Lantheus Holdings, Inc.
Form 10-K
March 02, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2015

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission File Number 001-36569

LANTHEUS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**35-2318913**
(State of incorporation)	**(IRS Employer Identification No.)**
331 Treble Cove Road, North Billerica, MA	**01862**
(Address of principal executive offices)	**(Zip Code)**

(978) 671-8001

(Registrant s telephone number, including area code)

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

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 x

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 x 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 x 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 x

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 ¨	Accelerated filer ¨
Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

The registrant had 31,478,119 of common stock, $0.01 par value per share, issued and outstanding as of March 2, 2016.

DOCUMENTS INCORPORATED BY REFERENCE

Listed hereunder are the documents, portions of which are incorporated by reference, and the parts of this Form 10-K into which such portions are incorporated:

The Registrant s Definitive Proxy Statement for use in connection with the Annual Meeting of Stockholders to be held on April 26, 2016, portions of which are incorporated by reference into Parts II and III of this Form 10-K. The 2016 Proxy Statement will be filed with the Securities and Exchange Commission no later than 120 days after the close of our year ended December 31, 2015.

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PART I

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements contained in this annual report are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and section 21E of the Securities Exchange act of 1934. 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, h expressions. Examples of forward-looking statements include, but are not limited to, statements we make regarding: (i) our outlook and expectations including, without limitation, in connection with continued market expansion and penetration for our commercial products, particularly DEFINITY in the face of increased competition; (ii) our outlook and expectations in connection with future performance of Xenon in the face of potential increased competition; (iii) our outlook and expectations related to products manufactured at Jubilant HollisterStier, or JHS, and Pharmalucence and global isotope supply; (iv) our outlook and expectations related to our intention to seek to engage strategic partners to assist in developing and potentially commercializing development candidates; and (v) our liquidity, including our belief that our existing cash, cash equivalents, anticipated revenues and availability under our revolving credit facility, or Revolving 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 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 Lumason from Bracco Diagnostics Inc., or Bracco;

- risks associated with revenues and unit volumes for Xenon in pulmonary studies and the prospect of increased competition in this generic segment;

- 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 dependence upon third parties for the manufacture and supply of a substantial portion of our products, including for DEFINITY at JHS;

risks associated with the technology transfer programs to secure production of our products at alternate contract manufacturer sites, including for DEFINITY at Pharmalucence;

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;

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;

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our being subject to extensive government regulation and our potential inability to comply with those regulations;

potential liability associated with our marketing and sales practices;

the occurrence of any side effects with our products;

our exposure to potential product liability claims and environmental liability;

risks associated with our lead agent in development, flurpiridaz F 18, including our ability to:

- attract strategic partners to successfully complete the Phase 3 clinical program and possibly commercialize the agent;
- obtain 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 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;

risks related to our outstanding indebtedness and our ability to satisfy those obligations;

costs and other risks associated with the Sarbanes-Oxley Act and the Dodd-Frank Act;

risks related to the ownership of our common stock; and

other factors that are described in Risk Factors, beginning on page 21.

Factors that could cause or contribute to such differences include, but are not limited to, those that are discussed in other documents we file with the Securities and Exchange Commission, or the SEC. 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.

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Item 1. Business

Unless the context requires otherwise, references to Lantheus, the Company, our company, we, us and our refer to Lantheus Holdings, Inc. and, as the context requires, its direct and indirect subsidiaries, references to Lantheus Holdings refer to Lantheus Holdings, Inc. and references to LMI refer to Lantheus Medical Imaging, Inc., our wholly-owned subsidiary.

Overview

We are a global leader in the development, manufacture and commercialization of innovative diagnostic medical imaging agents and products that assist clinicians in the diagnosis and treatment of cardiovascular and other diseases. 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 cardiologists, nuclear physicians, radiologists, internal medicine physicians, sonographers and technologists working in a variety of clinical settings. We sell our products to hospitals, clinics, group practices, integrated delivery networks, group purchasing organizations, radiopharmacies 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 contrast agents and medical radiopharmaceuticals (including technetium generators).

Contrast agents are typically non-radioactive compounds that are used in diagnostic procedures such as cardiac ultrasounds, or echocardiograms, x-ray imaging or MRI that are used by physicians to improve the clarity of the diagnostic image.

Radiopharmaceuticals are radioactive pharmaceuticals used by clinicians to perform nuclear imaging procedures.

In certain circumstances, a radioactive element, or radioisotope, is attached to a chemical compound to form the radiopharmaceutical. This act of attaching the radioisotope to the chemical compound is called radiolabeling, or labeling.

In other circumstances, a radioisotope can be used as a radiopharmaceutical without attaching any additional chemical compound.

Radioisotopes are most commonly manufactured in a nuclear research reactor, where a radioactive target is bombarded with subatomic particles, or on a cyclotron, which is a type of particle accelerator that also creates radioisotopes.

Two common forms of nuclear imaging procedures are single-photon emission computed tomography, or SPECT, which measures gamma rays emitted by a SPECT radiopharmaceutical, and positron emission tomography, or PET, which measures positrons emitted by a PET radiopharmaceutical. As an example of the procedures in which our products may be used, in the diagnosis of coronary artery disease, a typical diagnostic progression could include an electrocardiogram, followed by an echocardiogram

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(possibly using our agent DEFINITY), and then a nuclear myocardial perfusion imaging, or MPI, study using either SPECT or PET imaging (possibly using our technetium generator or one of our MPI agents). An MPI study assesses blood flow distribution to the heart. MPI is also used for diagnosing the presence of coronary artery disease.

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 total number of echocardiograms performed each year in the United States over 31 million in 2015 a third party source estimates that approximately 20%, or approximately 6 million echocardiograms in 2015, 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.

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 and is the only perflutren-based echo contrast agent made without albumin. As a result, we believe DEFINITY will be a key driver of the future growth of our business, both in the United States and in international markets as we continue to grow contrast penetration through sales and marketing efforts focused on the appropriate use of contrast and maintain our leading position.

Since its launch in 2001, DEFINITY has been used in imaging procedures in more than 6.7 million patients throughout the world. In 2015, 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 echocardiography procedures in the United States as of December 2015. DEFINITY currently competes with Optison, a GE Healthcare product, Lumason, a recently-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 Risks Relating to our Business and Industry 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 $111.9 million, $95.8 million and $78.1 million for the years ended December 31, 2015, 2014 and 2013, respectively. DEFINITY represented approximately 38%, 32% and 28% of our revenues in 2015, 2014 and 2013, respectively.

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Our leading commercial radiopharmaceutical products are:

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 molybdenum-99, or 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 primarily in North America and Latin America, 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 Cardinal, United Pharmacy Partners, or UPPI, GE Healthcare and Triad Isotopes, Inc., or Triad. We also supply generators on a purchase order basis with other customers. As of December 2015, we believe TechneLite had approximately 28% of the U.S. generator market share, competing primarily with technetium-based generators produced by Mallinckrodt Pharmaceuticals, or Mallinckrodt. In Puerto Rico, we also supply TechneLite to our Company-owned radiopharmacy to prepare radiopharmaceutical imaging agent unit doses. In Canada, where we sold our radiopharmacies in January 2016, we have a supply agreement with Isologic, the buyer of those radiopharmacies. Under the supply agreement with Isologic, we will supply Isologic with certain of our products on commercial terms, including certain product purchase commitments by Isologic. The agreement expires on January 12, 2021 and may be terminated upon the occurrence of specified events, including a material breach by the other party, bankruptcy by either party and certain force majeure events.

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 2012, 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 reimbursement requirements under the applicable CMS rules.

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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 $72.6 million, $93.6 million and $92.2 million for the years ended December 31, 2015, 2014 and 2013, respectively. TechneLite represented approximately 25%, 31% and 33% of our revenues in 2015, 2014 and 2013, respectively.

Xenon Xe 133 Gas

Xenon is a radiopharmaceutical gas that is inhaled and used to assess pulmonary function and also to image cerebral 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 2015, 2014 and 2013, Xenon Xe 133 Gas represented approximately 17%, 12% and 11%, 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 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. 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.

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.

Gludef is an injectable, fluorine-18-radiolabeled imaging agent used with PET technology to identify and characterize tumors in patients undergoing oncologic diagnostic procedures. Gludef is our branded version of FDG in the United States.

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.

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For revenue and other financial information for our U.S. and International segments, see Note 20, 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, South Korea, New Zealand	EU, Israel, India(1), Singapore, Mexico
TechneLite	United States, Canada, Caribbean Islands, Colombia, Costa Rica, Taiwan	South Korea, Mexico, Panama, Australia
Xenon Xe 133 Gas	United States, Taiwan	Canada
Cardiolite	United States, Canada, Cost Rica, Israel, Japan, South Korea, Taiwan, Thailand, Australia, New Zealand, Hong Kong, Panama, Philippines	Colombia, Mexico
Neurolite	United States, Canada, Costa Rica, Japan, Hong Kong, Philippines, Australia, New Zealand, Taiwan, Thailand, Europe(2)(3)	South Korea, Taiwan, Mexico
Thallium Tl 201	United States, Canada, Australia, South Korea, Pakistan, Panama, Taiwan	New Zealand
Gallium Ga67	United States, Canada, Colombia, Mexico, Pakistan, Australia, Costa Rica, South Korea, Panama, Taiwan, New Zealand	None
FDG	Puerto Rico	None
Quadramet	United States	None
Ablavar	United States, Canada	Australia

(1) JHS is pending approval in India.
(2) JHS has regulatory approval for Neurolite in Austria, Belgium, Denmark, Finland, France, Germany, Italy, Luxembourg, Norway, Slovenia, Spain and Sweden.
(3) JHS has regulatory approval pending for Neurolite in Czech Repbulic.

In the United States and Canada, 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, 2015, DEFINITY sales represented approximately 38% of our revenues.

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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 Cardinal, UPPI, GE Healthcare and Triad. Our contractual distribution and other arrangements with these radiopharmacy groups are as follows:

Cardinal maintains approximately 131 radiopharmacies that are typically located in large, densely populated urban areas in the United States. We estimate that Cardinal s radiopharmacies distributed approximately 40% of the aggregate U.S. SPECT doses sold in the first half of 2015 (the latest information currently available to us). Our written supply agreements with Cardinal relating to TechneLite, Xenon, Neurolite, Cardiolite and certain other products expired in accordance with their terms on December 31, 2014. Following extended discussions with Cardinal, on November 19, 2015, the Company entered into a new contract for the distribution of TechneLite, Xenon, Neurolite and other products beginning in 2015 through 2017. The agreement specifies pricing levels and requirements to purchase minimum volumes of certain products during certain periods. The agreement, which expires on December 31, 2017, may be terminated upon the occurrence of specified events, including a material breach by other party and certain force majeure events. From January 1, 2015 until the signing of the new agreement on November 19, 2015, we continued to accept and fulfill product orders from this major customer on a purchase order basis at supply price.

