenses related to Ablavar. Offsetting the decreases were increases in variable compensation and marketing expenses related to DEFINITY. As a percentage of total U.S. revenues, sales and marketing expenses in the U.S. segment were 14.5% and 16.0% for the years ended December 31, 2013, and 2012, respectively.

For the year ended December 31, 2013, the International segment sales and marketing expense increased \$0.4 million or 10.6%, to \$4.2 million as compared to \$3.8 million in the prior year period due to increased headcount and higher variable compensation. Offsetting the increases was a decrease in professional services. As a percentage of total International revenues, sales and marketing expenses in the International segment were 6.0% and 4.9% for the years ended December 31, 2013, and 2012, respectively.

### **General and Administrative**

(dollars in thousands)	December 31,			2014 compared to 2013		2013 compared to 2012	
	2014	2013	2012	Change \$	Change %	Change \$	Change %
United States	\$32,609	\$30,865	\$30,192	\$1,744	5.7%	\$ 673	2.2%
International	2,312	2,294	2,328	18	0.8	(34)	(1.5)
Total General and Administrative	<u>\$34,921</u>	<u>\$33,159</u>	<u>\$32,520</u>	<u>\$1,762</u>	5.3%	<u>\$ 639</u>	2.0%

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.

### **2014 v. 2013**

Total general and administrative expenses increased approximately \$1.8 million, or 5.3%, to \$34.9 million in the year ended December 31, 2014, as compared to \$33.2 million in the year ended December 31, 2013. In the

## [Table of Contents](#)

U.S. segment, general and administrative expenses increased \$1.7 million, or 5.7%, to \$32.6 million, as compared to \$30.9 million in the prior year period. The increase was primarily due to an increase in employee related expenses. Offsetting these increases were non-recurrence of severance expense related to the reduction in force in the first quarter of 2013, decrease in depreciation expense, cost savings achieved through the renegotiation of certain information technology related contracts and lower legal costs.

For the year ended December 31, 2014, general and administrative expenses in the International segment remained relatively consistent as compared to the prior year period.

### **2013 v. 2012**

Total general and administrative expenses increased approximately \$0.6 million, or 2.0%, to \$33.2 million in the year ended December 31, 2013, as compared to \$32.5 million in the year ended December 31, 2012. In the U.S. segment, general and administrative expenses increased \$0.7 million, or 2.2%, to \$30.9 million, as compared to \$30.2 million in the prior year period. The increase was primarily due to additional variable compensation in the current period and severance expense from a reduction in workforce in the first quarter of 2013. Offsetting these increases were cost savings over the prior period through the renegotiation of certain information technology related contracts as support provided by certain vendors was reduced and reduced legal expense. In addition, compensation for performance-based awards was lower in the current period due to adjustments made based on the probability of achievement.

For the year ended December 31, 2013, general and administrative expenses in the International segment were consistent with the prior year period at \$2.3 million as lower salaries and employee related expenses, which were driven by lower headcount, were offset by increased bad debt expense and increased recruiting fees.

## **Research and Development**

(dollars in thousands)	December 31,			2014 compared to 2013		2013 compared to 2012	
	2014	2013	2012	Change \$	Change %	Change \$	Change %
United States	\$13,252	\$30,138	\$40,457	\$(16,886)	(56.0)%	\$(10,319)	(25.5)%
International	421	321	147	100	31.2	174	118.4
Total Research and Development	<u>\$13,673</u>	<u>\$30,459</u>	<u>\$40,604</u>	<u>\$(16,786)</u>	<u>(55.1)%</u>	<u>\$(10,145)</u>	<u>(25.0)%</u>

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

### **2014 v. 2013**

Total research and development expense decreased \$16.8 million, or 55.1%, to \$13.7 million for the year ended December 31, 2014, as compared to \$30.5 million in the year ended December 31, 2013. In the U.S. segment, research and development expense decreased approximately \$16.9 million, or 56.0%, to \$13.3 million, as compared to \$30.1 million in the prior year period. The decrease in the U.S. segment research and development expenses is primarily due to a decline in external expense associated with Phase 3 clinical trial for flurpiridaz F 18 as we completed patient enrollment during the third quarter of 2013. In addition, there were decreases in employee related costs as a result of the reduction in workforce from a strategic shift to use fewer internal resources and lower external expense as we expect to seek one or more strategic partners to assist in the future development and commercialization of our agents in development. Offsetting this decrease was a \$0.9 million increase in depreciation expense as we announced in November 2014 our plans to decommission certain



---

## [Table of Contents](#)

long-lived assets associated with our research and development operations in the United States. We expect the decommissioning to begin in the second half of 2015. As a result, we revised our estimates of the remaining useful lives of the affected long-lived assets to seven months, which increased depreciation expense by \$1.2 million which is included in research and development expenses. Future decommissioning costs are expected to impact our general and administrative expenses through 2015.

For the year ended December 31, 2014, the International segment research and development expenses increased approximately \$0.1 million, or 31.2%, to \$0.4 million, as compared to \$0.3 million in the prior year period. The increase in research and development expenses for the International segment was primarily due to depreciation expense since we shifted the primary utilization of certain assets to support research and development functions.

### **2013 v. 2012**

Total research and development expense decreased \$10.1 million, or 25.0%, to \$30.5 million for the year ended December 31, 2013, as compared to \$40.6 million in the year ended December 31, 2012. In the U.S. segment, research and development expense decreased approximately \$10.3 million, or 25.5%, to \$30.1 million, as compared to \$40.4 million in the prior year period. The decrease in the U.S. segment research and development expenses for the year ended December 31, 2013 over the prior year period is driven by a decline in external expense associated with the Phase 3 clinical trial for flurpiridaz F 18, as we completed patient enrollment during the third quarter of 2013. There were decreases in employee related costs as a result of the reduction in workforce from a strategic shift to use fewer internal resources and lower external expense as we expect to seek one or more strategic partners to assist in the future development and commercialization of our agents in development. Offsetting these decreases, in part, was an increase in severance expense and variable compensation.

For the year ended December 31, 2013, the International segment research and development expenses increased approximately \$0.2 million, or 118.4%, to \$0.3 million, as compared to \$0.1 million in the prior year period. The increase in research and development expenses for the International segment was primarily due to depreciation expense since we shifted the primary utilization of certain assets to support research and development functions.

### **Impairment of Land**

During the third quarter of 2013, we committed to a plan to sell certain of our excess land, which had a carrying value of \$7.5 million. This event qualified for held for sale accounting and the excess land was written down to its fair value, less costs to sell. The fair value was estimated utilizing Level 3 inputs and using a market approach, based on available data for transactions in the region as well as the asking price of comparable properties in our principal market. This resulted in a loss of \$6.4 million, which is included within operating income (loss) as impairment of land in the accompanying consolidated statement of comprehensive loss. During the fourth quarter of 2013, we sold the excess land for net proceeds of \$1.1 million.

### **Proceeds from Manufacturer**

For the year ended December 31, 2013, as compared to the same period in 2012, proceeds from manufacturer decreased by \$25.7 million as a result of the receipt of the \$35 million from BVL in 2012 to compensate us for business losses compared to proceeds of \$8.9 million from BVL under a further 2013 settlement.

During the fourth quarter of 2013, BVL and LMI entered into a Settlement and Release Agreement. Pursuant to the Settlement and Release Agreement, BVL and LMI agreed to a broad mutual waiver and release for all matters that occurred prior to the date of the Settlement Agreement, a covenant not to sue and settlement payments to us in the aggregate amount of \$8.9 million. In addition, the Settlement and Release Agreement

[Table of Contents](#)

provided that the Manufacturing and Service Contract terminate as of November 15, 2013, subject to BVL's obligations to use commercially reasonable efforts to finalize specific batches of DEFINITY, Cardiolute product and saline manufactured and not yet released by the BVL quality function for commercial distribution.

**Other Income (Expense), Net**

(dollars in thousands)	December 31,			2014 compared to 2013		2013 compared to 2012	
	2014	2013	2012	Change \$	Change %	Change \$	Change %
Interest expense	\$(42,288)	\$(42,915)	\$(42,014)	\$ 627	(1.5)%	\$ (901)	2.1%
Interest income	27	104	252	(77)	(74.0)	(148)	(58.7)
Other income (expense), net	478	1,161	(44)	(683)	(58.8)	1,205	2,738.6
Total Other Expense, net	<u>\$(41,783)</u>	<u>\$(41,650)</u>	<u>\$(41,806)</u>	<u>\$ (133)</u>	0.3%	<u>\$ 156</u>	(0.4)%

*Interest Expense*

For the year ended December 31, 2014 compared to the same period in 2013, interest expense decreased by 1.5% to \$42.3 million from \$42.9 million, as a result of decreased amortization related to deferred financing costs.

For the year ended December 31, 2013 compared to the same period in 2012, interest expense increased by 2.1% to \$42.9 million from \$42.0 million, as a result of increased amortization related to the capitalization of additional deferred financing costs in connection with our new line of credit and the write off of the existing unamortized deferred financing costs related to our old facility.

*Interest Income*

For the year ended December 31, 2014, as compared to the same period in 2013, interest income decreased by 74.0% to \$27,000 from \$104,000, primarily as a result of the change in balances in interest bearing accounts.

For the year ended December 31, 2013, as compared to the same period in 2012, interest income decreased by 58.7% to \$104,000 from \$252,000, primarily as a result of the change in balances in interest bearing accounts.

*Other Income (Expense), net*

For the year ended December 31, 2014, as compared to the same period in 2013, other income (expense), net decreased by \$0.7 million from \$1.2 million primarily due to a net \$1.2 million settlement indemnified by BMS during 2014.

For the year ended December 31, 2013, as compared to the same period in 2012, other income (expense), net increased by \$1.2 million from \$(44,000) primarily due to a \$0.8 million increase as a result of the closing of the statute of limitations relating to a federal research credit matter in 2012, which decreased the tax indemnification assets in the prior year. In addition, we received \$0.4 million in consideration from the extinguishment of our membership interests in a mutual insurance company.

**Provision (Benefit) for Income Taxes**

(dollars in thousands)	December 31,			2014 compared to 2013		2013 compared to 2012	
	2014	2013	2012	Change \$	Change %	Change \$	Change %
Provision (benefit) for income taxes	\$1,195	\$1,014	\$(555)	\$ 181	17.9%	\$ 1,569	282.7%

---

## Table of Contents

For the year ended December 31, 2014 compared to the same period in 2013, provision for income taxes increased by 17.9% to \$1.2 million from \$1.0 million.

We have generated domestic pre-tax losses for two of the past three years and continue to be in cumulative loss position. This loss history demonstrates negative evidence concerning our ability to utilize our gross deferred tax assets. In order to overcome the presumption of recording a valuation allowance against our net deferred tax assets, we must have sufficient positive evidence that we can generate sufficient taxable income to utilize these deferred tax assets within the carryover or forecast period. Although we have no history of expiring net operating losses or other tax attributes, based on the cumulative domestic loss incurred over the three-year period ended December 31, 2014, management has determined that all of the net U.S. deferred tax assets are not more-likely-than-not recoverable. As a result of this analysis, we maintained a valuation allowance against substantially all of our net deferred tax assets in 2014.

Considering our history of losses, our provision (benefit) for income taxes results primarily from taxes due in certain foreign jurisdictions where we generate taxable income, as well as interest and penalties associated with uncertain tax positions, offset by reversals of those positions as statutes lapse or are settled during the year. Provision (benefit) for income taxes increased in 2014 due to changes in taxable income in certain foreign jurisdictions and settlements and lapse of statute of limitations of uncertain tax positions in the current year.

For the year ended December 31, 2013, as compared to the same period in 2012, provision (benefit) for income taxes increased by 282.7% to \$1.0 million from \$(0.6) million due primarily to lower credits associated with settlements and lapse of statute of limitations of uncertain tax positions in the current year.

Our effective tax rates for the years ended December 31, 2014, 2013, and 2012 were, 4,581.7%, (1.7)%, and 1.3 %, respectively. Our tax rate is affected by recurring items, such as tax rates in foreign jurisdictions, which we expect to be fairly consistent in the near term, as well as non-recurring items such as the settlement of state audits. The following items had the most significant impact on the difference between our statutory U.S. federal income tax rate of 35% and our effective tax rate during the years ended:

### December 31, 2014

- A \$0.8 million increase attributable to prior year uncertain tax positions for a closed tax year.
- A \$0.4 million increase for taxes in foreign jurisdictions.

### December 31, 2013

- A \$25.6 million increase to our valuation allowance against net domestic deferred tax assets.
- A \$1.4 million reduction relating primarily to prior year uncertain tax positions for a closed tax year.
- A \$1.8 million reduction primarily relating to a state income tax benefit related to state NOL's.

### December 31, 2012

- A \$20.2 million increase to our valuation allowance against net domestic deferred tax assets.
- A \$2.3 million reduction relating to prior year uncertain tax positions for a closed tax year.
- A \$1.8 million reduction relating to a state income tax benefit consisting of \$1.1 million related to state NOL's, \$0.3 million related to research credits, and \$0.4 million to other changes to state deferred taxes.

---

[Table of Contents](#)**Liquidity and Capital Resources***Cash Flows*

The following table provides information regarding our cash flows:

	Year Ended December 31,			% Change	
	2014	2013	2012	2014 Compared to 2013	2013 Compared to 2012
	(dollars in thousands)				
Cash provided by (used in):					
Operating activities	\$11,573	\$(15,678)	\$ 523	173.8%	(3,097.7)%
Investing activities	(7,682)	(3,483)	(8,145)	120.6%	(57.2)%
Financing activities	(2,293)	5,535	(2,039)	(141.4)%	371.5%

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

Cash provided by operating activities is primarily driven by our earnings and changes in working capital. The increase in cash provided by operating activities for the year ended December 31, 2014 as compared to 2013 was primarily driven by a decrease in net loss and cash flow increase for inventory purchases primarily due to timing of the receipt of inventory. The improvement was partially offset by cash flow decreases in accounts receivable primarily due to increased revenues.

The decrease in cash provided by operating activities for the year ended December 31, 2013 as compared to 2012 was primarily driven by the receipt of \$35.0 million from the BVL settlement in 2012 as compared to the receipt of \$8.9 million from the BVL settlement in 2013. Offsetting this was an increase in gross profit and fewer expenditures related to research and development in 2013.

*Net Cash Used in Investing Activities*

Our primary uses of cash in investing activities are for the purchase of property and equipment. Net cash used in investing activities in 2014, 2013 and 2012 reflected the purchase of property and equipment for \$8.1 million, \$5.0 million and \$7.9 million, respectively.

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

Net cash used in financing activities during 2014 was due to payments made to our parent. Net cash provided by financing activities during 2013 was associated with an \$8.0 million draw against our outstanding line of credit. On March 21, 2011, we issued \$150.0 million of our Notes and paid associated financing costs. Net cash used in 2012 primarily represented the results of these activities.

Our primary source of cash flows from financing activities is draws against our outstanding line of credit. Going forward, we expect our primary source of cash flows from financing activities to be similar draws against our line of credit, issuances of securities or other financing arrangements into which we may enter. Our primary historical uses of cash in financing activities are principal payments on our term loan and line of credit as well as dividends to Holdings, our parent. See “—External Sources of Liquidity.”

*External Sources of Liquidity*

On May 10, 2010, we issued \$250.0 million in aggregate principal amount of 9.750% Senior Notes due in 2017, or the Restricted Notes, at face value, net of issuance costs of \$10.1 million, under the indenture, dated as of May 10, 2010. On February 2, 2011, we consummated an exchange offer where we exchanged \$250.0 million aggregate principal amount of our Restricted Notes for an equal principal amount of 9.750% Senior Notes due 2017, or the Exchange Notes, that were registered under the Securities Act, with substantially identical terms in all respects.

---

## [Table of Contents](#)

On March 21, 2011, we issued an additional \$150.0 million in aggregate principal amount of New Restricted Notes, net of issuance costs of \$4.9 million, under the indenture, dated as of May 10, 2010, as supplemented by the First Supplemental Indenture, dated as of March 14, 2011, and the Second Supplemental Indenture, dated as of March 21, 2011, or together, the Indenture. The net proceeds were used to repurchase all of the remaining Series A Preferred Stock at the accreted value of approximately \$44.0 million and to issue an approximate \$106.0 million dividend to our common security holders. On May 10, 2011, we consummated an exchange offer where we exchanged \$150.0 million aggregate principal amount of New Restricted Notes for an equal principal amount of 9.750% Senior Notes due 2017, or the New Exchange Notes, registered under the Securities Act, with substantially identical terms in all respects.

The Exchange Notes and the New Exchange Notes, or together, the Notes, mature on May 15, 2017. Interest on the Notes accrues at a rate of 9.750% per year and is payable semiannually in arrears on May 15 and November 15 commencing on November 15, 2010 for the Notes issued on May 10, 2010 and May 15, 2011 for the Notes issued on March 21, 2011.

In connection with the Restricted Notes issuance, we entered into a revolving facility, or the Old Facility, for total borrowings up to \$42.5 million. During 2012, we entered into an unfunded Standby Letter of Credit for up to \$8.8 million to support a surety bond related to a statutory decommissioning obligation we have in connection with our Billerica facility. The letter of credit decreased the borrowing availability under the Old Facility by \$8.8 million.

On July 3, 2013, we entered into an amended and restated asset-based revolving credit facility, or our revolving credit facility, in an aggregate principal amount not to exceed \$42.5 million. On June 24, 2014, we entered into an amendment of our revolving credit facility, which, among other things, increased the revolving credit commitments under our revolving credit facility to \$50.0 million; provided that, subsequent to the amendment, borrowings in excess of \$42.5 million thereunder are subject to certification of compliance with (x) the debt and lien covenants under the indenture for the Notes and (y) an additional \$3.0 million of secured debt capacity under the indenture for the Notes.

Subsequent to the amendment, the revolving loans under our revolving credit facility bear interest, with pricing based from time to time at our election at (i) LIBOR plus a spread of 2.00% or (ii) the Reference Rate (as defined in our revolving credit facility) plus a spread of 1.00%. Our revolving credit facility also includes an unused line fee, which, subsequent to the amendment, is set at 0.375%. Our revolving credit facility expires on the earlier of (i) July 3, 2018 or (ii) if the outstanding Notes are not refinanced in full, the date that is 91 days before the maturity thereof, at which time all outstanding borrowings are due and payable.

As of December 31, 2014 and 2013, we had an unfunded Standby Letter of Credit for up to \$8.8 million. The unfunded Standby Letter of Credit requires annual fees, payable quarterly, which, subsequent to the amendment, is set at LIBOR plus a spread of 2.00% and expires on February 5, 2016, which will automatically renew for a one year period at each anniversary date, unless we elect not to renew in writing within 60 days prior to such expiration.

Our revolving credit facility is secured by a pledge of substantially all of the assets of LMI, together with the assets of Lantheus Intermediate and assets of Lantheus MI Real Estate, LLC, or Lantheus Real Estate, including each such entity's accounts receivable, inventory and machinery and equipment, and is guaranteed by each of Lantheus Intermediate and Lantheus Real Estate. Borrowing capacity is determined by reference to a borrowing base, or the Borrowing Base, which is based on (i) a percentage of certain eligible accounts receivable, inventory and machinery and equipment minus (ii) any reserves. As of December 31, 2014, the aggregate Borrowing Base was approximately \$50.0 million, which was reduced by (i) an outstanding \$8.8 million unfunded Standby Letter of Credit and (ii) an \$8.0 million outstanding loan balance including interest, resulting in a net borrowing base availability of approximately \$33.2 million.

---

## [Table of Contents](#)

Our revolving credit facility contains affirmative and negative covenants, as well as restrictions on the ability of Lantheus Intermediate, us and our subsidiaries to: (i) incur additional indebtedness or issue preferred stock; (ii) repay subordinated indebtedness prior to its stated maturity; (iii) pay dividends on, repurchase or make distributions in respect of capital stock or make other restricted payments; (iv) make certain investments; (v) sell certain assets; (vi) create liens; (vii) consolidate, merge, sell or otherwise dispose of all or substantially all of our assets; and (viii) enter into certain transactions with our affiliates. Our revolving credit facility also contains customary default provisions as well as cash dominion provisions which allow the lender to sweep our accounts during the period (x) certain specified events of default are continuing under our revolving credit facility or (y) excess availability under our revolving credit facility falls below (i) the greater of \$5.0 million or 15% of the then-current borrowing base for a period of more than five consecutive Business Days or (ii) \$3.5 million. During a covenant trigger period, we are required to comply with a consolidated fixed charge coverage ratio of not less than 1:00:1:00. The fixed charge coverage ratio is calculated on a consolidated basis for Lantheus Intermediate and its subsidiaries for a trailing four-fiscal quarter period basis, as (i) EBITDA (as defined in the agreement) minus capital expenditures minus certain restricted payments divided by (ii) interest plus taxes paid or payable in cash plus certain restricted payments made in cash plus scheduled principal payments paid or payable in cash.

On December 27, 2012, we entered into a second amendment to a license and supply agreement with one of our customers, which extended the term from December 31, 2012 to December 31, 2014 and established new pricing and purchase requirements over the extended term. The second amendment also provided for the supply of TechneLite generators containing Moly sourced from LEU targets. The agreement included a \$3.0 million upfront payment by our customer to us and during 2013, we received an additional \$4.0 million, of which \$3.6 million is included in deferred revenue as a current liability at December 31, 2013. During 2012, we received the \$3.0 million upfront payment, of which \$1.5 million was included in deferred revenue as a current liability and \$1.5 million was included in other long-term liabilities at December 31, 2012. We have recognized the upfront payment as revenue on a straight-line basis over the term of the two year agreement.

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

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

### ***Funding Requirements***

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

- our ability to have product manufactured and released from JHS and other manufacturing sites in a timely manner in the future;
- the pricing environment and the level of product sales of our currently marketed products, particularly DEFINITY, and any additional products that we may market in the future;
- revenue mix shifts and associated volume and selling price changes that could result from contractual status changes with key customers;
- the costs of further commercialization of our existing products, particularly in international markets, including product marketing, sales and distribution and whether we obtain local partners to help share such commercialization costs;
- the costs of investing in our facilities, equipment and technology infrastructure;

---

## [Table of Contents](#)

- the costs and timing of establishing manufacturing and supply arrangements for commercial supplies of our products;
- the extent to which we acquire or invest in products, businesses and technologies;
- the extent to which we choose to establish collaboration, co-promotion, distribution or other similar arrangements for our marketed products;
- the legal costs relating to maintaining, expanding and enforcing our intellectual property portfolio, pursuing insurance or other claims and defending against product liability, regulatory compliance or other claims; and
- the cost of interest on any additional borrowings which we may incur under our financing arrangements.

Until we successfully become dual sourced for our principal products, we are vulnerable to future supply shortages. Disruption in the financial performance could also occur if we experience significant adverse changes in customer mix, broad economic downturns, adverse industry or company conditions or catastrophic external events. If we experience one or more of these events in the future, we may be required to implement 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. See “Item 1A—Risk Factors—We may not be able to generate sufficient cash flow to meet our debt service obligations.”

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 revolving credit facility and the Indenture. 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 revolving credit facility and under the Indenture, 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 the covenants of our revolving credit facility and the Indenture. 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 December 31, 2014, our only current committed external source of funds is our borrowing availability under our revolving credit facility. We generated a net loss of \$1.2 million during the year ended December 31, 2014 and had \$17.8 million of cash and cash equivalents at December 31, 2014. Availability under our revolving credit facility is calculated by reference to the Borrowing Base. If we are not successful in achieving our forecasted results, our accounts receivable and inventory could be negatively affected, reducing the Borrowing Base and limiting our borrowing availability.

Based on our current operating plans, we believe that our existing cash and cash equivalents, results of operations and availability under our revolving credit facility will be sufficient to continue to fund our liquidity requirements for at least the next twelve months.

## [Table of Contents](#)

### Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent contractual liabilities for which we cannot reasonably predict future payment, including contingencies related to potential future development, financing, certain suppliers, contingent royalty payments and/or scientific, regulatory, or commercial milestone payments under development agreements. The following table summarizes our contractual obligations as of December 31, 2014:

	Payments Due by Period				
	Total	Less than 1 Year	1 - 3 Years	3 - 5 Years	
(dollars in thousands)					
Debt obligations (principal)	\$400,000	\$ —	\$400,000	\$ —	\$ —
Interest on debt obligations	97,500	39,000	58,500	—	—
Operating leases(1)	3,864	854	1,023	797	1,190
Asset retirement obligation	7,435	—	—	—	7,435
Other long-term liabilities(2)	32,261	—	—	—	32,261
Total contractual obligations	<u>\$541,060</u>	<u>\$39,854</u>	<u>\$459,523</u>	<u>\$ 797</u>	<u>\$ 40,886</u>

(1) Operating leases include minimum payments under leases for our facilities and certain equipment.

(2) Due to the uncertainty related to the timing of the reversal of uncertain tax positions, the liability is not subject to fixed payment terms and the amount and timing of payments, if any, which we will make related to this liability are not known.

### Off-Balance Sheet Arrangements

We are required to provide the NRC and Massachusetts Department of Public Health financial assurance demonstrating our ability to fund the decommissioning of our North Billerica, Massachusetts production facility upon closure, though we do not intend to close the facility. We have provided this financial assurance in the form of a \$28.2 million surety bond and an \$8.8 million letter of credit.

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

### Effects of Inflation

We do not believe that inflation has had a significant impact on our revenues or results of operations since inception. We expect our cost of product sales and other operating expenses will change in the future in line with periodic inflationary changes in price levels. Because we intend to retain and continue to use our property and equipment, we believe that the incremental inflation related to the replacement costs of those items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources. While we generally believe that we will be able to offset the effect of price-level changes by adjusting our product prices and implementing operating efficiencies, any material unfavorable changes in price levels could have a material adverse effect on our financial condition, results of operations and cash flows.

### Recent Accounting Standards

In July 2013, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, No. 2013-11, "Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists," or ASU 2013-11. The amendments in ASU 2013-11 provide guidance on the financial statement presentation of unrecognized tax benefits when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. ASU 2013-11 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The amendments did not have a material impact on our financial position, results of operations or cash flows.



---

## [Table of Contents](#)

In April 2014, the FASB issued ASU No. 2014-08, “Presentation of Financial Statements (Topic 205) and Property, Plant, and Equipment (Topic 360): Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity,” or ASU 2014-08. The amendments in ASU 2014-08 change the criteria for reporting discontinued operations while enhancing disclosures in this area. The new guidance requires expanded disclosures about discontinued operations that will provide financial statement users with more information about the assets, liabilities, income and expenses of discontinued operations. The new guidance also requires disclosure of the pre-tax income attributable to a disposal of a significant part of an organization that does not qualify for discontinued operations reporting. The amendments in the ASU are effective in the first quarter of 2015 for public organizations with calendar year ends. Early adoption is permitted. We do not anticipate that this ASU will have a material impact to our financial position, results of operations or cash flows.

In May 2014, the FASB issued ASU No. 2014-09, “Revenue from Contracts with Customers (Topic 606)” or ASU 2014-09. ASU 2014-09 supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under existing U.S. GAAP including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. The amendments in ASU No. 2014-09 are effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early application is not permitted. We are currently evaluating the impact this ASU will have on our financial position, results of operations and cash flows.

In June 2014, the FASB issued ASU No. 2014-12, “Compensation—Stock Compensation (Topic 718)” or ASU 2014-12. ASU 2014-12 requires that a performance target that affects vesting and could be achieved after the requisite service period be treated as a performance condition. The amendments in ASU No. 2014-12 are effective for annual reporting periods beginning after December 15, 2015, including interim periods within that reporting period. We do not anticipate this ASU will have a material impact to our financial position, results of operations or cash flows.

In August 2014, the FASB issued ASU No. 2014-15, “Presentation of Financial Statements—Going Concern (Subtopic 205-4): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern” or ASU 2014-15. ASU 2014-15 to provide guidance on management’s responsibility in evaluating whether there is substantial doubt about a company’s ability to continue as a going concern and to provide related footnote disclosures. The amendments in ASU 2014-15 are effective for annual reporting periods ending after December 15, 2016. Early adoption is permitted. We do not anticipate this ASU will have a material impact to our financial position, results of operations or cash flows.

### **Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with GAAP. These financial statements require us to make estimates and judgments that affect our reported assets and liabilities, revenues and expenses, and other financial information. Actual results may differ materially from these estimates under different assumptions and conditions. In addition, our reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

We believe the following represent our critical accounting policies and estimates used in the preparation of our financial statements.

#### ***Revenue Recognition***

Our revenue is generated from the sales of our diagnostic imaging agents to wholesalers, distributors, and radiopharmacies and directly to hospitals and clinics. We recognize revenue when evidence of an arrangement

---

## [Table of Contents](#)

exists, title has passed, substantially all the risks and rewards of ownership have transferred to the customer, the selling price is fixed and determinable and collectability is reasonably assured. For transactions for which revenue recognition criteria have not yet been met, the respective amounts are recorded as deferred revenue until that point in time when criteria are met and revenue can be recognized. Revenue is recognized net of reserves, which consist of allowances for returns and sales rebates. The estimates of these allowances are based on historical sales volumes and mix and require assumptions and judgments to be made in order to make those estimates. In the event that the sales mix is different from our estimates, we may be required to pay higher or lower returns and sales rebates than we previously estimated. Any changes to these estimates are recorded in the current period. In 2014, 2013 and 2012, these changes in estimates were not material to our results.

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

### ***Inventory***

Inventories include material, direct labor and related manufacturing overhead, and are stated at the lower of cost or market determined on a first-in, first-out basis. We record inventory when we take title to the product. Any commitment for product ordered but not yet received is included as purchase commitments in our contractual obligations table. We assess the recoverability of inventory to determine whether adjustments for impairment are required. Inventory that is in excess of future requirements is written down to its estimated net realizable value-based upon estimates of forecasted demand for our products. The estimates of demand require assumptions to be made of future operating performance and customer demand. If actual demand is less than what has been forecasted by management, additional inventory write downs may be required.

Inventory costs associated with product that has not yet received regulatory approval are capitalized if we believe there is probable future commercial use of the product and future economic benefit of the asset. If future commercial use of the product is not probable, then inventory costs associated with that product are expensed during the period the costs are incurred. For the year ended December 31, 2014, the Company expensed \$1.9 million of such product costs in cost of goods sold relating to Neurolite that was manufactured by JHS. At December 31, 2014 and 2013, the Company had no capitalized inventories associated with product that did not have regulatory approval.

### ***Goodwill, Intangibles and Long-Lived Assets***

Goodwill is not amortized, but is instead tested for impairment at least annually and whenever events or circumstances indicate that it is more likely than not that it may be impaired. We have elected to perform the annual test of goodwill impairment as of October 31 of each year.

In performing tests for goodwill impairment, we are first permitted to perform a qualitative assessment about the likelihood of the carrying value of a reporting unit exceeding its fair value. If we determine that it is more likely than not that the fair value of a reporting unit is less than its carrying amount based on the qualitative assessment, we are required to perform the two-step goodwill impairment test described below to identify the

---

## [Table of Contents](#)

potential goodwill impairment and measure the amount of the goodwill impairment loss, if any, to be recognized for that reporting unit. However, if we conclude otherwise based on the qualitative assessment, the two-step goodwill impairment test is not required. The option to perform the qualitative assessment is not an accounting policy election and can be utilized at our discretion. Further, the qualitative assessment need not be applied to all reporting units in a given goodwill impairment test. For an individual reporting unit, if we elect not to perform the qualitative assessment, or if the qualitative assessment indicates that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, then we must perform the two-step goodwill impairment test for the reporting unit. If the implied fair value of goodwill is less than the carrying value, then an impairment charge would be recorded.