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 unaffiliated, independent radiopharmacies, distributed more than 28% of the aggregate U.S. SPECT doses sold in the first half of 2015. We currently have an agreement with UPPI for the distribution of TechneLite, Xenon and certain other 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 TechneLite generators. These radiopharmacies primarily distribute GE Healthcare s Myoview, a technetium-labeled MPI agent. We estimate that GE Healthcare distributed approximately 8% of the aggregate U.S. SPECT doses sold in the first half of 2015. We currently have an agreement with GE Healthcare for the distribution of TechneLite, Xenon and other products. The agreement provides that GE Healthcare will purchase a minimum percentage of TechneLite 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 TechneLite 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.

Triad maintains approximately 56 radiopharmacies in the United States that purchase a range of our products. We estimate that Triad distributed approximately 18% of the aggregate U.S. SPECT doses sold in

the first half of 2015. In June 2015, we entered into a new contract with Triad for the distribution of Xenon, Neurolite and Cardiolite products and, beginning in 2016, TechneLite generators. The agreement specifies pricing levels and requires Triad to purchase minimum volumes of certain products from the Company. The agreement expires on December 31, 2017 and may be terminated upon the occurrence of specified events, including a material breach by the other party and certain force majeure events.

In addition to the distribution arrangements for our radiopharmaceutical products described above, we also sell certain of our radiopharmaceutical products to independent radiopharmacies and directly to hospitals and

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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 commercialize the product. 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 can commence two small confirmatory clinical trials one for abdominal (liver and kidney) and one for cardiac. The CFDA approved the Clinical Trial Application in February 2016.

Third, approval of the Import Drug License. If the regulatory process, including the clinical trials, is 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 2015.

As of December 31, 2015, we sold our products (and others) directly to end users through four radiopharmacies that we either owned or operated in Canada, the two radiopharmacies we own in Australia and the one radiopharmacy we own in Puerto Rico. On January 12, 2016, we sold our Canadian radiopharmacies to Isologic and entered into a long-term supply agreement with Isologic under which we will supply Isologic with certain of our products on commercial terms, including certain product purchase commitments by Isologic. The agreement expires on January 12, 2021 and may be terminated upon the occurrence of specified events, including a material breach by the other party, bankruptcy by either party and certain force majeure events. We also maintain our own direct sales forces in these markets so we can control the importation, marketing, distribution and sale of our imaging agents in these regions.

Customers

For the year ended December 31, 2015, our largest customers were UPPI, Cardinal, and GE Healthcare, accounting for 12%, 11% and 10%, 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 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 Specialty

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Pharmaceuticals Inc. (an affiliate of JHS), or 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, 2015, our largest supplier of raw materials and supplies was Nordion, accounting for approximately 13% of our total purchases.

Molybdenum-99

Our TechneLite, 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 six of the seven main Moly-producing reactors in the world, namely, OPAL in Australia; BR2 in Belgium; 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 October 31, 2016, 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 HEU based medical isotopes from November 1, 2016 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 the latter part of 2016. In addition, IRE recently received approval from its regulator to expand its production capability by up to 50% of its former capacity. This new

ANSTO and IRE production capacity is expected to replace the NRU s current routine production. The NTP/ANSTO agreement contains minimum percentage volume requirements and

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provides for the increased supply of Moly 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/ANSTO. Similar to the agreement with NTP/ANSTO, 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 2019. 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 our cyclotron technology and Xenon using our hot cell infrastructure. We manufacture, finish and distribute our

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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 TechneLite 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.

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 anticipate that we will file for FDA approval in 2016 to manufacture DEFINITY at Pharmalucence. 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 For the past several years, we have relied on Bristol-Myers Squibb Company, or BMS Manati, Puerto Rico site for the manufacture of our Cardiolite supply. This relationship ended on December 31, 2015 following the completion of a terminal inventory build for our Cardiolite product. We also entered into a Manufacturing and Supply Agreement, effective as of May 3, 2012, with JHS for the manufacture of Cardiolite products. We are currently in the technology transfer process and

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anticipate that we will file for FDA approval in 2016 to manufacture Cardiolite at JHS. 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 for when the technology transfer process is completed 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.

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

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 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 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.

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Research and Development

For the years ended December 31, 2015, 2014 and 2013, we invested $14.4 million, $13.7 million, and $30.5 million, respectively, in research and development, or 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 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 176 subjects who received PET MPI performed with flurpiridaz F 18 and completed the trial, and a Phase 3 clinical trial conducted from 2011 to 2013 involving 755 subjects who received PET MPI procedures with flurpiridaz F 18, completed the trial and were included in the efficacy analysis.

Flurpiridaz F 18 Phase 2 Trial

We evaluated flurpiridaz F 18 in a Phase 2 trial consisting of 176 subjects who completed the trial 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

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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.

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±0.05 vs. 0.70±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 study with 755 subjects with known or suspected coronary artery disease, or CAD, and scheduled for coronary angiography and SPECT imaging who completed the trial and were included in the efficacy analysis. Subjects underwent flurpiridaz F 18 PET MPI and SPECT MPI studies with coronary angiography used as the truth standard for each. The study then compared MPI imaging using flurpiridaz F 18 versus SPECT with primary endpoints of superiority for sensitivity (identifying disease) and non-inferiority for specificity (ruling out disease).

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. In June 2011, we enrolled our first patient, and we completed patient enrollment in the third quarter of 2013

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 sensitivity. In addition, flurpiridaz F 18 showed statistically significant improvements in image quality and diagnostic certainty in comparison to SPECT. However, flurpiridaz F 18 did not meet the co-primary endpoint of non-inferiority for specificity.

In the fourth quarter of 2014, we completed a re-read of the 301 trial results, and in May 2015, we announced the complete results from the 301 trial. PET MPI with flurpiridaz F 18 consistently showed a balanced performance in sensitivity and specificity, when compared to coronary angiography, while SPECT

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imaging results were skewed with low sensitivity and high specificity when compared to coronary angiography. When the flurpiridaz F 18 results were compared to the SPECT results, flurpiridaz F 18 substantially outperformed SPECT in sensitivity but did not meet the non-inferiority endpoint in specificity, implying a substantial and unexpected under-diagnosis of CAD with SPECT imaging in the trial.

In subgroup analyses, the risk-benefit profile of flurpiridaz F 18 appeared to be favorable in women, obese patients and patients with multivessel disease. A significantly higher percentage of images were rated as either excellent or good with flurpiridaz F 18 as compared to SPECT, leading to a greater diagnostic certainty of interpretation. Importantly, radiation exposure associated with flurpiridaz F 18 was reduced to approximately 50% of SPECT. In addition, no drug-related serious adverse events were observed.

Based on these results, we have redesigned the protocol for our second Phase 3 trial with different primary endpoints. On March 13, 2015, the FDA granted us an SPA in connection with the new trial. We are currently in diligence discussions with several companies for potential partnership of flurpiridaz F 18. We are evaluating global, regional and functional opportunities relating to development, manufacturing and commercialization. After we finalize one or more of these partnering opportunities, we will then commence the second Phase 3 trial, which we currently believe will take between two and three years to complete. 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 currently working closely with independent investigators in the United States, Canada and Europe to develop

additional clinical data which may allow us to enter into pivotal clinical trials. We are seeking to engage strategic partners to assist us with the ongoing development activities relating to this agent.

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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.

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, 2016, our patent portfolio included a total of 33 issued

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U.S. patents, 192 issued foreign patents, 20 pending patent applications in the United States and 167 pending foreign applications. These patents and patent applications 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, various markets in Asia, 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 next generation 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 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. 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 composition of matter, use, formulation and manufacturing patents, with a composition of matter 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. Xenon, Thallium and Gallium are all generic radiopharmaceuticals.

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

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

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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.

Regulatory Matters

Food and Drug Laws

The development, manufacture and commercialization of our agents and 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 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.

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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.

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.

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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 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. The current version of PDUFA, the fifth reauthorization, or PDUFA V, was renewed as Title I of the FDA Safety and Innovation Act 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 next reauthorization of PDUFA in 2017 may bring changes or additions to regulatory requirements for drugs and medical devices regulated under the FDCA. In addition, both the U.S. House of Representatives, under the 21st Century Cures bill which passed the House in 2015, and the Senate, under several proposals collectively referred to as Innovations for Healthier Americans, are currently considering legislation that may change regulatory requirements for drugs and medical devices in the future. It is uncertain, however, whether or when any changes or additions to regulatory requirements for drugs or medical devices would be enacted.

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.

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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.

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 for 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, civil monetary penalties, 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 in 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, the 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,

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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 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.

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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:

- significantly increasing the presumed utilization rate for imaging equipment costing $1 million or more in the physician office and free-standing imaging facility setting which reduces the Medicare per procedure medical imaging reimbursement; subsequent legislation further increased the presumed utilization rate effective January 1, 2014;

- increasing drug rebates paid to state Medicaid programs under the Medicaid Drug Rebate Program for brand name prescription drugs and extending those rebates to Medicaid managed care organizations;

- 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 tax applied to applicable sales made from January 1, 2013 through December 31, 2015, has been suspended for 2016 and 2017, but is scheduled to be reapplied starting January 1, 2018.

The Healthcare Reform Act also establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending by proposing changes to Medicare payments if expenditures exceed certain targets. A proposal made by the IPAB must be implemented by CMS, unless Congress adopts a proposal that achieves the necessary savings. 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 until 2018 (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 includes provisions to reduce the federal deficit. The Budget Control Act, as amended, resulted in the imposition of 2% reductions to Medicare (but not Medicaid) payments to providers beginning in April 2013. More recent legislation extends reductions through 2025 and front loads the cuts in 2025 to the first half of the year.

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 Supreme 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 have continued in the wake of the Court s ruling.

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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. Violations of fraud and abuse laws may be punishable by crime 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 brining suits on behalf of the government under the federal False Claims Act, or FCA. 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.

The federal Anti-Kickback Statute generally prohibits, among other things, a pharmaceutical manufacturer from directly or indirectly soliciting, offering, receiving, or paying any remuneration in cash or in kind where one purpose is either to induce the referral of an individual for, or the purchase or prescription of a particular drug that is payable by a federal health care program, including Medicare or Medicaid. Violations of the federal Anti-Kickback Statute can result in exclusion from Medicare, Medicaid or other governmental programs as well as civil and criminal fines and penalties of up to $50,000 per violation and three times the amount of the unlawful remuneration. The majority of states also have anti-kickback, false claims, and similar fraud and abuse laws and 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 statutes or similar laws.

Federal and state false claims laws generally prohibit anyone from knowingly and willingly, among other activities, 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 (which may include claims for services not provided as claimed or claims for medically unnecessary services). False or fraudulent claims for purposes of the FCA carry fines and civil penalties for violations ranging from $5,500 to $11,000 for each false claim, plus up to three times the amount of damages sustained by the federal government and, most critically, may provide the basis for exclusion from federally funded healthcare programs. There is also a criminal FCA statute by which individuals or entities that submit false claims can face criminal penalties. In addition, under the federal Civil Monetary Penalty Law, the Department of Health and Human Services Office of Inspector General has the authority to exclude from participation in federal health care programs or to impose civil penalties against any person who, among other things, knowingly presents, or causes to be presented, certain false or otherwise improper claims. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws.