In performing the annual goodwill impairment test, we bypassed the option to perform a qualitative assessment and proceeded directly to performing the first step of the two-step goodwill impairment test. We completed our required annual impairment test for goodwill in the fourth quarter of 2014, 2013 and 2012 and determined that at each of those periods the carrying amount of goodwill was not impaired. In each year, our fair value was substantially in excess of our carrying value.

During the first quarter of 2013, the strategic shift in how we intend to fund our R&D programs significantly altered the expected future costs and revenues associated with our agents in development. Accordingly, this action was deemed to be a triggering event for an evaluation of the recoverability of our goodwill as of March 31, 2013. We performed an interim impairment test and determined that there was no impairment of goodwill as of March 31, 2013.

We calculate the fair value of our reporting units using the income approach, which utilizes discounted forecasted future cash flows and the market approach which utilizes fair value multiples of comparable publicly traded companies. The discounted cash flows are based on our most recent long-term financial projections and are discounted using a risk adjusted rate of return, which is determined using estimates of market participant risk-adjusted weighted average costs of capital and reflects the risks associated with achieving future cash flows. The market approach is calculated using the guideline company method, where we use market multiples derived from stock prices of companies engaged in the same or similar lines of business. There is not a quoted market price for our reporting units or the company as a whole, therefore, a combination of the two methods is utilized to derive the fair value of the business. We evaluate and weigh the results of these approaches as well as ensure we understand the basis of the results of these two methodologies. We believe the use of these two methodologies ensures a consistent and supportable method of determining our fair value that is consistent with the objective of measuring fair value. If the fair value were to decline, then we may be required to incur material charges relating to the impairment of those assets.

We test intangible and long-lived assets for recoverability whenever events or changes in circumstances suggest that the carrying value of an asset or group of assets may not be recoverable. We measure the recoverability of assets to be held and used by comparing the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. If those assets are considered to be impaired, the impairment equals the amount by which the carrying amount of the assets exceeds the fair value of the assets. Any impairments are recorded as permanent reductions in the carrying amount of the assets. Long-lived assets, other than goodwill and other intangible assets, that are held for sale are recorded at the lower of the carrying value or the fair market value less the estimated cost to sell.

In the first quarter of 2012, we reviewed the estimated useful life of our Cardiolite trademark as a result of a triggering event. Utilizing the most recent forecasted revenue data, we revised the estimate of the remaining useful life of the Cardiolite trademark to five years. We continue to monitor the recoverability of our branded Cardiolite trademark intangible asset due to the ongoing generic competition based on actual results and existing estimates of future undiscounted cash flows associated with the branded Cardiolite product. As of December 31, 2013, we conducted, using our revised sales forecast, an impairment analysis and concluded that the estimate of future undiscounted cash flows associated with the Cardiolite trademark intangible did not exceed the carrying

---

## [Table of Contents](#)

amount of the asset totaling \$19.2 million and therefore, the asset has been written down to its fair value. Fair value was calculated by utilizing Level 3 inputs in the relief from royalty method, an income-based approach. As a result of this analysis, we recorded an impairment charge of \$15.4 million to adjust the carrying value to its fair value of \$3.8 million. This expense was recorded within cost of goods sold in the accompanying consolidated statement of comprehensive loss in the fourth quarter of 2013.

In the third quarter of 2013, we were in negotiations with a new distributor for the sale of certain products within certain international markets. This agreement was signed in October 2013 and as a result we did not renew the agreements with our former distributors in these international markets. We determined the customer relationship intangible related to these former distributors was no longer recoverable and recorded an impairment charge of \$1.0 million in the third quarter of 2013. In the fourth quarter of 2013, we updated our strategic plan to reflect the non-renewal of these agreements and the uncertainty in the timing of product availability in this region. As a result, we reviewed the recoverability of certain of our customer relationship intangible assets in the International segment that were impacted by our revised strategic plan. We conducted an impairment analysis and concluded that the estimate of future undiscounted cash flows associated with the customer relationship intangible asset did not exceed the carrying amount of the asset and therefore, the asset would need to be written down to its fair value. In order to calculate the fair value of the acquired customer relationship intangible assets, we utilized Level 3 inputs to estimate the future discounted cash flows associated with remaining customers and as a result of this analysis, recorded an impairment charge of \$0.7 million in the fourth quarter of 2013. These impairment charges were recorded within cost of goods sold in the accompanying consolidated statement of comprehensive loss.

During the third quarter of 2013, we committed to a plan to sell certain of our excess land in the U.S. segment, which had a carrying value of \$7.5 million. This event qualified for held for sale accounting and the excess land was written down to its fair value, less estimated costs to sell. The fair value was estimated utilizing Level 3 inputs and using a market approach, based on available data for transactions in the region, discussions with real estate brokers and the asking price of comparable properties in its principal market. This resulted in a loss of \$6.4 million, which is included within operating loss as impairment of land in the accompanying consolidated statement of comprehensive loss. During the fourth quarter of 2013, we sold the excess land for net proceeds of \$1.1 million.

Fixed assets dedicated to R&D activities, which were impacted by the March 2013 R&D strategic shift, have a carrying value of \$4.5 million as of December 31, 2014. We believe these fixed assets will be utilized for either internally funded ongoing R&D activities or R&D activities funded by a strategic partner. If we are not successful in finding a strategic partner, and there are no alternative uses for those fixed assets, they could be subject to impairment in the future.

We also tested certain long-lived assets utilized in the manufacturing of certain products in the United States for recoverability as of December 31, 2013 due to a change in our contract to manufacture Quadramet. The analysis indicated that there was no impairment as of December 31, 2013. We also evaluated the remaining useful lives of long-lived assets that were tested for recoverability at December 31, 2013 and determined no revisions were required to the remaining periods of depreciation.

In the fourth quarter of 2014, we reviewed certain long-lived and intangible assets, associated with U.S. operations, for recoverability as a result of the expiration of an agreement with a customer. The analysis indicated that there was no impairment as of December 31, 2014. We also evaluated the remaining useful lives of the long-lived and intangible assets that were tested for recoverability at December 31, 2014 and determined no revisions were required to the remaining periods of depreciation and amortization.

Intangible assets, consisting of patents, trademarks and customer relationships related to our products are amortized in a method equivalent to the estimated utilization of the economic benefit of the asset. Trademarks and patents are amortized on a straight-line basis, and customer relationships are amortized on an accelerated basis.

---

[Table of Contents](#)

***Accounting for Stock-Based Compensation***

Our employees are eligible to receive awards from our 2013 Equity Plan. Our stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service period, which generally represents the vesting period, and includes an estimate of the awards that will be forfeited. We use the Black Scholes valuation model for estimating the fair value on the date of grant of stock options. The fair value of stock option awards is affected by the valuation assumptions, including the volatility of market participants, expected term of the option, risk-free interest rate and expected dividends as well as the estimated fair value of our common stock. The fair value of our common stock is determined quarterly and each award is approved by our Board of Directors at the fair value in effect as of such award date. Any material change to the assumptions used in estimating the fair value of the options could have a material impact on our results of operations. When a contingent cash settlement of vested options becomes probable, we reclassify the vested awards to a liability and account for any incremental compensation cost in the period in which the settlement becomes probable.

***Income Taxes***

The provision for income taxes has been determined using the asset and liability approach of accounting for income taxes. The provision for income taxes represents income taxes paid or payable for the current year plus the change in deferred taxes during the year. Deferred taxes result from differences between the financial and tax bases of our assets and liabilities. Deferred tax assets and liabilities are measured using the currently enacted tax rates that apply to taxable income in effect for the years in which those tax attributes are expected to be recovered or paid, and are adjusted for changes in tax rates and tax laws when changes are enacted.

Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The assessment of whether or not a valuation allowance is required involves the weighing of both positive and negative evidence concerning both historical and prospective information with greater weight given to evidence that is objectively verifiable. A history of recent losses is negative evidence that is difficult to overcome with positive evidence. In evaluating prospective information there are four sources of taxable income: reversals of taxable temporary differences, items that can be carried back to prior tax years (such as net operating losses), pre-tax income and tax planning strategies. Any tax planning strategies that are considered must be prudent and feasible, and would only be undertaken in order to avoid losing an operating loss carryforward. Adjustments to the deferred tax valuation allowances are made in the period when those assessments are made.

We account for uncertain tax positions using a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Differences between tax positions taken in a tax return and amounts recognized in the financial statements are recorded as adjustments to income taxes payable or receivable, or adjustments to deferred taxes, or both. We provide disclosure at the end of each annual reporting period on a tabular reconciliation of unrecognized tax benefits. We classify interest and penalties within the provision for income taxes.

We have a tax indemnification agreement with BMS related to certain contingent tax obligations arising prior to the acquisition of the business from BMS. The tax obligations are recognized in liabilities and the tax indemnification receivable is recognized within other noncurrent assets. The changes in the tax indemnification asset are recognized within other income, net in the statement of comprehensive loss, and the changes in the related liabilities are recorded within the tax provision. Accordingly, as these reserves change, adjustments are included in the tax provision while the offsetting adjustment is included in other income. Assuming that the receivable from BMS continues to be considered recoverable by us, there is no net effect on earnings related to these liabilities and no net cash outflows.

The calculation of our tax liabilities involves certain estimates, assumptions and the application of complex tax regulations in numerous jurisdictions worldwide. Any material change in our estimates or assumptions, or the tax regulations, may have a material impact on our results of operations.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

**Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to market risk from changes in interest rates and foreign currency exchange rates. We do not hold or issue financial instruments to reduce these risks or for trading purposes.

***Interest Rate Risk***

We are subject to interest rate risk in connection with our revolving credit facility, which is variable rate indebtedness. Interest rate changes could increase the amount of our interest payments and thus negatively impact our future earnings and cash flows. As of December 31, 2014, there was \$8.0 million outstanding including interest under our revolving credit facility and an \$8.8 million unfunded Standby Letter of Credit, which reduced availability to \$33.2 million on our revolving credit facility. Any increase in the interest rate under our revolving credit facility may have a negative impact on our future earnings to the extent we have outstanding borrowings under our revolving credit facility. The effect of a 100 basis points adverse change in market interest rates on our interest expense for the year ended December 31, 2014, would be approximately \$96,000. Historically, we have not used derivative financial instruments or other financial instruments to hedge such economic exposures.

***Foreign Currency Risk***

We face exposure to movements in foreign currency exchange rates whenever we, or any of our subsidiaries, enter into transactions with third parties that are denominated in currencies other than ours, or that subsidiary's, functional currency. Intercompany transactions between entities that use different functional currencies also expose us to foreign currency risk.

During years ended December 31, 2014, 2013 and 2012, the net impact of foreign currency changes on transactions was a loss of \$279,000, \$349,000 and \$579,000, respectively. Historically, we have not used derivative financial instruments or other financial instruments to hedge these economic exposures.

Gross margins for our products that are manufactured in the United States and are sold in currencies other than the U.S. Dollar are also affected by foreign currency exchange rate movements. Our gross margin on revenues was 41.6%, 27.3% and 26.1% during the years ended December 31, 2014, 2013 and 2012, respectively. If the U.S. Dollar had been stronger by 1%, 5% or 10%, compared to the actual rates during 2014, we estimate our gross margin on revenues would have increased by 0.1%, 0.3% and 0.6%, respectively. If the U.S. Dollar had been stronger by 1%, 5% or 10%, compared to the actual rates during 2013, we estimate our gross margin on revenues would have increased by 0.0%, 0.2% and 0.4%, respectively. If the U.S. Dollar had been stronger by 1%, 5% or 10%, compared to the actual rates during 2012, we estimate our gross margin on revenues would have increased by 0.0%, 0.2% and 0.3%, respectively.

In addition, a portion of our earnings is generated by our foreign subsidiaries, whose functional currencies are other than the U.S. Dollar. Our earnings could be materially impacted by movements in foreign currency exchange rates upon the translation of the earnings of those subsidiaries into the U.S. Dollar. The Canadian Dollar presents the primary currency risk on our earnings.

If the U.S. Dollar had been uniformly stronger by 1%, 5% or 10%, compared to the actual average exchange rates used to translate the financial results of our foreign subsidiaries, our revenues and net income for the year ended December 31, 2014 would have been impacted by approximately the following amounts:

<u>Increase in U.S. Dollar to Applicable Foreign Currency Exchange Rate</u>	<u>Approximate Change in Revenues</u>	<u>Approximate Change in Net Income</u>
	(dollars in thousands)	
1%	\$ (433)	\$ 52
5%	(2,167)	259
10%	(4,334)	517

---

[Table of Contents](#)

If the U.S. Dollar had been uniformly stronger by 1%, 5% or 10%, compared to the actual average exchange rates used to translate the financial results of our foreign subsidiaries, our revenues and net income for the year ended December 31, 2013 would have been impacted by approximately the following amounts:

<u>Increase in U.S. Dollar to Applicable Foreign Currency Exchange Rate</u>	<u>Approximate Change in Revenues</u>	<u>Approximate Change in Net Income</u>
	(dollars in thousands)	
1%	\$ (487)	\$ 38
5%	(2,436)	191
10%	(4,871)	382

If the U.S. Dollar had been uniformly stronger by 1%, 5% or 10%, compared to the actual average exchange rates used to translate the financial results of our foreign subsidiaries, our revenues and net income for the year ended December 31, 2012 would have been impacted by approximately the following amounts:

<u>Increase in U.S. Dollar to Applicable Foreign Currency Exchange Rate</u>	<u>Approximate Change in Revenues</u>	<u>Approximate Change in Net Income</u>
	(dollars in thousands)	
1%	\$ (519)	\$ 3
5%	(2,593)	17
10%	(5,187)	34

**Item 8. Financial Statements and Supplementary Data**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholder of  
Lantheus MI Intermediate, Inc.  
North Billerica, Massachusetts

We have audited the accompanying consolidated balance sheets of Lantheus MI Intermediate, Inc. and subsidiaries (the “Company”) as of December 31, 2014 and 2013, and the related consolidated statements of comprehensive loss, stockholder’s deficit, and cash flows for each of the three years in the period ended December 31, 2014. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Lantheus MI Intermediate, Inc. and subsidiaries as of December 31, 2014 and 2013, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014, in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE LLP

Boston, Massachusetts  
March 4, 2015



[Table of Contents](#)

**Lantheus MI Intermediate, Inc. and subsidiaries**  
**Consolidated Balance Sheets**

<b>(in thousands except share data)</b>	<b>December 31,</b>	<b>December 31,</b>
	<b>2014</b>	<b>2013</b>
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 17,817	\$ 16,669
Accounts receivable, net	41,540	38,910
Inventory	15,582	18,310
Income tax receivable	247	325
Deferred tax assets	256	18
Other current assets	<u>3,739</u>	<u>3,087</u>
Total current assets	79,181	77,319
Property, plant and equipment, net	96,014	97,653
Capitalized software development costs, net	2,421	1,470
Intangibles, net	27,191	34,998
Goodwill	15,714	15,714
Deferred financing costs	7,349	9,639
Deferred tax assets	328	15
Other long-term assets	<u>19,318</u>	<u>22,577</u>
Total assets	<u>\$ 247,516</u>	<u>\$ 259,385</u>
<b>Liabilities and Stockholder's Deficit</b>		
Current liabilities		
Line of credit	8,000	8,000
Accounts payable	15,665	18,103
Accrued expenses and other liabilities	24,579	25,492
Deferred tax liability	152	57
Deferred revenue	<u>132</u>	<u>3,979</u>
Total current liabilities	48,528	55,631
Asset retirement obligations	7,435	6,385
Long-term debt, net	399,280	399,037
Deferred tax liability	247	12
Other long-term liabilities	<u>32,995</u>	<u>35,408</u>
Total liabilities	<u>488,485</u>	<u>496,473</u>
Commitments and contingencies (see Notes 14 and 16)		
Stockholder's deficit		
Common stock (\$0.001 par value, 10,000 shares authorized; 1 share issued and outstanding)	—	—
Due from parent	(3,766)	(1,259)
Additional paid-in capital	3,934	2,903
Accumulated deficit	(239,507)	(238,338)
Accumulated other comprehensive loss	<u>(1,630)</u>	<u>(394)</u>
Total stockholder's deficit	<u>(240,969)</u>	<u>(237,088)</u>
Total liabilities and stockholder's deficit	<u>\$ 247,516</u>	<u>\$ 259,385</u>

See notes to consolidated financial statements.

[Table of Contents](#)

**Lantheus MI Intermediate, Inc. and subsidiaries**  
**Consolidated Statements of Comprehensive Loss**

(in thousands)	Year Ended December 31,		
	2014	2013	2012
Revenues	\$301,600	\$283,672	\$288,105
Cost of goods sold	176,081	206,311	211,049
Loss on firm purchase commitment	—	—	1,859
Total cost of goods sold	176,081	206,311	212,908
Gross profit	125,519	77,361	75,197
Operating expenses			
Sales and marketing expenses	35,116	35,227	37,437
General and administrative expenses	34,921	33,159	32,520
Research and development expenses	13,673	30,459	40,604
Proceeds from manufacturer	—	(8,876)	(34,614)
Impairment on land	—	6,406	—
Total operating expenses	83,710	96,375	75,947
Operating income (loss)	41,809	(19,014)	(750)
Interest expense	(42,288)	(42,915)	(42,014)
Interest income	27	104	252
Other income (expense), net	478	1,161	(44)
Income (loss) before income taxes	26	(60,664)	(42,556)
Provision (benefit) for income taxes	1,195	1,014	(555)
Net loss	(1,169)	(61,678)	(42,001)
Foreign currency translation	(1,236)	(1,729)	964
Total comprehensive loss	\$ (2,405)	\$ (63,407)	\$ (41,037)

See notes to consolidated financial statements.

**Lantheus MI Intermediate, Inc. and subsidiaries**  
**Consolidated Statements of Stockholder's Deficit**

(in thousands, except share data)	Common Stock		Due from Parent	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholder's Deficit
	Shares	Amount					
Balance at January 1, 2012	1	\$ —	\$ —	\$ 1,085	\$ (134,659)	\$ 371	\$ (133,203)
Net loss	—	—	—	—	(42,001)	—	(42,001)
Due from parent (see Note 17)	—	—	(1,353)	—	—	—	(1,353)
Foreign currency translation	—	—	—	—	—	964	964
Stock-based compensation	—	—	—	1,240	—	—	1,240
Balance at December 31, 2012	1	—	(1,353)	2,325	(176,660)	1,335	(174,353)
Net loss	—	—	—	—	(61,678)	—	(61,678)
Payments from parent	—	—	94	—	—	—	94
Foreign currency translation	—	—	—	—	—	(1,729)	(1,729)
Stock-based compensation	—	—	—	578	—	—	578
Balance at December 31, 2013	1	—	(1,259)	2,903	(238,338)	(394)	(237,088)
Net loss	—	—	—	—	(1,169)	—	(1,169)
Increase in amounts due from parent	—	—	(2,507)	—	—	—	(2,507)
Foreign currency translation	—	—	—	—	—	(1,236)	(1,236)
Stock-based compensation	—	—	—	1,031	—	—	1,031
Balance at December 31, 2014	<u>1</u>	<u>\$ —</u>	<u>\$ (3,766)</u>	<u>\$ 3,934</u>	<u>\$ (239,507)</u>	<u>\$ (1,630)</u>	<u>\$ (240,969)</u>

See notes to consolidated financial statements.

**Lantheus MI Intermediate, Inc. and subsidiaries**  
**Consolidated Statements of Cash Flows**

(in thousands)	Year ended December 31,		
	2014	2013	2012
<b>Cash flow from operating activities</b>			
Net loss	\$ (1,169)	\$(61,678)	\$(42,001)
Adjustments to reconcile net loss to cash flow from operating activities			
Depreciation	9,901	9,336	9,722
Amortization	8,350	15,819	17,680
Impairment of land	—	6,406	—
Impairment of intangible assets	—	17,175	—
Amortization of debt related costs	2,708	2,600	2,403
Write-off of deferred financing costs	—	598	—
Provision for bad debt	303	63	(117)
Provision for excess and obsolete inventory	1,593	4,854	12,809
Stock-based compensation	1,031	578	1,240
Accretion of asset retirement obligations	773	628	553
Loss on firm purchase commitment	—	—	1,859
Other	(215)	(237)	(143)
Long-term income tax receivable	2,719	(566)	299
Long-term income tax payable and other long-term liabilities	(2,560)	187	139
Increase (decrease) in cash from operating assets and liabilities			
Accounts receivable, net	(3,563)	2,627	(1,442)
Prepaid expenses and other current assets	(882)	1,043	1,304
Inventory	1,500	(4,741)	(6,903)
Deferred revenue	(3,881)	(4,874)	5,349
Accounts payable	(4,047)	(1,147)	(2,204)
Income tax payable	68	410	(2,217)
Accrued expenses and other liabilities	(1,056)	(4,759)	2,193
Cash provided by (used in) operating activities	<u>11,573</u>	<u>(15,678)</u>	<u>523</u>
<b>Cash flows from investing activities</b>			
Capital expenditures	(8,137)	(5,010)	(7,920)
Proceeds from sale of property, plant and equipment	227	1,527	—
Redemption (purchase) of certificate of deposit	228	—	(225)
Cash used in investing activities	<u>(7,682)</u>	<u>(3,483)</u>	<u>(8,145)</u>
<b>Cash flows from financing activities</b>			
Payments on note payable	(71)	(1,310)	(1,530)
Deferred financing costs	(175)	(1,249)	(442)
Payments from / (to) parent	(2,047)	94	(67)
Proceeds from line of credit	5,500	8,000	—
Payments on line of credit	(5,500)	—	—
Cash (used in) provided by financing activities	<u>(2,293)</u>	<u>5,535</u>	<u>(2,039)</u>
Effect of foreign exchange rate on cash	(450)	(1,300)	649
Increase (decrease) in cash and cash equivalents	1,148	(14,926)	(9,012)
Cash and cash equivalents, beginning of year	16,669	31,595	40,607
Cash and cash equivalents, end of year	<u>\$17,817</u>	<u>\$ 16,669</u>	<u>\$ 31,595</u>
<b>Supplemental disclosure of cash flow information</b>			
Interest paid	\$39,214	\$ 39,150	\$ 39,020
Income taxes paid, net	\$ 508	\$ 118	\$ 1,146
<b>Noncash investing and financing activities</b>			
Property, plant and equipment included in accounts payable and accrued expenses and other liabilities	\$ 2,916	\$ 1,243	\$ 963
Expenses to be paid on behalf of parent included in accounts payable and accrued expenses and other liabilities	\$ 460	\$ —	\$ —

See notes to consolidated financial statements.

**Lantheus MI Intermediate, Inc. and subsidiaries**  
**Notes to Consolidated Financial Statements**

Unless the context otherwise requires, references to the “Company,” “Lantheus,” “our company,” “we,” “us” and “our” refer to Lantheus MI Intermediate, Inc. and its direct and indirect subsidiaries, references to “Lantheus Intermediate” refer to only Lantheus MI Intermediate, Inc., the parent of Lantheus Medical Imaging, Inc., references to “Holdings” refer to Lantheus Holdings, Inc. (formerly known as Lantheus MI Holdings, Inc.), the parent of Lantheus Intermediate, and references to “LMI” refer to Lantheus Medical Imaging, Inc., the subsidiary of Lantheus Intermediate. Solely for convenience, we refer to trademarks, service marks and trade names without the TM, SM and ® symbols. Such references are not intended to indicate, in any way, that we will not assert, to the fullest extent permitted under applicable law, our rights to our trademarks, service marks and trade names.

**1. Description of Business**

*Overview*

The Company develops, manufactures, sells and distributes innovative diagnostic medical imaging agents and products that assist clinicians in the diagnosis of cardiovascular and other diseases. The Company’s commercial products are used by nuclear physicians, cardiologists, radiologists, internal medicine physicians, technologists and sonographers working in a variety of clinical settings. The Company sells its products to radiopharmacies, hospitals, clinics, group practices, integrated delivery networks, group purchasing organizations and, in certain circumstances, wholesalers. The Company sells its products globally and has operations in the United States, Puerto Rico, Canada and Australia and distribution relationships in Europe, Asia Pacific and Latin America.

The Company’s portfolio of 10 commercial products is diversified across a range of imaging modalities. The Company’s imaging agents include medical radiopharmaceuticals (including technetium generators) and contrast agents, including the following:

- DEFINITY is the leading ultrasound contrast imaging agent used by cardiologists and sonographers during cardiac ultrasound, or echocardiography, exams based on revenue and usage. DEFINITY is an injectable agent that, in the United States, is indicated for use in patients with suboptimal echocardiograms to assist in the visualization of the left ventricle, the main pumping chamber of the heart. The use of DEFINITY in echocardiography allows physicians to significantly improve their assessment of the function of the left ventricle.
- TechnoLite is a self-contained system, or generator, of technetium (Tc99m), a radioisotope with a six hour half-life, used by radiopharmacies to prepare various nuclear imaging agents.
- Xenon Xe 133 Gas is a radiopharmaceutical gas that is inhaled and used to assess pulmonary function and also to image blood flow.
- Cardiolite is an injectable, technetium-labeled imaging agent, also known by its generic name sestamibi, used with Single Photon Emission Computed Tomography, or SPECT, technology in myocardial perfusion imaging, or MPI, procedures that assess blood flow distribution to the heart.
- NeuroLite is an injectable, technetium-labeled imaging agent used with SPECT technology to identify the area within the brain where blood flow has been blocked or reduced due to stroke.

In the United States, the Company sells DEFINITY through its sales team that calls on healthcare providers in the echocardiography space, as well as group purchasing organizations and integrated delivery networks. The Company’s radiopharmaceutical products are primarily distributed through approximately 350 radiopharmacies owned or controlled by third parties. In Canada, Puerto Rico and Australia, the Company owns eight

---

## [Table of Contents](#)

radiopharmacies and sells its own radiopharmaceuticals, as well as others, directly to end users. In Europe, Asia Pacific and Latin America, the Company utilizes distributor relationships to market, sell and distribute its products.

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

### *Basis of Consolidation and Presentation*

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

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the discharge of liabilities in the normal course of business. The Company incurred a net loss of \$1.2 million during the year ended December 31, 2014 and had an accumulated deficit of \$239.5 million at December 31, 2014.

As of December 31, 2014, the Company had \$408.0 million of total principal indebtedness consisting of \$400.0 million of senior notes, which mature on May 15, 2017, and \$8.0 million outstanding under its revolving credit facility. The Company is obligated to make scheduled interest payments of \$39.0 million per year on the senior notes.

The Company experienced operating losses, resulting from supply shortages beginning in the third quarter of 2011 through the third quarter of 2013 in connection with the manufacture of DEFINITY, Cardiolite and Neulite at Ben Venue Laboratories, Inc. in Bedford, Ohio. As of November 2013, BVL ceased manufacturing any product for the Company. During 2012, the Company commenced a comprehensive manufacturing diversification strategy and currently relies on Jubilant HollisterStier, or JHS, as its sole source manufacturer of DEFINITY, Neulite and evacuation vials for TechneLite. The Company has additional ongoing technology transfer activities at JHS for its Cardiolite product supply, which is currently manufactured by a single manufacturer. In addition, the Company has ongoing technology transfer activities at Pharmeducence for the manufacture and supply of DEFINITY, and the Company believes Pharmeducence will file for FDA approval to manufacture DEFINITY in 2015.

The Company has historically been dependent on key customers and group purchasing organizations for the majority of the sales of its medical imaging products. Our ability to maintain and profitably renew those contracts and relationships with those key customers and group purchasing organizations is an important aspect of the Company's strategy. The Company's written supply agreements with a major customer relating to TechneLite, Xenon, Neulite, Cardiolite and certain other products expired in accordance with contract terms on December 31, 2014. Extended discussions with this customer have not yet resulted in new written supply agreements. Consequently, the Company is currently accepting and fulfilling product orders with this customer on a purchase order basis.

Until the Company successfully becomes dual sourced for its principal products, the Company is vulnerable to future supply shortages. Disruption in the financial performance of the Company could also occur if it experiences significant adverse changes in customer mix, broad economic downturns, adverse industry or Company conditions or catastrophic external events. If the Company experiences one or more of these events in the future, it may be required to implement additional expense reductions, such as a delay or elimination of discretionary spending in all functional areas, as well as scaling back select operating and strategic initiatives.

During 2013 and 2014, the Company has utilized its revolving line of credit as a source of liquidity from time to time. Borrowing capacity under the revolving credit facility, or the Facility, is calculated by reference to a borrowing base consisting of a percentage of certain eligible accounts receivable, inventory and machinery and

---

## [Table of Contents](#)

equipment minus any reserves, or the Borrowing Base. If the Company is not successful in achieving its forecasted operating results, the Company's accounts receivable and inventory could be negatively affected, thus reducing the Borrowing Base and limiting the Company's borrowing capacity. As of December 31, 2014, the aggregate Borrowing Base was approximately \$50.0 million, which was reduced by the \$8.8 million unfunded Standby Letter of Credit and the \$8.0 million outstanding loan balance, resulting in a net Borrowing Base availability of approximately \$33.2 million.

Based on the Company's current operating plans, the Company believes its existing cash and cash equivalents, results of operations and availability under the Facility will be sufficient to continue to fund the Company's liquidity requirements for at least the next twelve months.

### *Use of Estimates*

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. The more significant estimates reflected in the Company's consolidated financial statements include certain judgments regarding revenue recognition, goodwill, tangible and intangible asset valuation, inventory valuation and potential losses on purchase commitments, asset retirement obligations, income tax liabilities and related indemnification receivable, deferred tax assets and liabilities, accrued expenses and stock-based compensation. Actual results could materially differ from those estimates or assumptions.

### *Revenue Recognition*

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

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

On January 1, 2009, LMI executed an amendment to a license and supply agreement (the "Agreement") with one of its customers, granting non-exclusive U.S. license and supply rights to the customer for the period from January 1, 2009 through December 31, 2012. Under the terms of the Agreement, the customer paid LMI \$10.0 million in license fees; \$8.0 million of which was received upon execution of the Agreement and \$2.0 million of which was received in June 2009 upon delivery of a special license as defined in the Agreement. The Company's product sales under the Agreement are recognized in the same manner as its normal product sales. The Company recognized the license fees as revenue on a straight-line basis over the term of the four-year Agreement. The Company recognized \$2.5 million in fiscal year 2012 in license fee revenue pursuant to the Agreement.

---

## [Table of Contents](#)

In February 2012, the Company entered in to the first amendment to the Agreement. The amendment contained obligations for the Company to deliver a fixed minimum number of units of the same product at different specified unit prices throughout the 11-month amendment term. The fixed minimum number of units shipped at the beginning of the amendment term had a substantially higher unit selling price than the units shipped later in the amendment term. The Company determined the total arrangement consideration and allocated this to each unit of product by applying the relative selling price method; therefore, revenue under this arrangement is being recognized at an average selling price as the units are shipped. The Company recognized \$5.6 million and \$12.8 million in revenue pursuant to the first amendment during the years ended December 31, 2013 and 2012, respectively. There was no deferred revenue attributable to these units at December 31, 2013.

On December 27, 2012, the Company entered into the second amendment to the Agreement, which extended the term from December 31, 2012 to December 31, 2014 and established new pricing and purchase requirements over the extended term. The second amendment also provided for the supply of TechneLite generators containing molybdenum-99 sourced from LEU targets. The agreement includes a \$3.0 million upfront payment by the customer to the Company and potential future milestone payments. During 2012, the Company received the \$3.0 million upfront payment. During 2013, the Company received an additional \$4.0 million upon achievement of the required milestones. At December 31, 2013, \$3.6 million is included in deferred revenue as a current liability in the accompanying consolidated balance sheets. The Company recognized the upfront payment as revenue on a straight-line basis over the term of the two year agreement. At December 31, 2014, there was no deferred revenue related to this Agreement.