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). Recent scrutiny of pharmaceutical pricing practices by certain companies may lead to changes in laws that currently allow substantial flexibility in pricing decisions by pharmaceutical manufacturers. Such changes could occur at the federal level or state level and may be adopted by statute, rule, or sub-regulatory policies. 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.

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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.

Those laws also include the U.K. Bribery Act, or 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.

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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, 2015, we currently estimate the D&D cost at the Billerica site to be approximately $26.2 million. As of December 31, 2015 and 2014, we have a liability recorded associated with the fair value of the asset retirement obligations of approximately $8.1 million and $7.4 million, respectively. We have recorded accretion expense of $0.7 million, $0.8 million and $0.6 million during the years ended December 31, 2015, 2014 and 2013, 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 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 January 31, 2016, we had 474 employees, of which 406 were located in the United States and 68 were located internationally, and approximately 5 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. On June 30, 2015, the Company completed an initial public offering, or IPO, of its common stock at a price to the public of $6.00 per share. The Company s common stock is now traded on the NASDAQ under the symbol LNTH .

Available information

The Company maintains a global internet site at www.lantheus.com. The Company makes available on its website its Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to

those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act

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of 1934, as soon as reasonably practicable after such reports are electronically filed with, or furnished to the SEC. The Company s reports filed with, or furnished to, the SEC are also available on the SEC s website at www.sec.gov in a document, and for Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q, in an XBRL (Extensible Business Reporting Language) format. XBRL is an electronic coding language to create an interactive financial statement data over the internet. The information on the Company s website is neither part of nor incorporated by reference in this Annual Report on Form 10-K.

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. We 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 Pharmalucence 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 Pharmalucence. In the meantime, our DEFINITY, Neurolite, evacuation vial, saline and Cardiolite product supply is currently approved for manufacture by a single manufacturer. In addition, we 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 and sufficient supply of saline from our sole manufacturer. We also believe that we will have sufficient Cardiolite product supply from our current supplier and from JHS to meet expected demand when the technology transfer process is completed and we have obtained regulatory approval for this manufacturing site. 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. Our existing Ablavar inventory will expire in the third quarter of 2016, and we will have no further Ablavar inventory that we will be able to sell unless and until we engage in Ablavar technology transfer activities in the future with a new manufacturing partner.

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 and Xenon using our hot cell infrastructure. As with all manufacturing facilities, equipment and infrastructure age and become subject to

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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 Pharmalucence 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.

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.

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

A critical ingredient of TechneLite, 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 six of the seven main Moly-producing reactors in the world, namely, OPAL in Australia; BR2 in Belgium; 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 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 TechneLite generators and our decreased ability to sell other Moly-based medical imaging products, including Cardiolite, 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.

Starting in 2011, the NRU reactor has been shut down for at least four weeks at least once a year for inspection and maintenance. The most recent shutdown period ran from April 13, 2015 until May 13, 2015, 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 for an approximately two week period. 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 the latter part of 2016. In addition, IRE recently received approval from its regulator to expand its production capability by up to 50% of its former capacity. This new ANSTO and IRE 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. 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 2019. However, we cannot assure you that SHINE or any other possible additional sources of Moly

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will result in commercial quantities of Moly for our business, or that these new suppliers together with our current suppliers will be able to deliver a sufficient quantity of Moly to meet our needs.

U.S., Canadian and international governments have encouraged the development of a number of alternative Moly production projects with existing reactors and technologies as well as new technologies. However, 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 HEU based 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 and in some cases fuel for research reactors from which Moly is produced. Absent a new supplier, a supply disruption relating to uranium targets or fuel could have a substantial negative effect on our business, results of operations, financial condition and cash flows.

The 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 TechneLite 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 TechneLite. However, TechneLite 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.

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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 TechneLite 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 TechneLite 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 total number of echocardiograms performed each year in the United States over 31 million in 2015 based on medical literature, a third party source estimates that 20%, or approximately 6 million echocardiograms in 2015, produce suboptimal images. We estimate that DEFINITY had approximately 78% share of the market for contrast agents in echocardiography procedures in which a contrast agent is used in the United States as of December 2015. If we are not able to continue to grow DEFINITY sales through increased market penetration, we will not be able to grow the revenue and cash flow of the business or share the substantial overhead of the balance of our business, 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 Nordion as a by-product of the Moly production process. In January 2015, we entered 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 HEU based 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, 2015, Xenon represented approximately 17% 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 only supplier of packaged Xenon in the U.S., although historically several companies also sold packaged Xenon as a pulmonary imaging agent in the U.S. We understand that a radiopharmaceutical manufacturer is now seeking regulatory approval from the FDA to sell packaged Xenon in the U.S. If that manufacturer receives FDA approval and begins to sell packaged Xenon in the U.S., depending upon the pricing, extent of availability and market penetration of the new offering, we believe we are at risk for volume loss and price erosion for those customers which are not subject to price or volume commitments. See Part II, Item 7 Management s Discussion and Analysis of

Financial Condition and Results of Operations Key Factors Affecting Our Results Competition for Xenon.

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In addition to a possible new supplier of packaged Xenon in the U.S., if there is an increase in the use of other imaging modalities in place of packaged Xenon, our current sales volumes would decrease, which could have a negative effect on our business, results of operations, financial condition and cash flows.

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. In 2014, Draxis announced substantial price increases for MAA. The increased price of MAA, or difficulties in obtaining MAA, could decrease the frequency in which MAA is used for lung perfusion evaluation, in turn, decreasing the frequency that Xenon is used for pulmonary function evaluation, resulting in 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 33% of our revenues in the fiscal year ended December 31, 2015, with UPPI, Cardinal, and GE Healthcare accounting for approximately 12%, 11% and 10%, 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.

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 15%, 17% and 13% of non-U.S. revenues for the fiscal years ended December 31, 2015, 2014 and 2013, 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 losses for the years ended December 31, 2015, 2014 and 2013 of $14.7 million, $3.6 million and $61.6 million, respectively, and as of December 31, 2015, we had a total stockholders deficit of $185.3 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.

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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 GE Healthcare, Bracco, Mallinckrodt, Bayer and 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.

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. 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.

Xenon for lung ventilation diagnosis is our third largest product by revenue. Historically, several companies sold packaged Xenon as a pulmonary imaging agent in the U.S., but since 2010 we have been the only supplier of this imaging agent in the U.S. We understand that a radiopharmaceutical manufacturer is now seeking regulatory approval from the FDA to sell packaged Xenon in the U.S. If that manufacturer receives FDA approval and begins to sell packaged Xenon in the U.S., depending upon the pricing, extent of availability and market penetration of the new offering, we believe we are at risk for volume loss and price erosion for those customers which are not subject to price or volume commitments. See Part II, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations Key Factors Affecting Our Results Competition for Xenon.

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. For example, certain radiopharmaceuticals, when used for non-invasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease, are currently subject to a Medicare National Coverage Determination, or NCD. The NCD permits the coverage of such radiopharmaceuticals only when certain criteria are met. Our pipeline products, including flurpiridaz F 18, if approved, may become subject to this NCD, and may not be covered at all. If Medicare and other 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.

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.

In the physician office and free-standing imaging facility setting, services provided using our products are reimbursed under the Medicare physician fee schedule and, in April 2015, new legislation changed the methodology for updating the fee schedule. The Medicare physician fee schedule is no longer subject to mandatory cuts under Medicare s sustainable growth rate formula (which was intended to limit the increase in aggregate physician payments). Payments under the Medicare physician fee schedule are now subject to specific annual updates (0.5%) through 2019; no updates from 2020 to 2025; and, beginning in 2026, differential updates based on whether the physician participates in alternative payment models (with 0.75% updates for participants and 0.25% updates for non-participants). The legislation also adjusts the fee schedule payments, beginning in 2019, for certain physicians based on their performance under a consolidated measurement system (that measures performance with respect to quality, resource utilization, meaningful use of certified electronic health records technology, and clinical practice improvement activities). Also beginning in 2019, physicians may be eligible for a bonus based on the use of alternative payment models. The impact of these changes cannot be determined at this time.

We believe that Medicare changes to payment policies for imaging procedures applicable to non-hospital settings will continue to result in certain physician 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. Changes applicable to Medicare payment in the hospital outpatient setting could also influence the decisions by hospital outpatient physicians to perform procedures that involve our products. 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, since 2013, although Medicare generally does not provide separate payment to hospitals for the use of diagnostic radiopharmaceuticals administered in an outpatient setting, CMS has had 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 2016. Although

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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 is 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 believe that all these changes and their resulting pressures may incrementally reduce the overall number of diagnostic medical imaging procedures performed. 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.

We also expect increased regulation and oversight of advanced diagnostic testing in which our products are used. Recent federal legislation 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 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.

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 Patient Protection and Affordable Care Act, as amended by the Healthcare Reform Act. The Healthcare Reform Act substantially changed the way healthcare is financed by both governmental and private insurers. The law contains a number of provisions that affect coverage and reimbursement of drug products and medical imaging procedures in which our drug products are used and/or that could potentially reduce the aggregate number of diagnostic medical imaging procedures performed in the United States. See Business Regulatory Matters Healthcare Reform Act and Related Laws. More recently, the Medicare Access and CHIP Reauthorization Act of 2015 significantly revised the methodology for updating Medicare physician fee schedule. Congress continues to consider other healthcare reform legislation. There is no assurance 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 and subsequent Congressional actions includes provisions to reduce the federal deficit. These provisions have 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 the first half of 2025 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.

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.

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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. The Healthcare Reform Act amended the federal self-referral law to require that referring physicians inform patients that the patients 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.

Although certain provisions of the Healthcare Reform Act may 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 13 million by 2016 (based on January 2016 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

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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, Neurolite and evacuation vials. In 2013, JHS received a warning letter from the FDA in connection with their manufacturing facility in Spokane, Washington where our products are manufactured. Although the FDA upgraded JHS s compliance status to Voluntary Action Indicated, meaning that any issues are not of regulatory significance in June of 2015, if in the future the same or other issues arise, 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 products, which requires us to report certain price information to the federal government that could subject us to potential liability under the FCA, 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 for some of our products under Medicare and certain other third party payers, including government payers, depends upon information reported by us to the government. CMS recently published final rules on the determination and reporting of average manufacturer price and best price. 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.

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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 numerous domestic (federal, state and local) and foreign laws addressing fraud and abuse in the healthcare industry, including the FCA and Federal Anti-Kickback Statute, self-referral laws, the FCPA, the Bribery Act, FDA promotional restrictions, the federal disclosure (sunshine) law and state marketing and disclosure (sunshine) laws. 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.

The Healthcare Reform Act contains various provisions that further regulate sales and marketing practices. The Healthcare Reform Act imposes new requirements on certain device and drug manufacturers to report annually 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 annual report (submitted in two phases for the initial year) was submitted in 2014 (covering August 1, 2013 through December 31, 2013), and a second report was submitted in 2015. 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.