### *Product Returns*

The Company provides a reserve for its estimate of sales recorded for which the related products are expected to be returned. The Company does not typically accept product returns unless an over shipment or non-conforming shipment was provided to the customer, or if the product was defective. The Company adjusts its estimate of product returns if it becomes aware of other factors that it believes could significantly impact its expected returns, including product recalls. These factors include its estimate of actual and historical return rates for non-conforming product and open return requests. Historically, the Company's estimates of returns have reasonably approximated actual returns.

### *Distributor Relationships*

Revenue for product sold to distributors is recognized at shipment, unless revenue recognition criteria have not been met. In those instances where collectability cannot be determined or the selling price cannot be reasonably estimated until the distributor has sold through the goods, the Company defers that revenue until such time as the goods have been sold through to the end-user customer, or the selling price can be reasonably estimated based on history of transactions with that distributor.

### *Rebates and Allowances*

Estimates for rebates and allowances represent the Company's estimated obligations under contractual arrangements with third parties. Rebate accruals and allowances are recorded in the same period the related revenue is recognized, resulting in a reduction to revenue and the establishment of a liability which is included in accrued expenses in the accompanying consolidated balance sheets. These rebates result from performance-based offers that are primarily based on attaining contractually specified sales volumes and growth, Medicaid rebate programs for certain products, administration fees of group purchasing organizations 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.

The accrual for rebates and allowances was approximately \$2.2 million and \$1.7 million at December 31, 2014 and 2013, respectively. Rebate and allowance charges against gross revenues totaled \$5.2 million, \$4.8 million and \$2.8 million for the years ended December 31, 2014, 2013 and 2012, respectively.



---

## [Table of Contents](#)

### *Income Taxes*

The Company accounts for income taxes using an asset and liability approach. The provision for income taxes represents income taxes paid or payable for the current year plus the change in deferred taxes during the year. Deferred taxes result from differences between the financial and tax bases of the Company's assets and liabilities. Deferred tax assets and liabilities are measured using the currently enacted tax rates that apply to taxable income in effect for the years in which those tax attributes are expected to be recovered or paid, and are adjusted for changes in tax rates and tax laws when changes are enacted.

Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The assessment of whether or not a valuation allowance is required involves the weighing of both positive and negative evidence concerning both historical and prospective information with greater weight given to evidence that is objectively verifiable. A history of recent losses is negative evidence that is difficult to overcome with positive evidence. In evaluating prospective information there are four sources of taxable income: reversals of taxable temporary differences, items that can be carried back to prior tax years (such as net operating losses), pre-tax income, and tax planning strategies. Any tax planning strategies that are considered must be prudent and feasible, and would only be undertaken in order to avoid losing an operating loss carryforward. Adjustments to the deferred tax valuation allowances are made in the period when those assessments are made.

The Company accounts for uncertain tax positions using a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Differences between tax positions taken in a tax return and amounts recognized in the financial statements are recorded as adjustments to other long-term assets and liabilities, or adjustments to deferred taxes, or both. The Company provides disclosure at the end of each annual reporting period on a tabular reconciliation of unrecognized tax benefits. The Company classifies interest and penalties within the provision for income taxes.

### *Cash and Cash Equivalents*

Cash and cash equivalents include savings deposits, certificates of deposit and money market funds that have original maturities of three months or less when purchased.

### *Accounts Receivable*

Accounts receivable consist of amounts billed and currently due from customers. The Company maintains an allowance for doubtful accounts for estimated losses. In determining the allowance, consideration includes the probability of recoverability based on past experience and general economic factors. Certain accounts receivable may be fully reserved when specific collection issues are known to exist, such as pending bankruptcy. As of December 31, 2014 and 2013, the Company had allowances for doubtful accounts of approximately \$0.6 million and \$0.3 million, respectively.

Also included in accounts receivable are miscellaneous receivables of approximately \$2.0 million and \$1.9 million as of December 31, 2014 and 2013, respectively.

---

## [Table of Contents](#)

### *Concentration of Risks and Limited Suppliers*

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of trade accounts receivable. The Company periodically reviews its accounts receivable for collectability and provides for an allowance for doubtful accounts to the extent that amounts are not expected to be collected. The Company sells primarily to large national distributors, which in turn, may resell the Company's products. There were two customers that represented greater than 10% of the total net accounts receivable balance and revenue during the year ended December 31, 2014, the majority of which is included in the U.S. segment.

	Accounts Receivable as of December 31,		Revenue for the year ended December 31,		
	2014	2013	2014	2013	2012
Company A	16.5%	16.7%	18.0%	18.8%	27.4%
Company B	13.4%	13.2%	11.1%	10.2%	8.4%
Company C	9.8%	7.2%	8.8%	9.8%	11.5%

The Company's cash and cash equivalents are maintained with various financial institutions.

The Company relies on certain materials used in its development and manufacturing processes, some of which are procured from only one or a few sources. The failure of one of these suppliers to deliver on schedule could delay or interrupt the manufacturing or commercialization process and thereby adversely affect the Company's operating results. In addition, a disruption in the commercial supply of, or a significant increase in the cost of one of the Company's materials from these sources could have a material adverse effect on the Company's business, financial position and results of operations. From May 2009 until August 2010, Nordion, the Company's largest supplier of Moly, a key raw material in the Company's TechneLite product, was affected by a nuclear reactor shutdown. The Company was not fully able to replace all of the quantity of supply it previously received from Nordion, which had a negative impact on the Company's results of operations. As part of the conditions for the relicensing of the NRU reactor, the Canadian government has asked Atomic Energy of Canada Limited, or AECL, to shut down the reactor for at least four weeks at least once a year for inspection and maintenance. The scheduled 2012 shutdown period ran from mid-April 2012 until mid-May 2012, and during such period, some of LMI's customers diverted a small amount of business to LMI's competitor, which correspondingly reduced our aggregate orders during the shutdown period. With this diversion, LMI was able to fulfill all customer demand for Moly from other suppliers during the shutdown period. During 2012, the Company executed amendments to agreements with Nordion and NTP, the Company's Moly suppliers, which extended the contract terms of those agreements to December 31, 2015 and December 31, 2017, respectively. In addition, because Xenon is a by-product of the Moly production process and is currently captured only by Nordion, the Company is currently reliant on Nordion as the sole supplier of Xenon to meet customer demand. In March 2013, the Company entered into an agreement with Institute for Radioelements ("IRE") who had previously been supplying the Company with Moly under the previous agreement with NTP and this agreement expires on December 31, 2017.

Historically, the Company has relied on BVL as its sole manufacturer of DEFINITY and Neurolite and one of two manufacturers of its Cardiolite product supply. Following extended operational and regulatory challenges at BVL's Bedford, Ohio facility, as of November 15, 2013, BVL ceased manufacturing for the Company any DEFINITY, Cardiolite or Neurolite.

Following extensive technology transfer activities, the Company currently relies on JHS as its sole source manufacturer of DEFINITY, Neurolite and evacuation vials for TechneLite. The Company has additional ongoing technology transfer activities at JHS for its Cardiolite product supply. In the meantime, the Company has no other currently active supplier of DEFINITY, Neurolite, and its Cardiolite product supply is manufactured by a single manufacturer.

---

## [Table of Contents](#)

Based on current projections, the Company believes that it will have sufficient supply of DEFINITY and Neurolite from JHS to meet expected demand and sufficient Cardiolite product supply from its current supplier to meet expected demand. Currently, the regulatory authorities in certain countries prohibit the Company from marketing products previously manufactured by BVL, and JHS has not yet obtained approval of such regulatory authorities that would permit the Company to market certain products manufactured by JHS. Accordingly, until such regulatory approvals have been obtained, the Company will not be able to sell and distribute those products in the relevant markets.

The Company is also currently working to secure additional alternative suppliers for its key products as part of its ongoing supply chain diversification strategy. On November 12, 2013, the Company entered into a Manufacturing and Supply Agreement with Pharmalucence to manufacture and supply DEFINITY. However, the Company is uncertain on the timing in which the Pharmalucence arrangement or any other arrangements could provide meaningful quantities of product. The Company believes Pharmalucence will file for FDA approval to manufacture DEFINITY in 2015.

The following table sets forth revenues for the Company's products that represented greater than 10% of total revenue for the years ended December 31, 2014, 2013 and 2012.

	Year Ended		
	December 31,		
	2014	2013	2012
DEFINITY	31.8%	27.5%	17.9%
TechneLite	31.0%	32.5%	39.7%
Xenon	12.1%	11.3%	10.4%
Cardiolite	6.2%	9.2%	12.1%

### *Inventory*

Inventory includes material, direct labor and related manufacturing overhead, and is stated at the lower of cost or market on a first-in, first-out basis. The Company does have consignment arrangements with certain customers where the Company retains title and the risk of ownership of the inventory, which is included in the Company's inventory balance.

The Company assesses the recoverability of inventory to determine whether adjustments for excess and obsolete inventory are required. Inventory that is in excess of future requirements is written down to its estimated net realizable value based upon forecasted demand for its products. If actual demand is less favorable than what has been forecasted by management, additional inventory write-downs may be required.

Inventory costs associated with product that has not yet received regulatory approval are capitalized if the Company believes there is probable future commercial use of the product and future economic benefits of the asset. If future commercial use of the product is not probable, then inventory costs associated with such product are expensed during the period the costs are incurred. For the year ended December 31, 2014, the Company expensed \$1.9 million of such product costs in cost of goods sold relating to Neurolite that was manufactured by JHS. At December 31, 2014 and 2013, the Company had no capitalized inventories associated with product that did not have regulatory approval.

---

## [Table of Contents](#)

### *Property, Plant and Equipment*

Property, plant and equipment are stated at cost. Replacements of major units of property are capitalized, and replaced properties are retired. Replacements of minor components of property and repair and maintenance costs are charged to expense as incurred. Depreciation is computed on a straight-line method based on the estimated useful lives of the related assets. The estimated useful lives of the major classes of depreciable assets are as follows:

Buildings	50 years
Land improvements	15 - 40 years
Machinery and equipment	3 - 20 years
Furniture and fixtures	15 years
Leasehold improvements	Lesser of lease term or 15 years

Upon retirement or other disposal of property, plant and equipment, the cost and related amount of accumulated depreciation are removed from the asset and accumulated depreciation accounts, respectively. The difference, if any, between the net asset value and the proceeds is included in comprehensive loss.

### *Capitalized Software Development Costs*

Certain costs to obtain internal use software for significant systems projects are capitalized and amortized over the estimated useful life of the software, which ranges from 3 to 5 years. Costs to obtain software for projects that are not significant are expensed as incurred. Capitalized software development costs, net of accumulated amortization, were \$2.4 million and \$1.5 million at December 31, 2014 and 2013, respectively. Approximately \$1.7 million and \$0.7 million of software development costs were capitalized in the years ended December 31, 2014 and 2013, respectively. Amortization expense related to the capitalized software was \$0.7 million, \$1.5 million and \$1.5 million for the years ended December 31, 2014, 2013 and 2012, respectively.

### *Goodwill, Intangibles and Long-Lived Assets*

Goodwill is not amortized, but is instead tested for impairment at least annually and whenever events or circumstances indicate that it is more likely than not that they may be impaired. The Company has elected to perform the annual test for goodwill impairment as of October 31 of each year.

In performing tests for goodwill impairment, the Company is first permitted to perform a qualitative assessment about the likelihood of the carrying value of a reporting unit exceeding its fair value. If the Company determines that it is more likely than not that the fair value of a reporting unit is less than its carrying amount based on the qualitative assessment, it is required to perform the two-step goodwill impairment test described below to identify the potential goodwill impairment and measure the amount of the goodwill impairment loss, if any, to be recognized for that reporting unit. However, if the Company concludes otherwise based on the qualitative assessment, the two-step goodwill impairment test is not required. The option to perform the qualitative assessment is not an accounting policy election and can be utilized at the Company's discretion. Further, the qualitative assessment need not be applied to all reporting units in a given goodwill impairment test. For an individual reporting unit, if the Company elects not to perform the qualitative assessment, or if the qualitative assessment indicates that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, then the Company must perform the two-step goodwill impairment test for the reporting unit. If the implied fair value of goodwill is less than the carrying value, then an impairment charge would be recorded.

In performing the annual goodwill impairment test in 2014 and 2013, the Company bypassed the option to perform a qualitative assessment and proceeded directly to performing the first step of the two-step goodwill impairment test.

---

## [Table of Contents](#)

The Company calculates the fair value of its reporting units using the income approach, which utilizes discounted forecasted future cash flows, and the market approach which utilizes fair value multiples of comparable publicly traded companies. The discounted cash flows are based on our most recent long-term financial projections and are discounted using a risk adjusted rate of return, which is determined using estimates of market participant risk-adjusted weighted average costs of capital and reflects the risks associated with achieving future cash flows. The market approach is calculated using the guideline company method, where the Company uses market multiples derived from stock prices of companies engaged in the same or similar lines of business. There is not a quoted market price for the Company's reporting units or the company as a whole, therefore, a combination of the two methods is utilized to derive the fair value of the business. The Company evaluated and weighed the results of these approaches as well as ensures it understands the basis of the results of these two methodologies. The Company believes the use of these two methodologies ensures a consistent and supportable method of determining its fair value that is consistent with the objective of measuring fair value. If the fair value were to decline, then the Company may be required to incur material charges relating to the impairment of those assets. The Company completed its required annual impairment test for goodwill in the fourth quarter of 2014, 2013 and 2012 and determined that at each of those periods, the Company's fair value was substantially in excess of its carrying value. Goodwill is not deductible for tax purposes.

During the first quarter of 2013, the strategic shift in how the Company funds its R&D programs significantly altered the expected future costs and revenues associated with our agents in development. Accordingly, this action was deemed to be a triggering event for an evaluation of the recoverability of the Company's goodwill as of March 31, 2013. The Company performed an interim impairment test and determined that there was no impairment of goodwill as of March 31, 2013.

The Company tests intangible and long-lived assets for recoverability whenever events or changes in circumstances suggest that the carrying value of an asset or group of assets may not be recoverable. The Company measures the recoverability of assets to be held and used by comparing the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. If those assets are considered to be impaired, the impairment equals the amount by which the carrying amount of the assets exceeds the fair value of the assets. Any impairments are recorded as permanent reductions in the carrying amount of the assets. Long-lived assets, other than goodwill and other intangible assets, that are held for sale are recorded at the lower of the carrying value or the fair market value less the estimated cost to sell.

In the first quarter of 2012, the Company reviewed the estimated useful life of its Cardiolite trademark as a result of a triggering event. Utilizing the most recent forecasted revenue data, the Company revised the estimate of the remaining useful life of the Cardiolite trademark to five years. The Company monitors the recoverability of its branded Cardiolite trademark intangible asset due to the ongoing generic competition based on actual results and existing estimates of future undiscounted cash flows associated with the branded Cardiolite product. As of December 31, 2013, the Company conducted, using its revised sales forecast, an impairment analysis and concluded that the estimate of future undiscounted cash flows associated with the Cardiolite trademark intangible did not exceed the carrying amount of the asset totaling \$19.2 million and therefore, the asset has been written down to its fair value. Fair value was calculated by utilizing Level 3 inputs in the relief-from-royalty method, an income-based approach. As a result of this analysis, the Company recorded an impairment charge of \$15.4 million to adjust the carrying value to its fair value of \$3.8 million. This expense was recorded within cost of goods sold in the accompanying consolidated statement of comprehensive loss in the fourth quarter of 2013.

In the third quarter of 2013, the Company was in negotiations with a new distributor for the sale of certain products within certain international markets. This agreement was signed in October 2013 and as a result the Company did not renew the agreements with its former distributors in these international markets. The Company determined the customer relationship intangible related to these former distributors was no longer recoverable and recorded an impairment charge of \$1.0 million in the third quarter of 2013. In the fourth quarter of 2013, the Company updated its strategic plan to reflect the non-renewal of these agreements and the uncertainty in the timing of product availability in this region. As a result, the Company reviewed the recoverability of certain of its

---

## [Table of Contents](#)

customer relationship intangible assets in the International segment that were impacted by the Company's revised strategic plan. The Company conducted an impairment analysis and concluded that the estimate of future undiscounted cash flows associated with the customer relationship intangible asset did not exceed the carrying amount of the asset and therefore, the asset would need to be written down to its fair value. In order to calculate the fair value of the acquired customer relationship intangible assets, the Company utilized Level 3 inputs to estimate the future discounted cash flows associated with remaining customers and as a result of this analysis, recorded an impairment charge of \$0.7 million in the fourth quarter of 2013. These impairment charges were recorded within cost of goods sold in the accompanying consolidated statement of comprehensive loss.

During the third quarter of 2013, the Company committed to a plan to sell certain of its excess land in the U.S. segment, which had a carrying value of \$7.5 million. This event qualified for held for sale accounting and the excess land was written down to its fair value, less estimated costs to sell. The fair value was estimated utilizing Level 3 inputs and using a market approach, based on available data for transactions in the region, discussions with real estate brokers and the asking price of comparable properties in its principal market. This resulted in a loss of \$6.4 million, which is included within operating loss as impairment of land in the accompanying consolidated statement of comprehensive loss. During the fourth quarter of 2013, the Company sold the excess land for net proceeds of \$1.1 million.

Fixed assets dedicated to R&D activities, which were impacted by the March 2013 R&D strategic shift, have a carrying value of \$4.5 million as of December 31, 2014. The Company believes these fixed assets will be utilized for either internally funded ongoing R&D activities or R&D activities funded by a strategic partner. If the Company is not successful in finding a strategic partner, and there are no alternative uses for those fixed assets, they could be subject to impairment in the future.

The Company also tested certain long-lived assets utilized in the manufacturing of certain products in the U.S. for recoverability as of December 31, 2013, due to a change in the Company's contract to manufacture Quadramet. The analysis indicated that there was no impairment as of December 31, 2013. The Company also evaluated the remaining useful lives of these long-lived assets that were tested for recoverability at December 31, 2013 and determined no revisions were required to the remaining periods of depreciation.

In the fourth quarter of 2014, the Company tested certain long-lived and intangible assets, associated with its U.S. operations, for recoverability as a result of the expiration of an agreement with a customer. The analysis indicated that there was no impairment as of December 31, 2014. The Company also evaluated the remaining useful lives of the long-lived and intangible assets that were tested for recoverability at December 31, 2014 and determined no revisions were required to the remaining periods of depreciation and amortization.

Intangible assets, consisting of patents, trademarks and customer relationships related to the Company's products are amortized in a method equivalent to the estimated utilization of the economic benefit of the asset. Trademarks and patents are amortized on a straight-line basis, and customer relationships are amortized on an accelerated basis.

### *Deferred Financing Costs*

Deferred financing costs are capitalized and amortized to interest expense using the effective interest method. As of December 31, 2014 and 2013, the unamortized deferred financing costs were \$7.3 million and \$9.6 million, respectively. The expense associated with the amortization of deferred financing costs was \$2.5 million, \$2.4 million and \$2.2 million for the years ended December 31, 2014, 2013 and 2012, respectively, and was included in interest expense. In connection with the Facility, the Company wrote off \$0.6 million of the existing unamortized deferred financing costs related to the previous facility, which is included in interest expense in the accompanying consolidated statements of comprehensive loss during the year ended December 31, 2013.

---

## [Table of Contents](#)

### *Contingencies*

In the normal course of business, the Company is subject to loss contingencies, such as legal proceedings and claims arising out of its business, that cover a wide range of matters, including, among others, product and environmental liability. The Company records accruals for those loss contingencies when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. The Company does not recognize gain contingencies until realized.

### *Fair Value of Financial Instruments*

The estimated fair values of the Company's financial instruments, including its cash and cash equivalents, receivables, accounts payable and accrued expenses approximate the carrying values of these instruments due to their short term nature. Assets measured at fair value on a nonrecurring basis include long-lived assets held for sale and certain intangible assets. The estimated fair value of the debt, at December 31, 2014, based on Level 2 inputs of recent market activity available to the Company was \$384.0 million compared to the face value of \$400.0 million. At December 31, 2013, the estimated fair value of the debt based on Level 2 inputs of recent market activity available to the Company was \$356.0 million compared to the face value of \$400.0 million.

### *Shipping and Handling Revenues and Costs*

The Company typically does not charge customers for shipping and handling costs, but any shipping and handling costs charged to customers are included in revenues. Shipping and handling costs are included in cost of goods sold and were \$19.4 million, \$20.5 million and \$20.4 million for the years ended December 31, 2014, 2013 and 2012, respectively.

### *Advertising and Promotion Costs*

Advertising and promotion costs are expensed as incurred and totaled \$2.8 million, \$2.7 million and \$3.2 million for the years ended December 31, 2014, 2013 and 2012, respectively, and are included in sales and marketing expenses.

### *Research and Development*

Research and development costs are expensed as incurred and relate primarily to the development of new products to add to the Company's portfolio and costs related to its medical affairs and medical information functions. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and recognized as an expense as the goods are delivered or the related services are performed.

### *Foreign Currency*

The consolidated statements of comprehensive loss of the Company's foreign subsidiaries are translated into U.S. Dollars using average exchange rates. The net assets of the Company's foreign subsidiaries are translated into U.S. Dollars using the end of period exchange rates. The impact from translating the net assets of these subsidiaries at changing rates are recorded in the foreign currency translation adjustment account, which is included in consolidated accumulated other comprehensive loss.

For the years ended December 31, 2014, 2013 and 2012, losses arising from foreign currency transactions totaled approximately \$0.3 million, \$0.3 million and \$0.6 million, respectively. Transaction gains and losses are reported as a component of other income (expense), net.

---

## [Table of Contents](#)

### *Stock-Based Compensation*

The Company's stock-based compensation cost is measured at the grant date of the stock-based award based on the fair value of the award and is recognized as expense over the requisite service period, which generally represents the vesting period, and includes an estimate of the awards that will be forfeited. The Company uses the Black-Scholes valuation model for estimating the fair value of stock options. The fair value of stock option awards is affected by the valuation assumptions, including the estimated fair value of the Company's common stock, the expected volatility based on comparable market participants, expected term of the option, risk-free interest rate and expected dividends. When a contingent cash settlement of vested options becomes probable, the Company reclassifies its vested awards to a liability and accounts for any incremental compensation cost in the period in which the settlement becomes probable.

### *Accumulated Other Comprehensive Loss*

Comprehensive loss is comprised of net loss, plus all changes in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources, including any foreign currency translation adjustments. These changes in equity are recorded as adjustments to accumulated other comprehensive loss in the Company's consolidated balance sheet. The components of accumulated other comprehensive loss consist of foreign currency translation adjustments.

### *Asset Retirement Obligations*

The Company's compliance with federal, state, local and foreign environmental laws and regulations may require it to remove or mitigate the effects of the disposal or release of chemical substances in jurisdictions where it does business or maintains properties. The Company establishes accruals when those costs are legally obligated and probable and can be reasonably estimated. Accrual amounts are estimated based on currently available information, regulatory requirements, remediation strategies, historical experience, the relative shares of the total remediation costs and a relevant discount rate, when the time periods of estimated costs can be reasonably predicted. Changes in these assumptions could impact the Company's future reported results. The amounts recorded for asset retirement obligations in the accompanying balance sheets at December 31, 2014 and 2013 were \$7.4 million and \$6.4 million, respectively.

### *Self Insurance Reserves*

The Company's consolidated balance sheet at both December 31, 2014 and 2013 includes approximately \$0.4 million of accrued liabilities associated with employee medical costs that are retained by the Company. The Company estimates the required liability of those claims on an undiscounted basis based upon various assumptions which include, but are not limited to, the Company's historical loss experience and projected loss development factors. The required liability is also subject to adjustment in the future based upon changes in claims experience, including changes in the number of incidents (frequency) and change in the ultimate cost per incident (severity). The Company also maintains a separate cash account to fund these medical claims and must maintain a minimum balance as determined by the plan administrator. The balance of this restricted cash account was approximately \$0.1 million and \$0.2 million at December 31, 2014 and 2013, respectively, and is included in other current assets.

### *Recent Accounting Standards*

In July 2013, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, No. 2013-11, "Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists," or ASU 2013-11. The amendments in ASU 2013-11 provide guidance on the financial statement presentation of unrecognized tax benefits when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. ASU 2013-11 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The amendments did not have a material impact on the Company's financial position, results of operations or cash flows.



---

## [Table of Contents](#)

In April 2014, the FASB issued ASU No. 2014-08, “Presentation of Financial Statements (Topic 205) and Property, Plant, and Equipment (Topic 360): Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity,” or ASU 2014-08. The amendments in ASU 2014-08 change the criteria for reporting discontinued operations while enhancing disclosures in this area. The new guidance requires expanded disclosures about discontinued operations that will provide financial statement users with more information about the assets, liabilities, income, and expenses of discontinued operations. The new guidance also requires disclosure of the pre-tax income attributable to a disposal of a significant part of an organization that does not qualify for discontinued operations reporting. The amendments in the ASU are effective in the first quarter of 2015 for public companies with calendar year ends. Early adoption is permitted. The Company does not anticipate this ASU will have a material impact to the Company’s financial position, results of operations or cash flows.

In May 2014, the FASB issued ASU No. 2014-09, “Revenue from Contracts with Customers (Topic 606)” or ASU 2014-09. ASU 2014-09 supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under existing U.S. GAAP including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. The amendments in ASU No. 2014-09 are effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early application is not permitted. The Company is currently evaluating the impact this ASU will have on the Company’s financial position, results of operations and cash flows.

In June 2014, the FASB issued ASU No. 2014-12, “Compensation—Stock Compensation (Topic 718)” or ASU 2014-12. ASU 2014-12 requires that a performance target that affects vesting and could be achieved after the requisite service period be treated as a performance condition. The amendments in ASU 2014-12 are effective for annual reporting periods beginning after December 15, 2015, including interim periods within that reporting period. The Company does not anticipate this ASU will have a material impact to the Company’s financial position, results of operations or cash flows.

In August 2014, the FASB issued ASU No. 2014-15, “Presentation of Financial Statements-Going Concern (Subtopic 205-4): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern” or ASU 2014-15. ASU 2014-15 to provide guidance on management’s responsibility in evaluating whether there is substantial doubt about a company’s ability to continue as a going concern and to provide related footnote disclosures. The amendments in ASU 2014-15 are effective for annual reporting periods ending after December 15, 2016. Early adoption is permitted. The Company does not anticipate this ASU will have a material impact to the Company’s financial position, results of operations or cash flows.

### **3. Financial Instruments and Fair Value Measurements**

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 in fair value measurements, financial instruments are categorized based on a hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1—Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2—Inputs include quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that

[Table of Contents](#)

are observable for the asset or liability (i.e., interest rates, yield curves, etc.) and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

Level 3—Unobservable inputs that reflect a Company’s estimates about the assumptions that market participants would use in pricing the asset or liability. The Company develops these inputs based on the best information available, including its own data.

At December 31, 2014 and 2013, the Company’s financial assets that are measured at fair value on a recurring basis are comprised of money market securities and are classified as cash equivalents. The Company invests excess cash from its operating cash accounts in overnight investments and reflects these amounts in cash and cash equivalents on the consolidated balance sheet using quoted prices in active markets for identical assets (Level 1).

The tables below present information about the Company’s assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2014 and 2013:

<u>(in thousands)</u>	<u>Total fair value at December 31, 2014</u>	<u>Quoted prices in active markets (Level 1)</u>	<u>Significant other observable inputs (Level 2)</u>	<u>Significant unobservable inputs (Level 3)</u>
Money market	\$ 1,505	\$ 1,505	\$ —	\$ —
Certificates of deposit—restricted	89	—	89	—
	<u>\$ 1,594</u>	<u>\$ 1,505</u>	<u>\$ 89</u>	<u>\$ —</u>

<u>(in thousands)</u>	<u>Total fair value at December 31, 2013</u>	<u>Quoted prices in active markets (Level 1)</u>	<u>Significant other observable inputs (Level 2)</u>	<u>Significant unobservable inputs (Level 3)</u>
Money market	\$ 1,236	\$ 1,236	\$ —	\$ —
Certificates of deposit—restricted	322	—	322	—
	<u>\$ 1,558</u>	<u>\$ 1,236</u>	<u>\$ 322</u>	<u>\$ —</u>

At December 31, 2013, the Company had a \$0.2 million certificate of deposit for which the Company’s use of such cash was restricted and is included in the line item “Certificates of deposit—restricted” above. This investment was classified in other current assets on the consolidated balance sheet and was redeemed during the quarter ended September 30, 2014. The remaining \$0.1 million at both December 31, 2014 and 2013, represents a certificate of deposit that is collateral for a long-term lease and is included in other long-term assets on the consolidated balance sheet. Certificates of deposit are classified within Level 2 of the fair value hierarchy, as these are not traded on the open market.

At December 31, 2014, the Company had total cash and cash equivalents of \$17.8 million, which included approximately \$1.5 million of money market funds and \$16.3 million of cash on-hand. At December 31, 2013, the Company had total cash and cash equivalents of \$16.7 million, which included approximately \$1.2 million of money market funds and \$15.5 million of cash on-hand.

## Table of Contents

The table below presents information about the Company's assets and liabilities that are measured at fair value on a nonrecurring basis during the year ended December 31, 2013, due to the remeasurement of assets resulting in impairment charges.

Year ended December 31, 2013 (in thousands)	Total fair value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Cardiolite trademark	\$ 3,800	\$ —	\$ —	\$ 3,800
Customer relationships	—	—	—	—
<b>Total</b>	<b>\$ 3,800</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 3,800</b>

During the third quarter of 2013, the Company recorded an impairment charge of \$6.4 million to write down the carrying value of excess land held for sale in the U.S. segment totaling \$7.5 million to its fair value, less estimated costs to sell. See Note 6 for further discussion regarding the impairment charge. The fair value of land held for sale was determined using Level 3 inputs and was estimated using a market approach, based on available data for transactions in the region, discussions with real estate brokers and the asking price of comparable properties in its principal market. Unobservable inputs obtained from third parties are adjusted as necessary for the condition and attributes of the specific asset. The land sale was completed in the fourth quarter of 2013.

During the third and fourth quarters of 2013, the Company recorded an impairment charge of \$1.0 million and \$0.7 million, respectively, to write down the carrying value of a customer relationship intangible asset in the International segment totaling \$1.8 million and \$0.7 million, respectively, to its fair value of zero. See Note 8 for further discussion regarding the impairment charge. The determination of the customer relationship intangible assets impairment charge was based on Level 3 measurements under the fair value hierarchy. The Company utilized an income approach to calculate the discounted cash flows that would be generated by its remaining customer base. The unobservable inputs utilized by the Company included management's assumptions regarding future revenues and profitability from the remaining customers and a discount rate of 15% as of September 30, 2013 and December 31, 2013, respectively.

During the fourth quarter of 2013, the Company recorded an impairment charge of \$15.4 million to write down the Cardiolite trademark intangible asset in the U.S. segment totaling \$19.2 million to its fair value of \$3.8 million. See Note 8 for further discussion regarding the impairment charge. The fair value measurements were determined using a relief-from-royalty method, which incorporates unobservable inputs, thereby classifying the fair value measurements as a Level 3 measurement within the fair value hierarchy. The primary inputs used in the relief-from-royalty method, an income-based approach, included estimated prospective cash flows expected to be generated by Cardiolite and an estimated royalty rate that would be used by a market participant. The unobservable inputs utilized by the Company included management's assumptions regarding future revenues and profitability from the branded Cardiolite product, a royalty rate of 6%, a discount rate of 15% and a life of 15 years.

## 4. Income Taxes

The components of income (loss) before income taxes for the years ended December 31 were:

(in thousands)	2014	2013	2012
United States	\$ 4,593	\$(58,093)	\$(43,868)
International	(4,567)	(2,571)	1,312
	<u>\$ 26</u>	<u>\$(60,664)</u>	<u>\$(42,556)</u>

[Table of Contents](#)

The provision (benefit) for income taxes as of December 31 was:

(in thousands)	2014	2013	2012
<b>Current</b>			
Federal	\$ (208)	\$ (782)	\$(3,508)
State	1,285	1,712	2,763
International	325	356	618
	<u>1,402</u>	<u>1,286</u>	<u>(127)</u>
<b>Deferred</b>			
Federal	(277)	—	200
State	—	—	—
International	70	(272)	(628)
	<u>(207)</u>	<u>(272)</u>	<u>(428)</u>
	<u>\$1,195</u>	<u>\$1,014</u>	<u>\$ (555)</u>

The Company's provision (benefit) for income taxes in the years ended December 31, 2014, 2013 and 2012 was different from the amount computed by applying the statutory U.S. Federal income tax rate to (loss) income from operations before income taxes, as a result of the following:

(in thousands)	2014		2013		2012	
U.S. statutory rate	\$ 9	35.0%	\$(21,224)	35.0%	\$(14,895)	35.0%
Permanent items and foreign tax credits	149	569.4%	292	(0.5)%	(1,200)	2.8%
Uncertain tax positions	817	3,129.4%	809	(1.3)%	892	(2.1)%
Research credits	(1,204)	(4,608.8)%	(1,346)	2.2%	—	—
State and local taxes	234	895.0%	(1,780)	3.0%	(1,821)	4.3%
Impact of rate change on deferred taxes	61	233.2%	31	(0.1)%	(974)	2.3%
True-up of prior year tax	1,065	4,083.0%	(1,422)	2.3%	(2,345)	5.5%
Foreign tax rate differential	437	1,673.2%	92	(0.2)%	(455)	1.1%
Valuation allowance	121	464.6%	25,674	(42.3)%	20,243	(47.6)%
Tax on repatriation	(500)	(1,915.4)%	(18)	0.0%	—	—
Other	6	23.1%	(94)	0.2%	—	—
	<u>\$ 1,195</u>	4,581.7%	<u>\$ 1,014</u>	(1.7)%	<u>\$ (555)</u>	1.3%

The components of deferred income tax assets (liabilities) at December 31 were:

(in thousands)	2014	2013
<b>Deferred Tax Assets</b>		
Federal benefit of state tax liabilities	\$ 10,950	\$ 11,541
Reserves, accruals and other	38,285	29,242
Capitalized research and development	26,471	30,057
Capital loss carryforward	—	2,309
Amortization of intangibles other than goodwill	36,523	52,665
Net operating loss carryforwards	43,202	31,405
Deferred tax assets	<u>155,431</u>	<u>157,219</u>
<b>Deferred Tax Liabilities</b>		
Reserves, accruals and other	(642)	(500)
Customer relationships	(6,012)	(7,860)
Depreciation	(95)	(360)
Deferred tax liability	(6,749)	(8,720)
Less: Valuation allowance	<u>(148,497)</u>	<u>(148,535)</u>
	<u>\$ 185</u>	<u>\$ (36)</u>

[Table of Contents](#)

	<u>2014</u>	<u>2013</u>
Recorded in the accompanying consolidated balance sheet as:		
Current deferred tax assets	\$ 256	\$ 18
Current deferred tax liabilities	(152)	(57)
Noncurrent deferred tax assets	328	15
Noncurrent deferred tax liability	<u>(247)</u>	<u>(12)</u>
Net deferred tax liabilities	<u>\$ 185</u>	<u>\$(36)</u>

The Company files separate federal income tax returns for Lantheus MI Intermediate, Inc. and Lantheus Medical Imaging, Inc. For state tax purposes, the Company files combined tax returns with Lantheus Holdings, Inc. For income tax provision purposes, the Company uses the separate return method in calculating its state tax provision. As of December 31, 2014 and 2013, the Company reflects an amount payable to Lantheus Holdings of \$85,000 for the tax benefit of losses incurred by Lantheus Holdings, which is included in due from parent on the consolidated balance sheets.

A reconciliation of the Company's changes in uncertain tax positions for 2014, 2013 and 2012 is as follows:

<b>(in thousands)</b>	
Beginning balance of uncertain tax positions as of January 1, 2012	\$15,378
Additions related to current year tax positions	301
Reductions related to prior year tax positions	—
Settlements	(651)
Lapse of statute of limitations	<u>(1,122)</u>
Balance of uncertain tax positions as of December 31, 2012	13,906
Additions related to current year tax positions	18
Reductions related to prior year tax positions	—
Settlements	(34)
Lapse of statute of limitations	<u>(763)</u>
Balance of uncertain tax positions as of December 31, 2013	13,127
Additions related to current year tax positions	—
Reductions related to prior year tax positions	(8)
Settlements	(1,434)
Lapse of statute of limitations	<u>(416)</u>
Balance of uncertain tax positions as of December 31, 2014	<u>\$11,269</u>

As of December 31, 2014 and 2013, the total amount of unrecognized tax benefits was \$11.3 million and \$13.1 million, respectively, all of which would affect the effective tax rate, if recognized. These amounts are primarily associated with domestic state tax issues, such as the allocation of income among various state tax jurisdictions and transfer pricing. Since the Company operates in a number of countries in which it has income tax treaties, it believes that it is more-likely-than-not that the Company should be able to receive competent authority relief for potential adjustments in those countries. Included in the Company's uncertain tax positions for transfer pricing exposures are \$0.5 million, which is reflected within other long-term liabilities, and an offset of \$0.2 million for expected competent authority relief, which is reflected in other long-term assets. The tabular rollforward reflected above is net of the \$0.2 million of competent authority relief as of December 31, 2014. Within the next twelve months, unrecognized tax benefits of \$0.2 million may be recognized associated with transfer pricing due to the closing of the statute of limitations.

As of December 31, 2014 and 2013, total liabilities for tax obligations and associated interest and penalties were \$32.3 million and \$34.9 million, respectively, consisting of income tax provisions for uncertain tax benefits

---

## [Table of Contents](#)

of \$11.5 million and \$14.1 million, interest accruals of \$18.6 million and \$18.2 million and penalty accruals of \$2.2 million and \$2.6 million, respectively, which were included in other long-term liabilities on the consolidated balance sheets. Included in the 2014, 2013 and 2012 tax provision is \$0.4 million, \$1.9 million and \$2.6 million, respectively, relating to interest and penalties, net of benefits for reversals of uncertain tax position interest and penalties recognized upon settlements and lapse of statute of limitations.

In accordance with the Company's acquisition of the medical imaging business from Bristol Myers Squibb ("BMS") in 2008, the Company obtained a tax indemnification agreement with BMS related to certain tax obligations arising prior to the acquisition of the Company, for which the Company has the primary legal obligation. The tax indemnification receivable is recognized within other noncurrent assets. The total noncurrent asset related to the indemnification was \$17.8 million and \$19.7 million as of December 31, 2014 and 2013, respectively. The changes in the tax indemnification asset are recognized within other income (expense), net in the consolidated statement of comprehensive loss. In accordance with the Company's accounting policy, the change in the tax liability and penalties and interest associated with these obligations (net of any offsetting federal or state benefit) is recognized within the tax provision. Accordingly, as these reserves change, adjustments are included in the tax provision while the offsetting adjustment is included in other income (expense), net. Assuming that the receivable from BMS continues to be considered recoverable by the Company, there is no net effect on earnings related to these liabilities and no net cash outflows.

During the year ended December 31, 2014 and 2012, BMS, on behalf of the Company, made payments totaling \$6.3 million and \$0.7 million, respectively, to a number of states in connection with prior year state income tax filings. As a result of these payments, the amount due from BMS, included within other long-term assets, decreased by \$2.9 million and \$0.7 million, respectively, which represented the release of asset balances associated with pre-acquisition years. There were no payments made on behalf of the Company in 2013.

Included in other income (expense), net for the year ended December 31, 2014, is an expense of \$1.1 million relating to the reduction in the indemnification receivable from BMS associated with the expiration of statute of limitations and income of \$1.9 million relating to the increase in the indemnification receivable for current year interest and penalties.

The Company has generated domestic pre-tax losses in two of the past three years. This loss history demonstrates negative evidence concerning the Company's ability to utilize its domestic gross deferred tax assets. In order to overcome the presumption of recording a valuation allowance against the deferred tax assets, the Company must have sufficient positive evidence that it can generate sufficient taxable income to utilize these deferred tax assets within the carryover or forecast period. Although the Company has no history of expiring net operating losses or other tax attributes, based on the cumulative domestic loss incurred over the three-year period ended December 31, 2014, management determined that the net U.S. deferred tax assets are not more-likely-than-not recoverable. As a result of this analysis, the Company continues to maintain a full valuation allowance primarily against its net U.S. deferred tax assets in the amount of \$148.5 million at both December 31, 2014 and 2013.

---

[Table of Contents](#)

The following is a reconciliation of the Company's valuation allowance for the years ending December 31, 2014, 2013, and 2012.

<u>(in thousands)</u>	
Balance at January 1, 2012	\$102,692
Charged to provision for income taxes	20,243
Deductions	—
Balance at December 31, 2012	122,935
Charged to provision for income taxes	25,600
Deductions	—
Balance at December 31, 2013	148,535
Charged to provision for income taxes	121
Foreign currency	(159)
Deductions	—
Balance at December 31, 2014	<u>\$148,497</u>

The Company's U.S. income tax returns remain subject to examination for three years. The state income tax returns remain subject to examination for three to four years depending on the state's statute of limitations.

At December 31, 2014, the Company has federal net operating loss carryovers of \$114.0 million, which will begin to expire in 2031. The Company has \$2.4 million of federal research credits, which begin to expire in 2029. The Company has foreign tax credits of approximately \$4.7 million that will begin to expire in 2020. The Company has state research credits of \$2.8 million, which will expire between 2024 and 2029. The Company has Massachusetts investment tax credits of approximately \$0.5 million, which have no expiration date.

In 2010, the Company was granted a tax holiday from the Commonwealth of Puerto Rico, which expires on January 1, 2024. This grant provides for a 4% tax rate on activities relating to the operations of the Company's radiopharmacies. This grant is conditioned upon the Company meeting certain employment and investment thresholds. The impact of this tax holiday was to decrease foreign tax by approximately \$0.1 million, \$0.3 million and \$0.3 million in 2014, 2013 and 2012, respectively.

In September 2013, the Internal Revenue Service released final Tangible Property Regulations (the "Final Regulations"). The Final Regulations provide guidance on applying Section 263(a) of the Code to amounts paid to acquire, produce or improve tangible property, as well as rules for materials and supplies (Code Section 162). These regulations contain certain changes from the temporary and proposed tangible property regulations that were issued on December 27, 2011. The Final Regulations are generally effective for taxable years beginning on or after January 1, 2014. In addition, taxpayers are permitted to early adopt the Final Regulations for taxable years beginning on or after January 1, 2012. The Final Regulations did not have a material effect on the Company's results of operations or financial condition during the year ended December 31, 2014.

---

[Table of Contents](#)

## 5. Inventory

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

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

<u>(in thousands)</u>	<u>December 31,</u> <u>2014</u>	<u>December 31,</u> <u>2013</u>
Raw materials	\$ 6,043	\$ 7,063
Work in process	1,788	5,849
Finished goods	<u>7,751</u>	<u>5,398</u>
Inventory	15,582	18,310
Other long-term assets	<u>1,156</u>	<u>1,687</u>
Total	<u>\$ 16,738</u>	<u>\$ 19,997</u>

At December 31, 2014 and 2013, inventories reported as other long-term assets included \$1.2 million and \$1.7 million of raw materials, respectively.

The Company's Ablavar product was commercially launched in January 2010. The revenues for this product through December 31, 2014 have not been significant. At December 31, 2014 and 2013, the balances of inventory on-hand reflect approximately \$0.9 million and \$1.5 million, respectively, of finished products and raw materials related to Ablavar. At December 31, 2013, approximately \$0.5 million of Ablavar inventory were included in long-term assets. At December 31, 2014, there was no Ablavar inventory included in long-term assets.

The Company entered into an agreement and subsequent amendments with a supplier to provide Active Pharmaceutical Ingredient ("API") and finished products for Ablavar under which the Company was required to purchase future minimum quantities. At December 31, 2013, the remaining purchase commitment under the amended agreement was approximately \$1.8 million, of which the Company had accrued a loss of \$1.3 million associated with this future purchase commitment. At December 31, 2014, there were no remaining purchase commitments. The Company records the inventory when it takes delivery, at which time the Company assumes title and risk of loss.

In 2013, the Company transitioned the sales and marketing efforts for Ablavar from its direct sales force to the Company's customer service team. During the fourth quarter of 2013, the Company updated its strategic plan, which had a significant impact on the Ablavar sales forecast. The Company performed an inventory reserve analysis using its expected future Ablavar sales and recorded an additional write-down of \$1.6 million related to the API that the Company would not be able to convert or be able to sell prior to its expiry as of December 31, 2013. In the event that the Company does not meet its revised sales expectations for Ablavar or cannot sell the product prior to its expiration, the Company could incur additional inventory write-downs.

## 6. Property, Plant and Equipment, net

Property, plant and equipment consisted of the following at December 31:

<u>(in thousands)</u>	<u>2014</u>	<u>2013</u>
Land	\$ 14,950	\$ 14,950
Buildings	67,571	65,787
Machinery, equipment and fixtures	65,179	65,026
Construction in progress	9,746	8,029
Accumulated depreciation	<u>(61,432)</u>	<u>(56,139)</u>
Property, plant and equipment, net	<u>\$ 96,014</u>	<u>\$ 97,653</u>



---

## [Table of Contents](#)

Depreciation expense related to property, plant and equipment was \$9.9 million, \$9.3 million and \$9.7 million for the years ended December 31, 2014, 2013 and 2012, respectively.

Included within machinery, equipment and fixtures are spare parts of approximately \$2.5 million as of December 31, 2014 and 2013, respectively. Spare parts include replacement parts relating to plant and equipment and are either recognized as an expense when consumed or re-classified and capitalized as part of the related plant and equipment and depreciated over a time period not exceeding the useful life of the related asset.

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

During the third quarter of 2013, the Company committed to a plan to sell certain of its excess land in the U.S. segment, which had a carrying value of \$7.5 million. This event qualified for held for sale accounting and the excess land was written down to its fair value, less estimated costs to sell. The fair value was estimated utilizing Level 3 inputs and using a market approach, based on available data for transactions in the region, discussions with real estate brokers and the asking price of comparable properties in its principal market. This resulted in a loss of \$6.4 million, which is included within operating loss as impairment of land in the accompanying consolidated statement of comprehensive loss. During the fourth quarter of 2013, the Company sold the excess land for net proceeds of \$1.1 million.

### *Long-Lived Assets to Be Disposed of Other than by Sale*

In November 2014, the Company announced its plans to decommission certain long-lived assets associated with its R&D operations in the United States. The Company expects the decommissioning to begin in the second half of 2015. As a result, the Company revised its estimates of the remaining useful lives of the affected long-lived assets to seven months, which increased depreciation expense by \$1.2 million included in R&D expenses in the consolidated statement of comprehensive loss during the quarter ended December 31, 2014. At December 31, 2014, the net book value of these assets totaled \$7.4 million.

## **7. Asset Retirement Obligations**

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

The Company is required to provide the U.S. Nuclear Regulatory Commission and Massachusetts Department of Public Health financial assurance demonstrating the Company's ability to fund the decommissioning of the North Billerica, Massachusetts production facility upon closure, although the Company does not intend to close the facility. The Company has provided this financial assurance in the form of a \$28.2 million surety bond, which itself is currently secured by an \$8.8 million unfunded Standby Letter of Credit provided to the third party issuer of the bond.

The fair value of a liability for asset retirement obligations is recognized in the period in which the liability is incurred. As of December 31, 2014, the liability is measured at the present value of the obligation expected to be incurred, of approximately \$26.0 million, and is adjusted in subsequent periods as accretion expense is recorded. The corresponding asset retirement costs are capitalized as part of the carrying value of the related long-lived assets and depreciated over the asset's useful life.

[Table of Contents](#)

The following is a reconciliation of the Company's asset retirement obligations for the years ended December 31, 2014, 2013 and 2012:

<u>(in thousands)</u>	
Balance at January 1, 2012	\$4,868
Capitalization	—
Net decrease due to changes in estimated future cash flows	(5)
Accretion expense	553
Balance at December 31, 2012	5,416
Capitalization	—
Net increase due to changes in estimated future cash flows	341
Accretion expense	628
Balance at December 31, 2013	6,385
Capitalization	277
Accretion expense	773
Balance at December 31, 2014	<u>\$7,435</u>

The Company revises the asset retirement obligation as information about material changes to the liability becomes known. During the year ended December 31, 2013, the Company revised the asset retirement obligation, which resulted in an additional asset capitalization, in the amount of \$0.3 million.

**8. Intangibles, net**

Intangibles, net consisted of the following:

<u>(in thousands)</u>	<u>December 31, 2014</u>			<u>Amortization Method</u>
	<u>Cost</u>	<u>Accumulated amortization</u>	<u>Net</u>	
Trademarks	\$ 13,540	\$ 5,116	\$ 8,424	Straight-line
Customer relationships	105,373	88,931	16,442	Accelerated
Other patents	42,780	40,455	2,325	Straight-line
	<u>\$161,693</u>	<u>\$ 134,502</u>	<u>\$27,191</u>	

<u>(in thousands)</u>	<u>December 31, 2013</u>			<u>Amortization Method</u>
	<u>Cost</u>	<u>Accumulated amortization</u>	<u>Net</u>	
Trademarks	\$ 13,540	\$ 3,298	\$10,242	Straight-line
Customer relationships	106,298	84,476	21,822	Accelerated
Other patents	42,780	39,846	2,934	Straight-line
	<u>\$162,618</u>	<u>\$ 127,620</u>	<u>\$34,998</u>	

The Company recorded amortization expense for its intangible assets of \$7.6 million, \$14.4 million and \$16.1 million for the years ended December 31, 2014, 2013 and 2012, respectively.

---

## Table of Contents

Expected future amortization expense related to the intangible assets is as follows (in thousands):

<b>Years ended December 31,</b>	
2015	\$ 5,997
2016	5,318
2017	3,506
2018	2,780
2019	1,906
2020 and thereafter	7,684
	<u>\$27,191</u>

Changes in the gross carrying amount of intangible assets for the year ended December 31, 2014 and 2013, were as follows (in thousands):

<b>(in thousands)</b>	
Balance at December 31, 2012	\$210,170
Asset impairment	(46,592)
Effect of currency translation	(960)
Balance at December 31, 2013	162,618
Effect of currency translation	(925)
Balance at December 31, 2014	<u>\$161,693</u>

## 9. Accrued Expenses and Other Liabilities

Accrued expenses are comprised of the following at December 31:

<b>(in thousands)</b>	<b>2014</b>	<b>2013</b>
Compensation and benefits	\$11,198	\$10,209
Accrued interest	4,994	4,989
Accrued professional fees	1,508	1,361
Research and development services	248	338
Freight, distribution and operations	3,069	3,432
Accrued loss on firm purchase commitment	—	1,315
Marketing expense	978	749
Accrued rebates, discounts and chargebacks	2,164	1,739
Other	420	1,360
	<u>\$24,579</u>	<u>\$25,492</u>

As of December 31, 2013, the Company had accrued a contract loss of \$1.3 million associated with the portion of the committed purchases of Ablavar product from the Company's supplier that the Company did not believe it would sell prior to expiry. As of December 31, 2014, the accrued contract loss has been reclassified to a reserve against the Ablavar inventory balance, because the Company satisfied the remaining purchase commitments in the first quarter of 2014.

## 10. Financing Arrangements

On March 21, 2011, LMI issued \$150.0 million of New Restricted Notes. The New Restricted Notes were issued at a price of 101.50% and were issued as additional debt securities under the Indenture pursuant to which LMI previously issued in May 2010 \$250.0 million in aggregate principal amount of 9.750% Senior Notes due 2017. The New Restricted Notes were issued with the same terms and conditions as the Senior Notes, except that

---

## [Table of Contents](#)

the New Restricted Notes were subject to a separate registration rights agreement. The New Restricted Notes and the Senior Notes, or together, the Notes, vote as one class under the Indenture. As a result of the issuance of the New Restricted Notes, LMI has \$400.0 million in aggregate principal amount of Notes outstanding. The Notes bear interest at a rate of 9.750% per year, payable on May 15 and November 15 of each year, beginning May 15, 2011 with respect to the New Restricted Notes. Interest on the Senior Notes accrued from November 15, 2010. The Notes mature on May 15, 2017. The net proceeds of the Senior Notes were used to repay \$77.9 million due under LMI's then outstanding credit agreement to repay a \$75.0 million demand note and to repurchase \$90.0 million of the outstanding Series A Preferred Stock of Holdings at the accreted value. The net proceeds of the New Restricted Notes were used to fully redeem the balance of the then outstanding Series A Preferred Stock of Holdings at the accreted value of \$44.0 million, to pay a \$106.0 million dividend to the holders of common stock and to fund dividend equivalent rights granted to holders of Holdings stock options. In conjunction with the issuance of the New Restricted Notes, LMI also made a cash payment of \$3.75 million to the then Holders of the Senior Notes in exchange for their consent to amend the Indenture to modify the restricted payments covenant to provide for additional restricted payment capacity in order to accommodate the dividend payment. The premium of \$2.25 million and the consent fee of \$3.75 million were capitalized and are being amortized over the term of the Notes as an adjustment to interest expense. All of the Notes have been registered with the Securities and Exchange Commission.

### *Redemption*

LMI can redeem the Notes at 100% of the principal amount on May 15, 2016 or thereafter. LMI may also redeem the Notes prior to May 15, 2016 depending on the timing of the redemption during the twelve-month period beginning May 15 of each of the years indicated below:

<u>Year</u>	<u>Percentage</u>
2014	104.875%
2015	102.438%
2016	100.000%

Upon a change of control (as defined in the Indenture), LMI will be required to make an offer to purchase each holder's Note at a price of 101% of the principal amount thereof, plus accrued and unpaid interest, if any, to the date of purchase.

If LMI or its subsidiaries engage in asset sales (as defined in the Indenture), they generally must either invest the net cash proceeds from those sales in that business within a specified period of time, prepay certain indebtedness or make an offer to purchase a principal amount of the Notes equal to the excess net cash proceeds (as defined in the Indenture), subject to certain exceptions.

The Notes are unsecured and are equal in right of payment to all of the existing and future senior debt, including borrowings under its secured credit facilities, subject to the security interest thereof. LMI's obligations under the Notes are fully and unconditionally guaranteed, jointly and severally, on an unsecured senior basis by Lantheus Intermediate and by one of LMI's subsidiaries, and the obligations of those guarantors under their guarantees are equal in right of payment to all of their existing and future senior debt.

### *Revolving Line of Credit*

LMI had a Facility with an original aggregate principal amount not to exceed \$42.5 million. On June 24, 2014, the Company executed an amendment to the Facility, which (i) increased the committed availability for total borrowings under the Facility from \$42.5 million to \$50.0 million, (ii) set the interest at LIBOR plus 2.00% or the Reference Rate (as defined in the agreement) plus 1.00%, (iii) set the unused line fee at 0.375%, and (iv) further modified certain definitions. In connection with the amendment, LMI incurred approximately \$0.2 million in fees and expenses during the year ended December 31, 2014, which will be amortized on a straight-line basis over the term of the Facility.

---

## [Table of Contents](#)

The Facility expires on the earlier of (i) July 3, 2018, or (ii) if the outstanding Notes are not refinanced in full, the date that is 91 days before the maturity thereof, at which time all outstanding borrowings are due and payable.

As of December 31, 2014 and 2013, the Company has an unfunded Standby Letter of Credit for up to \$8.8 million. The unfunded Standby Letter of Credit requires an annual fee, payable quarterly, which is set at LIBOR plus a spread of 2.00% and expires on February 5, 2016, which will automatically renew for a one year period at each anniversary date, unless the Company elects not to renew in writing within 60 days prior to that expiration.

The Facility is secured by a pledge of substantially all of the assets of each of the Company, LMI and Lantheus Real Estate, including each entity's accounts receivable, inventory and machinery and equipment, and is guaranteed by each of Lantheus Intermediate and Lantheus Real Estate. Borrowing capacity is determined by reference to a Borrowing Base, which is based on a percentage of certain eligible accounts receivable, inventory and machinery and equipment minus any reserves. As of December 31, 2014, the aggregate Borrowing Base was approximately \$50.0 million, which was reduced by (i) an outstanding \$8.8 million unfunded Standby Letter of Credit and (ii) an \$8.0 million outstanding loan balance including interest, resulting in a net Borrowing Base availability of approximately \$33.2 million.

### *Covenants*

The Facility is secured by a pledge of substantially all of the assets of each of the Company, LMI and Lantheus Real Estate, including each entity's accounts receivable, inventory and machinery and equipment, and is guaranteed by each of Lantheus Intermediate and Lantheus Real Estate. Borrowing capacity is determined by reference to a borrowing base, which is based on (i) a percentage of certain eligible accounts receivable, inventory and machinery and equipment minus (ii) any reserves.

The Facility contains affirmative and negative covenants, as well as restrictions on the ability of the Company and its subsidiaries to: (i) incur additional indebtedness or issue preferred stock; (ii) repay subordinated indebtedness prior to its stated maturity; (iii) pay dividends on, repurchase or make distributions in respect of capital stock or make other restricted payments; (iv) make certain investments; (v) sell certain assets; (vi) create liens; (vii) consolidate, merge, sell or otherwise dispose of all or substantially all of its assets; and (viii) enter into certain transactions with its affiliates. The Facility also contains customary default provisions as well as cash dominion provisions which allow the lender to sweep its accounts during the period certain specified events of default are continuing under the Facility or excess availability under the New Facility falls below (i) the greater of \$5.0 million or 15% of the then-current borrowing base for a period of more than five consecutive Business Days or (ii) \$3.5 million. During a cash dominion period, the Company is required to comply with a consolidated fixed charge coverage ratio of not less than 1:00:1:00. The fixed charge coverage ratio is calculated on a consolidated basis for Lantheus Intermediate and its subsidiaries for a trailing four fiscal quarter period basis, as (i) EBITDA (as defined in the agreement) minus capital expenditures minus certain restricted payments divided by (ii) interest plus taxes paid or payable in cash plus certain restricted payments made in cash plus scheduled principal payments paid or payable in cash.

### *Financing Costs*

During the year ended December 31, 2013, the Company wrote off \$0.6 million of the existing unamortized deferred financing costs related to a previous facility, which is included in interest expense in the accompanying consolidated statements of comprehensive loss.

During the years ended December 31, 2014 and 2013, LMI incurred approximately \$0.2 million and \$1.1 million in fees and expenses, in connection with the Facility and amendments under the previous facility, which are being amortized on a straight-line basis over the term of the Facility.

[Table of Contents](#)

**11. Stockholder's Equity**

As of December 31, 2014 and 2013, the authorized capital stock of the Company consisted of 10,000 shares of voting common stock with a par value of \$0.001 per share and 1 share outstanding.

**12. Stock-Based Compensation**

The Company's employees are eligible to receive awards under the Holdings 2013 Equity Incentive Plan (the "2013 Plan"). The 2013 Plan is administered by the Holdings Board of Directors and permits the granting of nonqualified stock options, stock appreciation rights (or SARs), restricted stock and restricted stock units to employees, officers, directors and consultants of Holdings or any subsidiary of Holdings (including Lantheus Intermediate and LMI). On August 5, 2013, the Holdings Board of Directors adopted a resolution providing that no further grants be made under the Holdings 2008 Equity Incentive Plan (the "2008 Plan"). At the same time, the maximum number of shares that may be issued pursuant to awards under the 2013 Plan was increased from 1,500,000 to 2,700,000. Option awards under the 2013 Plan are granted with an exercise price equal to the fair value of Holdings' stock at the date of grant, as determined by the Board of Directors of Holdings. Time based option awards vest based on time, either four or five years, and performance based option awards vest based on the performance criteria specified in the grant. All option awards have a ten-year contractual term. The Company recognizes compensation costs for its time based awards on a straight-line basis equal to the vesting period. The compensation cost for performance based awards is recognized on a graded vesting basis, based on the probability of achieving the performance targets over the requisite service period. The fair value of each option award is estimated on the date of grant using a Black-Scholes valuation model that uses the assumptions noted in the following table. Expected volatilities are based on the historic volatility of a selected peer group. Expected dividends represent the dividends expected to be issued at the date of grant. The expected term of options represents the period of time that options granted are expected to be outstanding. The risk-free interest rate assumption is the U.S. Treasury rate at the date of the grant which most closely resembles the expected life of the options. The Company uses the following Black-Scholes inputs to determine the fair value of new stock option grants.

	Years Ended December 31,		
	2014	2013	2012
Expected volatility	27 – 35%	30 – 37%	36 – 41%
Expected dividends	—	—	—
Expected life (in years)	3.1 – 7.0	3.6 – 6.3	5.5 – 6.5
Risk-free interest rate	1.1 – 2.0%	0.5 – 1.7%	0.7 – 1.4%

A summary of option activity for 2014 is presented below:

	Time Based	Performance Based	Total	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2014	2,761,037	1,097,425	3,858,462	\$ 4.89	6.9	\$ 6,777,000
Options granted	527,153	3,696	530,849	4.64		
Options cancelled	(26,150)	(8,174)	(34,324)	5.68		
Options exercised	(4,500)	(1,737)	(6,237)	2.00		
Options forfeited and expired	(35,850)	(10,480)	(46,330)	7.56		
Outstanding at December 31, 2014	3,221,690	1,080,730	4,302,420	\$ 4.83	6.4	\$ 3,979,000
Vested and expected to vest at December 31, 2014	3,106,583	713,091	3,819,674	\$ 4.61	6.1	\$ 3,979,000
Exercisable at December 31, 2014	1,867,059	562,432	2,429,491	\$ 3.66	4.6	\$ 3,979,000

## Table of Contents

The weighted average grant-date fair value of options granted during the years ended December 31, 2014, 2013 and 2012 was \$1.70, \$2.45 and \$3.29, respectively.

During the year ended December 31, 2013, 631,518 stock options were exercised on a cashless basis for which 459,171 shares of Holdings' common stock were issued. No stock options were exercised on a cashless basis for the year ended December 31, 2014, but 6,237 options were exercised on a cash basis. The intrinsic value for the options exercised during the years ended December 31, 2014 and 2013, was approximately \$25,000 and \$3.4 million, respectively.

Stock-based compensation expense for both time based and performance based awards was recognized in the consolidated statements of comprehensive loss as follows:

(in thousands)	Years Ended December 31,		
	2014	2013	2012
Cost of goods sold	\$ 135	\$ 41	\$ 79
Sales and marketing	154	93	111
General and administrative	621	429	982
Research and development	121	15	68
Total stock-based compensation expense	<u>\$1,031</u>	<u>\$578</u>	<u>\$1,240</u>

Stock-based compensation expense recognized in the consolidated statement of comprehensive loss for the years ended December 31, 2014, 2013, and 2012 are based on awards ultimately expected to vest as well as any changes in the probability of achieving certain performance features as required. Upon termination of employment, Holdings has the right to call shares held by employees that were purchased or acquired through option exercise. As a result of this right, upon termination of service, vested stock-based awards are reclassified to liability-based awards when it is probable the employee will exercise the option and Holdings will exercise its call right. The Company did not reclassify any equity awards to liability-based awards as of December 31, 2014 and 2013, since the Company concluded it was not probable that Holdings would exercise its call right. There were no liability awards paid out during the years ended December 31, 2014, 2013 and 2012.

The Company did not recognize an income tax benefit for the years ended December 31, 2014, 2013 and 2012. As of December 31, 2014, there was approximately \$2.6 million of total unrecognized compensation costs related to non-vested stock options granted under the 2013 and 2008 Plans. These costs are expected to be recognized over a weighted-average remaining period of 1.4 years. In addition, performance based awards contain certain contingent features, such as change in control provisions, which allow for the vesting of previously forfeited and unvested awards. As of December 31, 2014, there was approximately \$1.0 million of unrecognized compensation expense relating to these features, which could be recognized through 2018 or longer.