The Healthcare Reform Act also separately requires manufacturers to submit information to the FDA on the identity and quantity of drug samples requested and distributed by a manufacturer during each year. 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 reporting requirements. Any irregularities or mistakes in our federal or state 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 clarifies 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 FCA 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 FCA. 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.

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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 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 recently approved ultrasound contrast agent, Lumason, has substantially similar safety labeling as DEFINITY and Optison. If additional safety issues arise, this may result in unfavorable 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;
- 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.

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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.

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. SPA

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agreements are not binding on the FDA and we can give no assurances that the FDA will abide by the terms of our SPA agreement. We also cannot assure 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 a 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 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.

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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;
- 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, CMS required the accreditation of facilities providing the technical component of advanced imaging services, including CT, MRI, PET and nuclear medicine, in non-hospital freestanding 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 took 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,

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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.

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 on 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.

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

- we might not have been the first to make the inventions covered by each of our pending patent applications and issued patents, and we could lose our patent rights as a result;
- we might not have been the first to file patent applications for these inventions or our patent applications may not have been timely filed, and we could lose our patent rights as a result;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that none of our pending patent applications will result in any further issued patents;
- our issued patents may not provide a basis for commercially viable drugs, may not provide us with any protection from unauthorized use of our intellectual property by third parties, and may not provide us with any competitive advantages;
- our patent applications or patents may be subject to interferences, oppositions, post-grant review, 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 choose not to seek patent protection in certain countries where the actual cost outweighs the perceived benefit at a certain time;
- patents issued in foreign jurisdictions may have different scopes of coverage as our 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

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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 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, TechneLite, 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

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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. 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, 2015, 2014 and 2013, 20%, 22% and 25%, respectively, of our revenues were derived from outside the fifty 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;
- 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 outside the fifty United States could have a material adverse effect on our business, results of operations, financial condition and cash flows. As our international exposure increases and as we execute our strategy of international expansion, these risks may intensify.

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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 fifty United States. During the years ended December 31, 2015, 2014 and 2013, the net impact of foreign currency changes on transactions was a loss of $1.8 million, $279,000 and $349,000, 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. In 2015, fluctuations in exchange rates had a $6.8 million negative effect on our revenues.

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.

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 Facility and/or term facility (collectively, our senior secured credit facilities) could be higher than under our current senior secured credit facilities. 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 senior secured credit facilities have 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 FCPA 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,

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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. Mary Anne Heino, 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 an employment agreement with Ms. Heino 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. All of the options granted to employees under our 2008 Equity Incentive Plan and 2013 Equity Incentive Plan are currently out-of-the-money, although we have also made restricted stock grants to employees under our 2013 Equity Incentive Plan and 2015 Equity Incentive Plan. 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.

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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, 2015, we had approximately $363.2 million of total principal indebtedness consisting entirely of the seven-year Term Facility, which matures on June 30, 2022. As of December 31, 2015, there is an $8.8 million

unfunded Standby Letter of Credit. Our aggregate Borrowing Base was approximately $48.2 million, which was reduced by an $8.8 million unfunded Standby Letter of Credit and $0.1 million in accrued interest, resulting in remaining availability under our Revolving Facility of $39.3 million. 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 our outstanding indebtedness, namely the payment of interest and principal;
- make it more difficult to refinance the outstanding indebtedness;
- 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;

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limit our ability to withstand competitive pressures;

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 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 and principal payments, 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 senior secured credit facilities. 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. 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 agreements governing our senior secured credit facilities 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.

Our agreements governing our senior secured credit facilities 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:

maintain net leverage above certain specified levels;

incur additional debt;

pay dividends or make other distributions;

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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 agreements governing our senior secured credit facilities. 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, 2015, we had federal income tax loss carryovers of $175.5 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.

Our stock price could fluctuate significantly, which could cause the value of your investment to decline, and you may not be able to resell your shares at or above the initial public offering price.

Securities markets worldwide have experienced, and may continue to experience, significant price and volume fluctuations. This market volatility, as well as general economic, market or political conditions, could reduce the market price of our common stock regardless of our operating performance. The trading price of our common stock is likely to be volatile and subject to wide price fluctuations in response to various factors, including:

market conditions in the broader stock market;

actual or anticipated fluctuations in our quarterly financial and operating results;

introduction of new products or services by us or our competitors;

anticipated and reported clinical trial results;

issuance of new or changed securities analysts reports or recommendations;

investor perceptions of us and the specialty pharmaceutical industry;

sales, or anticipated sales, of large blocks of our stock;

additions or departures of key personnel;

regulatory or political developments;

litigation and governmental investigations; and

changing economic conditions.

These and other factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management from our business, which could significantly harm our profitability and reputation.

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If securities or industry analysts do not publish research or reports about our business, if they adversely change their recommendations regarding our stock or if our results of operations do not meet their expectations, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, if one or more of the analysts who cover us downgrade our stock, or if our results of operations do not meet their expectations, our stock price could decline.

We do not anticipate paying any cash dividends for the foreseeable future.

We currently intend to retain our future earnings, if any, for the foreseeable future, to repay indebtedness and to fund the development and growth of our business. We do not intend to pay any dividends to holders of our common stock and the agreements governing our senior secured credit facilities limit our ability to pay dividends. As a result, capital appreciation in the price of our common stock, if any, will be your only source of gain on an investment in our common stock. See Item 5 Dividend Policy .

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, 2015, we lease five facilities in Canada, two in Australia and one 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 61,186 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, 2015:

Location	Square footage	Owned/Leased
United States		
North Billerica, Massachusetts	578,000	Owned
Canada		
Montreal	8,729	Leased
Dorval	13,079	Leased
Quebec	6,261	Leased
Mississauga	13,747	Leased
Vancouver	880	Leased
Australia		
Melbourne	4,634	Leased

Adelaide	4,306	Leased
Puerto Rico		
San Juan	9,550	Leased

On January 12, 2016, we sold our Canadian radiopharmacies to Isologic and entered into a long-term supply agreement with Isologic under which we will supply Isologic with certain of our products on commercial terms. As a condition to the consummation of that transaction, we agreed to remain a guarantor of the lease obligations to the Mississauga landlord through the current lease term in 2020, subject to certain limitations.

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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 expose us to greater risks associated with litigation, regulatory or other proceedings, as a result of which we could be required to pay significant fines or penalties. The 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, went on for more than three years. The defendant filed a motion for summary judgment on July 14, 2014. We 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. On March 25, 2015, the United States District Court for the Southern District of New York granted defendant s motion for summary judgment. On September 4, 2015, we filed an appeal of the District Court decision with the United States Court of Appeals for the Second Circuit. On December 4, 2015, the defendant filed an answer brief to our appeal, and on December 18, 2015, we filed a reply brief to the defendant s answer. We cannot be certain when, if ever, we will be able to recover for business interruption losses related to this matter and in what amount, if any.

Except as noted above, as of December 31, 2015, we had no material ongoing litigation, regulatory or other proceeding and had no knowledge of any investigations by governmental or regulatory authorities in which we are a target that could have a material adverse effect on our current business.

Item 4. Mine Safety Disclosures

Not applicable

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PART II

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

Market Information

On June 30, 2015, the Company completed an IPO of its common stock at a price to the public of $6.00 per share. The Company s common stock is now traded on the NASDAQ under the symbol LNTH . Prior to June 25, 2015, our common stock was privately held and there was no established public trading market for our common stock. The following table presents, for the periods indicated, the high and low closing prices per share of our common shares as reported on the NASDAQ.

	FY 2015	
Period	**High**	**Low**
Second Quarter (June 25, 2015 June 30, 2015)	$ 6.77	$ 6.15
Third Quarter (July 1, 2015 September 30, 2015)	$ 8.56	$ 4.30
Fourth Quarter (October 1, 2015 December 31, 2015)	$ 4.76	$ 2.93

Holders of Record

On March 2, 2016, there were approximately 90 shareholders of record of our common stock. This number does not include shareholders for whom shares are held in nominee or street name.

Issuer Purchase of Equity Securities

None.

Dividend Policy

We did not declare or pay any dividends and we do not currently intend to pay dividends in the foreseeable future. We currently expect to retain future earnings, if any, for the foreseeable future, to repay indebtedness and to finance the growth and development of our business.

Recent Sales of Unregistered Securities

None.

Securities Authorized for Issuance Under Equity Compensations Plans

The information required with respect to this item is incorporated herein by reference to our Definitive Proxy Statement for our 2016 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission no later than 120 days after the close of our year ended December 31, 2015.

Item 6. Selected Financial Data

Basis of Financial Information

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

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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 U.S. GAAP. They are not measurements of our financial performance under U.S. GAAP and should not be considered as alternatives to net income (loss) or any other performance measures derived in accordance with U.S. 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 U.S. 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;
- 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 U.S. GAAP results and using our Non-GAAP Measures only for supplemental purposes.

Selected Financial Data

The following tables set forth certain selected consolidated financial data as of December 31, 2015 and 2014 and for the fiscal years ended December 31, 2015, 2014, and 2013 are derived from our audited financial statements, included in this Annual Report on Form 10-K. The selected historical financial data as of December 31, 2013, and 2012 and for

the fiscal year ended December 31, 2012 are derived from our audited financial statements, which are not included in this Annual Report.

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The following selected financial information should be read in conjunction with our consolidated financial statements, the related notes and Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Annual Report on Form 10-K. The results indicated below and elsewhere in this Annual Report are not necessarily indicative of results to be expected for any future period.