### 13. Other Income (Expense), net

Other income, net consisted of the following:

(in thousands)	Years Ended December 31,		
	2014	2013	2012
Foreign currency losses	\$(279)	\$(349)	\$(579)
Tax indemnification income	754	1,141	346
Other income	3	369	189
Total other income (expense), net	<u>\$ 478</u>	<u>\$1,161</u>	<u>\$ (44)</u>

---

[Table of Contents](#)

**14. Commitments**

The Company leases certain buildings, hardware and office space under operating leases. In addition, the Company has entered into purchasing arrangements in which minimum quantities of goods or services have been committed to be purchased on an annual basis.

Minimum lease and purchase commitments under noncancelable arrangements are as follows (in thousands):

<u>Years ended December 31,</u>	<u>Operating Leases</u>
2015	\$ 854
2016	568
2017	455
2018	400
2019	397
2020 and thereafter	1,190
	<u>\$ 3,864</u>

Lease expense was \$1.0 million, \$0.9 million and \$1.0 million for the years ended December 31, 2014, 2013 and 2012, respectively.

The Company has entered into agreements which contain certain percentage volume purchase requirements. The Company has excluded these future purchase commitments from the table above since there are no minimum purchase commitments or payments under these agreements.

**15. 401(k) Plan**

The Company maintains a qualified 401(k) plan (the "401(k) Plan") for its U.S. employees. The 401(k) Plan covers U.S. employees who meet certain eligibility requirements. Under the terms of the 401(k) Plan, the employees may elect to make tax-deferred contributions through payroll deductions within statutory and plan limits, and the Company may elect to make non-elective discretionary contributions. Effective April 2012, the employer match was suspended and was subsequently reinstated in January 2013. The Company did not contribute any additional non-elective discretionary match during the years ended December 31, 2014, 2013 and 2012. The Company may also make optional contributions to the 401(k) Plan for any plan year at its discretion. Expense recognized by the Company for matching contributions related to the 401(k) Plan was \$1.5 million, \$1.2 million and \$0.4 million for the years ended December 31, 2014, 2013 and 2012, respectively.

**16. Legal Proceedings**

From time to time, the Company is a party to various legal proceedings arising in the ordinary course of business. In addition, the Company has in the past been, and may in the future be, subject to investigations by governmental and regulatory authorities, which expose it to greater risks associated with litigation, regulatory or other proceedings, as a result of which the Company could be required to pay significant fines or penalties. The outcome of litigation, regulatory or other proceedings cannot be predicted with certainty, and some lawsuits, claims, actions or proceedings may be disposed of unfavorably to the Company. In addition, intellectual property disputes often have a risk of injunctive relief which, if imposed against the Company, could materially and adversely affect its financial condition or results of operations. As of December 31, 2014, the Company had no material ongoing litigation in which the Company was a defendant or any material ongoing regulatory or other proceedings and had no knowledge of any investigations by government or regulatory authorities in which the Company is a target that could have a material adverse effect on its current business.

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



---

## [Table of Contents](#)

from May 2009 until August 2010. The defendant answered the complaint on January 21, 2011, denying substantially all of the allegations, presenting certain defenses and requesting dismissal of the case with costs and disbursements. Discovery, including international discovery and related motion practice, has been on-going for more than three years. The defendant filed a motion for summary judgment on July 14, 2014. The Company filed a memorandum of law in opposition to defendant's motion for summary judgment on August 25, 2014. The defendant filed a reply memorandum of law in further support of its motion for summary judgment on September 15, 2014. Expert witness discovery was completed on October 31, 2014. The Company cannot be certain what amount, if any, or when, if ever, it will be able to recover for business interruption losses related to this matter.

### **17. Related Party Transactions**

In the third quarter of 2012, LMI reclassified the then outstanding receivable from Holdings of \$1.2 million to stockholder's deficit since Holdings did not and continues to not have assets sufficient to repay amounts due to LMI. At December 31, 2014 and 2013, LMI had outstanding receivables from Holdings in the amount of \$3.8 million and \$1.3 million, respectively, which was included in due from parent within stockholder's deficit.

Avista, the majority shareholder of Holdings, provides certain advisory services to the Company pursuant to an advisory services and monitoring agreement. The Company is required to pay an annual fee of \$1.0 million and other reasonable and customary advisory fees, as applicable, paid on a quarterly basis. The initial term of the agreement is seven years. Upon termination, all remaining amounts owed under the agreement shall become due immediately. The Company incurred costs associated with this agreement totaling \$1.0 million for each of the years ended December 31, 2014, 2013 and 2012. At December 31, 2014 and 2013, \$10,000 and \$30,000, respectively, was included in accrued expenses.

The Company had a Master Contract Research Organization Services Agreement with INC Research, LLC, or INC, to provide clinical development services in connection with the flurpiridaz F 18 Phase III program. Avista and certain of its affiliates are principal owners of both INC and the Company. The agreement was cancelled during May 2014. The agreement had a term of five years and the Company did not incur any costs associated with this agreement in the year ended December 31, 2014. The Company incurred costs associated with this agreement of approximately \$0.5 million and \$0.9 million during the years ended December 31, 2013 and 2012, respectively. At December 31, 2014 and 2013, there was no balance outstanding.

The Company purchases inventory supplies from VWR Scientific, or VWR. Avista and certain of its affiliates are principal owners of both VWR and the Company. The Company made purchases of approximately \$0.5 million, \$0.3 million and \$0.3 million during each of the years ended December 31, 2014, 2013 and 2012, respectively. At December 31, 2014 and 2013, \$21,000 and \$1,000, respectively, was included in accounts payable and accrued expenses.

The Company retains Marsh for insurance brokering and risk management. In November 2013, Donald Bailey, brother of the Company's President and Chief Executive Officer, Jeffrey Bailey, was appointed head of sales for Marsh's U.S. and Canada division. In 2014, the Company paid Marsh approximately \$0.3 million. At both December 31, 2014 and 2013, there was a prepaid of \$43,000 included in other current assets.

At December 31, 2013, the Company had \$0.1 million due from an officer of the Company included in accounts receivable, net. This amount represented federal and state tax withholdings paid by the Company on behalf of the officer. During the second quarter of 2014, this amount was fully repaid by the officer.

### **18. Segment Information**

The Company reports two operating segments, U.S. and International, based on geographic customer base. The results of these operating segments are regularly reviewed by our chief operating decision maker, the President and Chief Executive Officer. The Company's segments derive revenues through the manufacturing,

[Table of Contents](#)

marketing, selling and distribution of medical imaging products, focused primarily on cardiovascular diagnostic imaging. The U.S. segment comprises 78.4%, 75.3% and 72.9% of consolidated revenues in 2014, 2013 and 2012, respectively, and 90.3% and 89.8% of consolidated assets at December 31, 2014 and 2013, respectively. All goodwill has been allocated to the U.S. operating segment.

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

<b>(in thousands)</b>	<b>2014</b>	<b>2013</b>	<b>2012</b>
<b>Revenues</b>			
U.S.	\$258,148	\$234,567	\$229,926
International	65,080	70,033	78,094
Total revenue, including inter-segment	323,228	304,600	308,020
Inter-segment revenue	(21,628)	(20,928)	(19,915)
	<u>\$301,600</u>	<u>\$283,672</u>	<u>\$288,105</u>
<b>Revenues from external customers</b>			
U.S.	\$236,520	\$213,639	\$210,011
International	65,080	70,033	78,094
	<u>\$301,600</u>	<u>\$283,672</u>	<u>\$288,105</u>
<b>Revenues by product</b>			
DEFINITY	\$ 95,760	\$ 78,094	\$ 51,431
TechneLite	93,588	92,195	114,249
Xenon	36,549	32,125	30,075
Cardiolite	18,823	26,137	34,995
Other	56,880	55,121	57,355
	<u>\$301,600</u>	<u>\$283,672</u>	<u>\$288,105</u>
<b>Geographical revenue</b>			
U.S.	\$236,520	\$213,639	\$210,011
Canada	31,363	35,502	37,017
All other	33,717	34,531	41,077
	<u>\$301,600</u>	<u>\$283,672</u>	<u>\$288,105</u>
<b>Operating income/(loss)</b>			
U.S.	\$ 40,802	\$ (18,904)	\$ (11,104)
International	353	703	9,820
Total operating income (loss), including inter-segment	41,155	(18,201)	(1,284)
Inter-segment operating income (loss)	654	(813)	534
Operating income (loss)	41,809	(19,014)	(750)
Interest expense	(42,288)	(42,915)	(42,014)
Interest income	27	104	252
Other income (expense), net	478	1,161	(44)
Income (loss) before income taxes	<u>\$ 26</u>	<u>\$ (60,664)</u>	<u>\$ (42,556)</u>
<b>Depreciation and amortization</b>			
U.S.	\$ 16,055	\$ 22,146	\$ 23,918
International	2,196	3,009	3,484
	<u>\$ 18,251</u>	<u>\$ 25,155</u>	<u>\$ 27,402</u>
<b>Capital expenditures</b>			
U.S.	\$ 7,811	\$ 4,903	\$ 7,353
International	326	107	567
	<u>\$ 8,137</u>	<u>\$ 5,010</u>	<u>\$ 7,920</u>

[Table of Contents](#)

	<u>2014</u>	<u>2013</u>
<b>Assets</b>		
U.S.	\$223,492	\$232,973
International	<u>24,024</u>	<u>26,412</u>
	<u>\$247,516</u>	<u>\$259,385</u>
	<u>2014</u>	<u>2013</u>
<b>Long-lived assets</b>		
U.S.	\$91,346	\$91,683
International	<u>4,668</u>	<u>5,970</u>
	<u>\$96,014</u>	<u>\$97,653</u>

**19. Valuation and Qualifying Accounts**

<u>(in thousands)</u>	<u>Balance at Beginning of Fiscal Year</u>	<u>Charge to Costs and Expenses (Recovery of write-offs)</u>	<u>Deductions From Reserves</u>	<u>Balance at End of Fiscal Year</u>
Year ended December 31, 2014:				
Allowance for doubtful accounts	\$ 290	\$ 303	\$ (8)	\$ 585
Year ended December 31, 2013:				
Allowance for doubtful accounts	\$ 301	\$ 63	\$ (74)	\$ 290
Year ended December 31, 2012:				
Allowance for doubtful accounts	\$ 462	\$ (117)	\$ (44)	\$ 301

Amounts charged to deductions from reserves represent the write-off of uncollectible balances.

**20. Guarantor Financial Information**

The Notes, issued by LMI, are guaranteed by Lantheus Intermediate (the "Parent Guarantor") and Lantheus Real Estate, one of Lantheus Intermediate's wholly-owned consolidated subsidiaries (the "Guarantor Subsidiary"). The guarantees are full and unconditional and joint and several. The following supplemental financial information sets forth, on a condensed consolidating basis, balance sheet information as of December 31, 2014 and 2013, and comprehensive (loss) income and cash flow information for the years ended December 31, 2014, 2013 and 2012 for Lantheus Intermediate, LMI, the Guarantor Subsidiary and Lantheus Intermediate's other wholly-owned subsidiaries (the "Non-Guarantor Subsidiaries"). The supplemental financial information have been prepared on the same basis as the consolidated financial statements of Lantheus Intermediate. The equity method of accounting is followed within this financial information.

**Consolidating Balance Sheet Information**

**December 31, 2014**

(in thousands)	Lantheus Intermediate	LMI	Guarantor Subsidiary	Non- Guarantor Subsidiaries	Eliminations	Total
<b>Assets:</b>						
Current assets						
Cash and cash equivalents	\$ —	\$ 12,586	\$ —	\$ 5,231	\$ —	\$ 17,817
Accounts receivable, net	—	32,280	—	9,260	—	41,540
Intercompany accounts receivable	—	7,444	—	—	(7,444)	—
Inventory	—	12,638	—	2,944	—	15,582
Income tax receivable	—	178	—	69	—	247
Deferred tax assets	—	239	—	17	—	256
Other current assets	—	3,544	—	195	—	3,739
Total current assets	—	68,909	—	17,716	(7,444)	79,181
Property, plant and equipment, net	—	75,811	15,535	4,668	—	96,014
Capitalized software development costs, net	—	2,421	—	—	—	2,421
Intangibles, net	—	24,891	—	2,300	—	27,191
Goodwill	—	15,714	—	—	—	15,714
Deferred financing costs	—	7,349	—	—	—	7,349
Deferred tax assets	—	277	—	51	—	328
Investment in subsidiaries	(240,969)	32,511	—	—	208,458	—
Intercompany note receivable	—	—	—	5,626	(5,626)	—
Other long-term assets	—	19,132	—	186	—	19,318
Total assets	<u>\$ (240,969)</u>	<u>\$ 247,015</u>	<u>\$ 15,535</u>	<u>\$ 30,547</u>	<u>\$ 195,388</u>	<u>\$ 247,516</u>
<b>Liabilities and (deficit) equity:</b>						
Current liabilities						
Line of credit	\$ —	\$ 8,000	\$ —	\$ —	\$ —	\$ 8,000
Accounts payable	—	14,027	—	1,638	—	15,665
Intercompany accounts payable	—	—	—	7,444	(7,444)	—
Accrued expenses and other liabilities	—	21,022	—	3,557	—	24,579
Deferred tax liability	—	—	—	152	—	152
Deferred revenue	—	132	—	—	—	132
Total current liabilities	—	43,181	—	12,791	(7,444)	48,528
Asset retirement obligations	—	7,232	—	203	—	7,435
Long-term debt, net	—	399,280	—	—	—	399,280
Intercompany note payable	—	5,626	—	—	(5,626)	—
Deferred tax liability	—	239	—	8	—	247
Other long-term liabilities	—	32,426	—	569	—	32,995
Total liabilities	—	487,984	—	13,571	(13,070)	488,485
(Deficit) equity	(240,969)	(240,969)	15,535	16,976	208,458	(240,969)
Total liabilities and (deficit) equity	<u>\$ (240,969)</u>	<u>\$ 247,015</u>	<u>\$ 15,535</u>	<u>\$ 30,547</u>	<u>\$ 195,388</u>	<u>\$ 247,516</u>

**Consolidating Balance Sheet Information**

**December 31, 2013**

(in thousands)	Lantheus Intermediate	LMI	Guarantor Subsidiary	Non- Guarantor Subsidiaries	Eliminations	Total
<b>Assets:</b>						
Current assets						
Cash and cash equivalents	\$ —	\$ 11,995	\$ —	\$ 4,674	\$ —	\$ 16,669
Accounts receivable, net	—	28,099	—	10,811	—	38,910
Intercompany accounts receivable	—	2,671	—	—	(2,671)	—
Inventory	—	15,414	—	2,896	—	18,310
Income tax receivable	—	297	—	28	—	325
Deferred tax assets	—	—	—	18	—	18
Other current assets	—	2,906	—	181	—	3,087
Total current assets	—	61,382	—	18,608	(2,671)	77,319
Property, plant and equipment, net	—	76,068	15,615	5,970	—	97,653
Capitalized software development costs, net	—	1,468	—	2	—	1,470
Intangibles, net	—	31,838	—	3,160	—	34,998
Goodwill	—	15,714	—	—	—	15,714
Deferred financing costs	—	9,639	—	—	—	9,639
Deferred tax assets	—	—	—	15	—	15
Investment in subsidiaries	(237,088)	40,289	—	—	196,799	—
Intercompany note receivable	—	—	—	5,396	(5,396)	—
Other long-term assets	—	22,370	—	207	—	22,577
Total assets	<u>\$ (237,088)</u>	<u>\$ 258,768</u>	<u>\$ 15,615</u>	<u>\$ 33,358</u>	<u>\$ 188,732</u>	<u>\$ 259,385</u>
<b>Liabilities and (deficit) equity:</b>						
Current liabilities						
Line of Credit	\$ —	\$ 8,000	\$ —	\$ —	\$ —	\$ 8,000
Accounts payable	—	16,672	—	1,431	—	18,103
Intercompany accounts payable	—	—	—	2,671	(2,671)	—
Accrued expenses and other liabilities	—	21,409	—	4,083	—	25,492
Deferred tax liability	—	—	—	57	—	57
Deferred revenue	—	3,979	—	—	—	3,979
Total current liabilities	—	50,060	—	8,242	(2,671)	55,631
Asset retirement obligations	—	6,212	—	173	—	6,385
Long-term debt, net	—	399,037	—	—	—	399,037
Intercompany note payable	—	5,396	—	—	(5,396)	—
Deferred tax liability	—	—	—	12	—	12
Other long-term liabilities	—	35,151	—	257	—	35,408
Total liabilities	—	495,856	—	8,684	(8,067)	496,473
(Deficit) equity	(237,088)	(237,088)	15,615	24,674	196,799	(237,088)
Total liabilities and (deficit) equity	<u>\$ (237,088)</u>	<u>\$ 258,768</u>	<u>\$ 15,615</u>	<u>\$ 33,358</u>	<u>\$ 188,732</u>	<u>\$ 259,385</u>

**Consolidating Comprehensive Loss Information**  
**Year Ended December 31, 2014**

(in thousands)	Lantheus Intermediate	LMI	Guarantor Subsidiary	Non- Guarantor Subsidiaries	Eliminations	Total
Revenues	\$ —	\$268,204	\$ —	\$ 55,024	\$ (21,628)	\$301,600
Cost of goods sold	—	144,286	—	53,423	(21,628)	176,081
Gross profit	—	123,918	—	1,601	—	125,519
Operating expenses						
Sales and marketing expenses	—	31,505	—	3,611	—	35,116
General and administrative expenses	—	32,529	80	2,312	—	34,921
Research and development expenses	—	13,252	—	421	—	13,673
Operating income (loss)	—	46,632	(80)	(4,743)	—	41,809
Interest expense	—	(42,518)	—	—	230	(42,288)
Interest income	—	1	—	256	(230)	27
Other income (expense)	—	558	—	(80)	—	478
Equity in earnings (losses) of affiliates	(1,169)	(5,042)	—	—	6,211	—
(Loss) income before income taxes	(1,169)	(369)	(80)	(4,567)	6,211	26
Provision (benefit) for income taxes	—	800	—	395	—	1,195
Net (loss) income	(1,169)	(1,169)	(80)	(4,962)	6,211	(1,169)
Foreign currency translation	—	—	—	(1,236)	—	(1,236)
Equity in other comprehensive income (loss) of subsidiaries	(1,236)	(1,236)	—	—	2,472	—
Total other comprehensive (loss) income	\$ (2,405)	\$ (2,405)	\$ (80)	\$ (6,198)	\$ 8,683	\$ (2,405)

**Consolidating Comprehensive Loss Information**  
**Year Ended December 31, 2013**

(in thousands)	Lantheus Intermediate	LMI	Guarantor Subsidiary	Non- Guarantor Subsidiaries	Eliminations	Total
Revenues	\$ —	\$243,079	\$ —	\$ 61,521	\$ (20,928)	\$283,672
Cost of goods sold	—	169,334	—	57,905	(20,928)	206,311
Gross profit	—	73,745	—	3,616	—	77,361
Operating expenses						
Sales and marketing expenses	—	31,668	—	3,559	—	35,227
General and administrative expenses	—	30,785	80	2,294	—	33,159
Research and development expenses	—	30,138	—	321	—	30,459
Proceeds from manufacturer	—	(8,876)	—	—	—	(8,876)
Impairment on land	—	—	6,406	—	—	6,406
Operating loss	—	(9,970)	(6,486)	(2,558)	—	(19,014)
Interest expense	—	(43,011)	—	—	96	(42,915)
Interest income	—	1	—	199	(96)	104
Other income (expense)	—	1,373	—	(212)	—	1,161
Equity in earnings (losses) of affiliates	(61,678)	(9,142)	—	—	70,820	—
(Loss) income before income taxes	(61,678)	(60,749)	(6,486)	(2,571)	70,820	(60,664)
Provision (benefit) for income taxes	—	929	—	85	—	1,014
Net (loss) income	(61,678)	(61,678)	(6,486)	(2,656)	70,820	(61,678)
Foreign currency translation	—	—	—	(1,729)	—	(1,729)
Equity in other comprehensive income (loss) of subsidiaries	(1,729)	(1,729)	—	—	3,458	—
Total other comprehensive (loss) income	<u>\$ (63,407)</u>	<u>\$ (63,407)</u>	<u>\$ (6,486)</u>	<u>\$ (4,385)</u>	<u>\$ 74,278</u>	<u>\$ (63,407)</u>

**Consolidating Comprehensive Loss Information**  
**Year Ended December 31, 2012**

(in thousands)	Lantheus Intermediate	LMI	Guarantor Subsidiary	Non- Guarantor Subsidiaries	Eliminations	Total
Revenues	\$ —	\$241,406	\$ —	\$ 66,614	\$ (19,915)	\$288,105
Cost of goods sold	—	171,257	—	59,707	(19,915)	211,049
Loss on firm purchase commitment	—	1,859	—	—	—	1,859
Total cost of goods sold	—	173,116	—	59,707	(19,915)	212,908
Gross profit	—	68,290	—	6,907	—	75,197
Operating expenses						
Sales and marketing expenses	—	34,220	—	3,217	—	37,437
General and administrative expenses	—	30,112	80	2,328	—	32,520
Research and development expenses	—	40,457	—	147	—	40,604
Proceeds from manufacturer	—	(34,614)	—	—	—	(34,614)
Operating income (loss)	—	(1,885)	(80)	1,215	—	(750)
Interest expense	—	(42,014)	—	—	—	(42,014)
Interest income	—	1	—	251	—	252
Other income (expense)	—	110	—	(154)	—	(44)
Equity in earnings (losses) of affiliates	(42,001)	1,242	—	—	40,759	—
(Loss) income before income taxes	(42,001)	(42,546)	(80)	1,312	40,759	(42,556)
Provision (benefit) for income taxes	—	(545)	—	(10)	—	(555)
Net (loss) income	(42,001)	(42,001)	(80)	1,322	40,759	(42,001)
Foreign currency translation	—	200	—	764	—	964
Equity in other comprehensive income (loss) of subsidiaries	964	764	—	—	(1,728)	—
Total other comprehensive (loss) income	\$ (41,037)	\$ (41,037)	\$ (80)	\$ 2,086	\$ 39,031	\$ (41,037)



**Condensed Consolidating Cash Flow Information**  
**Year Ended December 31, 2014**

	<u>Lantheus Intermediate</u>	<u>LMI</u>	<u>Guarantor Subsidiary</u>	<u>Non-Guarantor Subsidiaries</u>	<u>Eliminations</u>	<u>Total</u>
<b>Cash provided by operating activities</b>	\$ —	\$10,240	\$ —	\$ 2,833	\$ (1,500)	\$11,573
<b>Cash flows from investing activities</b>						
Capital expenditures	—	(7,811)	—	(326)	—	(8,137)
Payments from subsidiary	2,047	—	—	—	(2,047)	—
Proceeds from sale of property, plant and equipment	—	227	—	—	—	227
Redemption of certificate of deposit	—	228	—	—	—	228
Cash used in investing activities	<u>2,047</u>	<u>(7,356)</u>	<u>—</u>	<u>(326)</u>	<u>(2,047)</u>	<u>(7,682)</u>
<b>Cash flows from financing activities</b>						
Payments on note payable	—	(71)	—	—	—	(71)
Payments of deferred financing costs	—	(175)	—	—	—	(175)
Due from parent	(2,047)	(2,047)	—	—	2,047	(2,047)
Proceeds from line of credit	—	5,500	—	—	—	5,500
Payments on line of credit	—	(5,500)	—	—	—	(5,500)
Payment of dividend	—	—	—	(1,500)	1,500	—
Cash provided by (used in) financing activities	<u>(2,047)</u>	<u>(2,293)</u>	<u>—</u>	<u>(1,500)</u>	<u>3,547</u>	<u>(2,293)</u>
Effect of foreign exchange rate on cash	—	—	—	(450)	—	(450)
Increase in cash and cash equivalents	—	591	—	557	—	1,148
Cash and cash equivalents, beginning of year	—	11,995	—	4,674	—	16,669
Cash and cash equivalents, end of year	<u>\$ —</u>	<u>\$12,586</u>	<u>\$ —</u>	<u>\$ 5,231</u>	<u>\$ —</u>	<u>\$17,817</u>

**Condensed Consolidating Cash Flow Information**  
**Year Ended December 31, 2013**

	Lantheus Intermediate	LMI	Guarantor Subsidiary	Non-Guarantor Subsidiaries	Eliminations	Total
<b>Cash provided by operating activities</b>	\$ —	\$(17,273)	\$ —	\$ 3,333	\$ (1,738)	\$(15,678)
<b>Cash flows from investing activities</b>						
Capital expenditures	—	(4,903)	—	(107)	—	(5,010)
Proceeds from dividend	—	5,268	—	—	(5,268)	—
Proceeds from sale of property, plant and equipment	—	433	1,094	—	—	1,527
Cash provided by (used in) investing activities	—	798	1,094	(107)	(5,268)	(3,483)
<b>Cash flows from financing activities</b>						
Proceeds on line of credit	—	8,000	—	—	—	8,000
Payments on note payable	—	(1,310)	—	—	—	(1,310)
Payments of deferred financing costs	—	(1,249)	—	—	—	(1,249)
Due from parent	—	94	—	—	—	94
Intercompany note	—	5,300	—	(5,300)	—	—
Payment of dividend	—	—	(1,094)	(5,912)	7,006	—
Cash provided by (used in) financing activities	—	10,835	(1,094)	(11,212)	7,006	5,535
Effect of foreign exchange rate on cash	—	—	—	(1,300)	—	(1,300)
Decrease in cash and cash equivalents	—	(5,640)	—	(9,286)	—	(14,926)
Cash and cash equivalents, beginning of year	—	17,635	—	13,960	—	31,595
Cash and cash equivalents, end of year	<u>\$ —</u>	<u>\$ 11,995</u>	<u>\$ —</u>	<u>\$ 4,674</u>	<u>\$ —</u>	<u>\$ 16,669</u>

**Condensed Consolidating Cash Flow Information**  
**Year Ended December 31, 2012**

	<u>Lantheus Intermediate</u>	<u>LMI</u>	<u>Guarantor Subsidiary</u>	<u>Non-Guarantor Subsidiaries</u>	<u>Eliminations</u>	<u>Total</u>
<b>Cash provided by operating activities</b>	\$ —	\$ 3,829	\$ —	\$ 4,568	\$ (7,874)	\$ 523
<b>Cash flows from investing activities</b>						
Capital expenditures	—	(7,353)	—	(567)	—	(7,920)
Purchase of certificate of deposit	—	(225)	—	—	—	(225)
Proceeds from dividend	—	2,949	—	—	(2,949)	—
Cash provided by (used in) investing activities	—	(4,629)	—	(567)	(2,949)	(8,145)
<b>Cash flows from financing activities</b>						
Payments on note payable	—	(1,530)	—	—	—	(1,530)
Payments of deferred financing costs	—	(442)	—	—	—	(442)
Due from parent	—	(67)	—	—	—	(67)
Payment of dividend	—	—	—	(10,823)	10,823	—
Cash used in financing activities	—	(2,039)	—	(10,823)	10,823	(2,039)
Effect of foreign exchange rate on cash	—	—	—	649	—	649
Decrease in cash and cash equivalents	—	(2,839)	—	(6,173)	—	(9,012)
Cash and cash equivalents, beginning of year	—	20,474	—	20,133	—	40,607
Cash and cash equivalents, end of year	<u>\$ —</u>	<u>\$17,635</u>	<u>\$ —</u>	<u>\$ 13,960</u>	<u>\$ —</u>	<u>\$31,595</u>

---

[Table of Contents](#)

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

Not applicable.

**Item 9A. Controls and Procedures**

**Disclosure Controls and Procedures**

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) or 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report.

**Management’s Annual Report on Internal Control Over Financial Reporting**

Our management, with the participation of our principal executive officer and principal financial officer, is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control system is designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2014. In making its assessment of internal control over financial reporting, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control—Integrated Framework (2013)*. Based on this assessment, management concluded that, as of December 31, 2014, our internal control over financial reporting was effective.

We do not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting in this annual report. Our report was not subject to attestation by the Company’s independent registered public accounting firm pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act signed into law on July 21, 2010 (“Dodd-Frank”). Dodd-Frank provides a permanent exemption from the requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002 for those entities that are neither large accelerated filers nor accelerated filers. As a result, we were not required to have our independent registered public accounting firm attest to, and report on, internal controls over financial reporting.

**Changes in Internal Control Over Financial Reporting**

There have been no changes during the quarter ended December 31, 2014 in our internal control over financial reporting (as defined in Rule 13a-15(f) promulgated under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

None.

### PART III

All information contained in Part III is included in this annual report and not incorporated by reference because we do not have any public equity that requires us to file a definitive proxy statement.

#### Item 10. Directors, Executive Officers and Corporate Governance

The following table sets forth the names, ages and positions of the executive officers and directors of Holdings and other key employees of Lantheus, as of March 4, 2015. Holdings is our ultimate parent company, and the Board of Directors of Holdings is the primary board that takes action with respect to our business and strategic planning.

<u>Name</u>	<u>Age</u>	<u>Position</u>
<i>Executive Officers and Key Employees</i>		
Jeffrey Bailey	52	President, Chief Executive Officer and Director
John Bakewell	53	Chief Financial Officer
William Dawes	43	Vice President, Manufacturing and Operations
Michael Duffy	54	Vice President, General Counsel and Secretary
Mary Anne Heino	55	Chief Commercial Officer
Michael Heslop	55	Vice President, Business Development and Strategic Planning
Cesare Orlandi	64	Chief Medical Officer
Simon Robinson	55	Vice President, Research and Pharmaceutical Development
Cyrille Villeneuve	63	Vice President, International
Carol Walker	52	Vice President, Quality
<i>Non-Employee Directors</i>		
Brian Markison	55	Director and Non-Executive Chairman of the Board
David Burgstahler	46	Director
Samuel Leno	69	Director
Patrick O'Neill	65	Director
Sriram Venkataraman	42	Director

Set forth below is a description of the business experience of the foregoing persons.

*Jeffrey Bailey* is our President and Chief Executive Officer since January 2013 and is a Director. Mr. Bailey has more than 26 years of diverse pharmaceutical leadership experience across multiple functions, including sales, marketing, manufacturing, supply chain and operations. Prior to joining Lantheus, Mr. Bailey served from July 2011 to July 2012 as Chief Operating Officer and a member of the executive committee of Fougera Pharmaceuticals, Inc. prior to its sale to Sandoz. Before joining Fougera, from April 2010 to June 2011, Mr. Bailey served as Chief Commercial Officer of King-Pfizer Pharmaceuticals. From January 2008 to April 2010, he worked with Novartis Pharmaceuticals as President and General Manager of the Northwest Operating Unit, and from June 1984 to June 2006, he served in several roles with increasing responsibilities across manufacturing operations, commercial operations and general management at the Johnson & Johnson Family of Companies. Mr. Bailey holds a Bachelor of Arts in Business from Rutgers University. Mr. Bailey was chosen to serve as a Director because of his extensive experience in the healthcare industry in senior commercial and operating positions. As our President and Chief Executive Officer and the only management representative on our Board of Directors, Mr. Bailey has significant knowledge of the pharmaceutical industry and provides valuable insight into a variety of business issues and challenges we face.