	Year Ended December 31,			
	2015	2014	2013	2012
	(dollars in thousands, except share data)			
Statement of Operations:				
Revenues	$ 293,461	$ 301,600	$ 283,672	$ 288,105
Cost of goods sold	157,939	176,081	206,311	211,049
Loss on firm purchase commitment				1,859
Sales and marketing expenses	34,740	35,116	35,227	37,437
General and administrative expenses	43,894	37,313	33,036	32,520
Research and development expenses	14,358	13,673	30,459	40,604
Proceeds from manufacturer			(8,876)	(34,614)
Impairment on land			6,406	
Operating income (loss)	42,530	39,417	(18,891)	(750)
Interest expense	(38,715)	(42,288)	(42,915)	(42,014)
Interest income	24	27	104	252
Loss on early extinguishment of debt	(15,528)			
Other income (expense), net	(89)	478	1,161	(44)
Loss before income taxes	(11,778)	(2,366)	(60,541)	(42,556)
Provision (benefit) for income taxes	2,968	1,195	1,014	(555)
Net loss	$ (14,746)	$ (3,561)	$ (61,555)	$ (42,001)
Net loss per common share:				
Basic and diluted	$ (0.60)	$ (0.20)	$ (3.42)	$ (2.35)
Common Shares:				
Basic and diluted	24,439,845	18,080,615	18,032,131	17,882,909
Statement of Cash Flows Data:				
Net cash flows provided by (used in):				
Operating activities	$ 21,762	$ 11,590	$ (15,572)	$ (372)
Investing activities	(13,151)	(7,682)	(3,483)	(8,145)
Financing activities	999	(2,297)	5,612	(5,114)
Other Financial Data:				
EBITDA(1)	$ 44,910	$ 58,165	$ 6,912	$ 26,815
Adjusted EBITDA(1)	76,329	70,755	38,483	21,598
Capital expenditures	13,151	8,137	5,010	7,920
Balance Sheet Data (at period end):				
Cash and cash equivalents	$ 28,596	$ 19,739	$ 18,578	$ 33,321
Total assets	242,379	243,153	252,682	314,031
Total liabilities	427,668	482,423	488,199	487,136

Total long-term debt, net	349,858	392,863	390,408	388,201
Total stockholders deficit	(185,289)	(239,270)	(235,517)	(173,105)

(1) EBITDA is defined as net (loss) income plus interest expense (net), income taxes, depreciation, amortization and accretion. EBITDA is a measure used by management to measure operating performance. Adjusted EBITDA is defined as EBITDA, further adjusted to exclude certain items and other adjustments required or permitted in calculating Adjusted EBITDA under the agreements governing the senior secured credit facilities. 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

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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 to EBITDA and Adjusted EBITDA for the periods presented:

	Year Ended December 31,			
	2015	2014	2013	2012
	(dollars in thousands)			
Net loss	$ (14,746)	$ (3,561)	$ (61,555)	$ (42,001)
Interest expense, net	38,691	42,261	42,811	41,762
Provision for income taxes(a)	1,314	441	(127)	(901)
Depreciation, amortization and accretion	19,651	19,024	25,783	27,955
EBITDA	44,910	58,165	6,912	26,815
Non-cash stock-based compensation	2,002	1,031	578	1,240
Loss on early extinguishment of debt	15,528			
Legal fees(b)	72	1,113	660	1,455
Loss on firm purchase commitment(c)				1,859
Asset write-off(d)	1,468	1,257	28,349	13,095
Severance and recruiting costs(e)	1,360	818	5,239	1,761
Sponsor fee and other(f)	7,104	1,020	1,457	1,042
New manufacturer costs(g)	3,649	4,959	4,164	8,945
Write-off of IPO costs	236	2,392		
Proceeds from manufacturer			(8,876)	(34,614)
Adjusted EBITDA	$ 76,329	$ 70,755	$ 38,483	$ 21,598

(a) Represents provision for income taxes, less tax indemnification associated with an agreement with BMS.
(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 did not believe we would 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 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.
(e) The amounts consist of severance and recruitment costs related to employees, executives and directors.
(f) Represents annual sponsor monitoring fee and related expenses, a $6.5 million payment for the termination of our advisory services and monitoring agreement with our sponsor 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.

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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 the development, manufacture and commercialization of innovative diagnostic medical imaging agents and products that assist clinicians in the diagnosis and treatment of cardiovascular and other diseases. 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.

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 next generation 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 cerebral blood flow. Xenon is manufactured by a third party and packaged by us.

Sales of our contrast agent, DEFINITY, are made in the United States and Canada 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 commercial radiopharmacies, the majority of which are controlled by or associated with Cardinal, UPPI, GE Healthcare and Triad. A small portion of our nuclear imaging product sales in the United States are made through our direct sales force to hospitals and clinics that maintain their own in-house radiopharmaceutical capabilities. Outside the fifty United States, we own two

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radiopharmacies in Australia and one in Puerto Rico. 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:

	Year Ended December 31,					
(dollars in thousands)	**2015**	**%**	**2014**	**%**	**2013**	**%**
DEFINITY	$ 111,859	38.1	$ 95,760	31.8	$ 78,094	27.5
TechneLite	72,562	24.7	93,588	31.0	92,195	32.5
Xenon	48,898	16.7	36,549	12.1	32,125	11.3
Other	60,142	20.5	75,703	25.1	81,258	28.7
Revenues	$ 293,461	100.0	$ 301,600	100.0	$ 283,672	100.0

Key Factors Affecting Our Results

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

Growth of DEFINITY

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

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 ultrasound contrast agent, Lumason, has substantially similar safety labeling as DEFINITY and Optison. The future growth of our DEFINITY sales will be dependent on our ability to continue to increase segment penetration for DEFINITY in suboptimal echocardiograms and, as discussed below in Inventory Supply, on the ability of JHS, and, if approved Pharmalucence, to continue to manufacture and release DEFINITY on a timely and consistent basis. 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 2015 had an approximately 78% segment share, Optison, and Lumason, which was 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

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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.

Competition for Xenon

Xenon gas for lung ventilation diagnosis is our third largest product by revenue. Historically, several companies sold packaged Xenon as a pulmonary imaging agent in the U.S., but since 2010 we have been the only supplier of this imaging agent in the U.S. We understand that a radiopharmaceutical manufacturer is now seeking regulatory approval from the FDA to sell packaged Xenon in the U.S. If that manufacturer receives FDA approval and begins to sell packaged Xenon in the U.S., depending upon the pricing, extent of availability and market penetration of the new offering, we believe we are at risk for volume loss and price erosion for those customers which are not subject to price or volume commitments. In order to increase the predictability of our Xenon business, we have entered into Xenon supply agreements at committed volumes and substantially reduced prices with previously non-contracted customers. These steps should result in more predictable Xenon unit volumes in 2016 at substantially lower revenue and gross margin contributions as compared to 2015. See Item 1A Risk Factors We face potential supply and demand challenges for Xenon.

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 and Xenon, we have supply agreements with Nordion that expire on October 31, 2016, and for moly, supply agreements with NTP of South Africa, ANSTO of Australia, and IRE of Belgium, each running through December 31, 2017. 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 2015 shutdown period ran from April 13, 2015 until May 13, 2015, 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 production process and is currently captured only by Nordion, 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 2015 budgeting process, the shutdown did not have a material adverse effect on our 2015 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 of HEU based 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 the latter part of 2016. In addition, IRE recently received approval from its regulator to expand its production capability by up to 50% of its former capacity. The new ANSTO and IRE production capacity is expected to replace 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 Risk Factors We face potential supply and demand challenges for Xenon.

Inventory Supply

Our products consist of contrast imaging agents and radiopharmaceuticals (including technetium generators). We obtain a substantial portion of our imaging agents from third party suppliers. JHS is currently

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our sole source manufacturer of DEFINITY, Neurolite and evacuation vials, an ancillary component for our TechneLite generators, and we have ongoing technology transfer activities at JHS for our Cardiolite product supply. In the meantime, our Cardiolite product supply is approved for manufacture 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 United States.

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 anticipate that we will file for FDA approval in 2016 to manufacture DEFINITY at Pharmalucence.

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, which takes place at our North Billerica, Massachusetts facility.

Demand for TechneLite

Since the global Moly supply shortage in 2009 to 2010, we have experienced reduced demand for TechneLite 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. See Risk Factors 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.

Separate from the Moly supply shortage, we believe there has also been a decline in the MPI study market because of 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. While the total number of patient studies has not returned to pre-shortage levels, the total MPI market has been essentially flat for the period 2011 through 2014.

In November 2015, CMS announced the 2016 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. In January 2013, we began to offer a TechneLite 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 TechneLite, Xenon, Neurolite, Cardiolite and certain other products expired in accordance with their terms on December 31, 2014. Following extended discussions with Cardinal, on November 19, 2015, we entered into a new contract for the distribution of TechneLite, Xenon, Neurolite and other products beginning in 2015 through 2017. The agreement specifies pricing levels and requirements to purchase minimum volumes of certain products during certain periods. The agreement, which expires on December 31, 2017, may be terminated upon the occurrence of specified events, including a material breach by the other party and certain force majeure events. From January 1, 2015 until the signing of the new agreement on November 19, 2015, we continued to accept and fulfill product orders from this major customer on a purchase order basis at supply price.

In 2016, we expect to sell a broader mix of products to Cardinal at lower contracted pricing than the pricing in effect for most of 2015, resulting in higher revenues but lower gross margins than in most of 2015.

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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 are also seeking 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.

Operating Results

The following have been included in our results for the year ended December 31, 2015:

- 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;
- decreased revenues for TechneLite as a result of lower volumes;
- 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;
- decreased revenues from our Cardiolite products resulting from continued generic competition;
- decreased international revenues resulting from unfavorable foreign exchange;
- lower material costs incurred for the production of TechneLite;
- $15.5 million loss on extinguishment of debt costs related to the redemption of LMI s outstanding Notes;

$6.5 million payment for the termination of our advisory services and monitoring agreement with Avista; and

decreased interest expense due to the refinancing of long-term debt.

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Years Ended December 31, 2015, 2014 and 2013

	December 31,			2015 compared to 2014		2014 compared to 2013	
(dollars in thousands)	2015	2014	2013	Change $	Change %	Change $	Change %
Revenues	$ 293,461	$ 301,600	$ 283,672	$ (8,139)	(2.7)%	$ 17,928	6.3%
Cost of goods sold	157,939	176,081	206,311	(18,142)	(10.3)	(30,230)	(14.7)
Gross profit	135,522	125,519	77,361	10,003	8.0	48,158	62.3
Operating expenses							
Sales and marketing expenses	34,740	35,116	35,227	(376)	(1.1)	(111)	(0.3)
General and administrative expenses	43,894	37,313	33,036	6,581	17.6	4,277	12.9
Research and development expenses	14,358	13,673	30,459	685	5.0	(16,786)	(55.1)
Proceeds from manufacturer			(8,876)			8,876	(100.0)
Impairment on land			6,406			(6,406)	(100.0)
Total operating expenses	92,992	86,102	96,252	6,890	8.0	(10,150)	(10.5)
Operating income (loss)	42,530	39,417	(18,891)	3,113	7.9	58,308	308.7
Interest expense	(38,715)	(42,288)	(42,915)	3,573	(8.4)	627	1.5
Interest income	24	27	104	(3)	(11.1)	(77)	(74.0)
Loss on extinguishment of debt	(15,528)			(15,528)	(100.0)		
Other income (expense), net	(89)	478	1,161	(567)	(118.6)	(683)	(58.8)
Income (loss) before income taxes	(11,778)	(2,366)	(60,541)	(9,412)	397.8	58,175	(96.1)
Provision for income taxes	2,968	1,195	1,014	1,773	148.4	181	17.9
Net loss	$ (14,746)	$ (3,561)	$ (61,555)	$ (11,185)	314.1%	$ 57,994	(94.2)%

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Comparison of the Years Ended December 31, 2015, 2014, and 2013

Revenues

Revenues are summarized as follows:

	Year ended December 31,			2015 compared to 2014		2014 compared to 2013	
	2015	2014	2013	Change $	Change %	Change $	Change %
	(dollars in thousands)						
United States							
DEFINITY	$ 109,656	$ 93,848	$ 76,539	$ 15,808	16.8%	$ 17,309	22.6%
TechneLite	62,034	82,321	80,609	(20,287)	(24.6)	1,712	2.1
Xenon	48,868	36,542	32,086	12,326	33.7	4,456	13.9
Other	15,266	23,809	24,405	(8,543)	(35.9)	(596)	(2.4)
Total U.S. revenues	$ 235,824	$ 236,520	$ 213,639	$ (696)	(0.3)%	$ 22,881	10.7%
International							
DEFINITY	$ 2,203	$ 1,912	$ 1,555	$ 291	15.2%	$ 357	23.0%
TechneLite	10,528	11,267	11,586	(739)	(6.6)	(319)	(2.8)
Xenon	30	7	39	23	328.6	(32)	(82.1)
Other	44,876	51,894	56,853	(7,018)	(13.5)	(4,959)	(8.7)
Total International revenues	$ 57,637	$ 65,080	$ 70,033	$ (7,443)	(11.4)	$ (4,953)	(7.1)
Revenues	$ 293,461	$ 301,600	$ 283,672	$ (8,139)	(2.7)%	$ 17,928	6.3%

2015 v. 2014

Total revenues decreased $8.1 million, or 2.7%, to $293.5 million in the year ended December 31, 2015, as compared to $301.6 million in the year ended December 31, 2014. U.S. segment revenue decreased $0.7 million, or 0.3%, to $235.8 million in the same period, as compared to $236.5 million in the prior year. The U.S. segment decrease is primarily due to a decrease of $20.3 million in TechneLite revenues driven by lower volumes, a decrease in license revenue of approximately of $3.9 million as a result of a contract ending in December 2014 that had contained a license fee that was recognized on a straight-line basis over the term of the agreement, $1.5 million in Neurolite revenues driven by lower volumes and $1.8 million in Thallium revenues driven by lower volumes. Offsetting these decreases was an increase of $15.8 million in DEFINITY revenues driven primarily by higher unit volumes and an increase of $12.3 million in Xenon revenues primarily as a result of higher selling prices.

International segment revenues decreased $7.4 million, or 11.4%, to $57.6 million in the year ended December 31, 2015, as compared to $65.1 million in the year ended December 31, 2014. 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 $6.8 million unfavorable foreign exchange and $2.2 million decrease in Cardiolite revenues as a result of competitive pressures. This was offset, in part, by $0.6 million in DEFINITY revenues driven by increased volume, $0.6 million

increase in TechneLite revenues driven by volumes and $0.3 million in other marketed products.

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 revenues as a result of higher unit

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volumes, a $6.8 million increase in Neurolite revenues as the product returned to market in September 2013, a $4.5 million increase in Xenon revenues primarily due to higher selling prices, a $1.9 million increase in Thallium revenues driven by higher unit volumes with significant customer and $1.7 million TechneLite revenues 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.

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.

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

(in thousands)	Rebates	Allowances	Total
Balance, as of January 1, 2013	$ 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	2,164	26	2,190
Current provisions relating to revenues in current year	6,413	357	6,770
Adjustments relating to prior years estimate	(84)	(9)	(93)

Payments/credits relating to revenues in current year	(4,784)	(319)	(5,103)
Payments/credits relating to revenues in prior years	(1,406)	(17)	(1,423)
Balance, as of December 31, 2015	$ 2,303	$ 38	$ 2,341

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Sales rebates accrued were approximately $2.3 million and $2.2 million at December 31, 2015 and 2014, respectively. The $0.1 million increase in accrued sales rebates is primarily related to the increase in the rebate reserve associated with the Quadramet product.

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:

	Year ended December 31,			2015 compared to 2014		2014 compared to 2013	
(dollars in thousands)	2015	2014	2013	Change $	Change %	Change $	Change %
United States	$ 106,982	$ 127,237	$ 149,018	$ (20,255)	(15.9)%	$ (21,781)	(14.6)%
International	50,957	48,844	57,293	2,113	4.3	(8,449)	(14.7)
Total Cost of Goods Sold	$ 157,939	$ 176,081	$ 206,311	$ (18,142)	(10.3)%	$ (30,230)	(14.7)%

2015 v. 2014

Total cost of goods sold decreased $18.1 million, or 10.3%, to $157.9 million in the year ended December 31, 2015, as compared to $176.1 million in the year ended December 31, 2014. U.S. segment cost of goods sold decreased approximately $20.3 million, or 15.9%, to $107.0 million in same period, as compared to $127.2 million in the prior year period. The decrease in the U.S. segment cost of goods sold for the year ended December 31, 2015 over the prior year period is primarily due to a decrease of $18.2 million in the cost of goods associated with TechneLite due to lower sales unit volumes. In addition, there was a $2.8 million decrease in Neurolite cost of goods due to lower unit volumes sold and lower technology transfer costs. We also incurred a decrease of $4.8 million in Thallium cost of goods due to lower unit volumes sold. Offsetting these decreases was a $4.5 million increase in DEFINITY cost of goods due to higher sales unit volumes and a $2.7 million increase in Xenon cost of goods due to an increase in material, labor and overhead costs.

For the year ended December 31, 2015, the International segment cost of goods sold increased $2.1 million, or 4.3%, to $51.0 million, as compared to $48.8 million in the prior year period. The increase in the International segment cost of goods sold during the year ended December 31, 2015, as compared to the prior year period, is primarily due to approximately $5.8 million in product cost pricing increases. Partially offsetting these increases was a $3.5 million favorable foreign exchange impact.

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. 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.

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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 a $1.7 million favorable foreign exchange impact.

Gross Profit

	Year ended December 31,			2015 compared to 2014		2014 compared to 2013	
(dollars in thousands)	2015	2014	2013	Change $	Change %	Change $	Change %
United States	$ 128,842	$ 109,283	$ 64,621	$ 19,559	17.9%	$ 44,662	69.1%
International	6,680	16,236	12,740	(9,556)	(58.9)	3,496	27.4
Total Gross Profit	$ 135,522	$ 125,519	$ 77,361	$ 10,003	8.0%	$ 48,158	62.3%

2015 v. 2014

Total gross profit increased $10.0 million, or 8.0%, to $135.5 million, or 46.2% of revenues in the year ended December 31, 2015, as compared to $125.5 million or 41.6% of revenues in the year ended December 31, 2014. U.S. segment gross profit increased $19.6 million, or 17.9%, to $128.8 million, as compared to $109.3 million in the prior year period. The increase in the U.S. segment gross profit for the year ended December 31, 2015 over the prior year period is primarily due to an increased DEFINITY gross profit of $11.3 million due to higher unit volumes and Xenon gross profit increased $9.6 million due to higher selling price. In addition, Thallium gross profit increased by $3.0 million primarily due to a higher average selling price and Neurolite gross profit increased by $1.3 million due to lower technology transfer costs. Offsetting these increases was a decrease in license revenue of $3.7 million as a result of a contract ending in December 2014 that had contained a license fee that was recognized on a straight-line basis over the term of the agreement and a decrease of $2.0 million in TechneLite gross profit due to lower sales unit volumes.

For the year ended December 31, 2015, the International segment gross profit decreased $9.6 million, or 58.9%, to $6.7 million, as compared to $16.2 million in the prior year period. The decrease in the International segment gross profit during the year ended December 31, 2015, as compared to the prior year period is primarily due to $3.3 million unfavorable foreign exchange impact, combined with approximately $5.6 million product cost pricing increases, as well as $0.7 million driven by lower sales volume in certain international markets.

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, TechneLite and Neurolite gross profit due to higher unit volumes and 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.

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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.

Sales and Marketing

	Year ended December 31,			2015 compared to 2014		2014 compared to 2013	
(dollars in thousands)	2015	2014	2013	Change $	Change %	Change $	Change %
United States	$ 31,130	$ 30,815	$ 31,024	$ 315	1.0%	$ (209)	(0.7)%
International	3,610	4,301	4,203	$ (691)	(16.1)	98	2.3
Total Sales and Marketing	$ 34,740	$ 35,116	$ 35,227	$ (376)	(1.1)%	$ (111)	(0.3)%

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.

2015 v. 2014

Total sales and marketing expenses decreased $0.4 million, or 1.1%, to $34.7 million in the year ended December 31, 2015, as compared to $35.1 million in the year ended December 31, 2014. In the U.S. segment, sales and marketing expense increased $0.3 million, or 1%, to $31.1 million in the same period, as compared to $30.8 million in the prior year. The increase in the U.S. segment sales and marketing expenses for the year ended December 31, 2015 over the prior year period is primarily due to increased headcount and related expenses offset, in part, by timing related to marketing research activities as well as lower FDA fees.

For the year ended December 31, 2015, the International segment sales and marketing expense decreased $0.7 million or 16.1%, to $3.6 million as compared to $4.3 million in the prior year period. The decrease in the International segment sales and marketing expenses for the year ended December 31, 2015 over the prior year period is primarily due to lower headcount and foreign exchange impact.

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, 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% and 14.5% for the years ended December 31, 2014 and 2013, 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

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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 foreign exchange impact. As a percentage of total International revenues, sales and marketing expenses in the International segment were 6.6% and 6.0% for the years ended December 31, 2014 and 2013, respectively.

General and Administrative

	Year ended December 31,			2015 compared to 2014		2014 compared to 2013	
(dollars in thousands)	2015	2014	2013	Change $	Change %	Change $	Change %
United States	$ 42,091	$ 35,001	$ 30,742	$ 7,090	20.3%	$ 4,259	13.9%
International	1,803	2,312	2,294	(509)	(22.0)	18	0.8
Total General and Administrative	$ 43,894	$ 37,313	$ 33,036	$ 6,581	17.6%	$ 4,277	12.9%

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.

2015 v. 2014

Total general and administrative expenses increased approximately $6.6 million, or 17.6%, to $43.9 million in the year ended December 31, 2015, as compared to $37.3 million in the year ended December 31, 2014. In the U.S. segment, general and administrative expenses increased $7.1 million, or 20.3%, to $42.1 million, as compared to $35.0 million in the prior year period. The increase was primarily due to the $6.5 million termination fee paid to terminate the advisory services and monitoring agreement with Avista, increased stock compensation costs, increases in insurance associated with the initial public offering in June 2015, higher software amortization expense and an increase in our provision for bad debt. This was offset by higher costs in the prior period due to a $2.4 million write-off of deferred initial public offering costs and $1.0 million higher legal fees related to business interruption claim.

For the year ended December 31, 2015, general and administrative expenses in the International segment decreased approximately $0.5 million, or 22%, to $1.8 million, as compared to $2.3 million in the prior year period. The decrease is primarily due to lower headcount, lower professional fees, lower bad debt expense and foreign exchange impact.

2014 v. 2013

Total general and administrative expenses increased approximately $4.3 million, or 12.9%, to $37.3 million in the year ended December 31, 2014, as compared to $33.0 million in the year ended December 31, 2013. In the U.S. segment, general and administrative expenses increased $4.3 million, or 13.9%, to $35.0 million, as compared to $30.7 million in the prior year period. The increase was primarily due to the write-off of deferred offering costs during

the third quarter of 2014 and 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 and cost savings achieved through the renegotiation of certain information technology related contracts.

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.