*John Bakewell* joined Lantheus in June 2014 as our Chief Financial Officer. Mr. Bakewell previously served as Chief Financial Officer of Interline Brands, Inc., or Interline, from June 2013 to May 2014. Prior to joining Interline, Mr. Bakewell served as the Executive Vice President and Chief Financial Officer of RegionalCare Hospital Partners from January 2010 to December 2011. In addition, Mr. Bakewell held the same position with

---

## [Table of Contents](#)

Wright Medical Group, a global orthopedic medical device manufacturer from 2000 to 2009. Mr. Bakewell also served as Chief Financial Officer of Altra Energy Technologies from 1998 to 2000, Cyberonics, Inc. from 1993 to 1998, and Zeos International from 1990 to 1993. Mr. Bakewell also serves on the Board of Keystone Dental, Inc. Mr. Bakewell holds a Bachelor of Arts in Accounting from the University of Northern Iowa and is a certified public accountant (Minnesota and Iowa licensure, current status inactive).

*William Dawes* is our Vice President, Manufacturing and Operations since November 2010. Mr. Dawes held the position of Vice President, Manufacturing & Supply Chain from January 2008 to November 2010. From 2005 to 2008, Mr. Dawes served as General Manager, Medical Imaging Technical Operations, Interim General Manager, Medical Imaging Technical Operations, and Director, Engineering and Maintenance for BMSMI. Mr. Dawes began his career with DuPont Merck Pharmaceuticals. He holds a Bachelor's degree in Engineering from Hofstra University.

*Michael Duffy* is our Vice President, General Counsel and Secretary, a position he has held since January 2008. From 2002 to 2008, he served as Senior Vice President, General Counsel and Secretary of Point Therapeutics, Inc., a Boston-based biopharmaceutical company. Between 1999 and 2001, Mr. Duffy served as Senior Vice President, General Counsel and Secretary of Digital Broadband Communications, Inc., a competitive local exchange carrier which filed for protection under Chapter 11 of the United States Bankruptcy Code in December 2000. After the filing, Mr. Duffy served as the court-appointed liquidating trustee of the bankruptcy estate. From 1996 to 1999, Mr. Duffy served as Senior Vice President, General Counsel and Secretary of ETC w/tci, a sub-portfolio of TCI Ventures, Inc./Liberty Media Corporation. Mr. Duffy began his legal career with the law firm Ropes & Gray and holds law degrees from the University of Pennsylvania and Oxford University and a Bachelor's degree in History of Science from Harvard College. Mr. Duffy is also the current Chairman of the Board of Directors of CORAR, the Council on Radionuclides and Radiopharmaceuticals, an international trade association for the radiopharmaceutical industry.

*Mary Anne Heino* joined Lantheus in April 2013 as Chief Commercial Officer. Ms. Heino brings more than 25 years of diverse pharmaceutical industry experience. Prior to joining Lantheus, Ms. Heino led Angelini Labopharm LLC and Labopharm USA in the roles of President and Senior Vice President of World Wide Sales and Marketing from February 2007 to March 2012. From May 2000 until February 2007, Ms. Heino served in numerous capacities at Centocor, Inc., a Johnson & Johnson Company, including Vice President Strategic Planning and Competitive Intelligence, Vice President Sales, Executive Director Customer Relationship Management and Senior Director Immunology Marketing. Ms. Heino began her professional career with Janssen Pharmaceutica as a Sales Representative in June 1989 and worked her way up to the role of Field Sales Director in 1999. Ms. Heino received her Master's in Business Administration from New York University. She earned a Bachelor's of Science in Nursing from the City University of New York and a Bachelor's of Science in Biology from the State University of New York at Stony Brook.

*Michael Heslop* joined Lantheus in June 2012 as our Vice President, International and became our Vice President, Business Development and Strategic Planning in April 2013. Mr. Heslop possesses more than 25 years of general management and commercial experience. Prior to joining Lantheus, Mr. Heslop was General Manager and Senior Vice President, Biosurgical Specialties at Genzyme Corporation from 2009 to 2011. While at Genzyme, Mr. Heslop also held the positions of General Manager and Senior Vice President, Endocrinology from 2003 to 2009, and Vice President, Global Marketing, PGH Business from 2000 to 2003. Previously Mr. Heslop held the positions of Vice President, Business Development at Sciptgen Pharmaceuticals from 1998 to 2000 and Director, Marketing Anti-Infectives at Glaxo Wellcome USA from 1996 to 1998. Mr. Heslop received a B.S. degree in Biology from McGill University and an M.B.A. from Concordia University.

*Dr. Cesare Orlandi* joined Lantheus in March 2013 as Chief Medical Officer. Dr. Orlandi brings more than 20 years of diverse pharmaceutical industry experience. Prior to joining Lantheus, Dr. Orlandi served from January 2012 until February 2013 as Senior Vice President and Chief Medical Officer of TransTech Pharma, Inc., a clinical stage pharmaceutical company focused on discovery and development of human therapeutics. From 2007 until 2011, Dr. Orlandi served as Senior Vice President and Chief Medical Officer of

---

## [Table of Contents](#)

Cardiokine, Inc., a specialty pharmaceutical company developing hospital products for cardiovascular indications. From 1998 until 2007, Dr. Orlandi served, in among other positions, as Vice President, Global Clinical Development of Otsuka Pharmaceuticals, a large Japanese pharmaceutical company. Earlier in his career, Dr. Orlandi served in increasing roles of clinical research responsibility at Medco Research, Inc. and the Radiopharmaceutical Division of The DuPont Merck Pharmaceutical Company, a predecessor organization to Lantheus, and The Upjohn Company. Dr. Orlandi received his medical degree from the University of Pavia Medical School in Pavia, Italy. He is currently an Adjunct Assistant Professor of Medicine at Tufts University School of Medicine in Boston, Massachusetts, and he is a founding member of the American Society of Nuclear Cardiology and a Fellow of the American College of Cardiology, the European Society of Cardiology and the American College of Angiology.

*Dr. Simon Robinson* is our Vice President, Research and Pharmaceutical Development, a position he has held since February 2010. Dr. Robinson was our Senior Director Discovery Research from 2008 to 2010 and our Director Discovery Biology and Veterinary Sciences from 2001 to 2008. Prior to joining us, he held research positions at BMS, Sphinx Pharmaceuticals, BASF and Dupont Pharmaceuticals. He holds a Ph.D. and B.Sc. in Pharmacology from the University of Leeds, England and did post-doctoral training at the University of Wisconsin Clinical Cancer Center.

*Cyrille Villeneuve* is our Vice President, International and previously served as Chief Commercial Officer from October 2011 to April 2013, responsible for global sales and marketing. Previously Mr. Villeneuve was our Vice President and General Manager, International, a position he held since November 2008. Prior to joining us in 1985, Mr. Villeneuve held positions at the Montreal Heart Institute and Hospital Hotel-Dieu Montreal. He holds a Bachelor of Arts from Montreal University and a Master of Public Administration from the Ecole Nationale Administration Publique.

*Carol Walker* joined Lantheus Medical Imaging in February 2015 as Vice President, Quality. Ms. Walker brings more than 30 years of industry experience in quality and medical technology primarily the medical device area. Prior to joining Lantheus, Ms. Walker served as Vice President of Quality for Intelligent Medical Devices, Inc. from 2012 to 2015. Previously she held a number of successive Quality management roles at Siemens Healthcare Diagnostics (formerly Bayer Healthcare Diagnostics) including Vice President, Quality Assurance from 2007 to 2011 and Director, Quality Assurance from 2001 to 2007. Ms. Walker received a B.S. degree in Medical Technology from the Rochester Institute of Technology.

*Brian Markison* is our Non-Executive Chairman of the Board of Directors. Mr. Markison joined the Board in September 2012 and was elevated to Chairman in January 2013. Mr. Markison has been a Healthcare Industry Executive for Avista since September 2012. Mr. Markison is a seasoned executive with more than 30 years of operational, marketing, commercial development and sales experience with international pharmaceutical companies. He most recently held the position of President and Chief Executive Officer and member of the Board of Directors of Fougere Pharmaceuticals Inc., a specialty pharmaceutical company in dermatology, prior to its sale to Sandoz, the generics division of Novartis AG. Before leading Fougere, Mr. Markison was Chairman and Chief Executive Officer of King Pharmaceuticals, which he joined as Chief Operating Officer in March 2004, and was promoted to President and CEO later that year and elected Chairman in 2007. Prior to joining King, Mr. Markison held various senior leadership positions at BMS, including President of Oncology, Virology and Oncology Therapeutics Network; President of Neuroscience, Infectious Disease and Dermatology; and Senior Vice President, Operational Excellence and Productivity. Mr. Markison also serves on the Board of Directors of Immunomedics, Inc. and PharmAthene, Inc. He also serves as Board Chairman for Rosetta Genomics, Ltd. and Executive Chairman of Vertical/Trigen Holdings, LLC. He is also a Director of the College of New Jersey. Mr. Markison holds a B.S. degree from Iona College. Mr. Markison was chosen as a Director because of his strong commercial and operational management background and extensive experience in the pharmaceutical industry.

*David Burgstahler* is a Director and the Chairman of our Compensation Committee, serving on our Board of Directors since January 2008. He was a founding partner of Avista in 2005 and, since 2009, has been President of

---

## [Table of Contents](#)

Avista. Prior to forming Avista, he was a Partner of DLJMB. He was at DLJ Investment Banking from 1995 to 1997 and at DLJMB from 1997 through 2005. Prior to that, he worked at Andersen Consulting (now known as Accenture) and McDonnell Douglas (now known as Boeing). He currently serves as a Director of AngioDynamics Inc. (Nasdaq: ANGO), Armored AutoGroup Inc., ConvaTec Inc., INC Research Holdings, Inc. (Nasdaq: INCR), Strategic Partners, Inc., Vertical/Trigen Holdings, LLC, Visant Corporation and WideOpenWest, LLC. He previously served as a Director of a number of public and private companies, including Wamer Chilcott plc (Nasdaq: WCRX) and BioReliance Holdings, Inc. He holds a Bachelor of Science in Aerospace Engineering from the University of Kansas and a Master of Business Administration from Harvard Business School. Mr. Burgstahler is also a Trustee of the Trinity School in New York City. Mr. Burgstahler was chosen as a Director because of his strong finance and management background, with over 19 years in banking and private equity finance. He has extensive experience serving as a director for a diverse group of private and public companies.

*Samuel Leno* is a Director and the Chairman of our Audit Committee, serving on the Board of Directors since May 2012. Mr. Leno is a strategic executive with more than 40 years of experience with complex multinational companies. He most recently held the positions of Executive Vice President and Chief Operations Officer at Boston Scientific. He previously served as Executive Vice President, Finance and Information Systems and Chief Financial Officer. He retired from Boston Scientific in December 2011. Prior to joining Boston Scientific, Mr. Leno served as Executive Vice President, Finance and Corporate Services and Chief Financial Officer at Zimmer Holdings, Inc. and Chief Financial Officer positions at Arrow Electronics, Inc., Corporate Express, Inc. and Coram Healthcare. Previously, he held a variety of senior financial positions at Baxter International, Inc. and American Hospital Supply Corporation. He is a member of the Board of Directors and the audit committee of Omnicare, is the Chairman of the Board of Zest Anchors, Inc. and serves as a Director of Endotronix Inc. He is also a member of the Advisory Board of the Harvard Business School Healthcare Initiative. He previously served on the Board and audit committee of Tomotherapy, Inc. Mr. Leno served as a Lieutenant in the United States Navy and is a Vietnam veteran. He holds a Bachelor of Science in Accounting from Northern Illinois University and an MBA from Roosevelt University. Mr. Leno was chosen as a Director because of his financial expertise and industry background.

*Dr. Patrick O'Neill* is a Director, serving on the Board of Directors since February 2008. He is also an Industry Advisor for Avista, a position he has held since 2008. Dr. O'Neill was at Johnson & Johnson from 1976 to 2006, holding Research and Development and New Business Development leadership positions in Johnson & Johnson's pharmaceutical business, their Medical Devices and Diagnostics Group, and the surgical and interventional cardiology/radiology business units until he retired in February 2006. He served as Executive in Residence at New Enterprise Associates from March 2006 through 2007. Dr. O'Neill holds a Bachelor of Science in Pharmacy and Ph.D. in Pharmacology from The Ohio State University. He currently serves as Director of OptiNose US Inc. and Zest Anchors, Inc. Dr. O'Neill was chosen as a Director because of his experience in the pharmaceutical industry. Dr. O'Neill has participated directly in the development of pharmaceutical products for other companies, which provides valuable insight into strategic business decisions.

*Sriram Venkataraman* is a Director, serving on the Board of Directors since November 2010. He is also a Partner of Avista, having joined in May 2007. Prior to joining Avista, Mr. Venkataraman was a Vice President in the Healthcare Investment Banking group at Credit Suisse Group AG from 2001 to 2007. Previously, he worked at GE Healthcare (formerly known as GE Medical Systems) from 1996 to 1999. Mr. Venkataraman holds a Master of Science in Electrical Engineering from the University of Illinois, Urbana-Champaign and a Master of Business Administration with Honors from The Wharton School. He currently serves as a Director of AngioDynamics, Inc., OptiNose Inc., Zest Anchors, Inc. and Vertical/Trigen Holdings, LLC. Mr. Venkataraman was chosen as a Director because of his experience in the healthcare industry and his strong finance and management background. He also has experience serving as a director of private and public companies.



---

## [Table of Contents](#)

### **Board of Directors**

Our Board of Directors is responsible for the management of our business and is comprised of six directors who are elected to serve in their position until their next election and until their successors are elected and qualified. Pursuant to the management and employee Shareholders Agreements described in “Item 13—Certain Relationships and Related Transactions, and Director Independence—Transactions with Related Persons—Shareholders Agreement,” Avista has designation rights with respect to the composition of the Holdings board of directors and Avista is entitled to majority representation on any committee that the Board creates. Messrs. Burgstahler, O’Neill and Venkataraman were appointed pursuant to these agreements.

Although not formally considered by the Board of Directors of Holdings because our securities are not registered or traded on any national securities exchange, we believe that Mr. Markison, Mr. Leno and Dr. O’Neill would be considered independent for our Board of Directors and that Mr. Leno would be considered independent for our Audit Committee and that Mr. Markison would be considered independent for our Compensation Committee and Nominating and Governance Committee based upon the listing standards of the New York Stock Exchange.

### **Board Committees**

Our Board of Directors has the authority to appoint committees to perform certain management and administration functions. Our Board of Directors has three committees: the Audit Committee, the Compensation Committee and the Nominating and Corporate Governance Committee.

#### ***Audit Committee***

The primary purpose of the Audit Committee is to assist the Board’s oversight of:

- the integrity of our financial statements;
- our systems of internal control over financial reporting and disclosure controls and procedures;
- our independent auditors’ qualifications, engagement, compensation and independence;
- the performance of our independent auditors and our internal audit function;
- our legal and regulatory compliance;
- our related person transaction policy; and
- our codes of business conduct and ethics.

The Audit Committee is composed of Messrs. Leno and Venkataraman. Mr. Leno, the Chairman of the Audit Committee, has been designated by the Board of Directors of Holdings as our “Audit Committee Financial Expert” as that term has been defined by the SEC in Item 407(d)(5) of Regulation S-K. Our Board of Directors has affirmatively determined that Mr. Leno meets the definition of “independent director” for the purposes of serving on the Audit Committee under the SEC rules.

#### ***Compensation Committee***

The primary purpose of our Compensation Committee is to assist the Board’s oversight of:

- our management compensation policies and practices;
- the determination and approval of the compensation of our executive officers and other members of senior management;
- the review, approval and administration of our incentive compensation policies and programs;

---

## [Table of Contents](#)

- the review, approval and administration of our equity compensation programs; and
- the preparation of the Compensation Committee report required by the SEC rules to be included in our annual report.

Messrs. Burgstahler and Markison currently serve on our Compensation Committee.

### ***Nominating and Governance Committee***

The primary purpose of our Nominating and Governance Committee is to:

- identify and recommend to the Board individuals qualified to serve as directors of our company and on committees of the Board;
- assist the Board in overseeing our policies and procedures for the receipt of stockholder suggestions regarding Board compensation and recommendations of the Board;
- develop, recommend to the Board and oversee the implementation of a set of corporate governance guidelines and principles applicable to us; and
- review the overall corporate governance of our Company and recommend improvements when necessary.

Messrs. Markison and Burgstahler currently serve on our Nominating and Governance Committee.

### **Code of Ethics**

We have a code of conduct and ethics for all of our employees, including our principal executive, financial and accounting officers and our controller, or persons performing similar functions, and each of the non-employee directors on our Board of Directors. Our Company Code of Conduct is currently available on our website, [www.lantheus.com](http://www.lantheus.com). The information on our web site is not part of, and is not incorporated into, this annual report. We intend to provide any required disclosure of any amendment to or waiver from such code that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, in a Current Report on Form 8-K filed with the Commission.

## **Item 11. Executive Compensation**

### **Compensation Discussion and Analysis**

The Compensation Committee is generally charged with the oversight of our executive compensation program. The Compensation Committee is composed of Messrs. Burgstahler and Markison. Responsibilities of the Compensation Committee include the review and approval of the following items:

- executive compensation strategy and philosophy;
- compensation arrangements for executive management;
- design and administration of the annual incentive plan;
- design and administration of our equity incentive plans;
- executive benefits; and
- any other compensation or benefits related items deemed appropriate by the Compensation Committee.

In addition, the Compensation Committee considers the proper alignment of executive pay with our values and strategy by overseeing executive compensation policies, measuring and assessing corporate performance and taking into account our Chief Executive Officer's performance assessment of the Company.

---

## [Table of Contents](#)

The Compensation Committee engaged the services of an independent compensation consultant, Pearl Meyers & Partners, to assist in the strategic review of programs and arrangements relating to executive compensation and performance.

The following executive compensation discussion and analysis describes the principles underlying our executive compensation policies and decisions including material elements of compensation for our named executive officers. Our named executive officers for 2014 were:

- Jeffrey Bailey, President and Chief Executive Officer;
- John Bakewell, Chief Financial Officer;
- John Golubieski, (former) Interim Chief Financial Officer;
- Mary Anne Heino, Chief Commercial Officer;
- Dr. Cesare Orlandi, Chief Medical Officer; and
- Michael Duffy, Vice President, General Counsel and Secretary;

As discussed in more detail below, the material elements and structure of our executive compensation program were negotiated and determined in connection with the Acquisition.

### ***Compensation Philosophy and Objectives***

The core philosophy of our executive compensation program is to support our primary objective of providing innovative medical imaging solutions to improve the treatment of human disease while enhancing our long-term value to our stockholders.

Specifically, the Compensation Committee believes the most effective executive compensation program for all executives, including named executive officers:

- reinforces our strategic initiatives;
- aligns the economic interests of our executives with those of our stockholders; and
- encourages attraction and long-term retention of key contributors.

The Compensation Committee considers the following factors when determining compensation for our executive officers, including our named executive officers:

- the executive's individual performance during the year;
- his or her projected role and responsibilities for the coming year;
- his or her actual and potential impact on the successful execution of our strategy;
- recommendations from our President and Chief Executive Officer and any independent compensation consultants, if used;
- an officer's prior compensation, experience, and professional status;
- the requirements of any applicable employment agreements;
- relative pay among the executive officers; and
- employment market conditions and compensation practices within our peer group.

The weighting of these and other relevant factors is determined on an individual basis for each executive upon consideration of the relevant facts and circumstances.

---

## [Table of Contents](#)

The Compensation Committee is committed to a strong, positive link between our objectives and our compensation practices. Our compensation philosophy also allows for flexibility in establishing executive compensation based on an evaluation of information prepared by management or other advisors and other objective and subjective considerations deemed appropriate by the Compensation Committee, subject to any contractual agreements with our executives. This flexibility is important to ensure our compensation programs are competitive and that our compensation decisions appropriately reflect the unique contributions and characteristics of the Company executive officers.

### ***Compensation Benchmarking***

The Compensation Committee ensures executives' pay levels are materially consistent with our compensation philosophy and objectives described above by conducting annual assessments of competitive executive compensation. We utilize data from publicly traded, similarly-sized pharmaceutical, biopharmaceutical and other life science companies as our primary source for competitive pay levels. However, the Compensation Committee does not support rigid adherence to benchmarks or compensatory formulas and strives to make compensation decisions which effectively support our compensation objectives and reflect the unique attributes of the Company and each executive.

For 2014 compensation for our executive officers, including our named executive officers, the Compensation Committee reviewed executive compensation data provided by Radford Life Sciences Survey, a nationally recognized survey source. The Compensation Committee looked at compensation data for life sciences companies, which most closely approximated our size, and, to the extent possible, had comparable position matches and compensation components.

For 2014 compensation for our President and Chief Executive Officer, data were also collected from a review of the following industry peers:

Abiomed, Accuray, Accorda Therapeutics, AngioDynamics, Atrion, Auxilium Pharmaceuticals, Cyrolife, DepoMed, Emergent BioSolutions, Genomic Health, ICU Medical, Impax Laboratories, Lannett Company, Luminex, Merit Medical Systems, Nordion, The Medicines Company and Volcano. The data used were from the most recent proxy available as of February 2014. This peer group had mean revenue of \$312 million and a mean enterprise value of \$804 million. This peer group selection included 18 life science and specialty pharmaceutical companies. It was selected to best reflect similarly-sized companies in our industry with mature products and full field sales operations.

### ***Employment Agreements***

The compensation committee determined that it was appropriate to enter into employment agreements with each of our named executive officers. Among other things, these agreements set the executives' compensation terms, their rights upon a termination of employment, and restrictive covenants relating to non-competition, non-solicitation and confidentiality. See “—Potential Payment Upon Termination or Change of Control—Employment Agreements and Arrangements” for the material terms of these employment agreements.

### ***Mr. Golubieski's Consulting Agreement***

Mr. Golubieski, our former interim Chief Financial Officer, had a consulting agreement with us which provided that he will serve as our interim Chief Financial Officer on a month-to-month basis unless otherwise terminated by the parties. His compensation was \$25,000 per month plus reimbursement for reasonable and necessary travel expenses. The agreement was terminated on June 2, 2014. Mr. Golubieski was paid a bonus, as determined by the Compensation Committee, in recognition of his contribution as interim Chief Financial Officer in 2013, but was not eligible for a bonus in 2014.

---

[Table of Contents](#)

***Elements of Compensation***

Our compensation program is heavily weighted towards performance-based compensation, reflecting our philosophy of increasing our long-term value and supporting strategic imperatives, as discussed above. Total compensation and other benefits consist of the following elements:

- base salary;
- annual non-equity incentive compensation; and
- long-term equity incentives in the form of stock options.

We do not offer a defined benefit pension plan. The Compensation Committee supports a competitive employee benefit package, but does not support executive perquisites or other supplemental programs targeted to executives.

***Base Salary***

Base salaries are intended to provide reasonable and competitive fixed compensation for regular job duties. In 2014, the Compensation Committee approved adjustments to Mr. Bailey’s, Ms. Heino’s, Dr. Orlandi’s and Mr. Duffy’s respective salaries to \$500,000, \$360,000, \$376,000 and \$334,000, respectively, in recognition of their performance and roles within the Company. Mr. Bakewell’s salary was negotiated as part of his employment offer and was deemed to be in line with our assessment of competitive salaries for his respective roles.

Our general practice with respect to cash compensation is that executive base salaries and annual cash incentive compensation values should generally position total annual cash compensation at or below market median of similarly-sized life science companies. See “—Compensation Discussion and Analysis—Compensation Benchmarking.” Cash compensation is generally between the 25th percentile and the median relative to our peers.

As of December 31, 2014, the base salaries of Mr. Bailey, Mr. Bakewell, Ms. Heino, Dr. Orlandi, and Mr. Duffy, were as follows:

<b>Name</b>	<b>Base Salary</b>
Jeffrey Bailey	\$500,000
John Bakewell	\$400,000
Mary Anne Heino	\$360,000
Cesar Orlandi	\$376,000
Michael Duffy	\$334,000

***Annual Cash Incentive Compensation***

Our 2014 Executive Leadership Team Incentive Bonus Plan (the “Bonus Plan”) was intended to reward executive officers, including our named executive officers, for annual financial performance, performance of other corporate goals that may be long-term in nature and meeting or exceeding certain short-term objectives.

Cash incentive compensation under the Bonus Plan is subject to the achievement of a certain EBITDA target. For purposes of the Bonus Plan, we utilize management EBITDA, see “Item 6—Selected Financial Data—Non-GAAP Financial Measures” for the calculation of EBITDA as defined in the award agreements. The Bonus Plan provides for adjustments to the EBITDA targets by the Compensation Committee for extraordinary and unforeseen events.

---

## [Table of Contents](#)

The Compensation Committee chose EBITDA as the primary performance measure from which to structure annual incentives. EBITDA was selected as the primary metric for a number of reasons:

- it effectively measures our overall performance;
- it can be considered an important surrogate for cash flow, a critical metric related to servicing our outstanding debt;
- it is a key metric driving our valuation, consistent with the valuation approach used by industry analysts; and
- it is consistent with the metric used for the vesting of the financial performance portion of our option grants.

The EBITDA target should not be understood as management's predictions of future performance or other guidance, and investors should not apply these in any other context. EBITDA targets were linked to our short-term and long-term business objectives to ensure incentives are provided for appropriate performance.

The Compensation Committee believes our cash incentive compensation structure is consistent with competitive practice.

The potential bonus payouts under various scenarios in 2014 for our named executive officers were as follows:

<b>Named Executive Officer</b>	<b>Threshold Bonus(1) (as % of Base Salary)</b>	<b>Target Bonus (as % of Base Salary)</b>	<b>Above Target Bonus (as % of Base Salary)</b>
Jeffrey Bailey	50%	100%	180%
John Bakewell	30%	60%	108%
John Golubieski(2)	N/A	N/A	N/A
Mary Anne Heino	22.5%	45%	81%
Cesare Orlandi	20%	40%	72%
Michael Duffy	20%	40%	72%

(1) Assuming that the EBITDA threshold was achieved and the named executive achieved his/her department and individual performance goals.

(2) Mr. Golubieski was not eligible for a bonus under the Bonus Plan in 2014.

For our participating named executives, pursuant to their employment agreements, payout of the target level bonus was tied to the achievement of the EBITDA target and other corporate performance goals established by the Compensation Committee.

Pursuant to the Bonus Plan, payout of the target level bonus for our other named executive officers was tied to the achievement of the EBITDA target and the achievement of certain department performance and individual performance goals.

If we did not meet the threshold of 90% of the EBITDA target of \$64.5 million, no bonus would be awarded under the plan. If we achieve the stretch goals above the EBITDA targets established for the year, each participating named executive offer would be eligible for additional payout above their target bonus subject to the application of their individual performance multiplier.

The achievement of department performance and individual performance goals is applied as a multiplier from 0% to a maximum of 150%. Department performance goals are recommended and approved by our Chief Executive Officer at the start of each year. Achievement of individual performance goals are assessed by our Chief Executive Officer at the end of each year. These targets were intended to provide a meaningful incentive for executives to achieve or exceed performance goals.

---

## [Table of Contents](#)

Our EBITDA target relative to the Bonus Plan for the fiscal year ended December 31, 2014 was established at \$64.5 million. In the fiscal year ended December 31, 2014, our Adjusted EBITDA was approximately \$70.8 million.

For Mr. Bailey in 2014, performance goals included: in addition to our EBITDA goals: driving revenue from DEFINITY and the nuclear product portfolio; advancing numerous growth initiatives including commercial expansion (e.g., expanding the International business into China), product pipeline (e.g., advancing flupiridaz F 18 in Phase 3) and business development milestones, improving the yield and reliability of product suppliers, driving efficiencies and cost control, and delivering on initiatives to improve the balance sheet.

For Mr. Bakewell, performance goals included: in addition to our EBITDA goals: quickly coming up to speed in the business and industry (new hire in 2014) as necessary to be effective as Chief Financial Officer role, leading and supporting all aspects of a potential initial public offering, developing and instituting company-wide disciplines for success in the public markets; developing and refining the Company's financial planning capabilities to improve the predictability of the business and improving the Company's decision-making capabilities from a financial perspective.

For Ms. Heino, performance goals included: in addition to our EBITDA goals: achieving worldwide revenue targets for key products, defining and launching formal global expansion initiatives relative to DEFINITY, evolving the international business unit model, fostering the adoption of TechniLite LEU, and driving operational efficiencies throughout the Commercial organization.

For Dr Orlandi, performance goals included: in addition to our EBITDA goals: providing strategic leadership for the flupiridaz F18 program, supporting commercial activities via medical affairs, medical information, investigator trials and direct support with key opinion leaders, supporting partnering efforts for flupiridaz, CNA and VRI, and maintaining, safety, pharmacovigilance and global regulatory compliance.

For Mr. Duffy, performance goals included: in addition to our EBITDA goals: leading consummation of corporate financing transactions, enhancing the patent portfolio with an emphasis on DEFINITY, obtaining optimal results in our business interruption insurance litigation with Zurich, consummating development pipeline and supply chain transactions, leading public disclosure and corporate compliance activities, and supporting the operating business from a legal perspective.

The Compensation Committee reviewed each executive's performance relative to the goals set forth above and recognized significant achievements and attainment of most individual objectives. The Compensation Committee concluded that cash incentives should be paid as detailed in the Summary Compensation Table for each participating executive.

### *Long-Term Equity Incentive Awards*

In connection with the Acquisition, the Board of Directors approved and adopted the Lantheus MI Holdings, Inc. 2008 Equity Incentive Plan and the Lantheus MI Holdings, Inc. 2013 Equity Incentive Plan, or the Equity Plans, which allow grants of equity awards and options for shares of Holdings. The purpose of the Equity Plans are to:

- promote our long-term financial interests and growth by attracting and retaining management and other personnel and key service providers with the training, experience and abilities to enable them to make substantial contributions to the success of our business;
- motivate management personnel by means of growth-related incentives to achieve long range goals; and
- further the alignment of interests of participants with those of our stockholders through opportunities for increased stock or stock-based ownership in us.

---

## [Table of Contents](#)

We look at competitive long-term equity incentive award values when assessing our compensation programs, as described above under “— Compensation Discussion and Analysis—Compensation Benchmarking”. In the five year period following the Acquisition, we issued large upfront stock option grants that vested over time and with the achievement of certain performance goals in lieu of annual grants. In 2014, the Committee did not grant any options to the management team other than the new hire grant options to our Chief Financial Officer.

Options granted have an exercise price equal to fair market value on the date of grant. Since our common stock is not currently traded on a national securities exchange, fair market value is determined reasonably and in good faith by the Board of Directors. These options have a ten-year term.

Options are generally issued either as time based options, or the Time Vesting Options or EBITDA-based performance options, or the Performance Vesting Options.

The Performance Vesting Options are intended to motivate financial performance in line with investors’ outlook for performance during our first five years. We chose EBITDA as the performance metric since it is a key driver of our valuation and for the reasons described above in “Annual Cash Incentive Compensation.” EBITDA is defined in the award agreements as the sum of net income (or loss) of the business or entity for such period; plus interest expense, income taxes, depreciation expenses, amortization expenses, all fees paid by us or any of our subsidiaries pursuant to the Advisory Services Agreement with Avista, dated as of January 8, 2008, and as from time to time in effect, non-recurring expenses for executive severance, relocation, recruiting and one-time compensation, the aggregate amount of all other non-cash charges reducing net income including stock-based compensation expense, retention bonuses paid in fiscal year 2008; all extraordinary losses; less all extraordinary gains in each case determined in accordance with GAAP.

The Time Vesting Options are also granted to align our executives with factors that drive the valuation of the Company and to aid in their long-term retention. The combination of time and performance-based vesting of these awards is designed to compensate our executive officers, including our named executive officers, for their long-term commitment to us.

All of our stock options are issued with provisions that join the optionees to the Lantheus Shareholder Agreement in the event of an exercise of their options. The provisions for control, forfeiture and ownership of the Shareholder Agreements are designed to help ensure that the investors have received an appropriate return on their invested capital before executive officers receive significant value from these options.

Options granted to Mr. Bakewell were 100% Time Vesting Options in which 339,367 options will vest ratably on the anniversary of his date of employment over a four year period and 113,122 options will cliff vest on the fourth anniversary of his date of employment.

The EBITDA targets can be adjusted by the Board of Directors in consultation with our Chief Executive Officer as described below.

Due to the number of events that can occur within our industry in any given year that are beyond the control of management but may significantly impact EBITDA and our financial performance, such as significant fluctuations in the cost of raw materials and unit sales volume, and regulatory and reimbursement changes, we have incorporated certain vesting provisions into each stock option grant agreement that allow such Performance Vesting Options to vest later than the date specified. Performance Vesting Options that were eligible to vest but failed to vest due to our failure to achieve an EBITDA target in any given year may vest if we exceed the annual EBITDA target in a subsequent year.

Consistent with the EBITDA targets under the Bonus Plan, pursuant to the terms of the 2008 and 2013 Equity Plans and the individual Stock Option Agreements governing each option grant, the Board of Directors, in consultation with our Chief Executive Officer, has the ability to adjust the EBITDA targets for significant events,



---

## [Table of Contents](#)

changes in accounting rules and other customary adjustment events. We believe these adjustments may be necessary in order to effectuate the intents and purposes of our compensation plans and to avoid unintended consequences that are inconsistent with these intents and purposes. If our EBITDA is below the EBITDA target but is equal to at least 90% of the EBITDA target, then a percentage of the Performance Vesting Options vests in that year, calculated as follows:

$$\begin{array}{rcccl} & & \text{(Incremental EBITDA over} & & \\ & & \text{90\% of EBITDA target)} & & \\ \text{(10\% of possible} & \times & & + & \text{(90\% of possible} \\ \text{vested Performance} & & \text{(EBITDA target—10\% of} & & \text{vested Performance} \\ \text{Vesting Options)} & & \text{EBITDA target)} & & \text{Vesting Options)} \end{array}$$

Our EBITDA target relative to performance vesting of options in 2014 was \$64.5 million. In the fiscal year ended December 31, 2014, our actual EBITDA relative to performance vesting of options in 2014 was \$70.2 million.

Our EBITDA target relative to performance vesting of options in 2013 was \$49.5 million. In the fiscal year ended December 31, 2013, our actual EBITDA relative to performance vesting of options in 2013 was \$46.4 million. As a result, 94% of the Performance Vesting Options vested in 2013. A carry back of \$5.7 million was applied from 2014 to Performance Vesting Options in 2013 which resulted in those options becoming 100% vested.

For additional information concerning the options awarded in 2014, 2013 and 2012, see “—2014 Grants of Plan-Based Awards” and “—Outstanding Equity Awards at 2014 Fiscal Year-End.”

### ***Other Benefits***

#### *Retirement Plans*

We offer a 401(k) qualified defined contribution retirement plan for U.S.-based employees, including named executive officers, with a 4.5% company match of the contributor’s base salary.

#### *Personal Benefits*

Except as otherwise discussed herein, other welfare and employee-benefit programs are the same for all of our eligible employees, including our named executive officers. Our other named executive officers do not receive additional benefits outside of those offered to our other employees.

### ***Ownership Guidelines***

In the event of exercise of an option grant, the resulting shares are subject to the provisions of the Employee Shareholder Agreement which restricts transfer and voting rights to ensure alignment with the initial investors. For example, Employee Shareholders (as defined in the Employee Shareholder Agreement) are restricted from transferring any of our securities, subject to certain exceptions outlined in the Employee Shareholder Agreement. We do not maintain formal ownership guidelines.

### ***Severance and Change in Control Benefits***

We believe that reasonable severance benefits are appropriate in order to be competitive in our executive retention efforts. These benefits reflect the fact that it may be difficult for such executives to find comparable employment within a short period of time. We also believe formalized severance arrangements are at times a competitive requirement to attract the required talent for the role.

---

## [Table of Contents](#)

Mr. Bailey's employment agreement provides for 12 months of salary, bonus and health benefit subsidies in the event of termination by the company without cause or by Mr. Bailey with good reason. If his termination under these provisions is within 12 months following a change of control, the agreement provides for 12 months of 2 times his salary, 2 times in bonus and 12 months of certain benefit subsidies. See "—Potential Payment Upon Termination or Change in Control."

All of our other current named executive officers are covered by employment agreements which provide for 12 months of salary, prorated bonus and certain benefit subsidies in the event of termination by the company without cause. If their termination is by the company without cause or by the executive for good reason within 12 months following a change of control, the agreements provides for 12 months salary, full target bonus and 12 months of certain benefit subsidies. See "—Potential Payment Upon Termination or Change in Control."

### ***Tax and Accounting Implications***

We were not subject to Section 162(m) of the Internal Revenue Code. For 2013 and beyond, the Compensation Committee will consider the impact of Section 162(m) in the design of its compensation strategies. Under Section 162(m), compensation paid to executive officers in excess of \$1,000,000 cannot be taken by us as a tax deduction unless the compensation qualifies as performance-based compensation. We have determined, however, that we will not necessarily seek to limit executive compensation to amounts deductible under Section 162(m) if such limitation is not in the best interests of our stockholders. While considering the tax implications of its compensation decisions, the Compensation Committee believes its primary focus should be to attract, retain and motivate executives and to align the executives' interests with those of our stockholders.

The Compensation Committee operates its compensation programs with the good faith intention of complying with Section 409A of the Internal Revenue Code. We account for stock based payments with respect to our long-term equity incentive award programs in accordance with the requirements of ASC 718.

### **Compensation Risk Assessment**

In consultation with the Compensation Committee, members of Human Resources, Legal and Finance groups conducted an annual assessment of whether our compensation policies and practices encourage excessive or inappropriate risk taking by our employees, including employees other than our named executive officers. This assessment included a review of the risk characteristics of our business and the design of our incentive plans and policies. Although a significant portion of our executive compensation program is performance-based, the Compensation Committee has focused on aligning our compensation policies with our long-term interests and avoiding rewards or incentive structures that could create unnecessary risks to us.

Management reported its findings to the Compensation Committee, which agreed with management's assessment that our plans and policies do not encourage excessive or inappropriate risk taking and determined such policies or practices are not reasonably likely to have a material adverse effect on us.

[Table of Contents](#)

**Summary Compensation Table**

The following table sets forth certain information with respect to compensation for the years ended December 31, 2014, 2013 and 2012 earned by or paid to our named executive officers.

Name and Principal Position	Year	Salary (\$)	Bonus \$(1)	Option Awards \$(2)(3)	Non-Equity Incentive Plan Compensation \$(4)	All Other Compensation \$(5)(6)(7)	Total (\$)
Jeffrey Bailey	2014	\$484,615	\$ —	\$ —	\$ 635,000	\$ 39,269	\$1,158,884
President & Chief Executive Officer	2013	\$401,538	\$ —	\$2,440,000	\$ 500,000	\$ 79,281	\$3,420,819
	2012				(New hire in 2013)		
John Bakewell	2014	\$215,385	\$ —	\$ 744,344	\$ 139,000	\$ 28,551	\$1,127,280
Chief Financial Officer	2013						
	2012				(New hire in 2014)		
John Golubieski	2014	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
(Former) Interim Chief Financial Officer	2013	\$ —	\$70,000	\$ —	\$ —	\$ 120,415	\$ 190,415
	2012				(New hire in 2013)		
Mary Anne Heino	2014	\$353,846	\$ —	\$ —	\$ 210,000	\$ 45,052	\$ 608,898
Chief Commercial Officer	2013	\$228,846	\$ —	\$ 312,500	\$ 112,000	\$ 150,432	\$ 803,778
	2012				(New hire in 2013)		
Dr. Cesare Orlandi	2014	\$372,616	\$ —	\$ —	\$ 179,000	\$ 13,010	\$ 564,626
Chief Medical Officer	2013	\$287,787	\$30,000	\$ 211,750	\$ 108,000	\$ 9,172	\$ 646,709
	2012				(New hire in 2013)		
Michael Duffy	2014	\$328,154	\$ —	\$ —	\$ 167,000	\$ 9,215	\$ 504,369
Vice President, General Counsel & Secretary	2013	\$304,581	\$ —	\$ 177,100	\$ 129,000	\$ 10,876	\$ 621,557
	2012	\$268,163	\$ —	\$ —	\$ —	\$ 248,933	\$ 517,096

- (1) Mr. Golubieski was awarded a bonus in recognition of his contributions as interim Chief Financial Officer in 2013. Dr. Orlandi was granted a \$30,000 sign-on bonus to offset certain reimbursements required of his previous employer.
- (2) Mr. Bakewell received initial stock option grants in conjunction with his employment offer in 2014. Mr. Bailey, Ms. Heino and Dr. Orlandi received initial stock option grants in conjunction with their employment offer in 2013. Dr. Orlandi and Mr. Duffy were granted supplemental grants in August 2013 in recognition of their performance and to improve our competitive position.
- (3) Includes the grant date fair value of the stock option awards granted during the fiscal years ended December 31, 2014, 2013 and 2012, in accordance with ASC 718 with respect to options to purchase shares of our common stock awarded to the named executive officers in 2014, 2013 and 2012 under our 2008 and 2013 Equity Plans. See “Item 7—Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates—Accounting for Stock-Based Compensation.”
- (4) For 2014, the Compensation Committee awarded bonuses to Mr. Bailey, Mr. Bakewell, Ms. Heino, Dr. Orlandi, and Mr. Duffy under the Bonus Plan. For 2013, the Compensation Committee awarded bonuses to Mr. Bailey, Ms. Heino, Dr. Orlandi, and Mr. Duffy under the Bonus Plan. For 2012, Mr. Duffy did not earn a bonus under the Bonus Plan.
- (5) For Mr. Bailey, Mr. Bakewell, Ms. Heino, Dr. Orlandi and Mr. Duffy, the amounts reflect matching contributions to our defined contribution retirement plans in 2014 of \$9,750, \$692, \$11,700, \$11,700 and \$7,905, respectively. For Mr. Bailey, Ms. Heino, Dr. Orlandi, and Mr. Duffy, the amounts reflect matching contributions to our defined contribution retirement plans in 2013 of \$7,057, \$2,877, \$4,853 and \$9,566, respectively. For Mr. Duffy, the amounts reflect matching contributions to our defined contribution retirement plans in 2012 of \$3,082.

[Table of Contents](#)

- (6) For Mr. Bailey, Mr. Bakewell, Ms. Heino, Dr. Orlandi and Mr. Duffy, the amounts reflect employer contributions to our long term disability insurance premiums in 2014 of \$1,310, \$706, \$1,310, \$1,310 and \$1,310, respectively. For Mr Bailey, Ms. Heino, Dr. Orlandi, and Mr. Duffy, the amounts reflect employer contributions to our long term disability insurance premiums in 2013 of \$1,159, \$907, \$1,058 and \$1,310, respectively. For Mr. Duffy, the amounts reflect employer contributions to our long term disability insurance premiums in 2012 of \$1,310.
- (7) As part of Mr. Bailey’s agreement he had been compensated for his commuting expenses from his former home in New Jersey and temporary housing expenses in Massachusetts, and that compensation arrangement terminated as of March 31, 2014. Included in his “All Other Compensation” is \$28,209 and \$71,065 for these expenses which included a tax gross up on aggregate basis in 2014 and 2013, respectively. As part of Mr. Bakewell’s agreement he has been compensated for basic transition-related expenses in connection with temporary housing expenses in Massachusetts. Included in his “All Other Compensation” is \$27,153 for these expenses which included a tax gross up on aggregate basis in 2014. As part of Ms. Heino’s agreement she was reimbursed for certain relocation expenses from her former home in New Jersey to Massachusetts. Included in her “All Other Compensation” is \$32,042 and \$146,639 for taxable expenses associated with her home sales, temporary housing and physical move which includes the associated tax gross up on an aggregate basis for 2014 and 2013, respectively. As part of Dr. Orlandi’s agreement he was reimbursed for certain relocation expenses. Included in his “All Other Compensation” is \$3,261 for taxable expenses associated with the physical move which includes the associated tax gross up on an aggregate basis for 2013.

**2014 Grants of Plan-Based Awards**

The following table sets forth certain information with respect to grants of plan-based awards for the year ended December 31, 2014 with respect to the named executive officers.

Name	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards			Estimated Future Payouts Under Equity Incentive Plan Awards			All Other Option Awards:	Exercise or Base Price of Option Awards (\$/Sh)
		Threshold (\$)(1)	Target (\$)(2)	Maximum (\$)(3)	Threshold (#)	Target (#)	Maximum (#)	Number of Securities Underlying Options (#)	
Jeffrey Bailey		\$250,000	\$500,000	\$900,000					
John Bakewell		\$ 69,699	\$139,397	\$250,915					
	12/31/14(4)							339,367	\$ 4.42
	12/31/14(4)							113,122	\$ 4.42
John Golubieski		—	—	—					
Mary Anne Heino		\$ 81,000	\$162,000	\$291,600					
Cesare Orlandi		\$ 75,200	\$150,400	\$270,720					
Michael Duffy		\$ 66,800	\$133,600	\$240,480					

- (1) The amounts shown in the “Threshold” column reflect the threshold payment, which is 50% of the amount shown in the “Target” column. See “— Compensation Discussion and Analysis—Elements of Compensation—Annual Cash Incentive Compensation.”
- (2) The amount shown in the “Target” column is the potential cash incentive award given to our named executive officers if the EBITDA target is hit in 2014. For Mr. Bailey that amount is 100% of his respective 2014 base salary. For Mr. Bakewell that amount is 60% of his respective 2014 base salary prorated for his time in service during 2014. For Ms. For Ms. Heino, Dr. Orlandi and Mr. Duffy that amount is 45%, 40% and 40% of their respective 2014 base salaries. See “—Compensation Discussion and Analysis—Elements of Compensation—Annual Cash Incentive Compensation.”
- (3) The amount shown in the “Maximum” column is 180% of the amount shown in the “Target” column. Pursuant to the Bonus Plan, if we achieve an EBITDA level that is at the stretch target, the Bonus Plan specifies a cap of 120% target with an individual multiplier capped at 150% for amounts achieved above the

[Table of Contents](#)

Target. The maximum payment from the Bonus Pool for Mr. Bailey is 180% of his base salary. The maximum for all other participants, including our other named executive officers, ranges from 71% to 82% of their respective base salaries. See “—Compensation Discussion and Analysis—Elements of Compensation—Annual Cash Incentive Compensation.”

- (4) The supplemental options granted to Mr. Bakewell were 100% Time Vesting Option in which 339,367 options will vest ratably on the anniversary of his date of employment over a four year period and 113,122 options will cliff vest on the fourth year of his date of employment. See “—Compensation Discussion and Analysis—Elements of Compensation—Long-Term Equity Incentive Awards.”

**Outstanding Equity Awards at 2014 Fiscal Year-End**

The following table includes certain information with respect to options held by the named executive officers as of December 31, 2014.

Name	Option Awards				
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Securities of Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Option Expiration Date
Jeffrey Bailey					
Stock Options(2)	239,583	260,417	500,000	\$ 6.80	05/07/23
John Bakewell					
Stock Options(1)	—	339,367	—	\$ 4.42	12/31/2024
Stock Options(1)	—	113,122	—	\$ 4.42	12/31/2024
John Golubieski(5)	—	—	—	—	—
Mary Anne Heino					
Stock Options(2)	31,250	46,875	46,875	\$ 6.80	04/14/23
Cesare Orlandi					
Stock Options(2)	18,750	28,125	28,125	\$ 7.51	03/03/23
Stock Options(3)	6,250	18,750	—	\$ 6.64	08/04/23
Michael Duffy					
Stock Options(3)	17,500	52,500	—	\$ 6.64	08/04/23
Stock Options(4)	173,250	—	76,750	\$ 2.00	04/03/18

- (1) The options granted to Mr. Bakewell in conjunction with his employment offer are 100% Time Vesting Options. 339,367 Time Vesting Options will vest ratably on the anniversary of his date of employment over a four year period and 113,122 Time Vesting Options will cliff vest on the fourth year of his date of employment. See “—Compensation Discussion and Analysis—Elements of Compensation—Long-Term Equity Incentive Awards.”
- (2) The options granted to Mr. Bailey in conjunction with his employment offer are 50% Time Vesting Options and 50% EBITDA-based performance options. Mr. Bailey’s Time Vesting Options vest ratably each month over a four year period from his date of hire; the options granted to Ms. Heino and Dr. Orlandi in conjunction with their employment offers vest ratably on the anniversary of grant date over a four year period; 50% are Time Vesting and Options and 50% are EBITDA-based performance options. See “—Compensation Discussion and Analysis—Elements of Compensation—Long-Term Equity Incentive Awards.”
- (3) In 2013, the supplemental options granted to Mr. Duffy and Dr. Orlandi were 100% Time Vesting Option which will vest ratably on the anniversary of grant date over a four year period.

---

## [Table of Contents](#)

- (4) Relative to Mr. Duffy's grant in 2008, 100% of his Time Vesting Options were vested as of December 31, 2013 with 20% vesting in each of January 2009, 2010, 2011, 2012 and 2013. Upon the Compensation Committee's determination that we achieved the EBITDA performance targets, 20% of the Performance Vesting Options vested in April 2009 and 18.6% vested in April 2010. We did not meet our EBITDA targets in 2010, 2011 or 2012, and as such, none of the Performance Vesting Options vested for those years. As EBITDA targets were not met for 2012, these options will remain unvested, subject to other vesting opportunities under the 2008 Equity Plan.
- (5) As a consultant and interim CFO, Mr. Golubieski has not been granted equity in the company (see "Mr. Golubieski's Consulting Agreement").

No other named executive officers exercised any options during 2014. We do not offer any stock awards, other than stock options, from which vesting would occur.

### **2014 Pension Benefits**

We do not offer our executives or others a pension plan. Retirement benefits are limited to participation in our 401(k) plan with a 4.5% employer match of the contributor's salary and a corresponding international plan.

### **Nonqualified Deferred Compensation**

We do not offer our executives any nonqualified deferred compensation.

### **Potential Payment Upon Termination or Change in Control**

The information below describes and quantifies certain compensation that would become payable under certain named executive officer's employment agreements if, as of December 31, 2014, his or her employment had terminated or there was a change in control. Due to the number of factors that affect the nature and amount of any benefits provided upon the events discussed below, any actual amounts paid or distributed may be different. Factors that could affect these amounts include the timing during the year of any such event.

### ***Employment Agreements and Arrangements***

#### *Jeffrey Bailey*

Mr. Bailey's employment agreement provides for 12 months of salary of \$500,000, a bonus of \$500,000 and health benefit subsidies of \$21,289 in the event of termination by the company without cause or by Mr. Bailey with good reason totaling to \$1,021,289. If his termination under these provisions is within 12 months following a change of control, the agreement provides for 12 months of two times his salary in the amount of \$1,000,000, two times in bonus payment of \$1,000,000 and 12 months of certain benefit subsidies of \$31,934 totaling to \$2,031,934.

#### *Other Active Named Executive Officers*

The following table sets forth certain information with respect to agreements for Mr. Bakewell, Ms. Heino, Dr. Orlandi and Mr. Duffy who are covered by employment agreements which provide for 12 months of salary, prorated bonus and 12 months of certain benefit subsidies in the event of termination by the company without cause.

<u>Name</u>	<u>Salary</u>	<u>Bonus</u>	<u>Benefits</u>	<u>Total</u>
John Bakewell	\$400,000	\$140,000	\$21,289	\$561,289
Mary Anne Heino	\$360,000	\$162,000	\$21,289	\$543,289
Cesare Orlandi	\$376,000	\$150,400	\$14,908	\$541,308
Michael Duffy	\$334,000	\$133,600	\$22,652	\$490,252

## Table of Contents

If their termination is by the company without cause or by the executive for good reason within 12 months following a change of control, the agreements provides for 12 months salary, full target bonus and 12 months of certain benefit subsidies.

<u>Name</u>	<u>Salary</u>	<u>Bonus</u>	<u>Benefits</u>	<u>Total</u>
John Bakewell	\$400,000	\$240,000	\$21,289	\$661,289
Mary Anne Heino	\$360,000	\$162,000	\$21,289	\$543,289
Cesare Orlandi	\$376,000	\$150,400	\$14,908	\$541,308
Michael Duffy	\$334,000	\$133,600	\$22,652	\$490,252

### The Equity Plans

The Equity Plans and each individual Stock Option Agreement provides for accelerated vesting of both Time Vesting Options and Performance Vesting Options granted under the 2008 and 2013 Equity Plans upon a change of control if net cumulative cash proceeds received by our investors exceed certain multiples of their initial investment. If such a change in control occurred on December 31, 2014, each named executive officer's unvested Time Vesting Options and Performance Vesting Options would immediately vest and become exercisable. The aggregate dollar value of unvested stock options held by such named executive officer on December 31, 2014 as listed below.

<u>Name</u>	<u>Aggregate Dollar Value of Options(1)</u>
Jeffrey Bailey	\$ —
John Bakewell	\$ —
Mary Anne Heino	\$ —
Cesare Orlandi	\$ —
Michael Duffy	\$ 185,735

- (1) The aggregate dollar value is the difference between the fair market value of shares of common stock on December 31, 2014 based upon an internal valuation model and the per share exercise price of each option, multiplied by the number of shares subject to the unvested option.

### Director Compensation

The compensation paid to Messrs. Bailey, our President and CEO, and Directors, is reported in the Summary Plan Compensation Table as they were paid only as named executive officers. We do not compensate our board members with per meeting fees. Our directors are reimbursed for any expenses incurred in connection with their services and as detailed in the table and notes below.

<u>Name</u>	<u>Fees Earned or Paid in Cash (\$)</u>	<u>All Other Compensation (\$)</u>	<u>Total (\$)</u>
Brian Markison(1)	\$ 75,000	\$ 69,852	\$144,852
David Burgstahler(2)	\$ —	\$ —	\$ —
Samuel Leno(3)	\$ 48,750	\$ 32,930	\$ 81,680
Dr. Patrick O'Neill(4)	\$ 37,500	\$ 34,595	\$ 72,095
Sriram Venkataraman(2)	\$ —	\$ —	\$ —

- (1) On January 23, 2013, Mr. Markison was appointed Non-Executive Chairman of the Board. For 2014, Mr. Markison was compensated with an annual retainer for his services on the Board of Directors of \$100,000, paid in quarterly increments. On January 23, 2014, Mr. Markison received a grant of 32,949 time vesting option shares that have a ten-year term and vest monthly over a 12-month basis, and on each anniversary date of his appointment, in consideration of his services as Chairman and for so long as he

---

## [Table of Contents](#)

- serves in that capacity, he will be granted a stock option to purchase \$200,000 worth of common stock, calculated as the multiple of the then fair market value times the number of shares necessary to equal \$200,000.
- (2) Messrs. Burgstahler and Venkataraman are Principals of Avista and do not receive any direct compensation for their services as Directors. We pay Avista a management fee of \$1,000,000 annually pursuant to the Advisory Services and Management Agreement, dated as of January 8, 2008. See “Item 13—Certain Relationships and Related Party Transactions, and Director Independence—Transactions with Related Persons—Advisory and Monitoring Services Agreement.”
  - (3) Samuel Leno is compensated with an annual retainer for his services on the Board of Directors of \$50,000, paid in quarterly increments. In addition, Mr. Leno receives \$15,000, paid in quarterly increments for his role as Chairman of the Audit Committee. Effective May 16, 2014, Mr. Leno received a grant of 17,241 time vesting option shares that have a ten- year term and vest monthly over a 12-month basis, and on each anniversary date of his appointment, in consideration of his services as a Director of Holdings and for so long as he serves in that capacity, he will be granted a stock option to purchase \$100,000 worth of common stock, calculated as the multiple of the then fair market value times the number of shares necessary to equal \$100,000.
  - (4) Dr. Patrick O’Neill is compensated with an annual retainer for his services on the Board of Directors of \$50,000, paid in quarterly increments. Effective February 26, 2014, Dr. O’Neill received a grant of 16,474 time vesting option shares that have a ten- year term and vest monthly over a 12-month basis, and on each anniversary date of his appointment, in consideration of his services as a Director of Holdings and for so long as he serves in that capacity, he will be granted a stock option to purchase \$100,000 worth of common stock, calculated as the multiple of the then fair market value times the number of shares necessary to equal \$100,000.

### **Compensation Committee Interlocks and Insider Participation**

During 2014, the members of our Compensation Committee were Messrs. Burgstahler and Markison. Mr. Burgstahler is the President of Avista. Mr. Markison is a Healthcare Industry Executive with Avista. Avista provides us with advisory services pursuant to the Advisory Services and Monitoring Agreement (as defined below) and has entered into other transactions with us. See “Item 13—Certain Relationships and Related Person Transactions, and Director Independence—Transactions with Related Persons—Advisory and Monitoring Services Agreement.”

### **Compensation Committee Report**

Our Compensation Committee has reviewed and discussed the “Item 11—Executive Compensation—Compensation Discussion and Analysis” section with our management. Based upon this review and discussion, the Compensation Committee recommended to the Board of Directors that the “Item 11—Executive Compensation—Compensation Discussion and Analysis” section be included in this Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

Respectfully submitted by the Compensation Committee of the Board of Directors.

David Burgstahler  
Brian Markison

*The information contained in the foregoing report shall not be deemed to be “filed” or to be “soliciting material” with the Commission, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933 or the Exchange Act, except to the extent that we specifically incorporate it by reference in a filing.*



---

[Table of Contents](#)**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters****Principal Stockholders**

Holdings indirectly owns all of our issued and outstanding capital stock through its direct subsidiary and our direct parent, Lantheus Intermediate. Avista Capital Partners, L.P., Avista Capital Partners (Offshore), L.P. and ACP-Lantern Co-Invest, LLC, or, together, the Avista Entities, collectively own approximately 98.4% of Holdings' issued and outstanding capital stock. Avista Capital Partners GP, LLC ultimately exercises voting and dispositive power over the shares held by Avista Capital Partners, L.P., Avista Capital Partners (Offshore), L.P. and ACP-Lantern Co-Invest, LLC. Voting and disposition decisions at Avista Capital Partners GP, LLC with respect to such shares are made by an investment committee, the members of which are Thompson Dean, Steven Webster, David Burgstahler and David Durkin. In connection with the Acquisition, certain members of management purchased shares of Holdings' common stock equaling approximately 0.5% of Holdings' issued and outstanding capital stock.

**Securities Authorized for Issuance Under Equity Compensation Plans**

The following table gives information as of December 31, 2014 about the common stock that may be issued under all of our existing equity compensation plans.

<u>Plan Category</u>	<u>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</u>	<u>Weighted Average Exercise Price of Outstanding Options, Warrants and Rights</u>	<u>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))</u>
Equity compensation plans approved by security holders	5,071,790	\$ 4.59	465,670
Equity compensation plans not approved by security holders(1)	—	—	—
<b>Total</b>	<b>5,071,790</b>	<b>\$ 4.59</b>	<b>465,670</b>

(1) Represents the Lantheus MI Holdings, Inc. 2008 and 2013 Equity Incentive Plans.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

The Board of Directors has the responsibility to review and approve all transactions or series of related financial transactions, arrangements or relationships between us and any related party if the amount involved exceeds \$120,000. We do not otherwise have any policies or procedures for the review, approval or ratification of such transactions.

**Transactions with Related Persons****Shareholders Agreements**

In connection with the Acquisition, Holdings entered into (i) a Shareholders Agreement with the Avista Entities and Don Kiepert, our prior President and Chief Executive Officer, as Management Shareholder, dated January 8, 2008 and subsequently amended on February 26, 2008, or the Initial Shareholders Agreement, and (ii) an Employee Shareholders Agreement with the Avista Entities and certain employee shareholders named therein, dated as of May 30, 2008, or the Employee Shareholders Agreement and, collectively with the Initial Shareholders Agreement, the Shareholders Agreements. Messrs. Markison, Bailey and Leno and Dr. O'Neill joined as parties to the Initial Shareholders Agreement. The Shareholders Agreements govern the parties' respective rights, duties and obligations with respect to the ownership of Holdings securities. The Initial Shareholders Agreement includes provisions regarding tag-along rights in favor of the Management Shareholders

---

## [Table of Contents](#)

(which terminate upon the consummation of an initial public offering), demand registration rights in favor of the Avista Entities and piggy-back registration rights in favor of the Avista Entities and the Management Shareholders. Both Shareholders Agreements contain provisions for drag-along rights in favor of the Avista Entities (which terminate upon the consummation of an initial public offering), and regarding the right of Holdings to repurchase shares held by Management Shareholders or employee shareholders who cease to be employed by Holdings, the Company or any of their subsidiaries (which terminate one year after the consummation of an initial public offering). The Shareholders Agreements contain restrictions on the ability of the Management Shareholders and employee shareholders to transfer shares of Holdings that they own, including provisions that only allow Management Shareholders and employee shareholders to transfer shares of Holdings for one year following the consummation of an initial public offering, but only in proportion with any transfers by the Avista Entities (which terminate one year after the consummation of an initial public offering). Pursuant to the option award agreements between Holdings and its options holders, as a condition to a valid exercise of any such options, the optionee is obligated to join either the Initial Shareholders Agreement or the Employee Shareholders Agreement, as applicable, with respect to the shares of Holdings it is to receive upon exercise of any such option. Following the consummation of an initial public offering, Avista will have the right to nominate two directors to the Board for so long as it owns 25% or more of our issued and outstanding common stock and the right to nominate one director for election to the Board for so long as it beneficially owns 10% or more, but less than 25%, of our issued and outstanding common stock.

### ***Advisory and Monitoring Services Agreement***

In connection with the closing of the Acquisition, LMI entered into an advisory services and monitoring agreement with Avista Capital Holdings, L.P., or Avista Capital Holdings, dated as of January 8, 2008, or the Advisory Services and Monitoring Agreement, pursuant to which ACP Lantern Acquisition, Inc. (a corporation which was merged into us as part of the Acquisition), paid Avista Capital Holdings a one-time fee equal to \$10 million for the consulting and advisory and monitoring services to us, our subsidiaries and our parent companies, in connection with the Acquisition. In addition, the agreement provided for the payment of an annual fee equal to \$1 million as consideration for ongoing advisory services. Under the agreement, to the extent of any future transaction entered into by us or our affiliates, Avista Capital Holdings was entitled to receive an additional fee that is reasonable and customary for the services it provided in connection with such a future transaction. In addition, we are required to pay directly, or reimburse Avista Capital Holdings for, its out-of-pocket expenses in connection with its performance of services under the Advisory Services and Monitoring Agreement. The Advisory Services and Monitoring Agreement has a seven-year term and automatically renews on each anniversary of its execution date such that it has a seven-year term from the date of each such renewal.

### ***INC Research Master Services Agreement***

In 2012, we entered into a Master Contract Research Organization Services Agreement with INC Research, LLC, or INC, to provide clinical development services in connection with the flurpiridaz F 18 Phase 3 program. The agreement was terminated during May 2014. The agreement had a term of five years, and we incurred costs associated with this agreement of approximately \$0.5 million and \$0.9 million in the years ended December 31, 2013 and 2012, respectively. Avista and its affiliates are principal owners of both INC and the Company.

### ***VWR Scientific Purchases***

We purchase inventory supplies from VWR Scientific, VWR. Avista and certain affiliates, our principal stockholder, is a minority owner of VWR. We made purchases of approximately \$0.5 million, \$0.3 million and \$0.3 million during each of the years ended December 31, 2014, 2013 and 2012.

---

[Table of Contents](#)

**Marsh**

We retain Marsh for insurance brokering and risk management. In November 2013, Donald Bailey, brother of our President and Chief Executive Officer, Jeffrey Bailey, was appointed head of sales for Marsh's U.S. and Canada division. In 2014, we paid Marsh approximately \$0.3 million.