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Research and Development

(dollars in thousands)	Year ended December 31, 2015	2014	2013	2015 compared to 2014 Change $	Change %	2014 compared to 2013 Change $	Change %
United States	$ 13,613	$ 13,252	$ 30,138	$ 361	2.7%	$ (16,886)	(56.0)%
International	$ 745	421	321	324	76.9	100	31.2
Total Research and Development	$ 14,358	$ 13,673	$ 30,459	$ 685	5.0%	$ (16,786)	(55.1)%

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.

2015 v. 2014

Total research and development expense increased $0.7 million, or 5.0%, to $14.4 million for the year ended December 31, 2015, as compared to $13.7 million in the year ended December 31, 2014. In the U.S. segment, research and development expense increased approximately $0.4 million, or 2.7%, to $13.6 million, as compared to $13.3 million in the prior year period. The increase in the U.S. segment research and development expenses is primarily due to an increase of depreciation expense as a result of the scheduled decommissioning of certain long-lived assets associated with R&D operations, a gain in the prior year associated with the sale of certain long-lived assets and change in headcount, offset by a reduction in overhead costs associated with the decommissioning of certain long-lived assets.

For the year ended December 31, 2015, the International segment research and development expenses increased approximately $0.3 million, 76.9%, to $0.7 million, as compared to $0.4 million in the prior year period. The increase in research and development expenses for the International segment was primarily due to increased regulatory costs.

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 long-lived assets associated with our research and development operations in the United States. We expected 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 and is included in research and development expenses.

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.

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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 operations. 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, we received $8.9 million from BVL to compensate us for business losses under a 2013 settlement.

Other Income (Expense), Net

	Year ended December 31,			2015 compared to 2014		2014 compared to 2013	
(dollars in thousands)	2015	2014	2013	Change $	Change %	Change $	Change %
Interest expense	$ (38,715)	$ (42,288)	$ (42,915)	$ 3,573	(8.4)%	$ 627	(1.5)%
Interest income	24	27	104	(3)	(11.1)	(77)	(74.0)
Loss on extinguishment of debt	(15,528)			(15,528)	(100.0)		
Other income (expense), net	(89)	478	1,161	(567)	(118.6)	(683)	(58.8)
Total Other Expense, net	$ (54,308)	$ (41,783)	$ (41,650)	$ (12,525)	30.0%	$ (133)	0.3%

Interest Expense

For the year ended December 31, 2015 compared to the same period in 2014, interest expense decreased by 8.4% to $38.7 million from $42.3 million, as a result of the refinancing of long-term debt offset by a $3.3 million interest payment made for interest through the redemption date (July 30, 2015) on the Senior Notes.

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.

Interest Income

For the year ended December 31, 2015, as compared to the same period in 2014, interest income remained consistent.

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.

Extinguishment of Debt

For the year ended December 31, 2015, we incurred a $15.5 million loss on extinguishment of debt related to the redemption of LMI s Notes. For information regarding our loss on extinguishment of debt, see Note 11, Financing Arrangements to our consolidated financial statements.

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Other Income (Expense), net

For the year ended December 31, 2015, as compared to the same period in 2014, other income (expense), net decreased by 118.6% to $(0.1) million from $0.5 million primarily due to a $1.5 million increase in foreign currency losses offset by a $0.9 million increase in tax indemnification income as a result of settlement of state tax audits.

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.

Provision for Income Taxes

	Year ended December 31,			2015 compared to 2014		2014 compared to 2013	
(dollars in thousands)	2015	2014	2013	Change $	Change %	Change $	Change %
Provision for income taxes	$ 2,968	$ 1,195	$ 1,014	$ 1,773	148.4%	$ 181	17.9%

For the year ended December 31, 2015 compared to the same period in 2014, provision for income taxes increased to $3.0 million from $1.2 million. Provision for income taxes increased in 2015 due to settlements and lapse of statute of limitations of uncertain tax positions in the current year.

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

We have generated domestic pre-tax losses for two of the past three years and continue to be in a 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, 2015, 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 2015.

Considering our history of losses, our provision 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. Accordingly, fluctuations in our effective tax rate in recent years are not overly meaningful, or indications of on-going trends. Our effective tax rates for the years ended December 31, 2015, 2014, and 2013 were, 25.2%, 50.5%, and 1.7%, 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, 2015

A $2.5 million increase attributable to uncertain tax positions.

A $0.5 million increase for taxes in foreign and state jurisdictions.

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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 $1.5 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.

Liquidity and Capital Resources

Cash Flows

The following table provides information regarding our cash flows:

	Year Ended December 31,			% Change	
	2015	2014	2013	2015 Compared to 2014	2014 Compared to 2013
	(dollars in thousands)				
Cash provided by (used in):					
Operating activities	$ 21,762	$ 11,590	$ (15,572)	87.8%	174.4%
Investing activities	(13,151)	(7,682)	(3,483)	71.2%	120.6%
Financing activities	999	(2,297)	5,612	143.5%	(140.9)%

Net Cash Provided by (Used in) Operating Activities

Cash provided by operating activities is primarily driven by our earnings and changes in working capital. Cash provided by operating activities during 2015 increased by $10.2 million, which resulted from a decrease in net loss, as adjusted for non-cash items, in the amount of $6.6 million over the prior year and a decrease in cash used for net working capital requirements in the amount of $3.6 million over the prior year. The $6.6 million increase in cash flows from our net loss, as adjusted for non-cash items, was driven by an increased gross profit margin as compared to the prior year. The $3.6 million increase in cash flows from our net working capital requirements was due to decreases in accounts receivable as a result of decreases in certain major customer balances and decreases in accounts payable as a result of the timing of payments. The improvement in cash flows from our net working capital requirements was partially offset by cash flow decreases in inventory due to timing of the receipt of inventory.

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.

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 2015, 2014 and 2013 reflected the purchase of property and equipment for $13.1 million, $8.1 million and $5.0 million, respectively.

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Net Cash Provided by (Used in) Financing Activities

During the year ended December 31, 2015, we generated $421.3 million from the net proceeds of the Term Facility together with the net proceeds from the initial public offering. The net proceeds generated from the Term Facility and the initial public offering were used to repay in full the aggregate principal amount of the $400.0 million Notes, pay related premiums and expenses and pay down the $8.0 million of outstanding borrowings under the Revolving Facility, which totaled $417.8 million. Net cash used in financing activities during 2014 was due to payments made for offering costs. Net cash provided by financing activities during 2013 was associated with an $8.0 million draw against our outstanding Revolving Facility.

Historically, our primary source of cash flows from financing activities is draws against our outstanding Revolving Facility. Going forward, we expect our primary source of cash flows from financing activities to be similar draws against our Revolving Facility, issuances of stock 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 Revolving Facility as well as dividends to our shareholders. See External Sources of Liquidity.

External Sources of Liquidity

On June 30, 2015, we completed our initial public offering, entered into a new $365.0 million seven-year Term Facility and amended and restated our Revolving Facility that has a borrowing capacity of $50.0 million. The net proceeds of the Term Facility and the initial public offering together with available cash were used to repay in full the aggregate principal amount of the $400.0 million Notes, and pay related premiums, interest and expenses and pay down $8.0 million of borrowings under the Revolving Facility.

We have the right to request an increase of the Term Facility in an aggregate amount up to $37.5 million plus additional amounts subject to certain leverage ratios. The term loans under the Term Facility bear interest, with pricing based from time to time at our election at (i) LIBOR plus a spread of 6.00% (with a LIBOR rate floor of 1.00%) or (ii) the Base Rate (as defined in our Term Facility) plus a spread of 5.00%. Interest under term loans based on (i) the LIBOR rate is payable at the end of each interest period (as defined in our Term Facility) and (ii) the Base Rate is payable at the end of each quarter. At December 31, 2015, our interest rate under the Term Facility was 7.00%. Our Term Facility is guaranteed by the Lantheus Holdings and Lantheus Real Estate, and obligations under the Term Facility are secured by substantially all the property and assets and all interests of Lantheus Holdings, LMI and Lantheus Real Estate.

Our Term Facility contains a number of affirmative, negative, reporting and financial covenants, in each case subject to certain exceptions and materiality thresholds. Incremental borrowings under the Revolving Facility may affect our ability to comply with the covenants in the Term Facility, including the financial covenant restricting total net leverage, accordingly, we may be limited in utilizing our net Borrowing Base availability as a source of liquidity. Our Term Facility requires us to be in quarterly compliance, measured on a trailing four quarter basis. The financial covenants are displayed in the table below:

Term Facility Financial Covenants

Period	Total Net Leverage Ratio
Q3 2015 to Q1 2016	6.25 to 1.00
Q2 2016 to Q4 2016	6.00 to 1.00

Q1 2017 to Q2 2017	5.50 to 1.00
Thereafter	5.00 to 1.00

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

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As of December 31, 2015, we had an unfunded Standby Letter of Credit of $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 expired during February 2016. It automatically renewed for a one year period and will continue to 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 Facility is secured by a pledge of substantially all of the assets of LMI, together with the assets of the Company and assets of Lantheus Real Estate, including each such entity s accounts receivable, inventory and machinery and equipment, and is guaranteed by each of Lantheus Holdings 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, 2015, the aggregate Borrowing Base was approximately $48.2 million, which was reduced by an outstanding $8.8 million unfunded Standby Letter of Credit and $0.1 million in accrued interest, resulting in a net borrowing base availability of approximately $39.3 million.

The loans under our Revolving 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 Facility) plus a spread of 1.00%. Our Revolving Facility also includes an unused line fee of 0.375% and expires on June 30, 2020.

Our Revolving Facility contains affirmative and negative covenants, as well as restrictions on the ability of LMI, 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 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 Facility or (y) excess availability under our Revolving Facility falls below (i) the greater of $7.5 million or 15% of the then-current line cap (as defined in the Revolving Facility) for a period of more than five consecutive Business Days or (ii) $5.0 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 Holdings 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.

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;

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revenue mix shifts and associated volume and selling price changes that could result from contractual status changes with key customers and additional competition;

the costs of further commercialization of our existing products, particularly in international markets, including product marketing, sales and distribution and whether we obtain local partners to help share such commercialization costs;

the costs of investing in our facilities, equipment and technology infrastructure;

the costs and timing of establishing manufacturing and supply arrangements for commercial supplies of our products;

the extent to which we acquire or invest in 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 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. 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 the agreements governing our senior secured credit facilities. Additional equity or debt financing, or other transactions, may not be available on acceptable terms, if at all. If any of these transactions require an amendment or waiver under the covenants in the agreements governing our senior secured credit facilities, which could result in additional expenses associated with obtaining the amendment or waiver, we will seek to obtain such a waiver to remain in compliance with those covenants. However, we cannot be assured that such an amendment or waiver would be granted, or that additional capital will be available on acceptable terms, if at all.

At December 31, 2015, our only current committed external source of funds is our borrowing availability under our Revolving Facility. We generated a net loss of $14.7 million during the year ended December 31, 2015 and had $28.6

million of cash and cash equivalents at December 31, 2015. Availability under our Revolving 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. Our new Term Facility contains a number of affirmative, negative, reporting and financial covenants, in each case subject to certain exceptions and materiality thresholds. Incremental borrowings under the Revolving Facility may affect our ability to comply with the covenants in the Term Facility, including the financial covenant restricting total net leverage. Accordingly, we may be limited in utilizing our net Borrowing Base availability as a source of liquidity.