**Director Independence**

As disclosed in "Item 10—Directors, Executive Officers and Corporate Governance," although not formally considered by the Board of Directors of Holdings because our securities are not registered or traded on any national securities exchange, we believe that Mr. Markison, Mr. Leno and Dr. O'Neill would be considered independent for our Boards of Directors, that Mr. Leno would be considered independent for our Audit Committee and that Mr. Markison would be considered independent for our Compensation Committee and Nominating and Governance Committee, based upon the listing standards of the New York Stock Exchange.

**Item 14. Principal Accountant Fees and Services**

Deloitte & Touche LLP, or Deloitte, serves as our independent registered public accounting firm. The following table presents fees paid for the audit of our annual consolidated financial statements and all other professional services rendered by Deloitte for the years ended December 31, 2014 and 2013:

	Year Ended December 31,	
	2014	2013
Audit Fees	\$ 1,236,402	\$ 1,439,170
Audit-Related Fees	—	—
Tax Fees	6,800	—
Total Fees	\$ 1,243,202	\$ 1,439,170

**Audit Fees**

These are fees related to professional services rendered in connection with the audit of our annual financial statements, the reviews of the interim financial statements included in each of our quarterly reports on Form 10-Q, and other professional services provided by our independent registered public accounting firm in connection with statutory or regulatory filings or engagements. All other fees consist primarily of the reimbursement of expenses associated with completion of services noted above.

**Audit-Related Fees**

These are fees for assurance and related services that are reasonably related to performance of the audit and review of our financial statements, and which are not reported under "Audit Fees." These services consisted primarily of attestation services for such matters as required for consents related to financings, registration statements and other filings with the Commission.

**Tax Fees**

These are fees billed for professional services for tax compliance, tax advice and tax planning services.

**Pre-Approval Policies**

The services provided by Deloitte were pre-approved by the Audit Committee. The Audit Committee has considered whether the provision of the above-noted services is compatible with maintaining the independence of the independent registered public accounting firm and has determined that the provision of such services has not adversely affected Deloitte's independence. The Audit Committee approved 100% of the services covered by audit-related fees, tax fees and all other similar fees.

**PART IV**

**Item 15. Exhibits and Financial Statement Schedules**

**(a)(1) Financial Statements**

Included in Part II of this annual report:

	<b><u>Page</u></b>
<a href="#">Report of Independent Registered Public Accounting Firm</a>	85
<a href="#">Consolidated Balance Sheets as of December 31, 2014 and 2013</a>	86
<a href="#">Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2014, 2013 and 2012</a>	87
<a href="#">Consolidated Statements of Stockholder's (Deficit) Equity for the Years Ended December 31, 2014, 2013 and 2012</a>	88
<a href="#">Consolidated Statements of Cash Flows for the Years Ended December 31, 2014, 2013 and 2012</a>	89
<a href="#">Notes to Consolidated Financial Statements as of and for the Years Ended December 31, 2014, 2013 and 2012</a>	90

**(a)(2) Schedules**

None.

---

[Table of Contents](#)

**(a)(3) Exhibits**

<u>Exhibit</u>	<u>Description</u>
3.1	Certificate of Incorporation of Lantheus Medical Imaging, Inc., as amended (incorporated by reference to Exhibit 3.1 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).
3.2	Second Amended and Restated By-Laws of Lantheus Medical Imaging, Inc (incorporated by reference to Exhibit 3.2 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).
4.1	Indenture, dated as of May 10, 2010, among Lantheus Medical Imaging, Inc., Lantheus MI Intermediate, Inc. and Lantheus MI Real Estate, LLC as guarantors, and Wilmington Trust FSB, as trustee (incorporated by reference to Exhibit 4.1 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).
4.2	First Supplemental Indenture, dated as of March 14, 2011, among Lantheus Medical Imaging, Inc., Lantheus MI Intermediate, Inc. and Lantheus MI Real Estate, LLC as guarantors, and Wilmington Trust FSB, as trustee (incorporated by reference to Exhibit 4.1 to Lantheus Medical Imaging, Inc.'s Current Report on Form 8-K filed with the Commission on March 16, 2011 (file number 333-169785)).
4.3	Second Supplemental Indenture, dated as of March 21, 2011, among Lantheus Medical Imaging, Inc., Lantheus MI Intermediate, Inc. and Lantheus MI Real Estate, LLC as guarantors, and Wilmington Trust FSB, as trustee (incorporated by reference to Exhibit 4.1 to Lantheus Medical Imaging, Inc.'s Current Report on Form 8-K filed with the Commission on March 21, 2011 (file number 333-169785)).
4.4	Registration Rights Agreement, dated May 10, 2010, by and among Lantheus Medical Imaging, Inc., Lantheus MI Intermediate, Inc. and Lantheus MI Real Estate, LLC, as guarantors, and Jefferies & Company, Inc. (incorporated by reference to Exhibit 4.2 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).
4.5	Registration Rights Agreement, dated March 21, 2011, by and among Lantheus Medical Imaging, Inc., Jefferies & Company, Inc., as representative of the initial purchasers and the guarantors party thereto (incorporated by reference to Exhibit 4.2 to Lantheus Medical Imaging, Inc.'s Current Report on Form 8-K filed with the Commission on March 21, 2011 (file number 333-169785)).
4.6	Form of 9.750% Senior Notes due 2017 (included in Exhibit 4.1).
10.1	Advisory Services and Monitoring Agreement, dated January 8, 2007, by and between ACP Lantern Acquisition, Inc. (now known as Lantheus Medical Imaging, Inc.) and Avista Capital Holdings, L.P. (incorporated by reference to Exhibit 10.3 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).
10.2	Amended and Restated Shareholders Agreement, dated as of February 26, 2008 among Lantheus MI Holdings, Inc., Avista Capital Partners, L.P., Avista Capital Partners (Offshore), L.P., ACP-Lantern Co-Invest, LLC and certain management shareholders named therein (incorporated by reference to Exhibit 10.4 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).
10.3	Employee Shareholders Agreement, dated as of May 8, 2008, among Lantheus MI Holdings, Inc., Avista Capital Partners, L.P., Avista Capital Partners (Offshore), L.P., ACP-Lantern Co-Invest, LLC and certain employee shareholders named therein (incorporated by reference to Exhibit 10.5 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).

---

## Table of Contents

<u>Exhibit</u>	<u>Description</u>
10.4†	Sales Agreement, dated as of April 1, 2009, between Lantheus Medical Imaging, Inc. and NTP Radioisotopes (Pty) Ltd. (incorporated by reference to Exhibit 10.9 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on December 23, 2010 (file number 333-169785)).
10.5†	Amendment No. 1 to Sales Agreement, dated as of January 1, 2010, between Lantheus Medical Imaging, Inc. and NTP Radioisotopes (Pty) Ltd. (incorporated by reference to Exhibit 10.10 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on December 1, 2010 (file number 333-169785)).
10.6†	Amendment No. 2 to Sales Agreement, dated as of January 1, 2010, between Lantheus Medical Imaging, Inc. and NTP Radioisotopes (Pty) Ltd. (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2011 (file number 333-169785)).
10.7†	Purchase and Supply Agreement, dated as of April 1, 2010, between Lantheus Medical Imaging, Inc. and Nordion (Canada) Inc. (formerly known as MDS Nordion, a division of MDS (Canada) Inc.) (incorporated by reference to Exhibit 10.12 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on December 23, 2010 (file number 333-169785)).
10.8†	Amendment No. 1 to the Purchase and Supply Agreement, dated as of December 1, 2010, between Lantheus Medical Imaging, Inc. and Nordion (Canada) Inc. (incorporated by reference to Exhibit 10.13 to Lantheus Medical Imaging, Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (file number 333-169785)).
10.9†	Amendment No. 1 to the Amended and Restated Supply Agreement (Thallium and Generators), dated as of December 29, 2009 between Lantheus Medical Imaging, Inc. and Cardinal Health 414, LLC (incorporated by reference to Exhibit 10.26 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on December 1, 2010 (file number 333-169785)).
10.10†	Amended and Restated Supply Agreement (Thallium and Generators), dated October 1, 2004, by and between Lantheus Medical Imaging, Inc. and Cardinal Health 414, LLC (incorporated by reference to Exhibit 10.14 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on December 23, 2010 (file number 333-169785)).
10.11†	Distribution Agreement, dated as of October 31, 2001, by and between Bristol-Myers Squibb Pharma Company (now known as Lantheus Medical Imaging, Inc.) and Medi-Physics Inc., doing business as Amersham Health (incorporated by reference to Exhibit 10.16 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on December 29, 2010 (file number 333-169785)).
10.12†	First Amendment to Distribution Agreement, dated as of January 1, 2005, by and between Bristol-Myers Squibb Medical Imaging, Inc. (formerly known as Bristol-Myers Squibb Pharma Company and now known as Lantheus Medical Imaging, Inc.) and Medi-Physics Inc., doing business as G.E. Healthcare (incorporated by reference to Exhibit 10.17 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on December 1, 2010 (file number 333-169785)).
10.13	Lantheus MI Holdings, Inc. 2008 Equity Incentive Plan (incorporated by reference to Exhibit 10.18 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).
10.14	Amendment No. 1 to Lantheus MI Holdings, Inc. 2008 Equity Incentive Plan (incorporated by reference to Exhibit 10.19 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).

---

## Table of Contents

<u>Exhibit</u>	<u>Description</u>
10.15	Amendment No. 2 to Lantheus MI Holdings, Inc. 2008 Equity Incentive Plan (incorporated by reference to Exhibit 10.20 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).
10.16	Form of Option Grant Award Agreement (incorporated by reference to Exhibit 10.21 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).
10.17	Lantheus Medical Imaging, Inc. Severance Plan Policy (incorporated by reference to Exhibit 10.24 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).
10.18†	Second Amendment, effective as of January 1, 2012, to the Distribution Agreement, dated as of October 31, 2001, by and between Lantheus Medical Imaging, Inc., formerly known as Bristol-Myers Squibb Medical Imaging, Inc., and Medi-Physics, Inc., doing business as G.E. Healthcare Inc. (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2012 (file number 333-169785)).
10.19†	Manufacturing and Supply Agreement, dated as of February 1, 2012, for the manufacture of DEFINITY® by and between Lantheus Medical Imaging, Inc. and Jubilant HollisterStier LLC (incorporated by reference to Exhibit 10.2 to Lantheus Medical Imaging, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2012 (file number 333-169785)).
10.20†	First Amendment to Manufacturing and Supply Agreement, dated as of May 3, 2012, for the manufacture of DEFINITY® by and between Lantheus Medical Imaging, Inc. and Jubilant HollisterStier LLC (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2012 (file number 333-169785)).
10.21†	Amendment No. 2, dated as of October 15, 2012, to the Purchase and Supply Agreement between Lantheus Medical Imaging, Inc. and Nordion (Canada) Inc. (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2012 (file number 333-169785)).
10.22†	Amendment No. 3, effective as of October 1, 2012, to Sales Agreement between Lantheus Medical Imaging, Inc. and NTP Radioisotopes (Pty) Ltd. (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2012 (file number 333-169785)).
10.23†	Amendment No. 2, effective as of December 27, 2012, to the Amended and Restated Supply Agreement (Thallium and Generators) between Lantheus Medical Imaging, Inc. and Cardinal Health 414, LLC (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2012 (file number 333-169785)).
10.24	Separation Agreement, dated February 19, 2013, by and between Lantheus Medical Imaging, Inc. and Don Kiepert (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2012 (file number 333-169785)).
10.25	Fission Mo-99 Supply Agreement, effective January 1, 2013, by and between Lantheus Medical Imaging, Inc. and the Institut National des Radioelements (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2013 (file number 333-169785)).
10.26	Lantheus MI Holdings, Inc. 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Current Report on Form 8-K filed with the Commission on May 6, 2013 (file number 333-169785)).

---

[Table of Contents](#)

<u>Exhibit</u>	<u>Description</u>
10.27	Form of Employee Option Grant Award Agreement (incorporated by reference to Exhibit 10.2 to Lantheus Medical Imaging, Inc.'s Current Report on Form 8-K filed with the Commission on May 6, 2013 (file number 333-169785)).
10.28	Form of Non-Employee Director Option Grant Award Agreement (incorporated by reference to Exhibit 10.3 to Lantheus Medical Imaging, Inc.'s Current Report on Form 8-K filed with the Commission on May 6, 2013 (file number 333-169785)).
10.29	Employment Agreement, dated May 8, 2013, by and between Lantheus Medical Imaging, Inc. and Jeffrey Bailey (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2013 (file number 333-169785)).
10.30	Amended and Restated Credit Agreement date as of July 3, 2013, by and among Lantheus Medical Imaging Inc., Lantheus MI Intermediate Inc., Lantheus MI Real Estate, LLC, the lenders from time to time party thereto, and Well Fargo Bank, National Association collateral agent and administrative agent and as sole lead arranger, book runner and syndication agent (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2013 (file number 333-169785)).
10.32	Employment Agreement, effective August 12, 2013, by and between Lantheus Medical Imaging, Inc. and Mary Anne Heino (incorporated by reference to Exhibit 10.47 to Lantheus Medical Imaging, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2013 (file number 333-169785)).
10.33	Employment Agreement, effective August 12, 2013, by and between Lantheus Medical Imaging, Inc. and Cesare Orlandi (incorporated by reference to Exhibit 10.48 to Lantheus Medical Imaging, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2013 (file number 333-169785)).
10.34	Amendment to Amended and Restated Credit Agreement, dated June 24, 2014, by and among Lantheus Medical Imaging Inc., Lantheus MI Intermediate Inc., Lantheus MI Real Estate, LLC, the lenders from time to time party thereto, and Wells Fargo Bank, National Association collateral agent and administrative agent and as sole lead arranger, book runner and syndication agent (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014 (file number 333-169785)).
12.1*	Statements re: Computation of Ratio of Earnings to Fixed Charges.
14.1	Lantheus Medical Imaging, Inc. Company Code of Conduct and Ethics (incorporated by reference to Exhibit 14.1 to Lantheus Medical Imaging, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2010 (file number 333-169785)).
14.2	Lantheus Medical Imaging, Inc. Compliance Code. (incorporated by reference to Exhibit 14.2 to Lantheus Medical Imaging, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2010 (file number 333-169785)).
21.1	Subsidiaries of Lantheus MI Intermediate, Inc. and Lantheus Medical Imaging, Inc. (incorporated by reference to Exhibit 21.1 to Lantheus Medical Imaging, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2010 (file number 333-169785)).
24.1*	Power of Attorney (included as part of the signature page hereto).
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14 Securities Exchange Act Rules 13a- 14(a) and 15d-14(a), pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14 Securities Exchange Act Rules 13a- 14(a) and 15d-14(a), pursuant to section 302 of the Sarbanes-Oxley Act of 2002.



---

[Table of Contents](#)

<u>Exhibit</u>	<u>Description</u>
32.1**	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance
101.SCH*	XBRL Taxonomy Extension Schema
101.CAL*	XBRL Taxonomy Extension Calculation
101.DEF*	XBRL Taxonomy Extension Definition
101.LAB*	XBRL Taxonomy Extension Labels
101.PRE*	XBRL Taxonomy Extension Presentation

\* Filed herewith.

\*\* Furnished herewith.

† Confidential treatment requested as to certain portions, which portions have been filed separately with the Securities and Exchange Commission.

---

[Table of Contents](#)

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) 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 MEDICAL IMAGING, INC.

By: /s/ JEFFREY BAILEY

Name: Jeffrey Bailey

Title: *President and Chief Executive Officer*

Date: March 4, 2015

We, the undersigned directors and officers of Lantheus Medical Imaging, Inc., hereby severally constitute and appoint Jeffrey Bailey, John Golubieski and Michael P. Duffy, and each of them individually, with full powers of substitution and resubstitution, our true and lawful attorneys, with full powers to them and each of them to sign for us, in our names and in the capacities indicated below, any and all amendments to this Annual Report on Form 10-K filed with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, each acting alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that any such attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ JEFFREY BAILEY</u> Jeffrey Bailey	President, Chief Executive Officer and Director (Principal Executive Officer)	March 4, 2015
<u>/s/ JOHN BAKEWELL</u> John Bakewell	Chief Financial Officer (Principal Financial Officer)	March 4, 2015
<u>/s/ BRIAN MARKISON</u> Brian Markison	Chairman of the Board of Directors	March 4, 2015
<u>/s/ DAVID BURGSTAHLER</u> David Burgstahler	Director	March 4, 2015
<u>/s/ SAMUEL R. LENO</u> Samuel R. Leno	Director	March 4, 2015
<u>/s/ PATRICK J. O'NEILL</u> Patrick J. O'Neill	Director	March 4, 2015
<u>/s/ SRIRAM VENKATARAMAN</u> Sriram Venkataraman	Director	March 4, 2015

**EXHIBIT INDEX**

<u>Exhibit</u>	<u>Description</u>
3.1	Certificate of Incorporation of Lantheus Medical Imaging, Inc., as amended (incorporated by reference to Exhibit 3.1 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).
3.2	Second Amended and Restated By-Laws of Lantheus Medical Imaging, Inc (incorporated by reference to Exhibit 3.2 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).
4.1	Indenture, dated as of May 10, 2010, among Lantheus Medical Imaging, Inc., Lantheus MI Intermediate, Inc. and Lantheus MI Real Estate, LLC as guarantors, and Wilmington Trust FSB, as trustee (incorporated by reference to Exhibit 4.1 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).
4.2	First Supplemental Indenture, dated as of March 14, 2011, among Lantheus Medical Imaging, Inc., Lantheus MI Intermediate, Inc. and Lantheus MI Real Estate, LLC as guarantors, and Wilmington Trust FSB, as trustee (incorporated by reference to Exhibit 4.1 to Lantheus Medical Imaging, Inc.'s Current Report on Form 8-K filed with the Commission on March 16, 2011 (file number 333-169785)).
4.3	Second Supplemental Indenture, dated as of March 21, 2011, among Lantheus Medical Imaging, Inc., Lantheus MI Intermediate, Inc. and Lantheus MI Real Estate, LLC as guarantors, and Wilmington Trust FSB, as trustee (incorporated by reference to Exhibit 4.1 to Lantheus Medical Imaging, Inc.'s Current Report on Form 8-K filed with the Commission on March 21, 2011 (file number 333-169785)).
4.4	Registration Rights Agreement, dated May 10, 2010, by and among Lantheus Medical Imaging, Inc., Lantheus MI Intermediate, Inc. and Lantheus MI Real Estate, LLC, as guarantors, and Jefferies & Company, Inc. (incorporated by reference to Exhibit 4.2 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).
4.5	Registration Rights Agreement, dated March 21, 2011, by and among Lantheus Medical Imaging, Inc., Jefferies & Company, Inc., as representative of the initial purchasers and the guarantors party thereto (incorporated by reference to Exhibit 4.2 to Lantheus Medical Imaging, Inc.'s Current Report on Form 8-K filed with the Commission on March 21, 2011 (file number 333-169785)).
4.6	Form of 9.750% Senior Notes due 2017 (included in Exhibit 4.1).
10.1	Advisory Services and Monitoring Agreement, dated January 8, 2007, by and between ACP Lantern Acquisition, Inc. (now known as Lantheus Medical Imaging, Inc.) and Avista Capital Holdings, L.P. (incorporated by reference to Exhibit 10.3 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).
10.2	Amended and Restated Shareholders Agreement, dated as of February 26, 2008 among Lantheus MI Holdings, Inc., Avista Capital Partners, L.P., Avista Capital Partners (Offshore), L.P., ACP-Lantern Co-Invest, LLC and certain management shareholders named therein (incorporated by reference to Exhibit 10.4 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).
10.3	Employee Shareholders Agreement, dated as of May 8, 2008, among Lantheus MI Holdings, Inc., Avista Capital Partners, L.P., Avista Capital Partners (Offshore), L.P., ACP-Lantern Co-Invest, LLC and certain employee shareholders named therein (incorporated by reference to Exhibit 10.5 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).

---

## Table of Contents

<u>Exhibit</u>	<u>Description</u>
10.4†	Sales Agreement, dated as of April 1, 2009, between Lantheus Medical Imaging, Inc. and NTP Radioisotopes (Pty) Ltd. (incorporated by reference to Exhibit 10.9 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on December 23, 2010 (file number 333-169785)).
10.5†	Amendment No. 1 to Sales Agreement, dated as of January 1, 2010, between Lantheus Medical Imaging, Inc. and NTP Radioisotopes (Pty) Ltd. (incorporated by reference to Exhibit 10.10 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on December 1, 2010 (file number 333-169785)).
10.6†	Amendment No. 2 to Sales Agreement, dated as of January 1, 2010, between Lantheus Medical Imaging, Inc. and NTP Radioisotopes (Pty) Ltd. (incorporated by reference to Exhibit 10.11 to Lantheus Medical Imaging, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2011 (file number 333-169785)).
10.7†	Purchase and Supply Agreement, dated as of April 1, 2010, between Lantheus Medical Imaging, Inc. and Nordion (Canada) Inc. (formerly known as MDS Nordion, a division of MDS (Canada) Inc.) (incorporated by reference to Exhibit 10.12 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on December 23, 2010 (file number 333-169785)).
10.8†	Amendment No. 1 to the Purchase and Supply Agreement, dated as of December 1, 2010, between Lantheus Medical Imaging, Inc. and Nordion (Canada) Inc. (incorporated by reference to Exhibit 10.13 to Lantheus Medical Imaging, Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (file number 333-169785)).
10.9†	Amendment No. 1 to the Amended and Restated Supply Agreement (Thallium and Generators), dated as of December 29, 2009 between Lantheus Medical Imaging, Inc. and Cardinal Health 414, LLC (incorporated by reference to Exhibit 10.26 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on December 1, 2010 (file number 333-169785)).
10.10†	Amended and Restated Supply Agreement (Thallium and Generators), dated October 1, 2004, by and between Lantheus Medical Imaging, Inc. and Cardinal Health 414, LLC (incorporated by reference to Exhibit 10.14 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on December 23, 2010 (file number 333-169785)).
10.11†	Distribution Agreement, dated as of October 31, 2001, by and between Bristol-Myers Squibb Pharma Company (now known as Lantheus Medical Imaging, Inc.) and Medi-Physics Inc., doing business as Amersham Health (incorporated by reference to Exhibit 10.16 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on December 29, 2010 (file number 333-169785)).
10.12†	First Amendment to Distribution Agreement, dated as of January 1, 2005, by and between Bristol-Myers Squibb Medical Imaging, Inc. (formerly known as Bristol-Myers Squibb Pharma Company and now known as Lantheus Medical Imaging, Inc.) and Medi-Physics Inc., doing business as G.E. Healthcare (incorporated by reference to Exhibit 10.17 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on December 1, 2010 (file number 333-169785)).
10.13	Lantheus MI Holdings, Inc. 2008 Equity Incentive Plan (incorporated by reference to Exhibit 10.18 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).
10.14	Amendment No. 1 to Lantheus MI Holdings, Inc. 2008 Equity Incentive Plan (incorporated by reference to Exhibit 10.19 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).

---

## Table of Contents

<u>Exhibit</u>	<u>Description</u>
10.15	Amendment No. 2 to Lantheus MI Holdings, Inc. 2008 Equity Incentive Plan (incorporated by reference to Exhibit 10.20 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).
10.16	Form of Option Grant Award Agreement (incorporated by reference to Exhibit 10.21 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).
10.17	Lantheus Medical Imaging, Inc. Severance Plan Policy (incorporated by reference to Exhibit 10.24 to Lantheus Medical Imaging, Inc.'s Registration Statement on Form S-4 filed with the Commission on October 6, 2010 (file number 333-169785)).
10.18†	Second Amendment, effective as of January 1, 2012, to the Distribution Agreement, dated as of October 31, 2001, by and between Lantheus Medical Imaging, Inc., formerly known as Bristol-Myers Squibb Medical Imaging, Inc., and Medi-Physics, Inc., doing business as G.E. Healthcare Inc. (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2012 (file number 333-169785)).
10.19†	Manufacturing and Supply Agreement, dated as of February 1, 2012, for the manufacture of DEFINITY® by and between Lantheus Medical Imaging, Inc. and Jubilant HollisterStier LLC (incorporated by reference to Exhibit 10.2 to Lantheus Medical Imaging, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2012 (file number 333-169785)).
10.20†	First Amendment to Manufacturing and Supply Agreement, dated as of May 3, 2012, for the manufacture of DEFINITY® by and between Lantheus Medical Imaging, Inc. and Jubilant HollisterStier LLC (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2012 (file number 333-169785)).
10.21†	Amendment No. 2, dated as of October 15, 2012, to the Purchase and Supply Agreement between Lantheus Medical Imaging, Inc. and Nordion (Canada) Inc. (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2012 (file number 333-169785)).
10.22†	Amendment No. 3, effective as of October 1, 2012, to Sales Agreement between Lantheus Medical Imaging, Inc. and NTP Radioisotopes (Pty) Ltd. (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2012 (file number 333-169785)).
10.23†	Amendment No. 2, effective as of December 27, 2012, to the Amended and Restated Supply Agreement (Thallium and Generators) between Lantheus Medical Imaging, Inc. and Cardinal Health 414, LLC (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2012 (file number 333-169785)).
10.24	Separation Agreement, dated February 19, 2013, by and between Lantheus Medical Imaging, Inc. and Don Kiepert (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2012 (file number 333-169785)).
10.25	Fission Mo-99 Supply Agreement, effective January 1, 2013, by and between Lantheus Medical Imaging, Inc. and the Institut National des Radioelements (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2013 (file number 333-169785)).
10.26	Lantheus MI Holdings, Inc. 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Current Report on Form 8-K filed with the Commission on May 6, 2013 (file number 333-169785)).

---

## Table of Contents

<u>Exhibit</u>	<u>Description</u>
10.27	Form of Employee Option Grant Award Agreement (incorporated by reference to Exhibit 10.2 to Lantheus Medical Imaging, Inc.'s Current Report on Form 8-K filed with the Commission on May 6, 2013 (file number 333-169785)).
10.28	Form of Non-Employee Director Option Grant Award Agreement (incorporated by reference to Exhibit 10.3 to Lantheus Medical Imaging, Inc.'s Current Report on Form 8-K filed with the Commission on May 6, 2013 (file number 333-169785)).
10.29	Employment Agreement, dated May 8, 2013, by and between Lantheus Medical Imaging, Inc. and Jeffrey Bailey (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2013 (file number 333-169785)).
10.30	Amended and Restated Credit Agreement date as of July 3, 2013, by and among Lantheus Medical Imaging Inc., Lantheus MI Intermediate Inc., Lantheus MI Real Estate, LLC, the lenders from time to time party thereto, and Well Fargo Bank, National Association collateral agent and administrative agent and as sole lead arranger, book runner and syndication agent (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2013 (file number 333-169785)).
10.32	Employment Agreement, effective August 12, 2013, by and between Lantheus Medical Imaging, Inc. and Mary Anne Heino (incorporated by reference to Exhibit 10.47 to Lantheus Medical Imaging, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2013 (file number 333-169785)).
10.33	Employment Agreement, effective August 12, 2013, by and between Lantheus Medical Imaging, Inc. and Cesare Orlandi (incorporated by reference to Exhibit 10.48 to Lantheus Medical Imaging, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2013 (file number 333-169785)).
10.34	Amendment to Amended and Restated Credit Agreement, dated June 24, 2014, by and among Lantheus Medical Imaging Inc., Lantheus MI Intermediate Inc., Lantheus MI Real Estate, LLC, the lenders from time to time party thereto, and Wells Fargo Bank, National Association collateral agent and administrative agent and as sole lead arranger, book runner and syndication agent (incorporated by reference to Exhibit 10.1 to Lantheus Medical Imaging, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014 (file number 333-169785)).
12.1*	Statements re: Computation of Ratio of Earnings to Fixed Charges.
14.1	Lantheus Medical Imaging, Inc. Company Code of Conduct and Ethics (incorporated by reference to Exhibit 14.1 to Lantheus Medical Imaging, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2010 (file number 333-169785)).
14.2	Lantheus Medical Imaging, Inc. Compliance Code. (incorporated by reference to Exhibit 14.2 to Lantheus Medical Imaging, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2010 (file number 333-169785)).
21.1	Subsidiaries of Lantheus MI Intermediate, Inc. and Lantheus Medical Imaging, Inc. (incorporated by reference to Exhibit 21.1 to Lantheus Medical Imaging, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2010 (file number 333-169785)).
24.1*	Power of Attorney (included as part of the signature page hereto).
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14 Securities Exchange Act Rules 13a- 14(a) and 15d-14(a), pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14 Securities Exchange Act Rules 13a- 14(a) and 15d-14(a), pursuant to section 302 of the Sarbanes-Oxley Act of 2002.

---

[Table of Contents](#)

<u>Exhibit</u>	<u>Description</u>
32.1**	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance
101.SCH*	XBRL Taxonomy Extension Schema
101.CAL*	XBRL Taxonomy Extension Calculation
101.DEF*	XBRL Taxonomy Extension Definition
101.LAB*	XBRL Taxonomy Extension Labels
101.PRE*	XBRL Taxonomy Extension Presentation

\* Filed herewith.

\*\* Furnished herewith.

† Confidential treatment requested as to certain portions, which portions have been filed separately with the Securities and Exchange Commission.

**STATEMENTS RE: COMPUTATION OF RATIO OF  
EARNINGS TO FIXED CHARGES**

(in thousands)	Year-Ended December 31,				
	2014	2013	2012	2011	2010
<b>Earnings</b>					
Income (loss) from continuing operations	\$ 26	\$(60,664)	\$(42,556)	\$(52,371)	\$ 7,435
Fixed charges	42,384	43,607	42,111	37,753	22,767
Total earnings	\$42,410	\$(17,057)	\$ (445)	\$(14,618)	\$30,202
<b>Fixed Charges</b>					
Interest Expense	\$42,288	\$ 42,915	\$ 42,014	\$ 37,658	\$20,395
Estimated interest portion within rental expense	96	94	97	95	94
Write-off of deferred financing costs	—	598	—	—	2,278
Total fixed charges	\$42,384	\$ 43,607	\$ 42,111	\$ 37,753	\$22,767
Ratio of earnings to fixed charges(1)	1.0x	—	—	—	1.3x

(1) Earnings were insufficient to cover fixed charges by \$60.7 million, \$42.6 million and \$52.4 million, for the years ended December 31, 2013, 2012 and 2011, respectively.



**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO  
SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a), AS ADOPTED  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jeffrey Bailey, certify that:

1. I have reviewed this annual report on Form 10-K of Lantheus Medical Imaging, 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:
  - a. 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;
  - b. 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;
  - c. 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
  - d. 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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):
  - a. 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
  - b. 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.

Dated: March 4, 2015

/S/ JEFFREY BAILEY

Name: Jeffrey Bailey

Title: *President and Chief Executive Officer*

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO  
SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a), AS ADOPTED  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, John Bakewell, certify that:

1. I have reviewed this annual report on Form 10-K of Lantheus Medical Imaging, 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:
  - a. 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;
  - b. 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;
  - c. 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
  - d. 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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):
  - a. 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
  - b. 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.

Dated: March 4, 2015

/s/ JOHN BAKEWELL

Name: John Bakewell

Title: *Chief Financial Officer*

**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED  
BY SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Each of the undersigned hereby certifies that to his knowledge the Annual Report on Form 10-K for the fiscal year ended December 31, 2014 of Lantheus Medical Imaging, Inc. (the "Company") filed with the Securities and Exchange Commission on the date hereof fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 4, 2015

/S/ JEFFREY BAILEY

Name: Jeffrey Bailey

Title: *President and Chief Executive Officer*

Dated: March 4, 2015

/S/ JOHN BAKEWELL

Name: John Bakewell

Title: *Chief Financial 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.