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

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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, 2015:

		Payments Due by Period			
	Total	Less than 1 Year	1 - 3 Years	3 -5 Years	More than 5 Years
		(dollars in thousands)			
Debt obligations (principal)	$ 363,175	$ 3,650	$ 7,300	$ 7,300	$ 344,925
Interest on debt obligations(4)	160,054	25,326	49,886	48,864	35,978
Operating leases(1)	2,787	481	758	665	883
Other long-term liabilities(2)					
Asset retirement obligations(3)					
Total contractual obligations	$ 526,016	$ 29,457	$ 57,944	$ 56,829	$ 381,786

(1) Operating leases include minimum payments under leases for our facilities and certain equipment.
(2) Our other long-term liabilities in the consolidated balance sheet include unrecognized tax benefits and related interest and penalties. As of December 31, 2015, we had unrecognized tax benefits of $33.8 million, which included interest and penalties, classified as noncurrent liabilities. At this time, we are unable to make a reasonably reliable estimate of the timing of payments in individual years in connection with these tax liabilities; therefore, such amounts are not included in the above contractual obligation table.
(3) We have excluded asset retirement obligations from the table above due to the uncertainty of the timing of the future cash outflows related to the decommissioning of our radioactive operations. As of December 31, 2015, the liability, which was approximately $8.1 million, was measured at the present value of the obligation expected to be incurred, of approximately $26.6 million.
(4) Amount relates to the minimum interest under the Term Facility.

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 affect on our financial condition, results of operations and cash flows.

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Recent Accounting Standards

We have elected to opt out of the extended transition period for complying with new and revised accounting standards pursuant to Section 107 of the JOBS Act, and the election is irrevocable.

In May 2014, the FASB issued ASU 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. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606), Deferral of the Effective Date*, which defers the effective date of ASU 2014-09 to annual reporting periods beginning after December 15, 2017 with early adoption permitted as of its original effective date of December 15, 2016. The new guidance requires either a retrospective or a modified retrospective approach to adoption. We are currently evaluating the impact this ASU will have on our financial position, results of operations and cash flows.

In August 2014, the FASB issued ASU 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 U.S. 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 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 2015, 2014 and 2013, these changes in estimates were not material to our results.

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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.

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 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 2015, 2014 and 2013 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.

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

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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, which are held for sale, are recorded at the lower of the carrying value or the fair market value less the estimated cost to sell.

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 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 operations in the fourth quarter of 2013.

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.

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. Fixed assets dedicated to R&D activities, which were impacted by the March 2013 R&D strategic shift, have a carrying value of $4.6 million as of December 31, 2015. 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.

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.

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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 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 operations, 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

As a result of our new Term Facility, we have substantial variable rate debt. Fluctuations in interest rates may affect our business, financial condition, results of operations and cash flows. As of December 31, 2015, we had $363.2 million outstanding under our Term Facility with a variable interest rate that only varies to the extent LIBOR exceeds one percent.

Furthermore, we are subject to interest rate risk in connection with the Revolving Facility, which is variable rate indebtedness. Interest rate changes could increase the amount of our interest payments and thus negatively

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impact our future earnings and cash flows. As of December 31, 2015, there was an $8.8 million unfunded Standby Letter of Credit and $0.1 million accrued interest, which reduced availability to $39.3 million on the Revolving Facility. Any increase in the interest rate under the Revolving Facility may have a negative impact on our future earnings to the extent we have outstanding borrowings under the Revolving Facility. The effect of a 100 basis points adverse change in market interest rates, in excess of applicable minimum floors, on our interest expense would be approximately $1.9 million.

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, 2015, 2014 and 2013, the net impact of foreign currency changes on transactions was a loss of $1.8 million, $279,000 and $349,000, respectively. Historically, we have not used derivative financial instruments or other financial instruments to hedge these economic exposures.

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. The cost of goods for our products that are manufactured in the United States and are sold in currencies other than the U.S. Dollar by our foreign subsidiaries are also affected by foreign currency exchange rate movements. Our cost of goods would have increased by $2.0 million if the U.S. Dollar had been stronger by 10% when compared to the actual rates used during 2015.

If the U.S. Dollar had been uniformly stronger by 10%, compared to the actual average exchange rates, our revenues would have decreased by $3.8 million and our net loss would have increased by $1.1 million for the year ended December 31, 2015.

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Item 8. Financial Statements and Supplementary Data

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Lantheus Holdings, Inc.

North Billerica, Massachusetts

We have audited the accompanying consolidated balance sheets of Lantheus Holdings, Inc. and subsidiaries (the Company) as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, stockholders deficit, and cash flows for each of the three years in the period ended December 31, 2015. 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 Holdings, Inc. and subsidiaries as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 2, 2016

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Lantheus Holdings, Inc. and subsidiaries

Consolidated Balance Sheets

(in thousands, except per share data)	December 31, 2015	December 31, 2014
Assets		
Current assets		
Cash and cash equivalents	$ 28,596	$ 19,739
Accounts receivable, net	37,293	41,540
Inventory	15,622	15,582
Other current assets	3,946	4,374
Assets held for sale	4,644	
Total current assets	90,101	81,235
Property, plant and equipment, net	86,517	96,014
Capitalized software development costs, net	9,137	2,421
Intangibles, net	20,496	27,191
Goodwill	15,714	15,714
Other long-term assets	20,414	20,578
Total assets	$ 242,379	$ 243,153
Liabilities and Stockholders Deficit		
Current liabilities		
Current portion of long-term debt	$ 3,650	$
Line of credit		8,000
Accounts payable	11,657	15,665
Accrued expenses and other liabilities	18,696	24,863
Liabilities held for sale	1,715	
Total current liabilities	35,718	48,528
Asset retirement obligations	8,145	7,435
Long-term debt, net	349,858	392,863
Other long-term liabilities	33,947	33,597
Total liabilities	427,668	482,423
Commitments and contingencies (see Notes 16 and 18)		
Stockholders deficit		
Preferred stock ($0.01 par value, 25,000,000 shares authorized; no share issued and outstanding)		
Common stock ($0.01 par value, 250,000,000 shares authorized; 30,364,501 and 18,080,944, shares issued; 30,364,501 and 18,075,907 shares outstanding)	303	181
Treasury stock		(106)
Additional paid-in capital	175,553	106,699

Accumulated deficit	(359,160)	(344,414)
Accumulated other comprehensive loss	(1,985)	(1,630)
Total stockholders deficit	(185,289)	(239,270)
Total liabilities and stockholders deficit	$ 242,379	$ 243,153

See notes to consolidated financial statements.

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Lantheus Holdings, Inc. and subsidiaries

Consolidated Statements of Operations

(in thousands, except per share data)	Year Ended December 31, 2015	2014	2013
Revenues	$ 293,461	$ 301,600	$ 283,672
Cost of goods sold	157,939	176,081	206,311
Gross profit	135,522	125,519	77,361
Operating expenses			
Sales and marketing expenses	34,740	35,116	35,227
General and administrative expenses	43,894	37,313	33,036
Research and development expenses	14,358	13,673	30,459
Proceeds from manufacturer			(8,876)
Impairment on land			6,406
Total operating expenses	92,992	86,102	96,252
Operating income (loss)	42,530	39,417	(18,891)
Interest expense	(38,715)	(42,288)	(42,915)
Interest income	24	27	104
Loss on extinguishment of debt	(15,528)		
Other income (expense), net	(89)	478	1,161
Loss before income taxes	(11,778)	(2,366)	(60,541)
Provision for income taxes	2,968	1,195	1,014
Net loss	(14,746)	(3,561)	(61,555)
Net loss per common share:			
Basic and diluted	$ (0.60)	$ (0.20)	$ (3.42)
Weighted average common shares:			
Basic and diluted	24,439,845	18,080,615	18,032,131

See notes to consolidated financial statements.

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Lantheus Holdings, Inc. and subsidiaries

Consolidated Statements of Comprehensive Loss

	Year Ended December 31,		
(in thousands)	**2015**	**2014**	**2013**
Net loss	$ (14,746)	$ (3,561)	$ (61,555)
Foreign currency translation	(355)	(1,236)	(1,729)
Total comprehensive loss	$ (15,101)	$ (4,797)	$ (63,284)

See notes to consolidated financial statements.

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Lantheus Holdings, Inc. and subsidiaries

Consolidated Statements of Stockholders Deficit

(in thousands, except share data)

	Common Stock		Treasury Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders Deficit
	Shares	Amount	Shares	Amount				
Balance at January 1, 2013	17,894,386	$ 179			$ 104,679	$ (279,298)	$ 1,335	$ (173,105)
Repurchase of common stock			(5,037)	(106)				(106)
Net share option exercise	163,406	2			(2)			
Net loss						(61,555)		(61,555)
Issuance of Common Stock	20,933				400			400
Other comprehensive loss							(1,729)	(1,729)
Stock-based compensation					578			578
Balance at December 31, 2013	18,078,725	181	(5,037)	(106)	105,655	(340,853)	(394)	(235,517)
Net share option exercise	2,219				13			13
Net loss						(3,561)		(3,561)
Other comprehensive loss							(1,236)	(1,236)
Stock-based compensation					1,031			1,031
Balance at December 31, 2014	18,080,944	181	(5,037)	(106)	106,699	(344,414)	(1,630)	(239,270)
Issuance of common stock from initial public offering, net of $6,362 issuance costs	12,256,577	122			67,055			67,177
Treasury stock retired			5,037	106	(106)			
Net loss						(14,746)		(14,746)
Other comprehensive loss							(355)	(355)

Issuance of common stock	40,000					
Shares withheld to cover taxes	(13,020)		(97)			(97)
Stock-based compensation			2,002			2,002
Balance at December 31, 2015	30,364,501	$ 303	$ 175,553	$ (359,160)	$ (1,985)	$ (185,289)

See notes to consolidated financial statements.

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Lantheus Holdings, Inc. and subsidiaries

Consolidated Statements of Cash Flows

	Year ended December 31,		
(in thousands)	**2015**	**2014**	**2013**
Cash flow from operating activities			
Net loss	$ (14,746)	$ (3,561)	$ (61,555)
Adjustments to reconcile net loss to cash flow from operating activities			
Depreciation, amortization and accretion	19,651	19,024	25,783
Impairment of land			6,406
Impairment of intangible assets			17,175
Amortization of debt related costs	2,431	2,708	2,600
Write-off of deferred offering and financing costs	236	2,392	598
Provision for bad debt	773	303	63
Provision for excess and obsolete inventory	1,359	1,593	4,854
Stock-based compensation	2,002	1,031	578
Loss on extinguishment of debt	15,528		
Other	1,894	(215)	(237)
Long-term income tax receivable	230	2,719	(566)
Long-term income tax payable and other long-term liabilities	638	(2,560)	187
Increase (decrease) in cash from operating assets and liabilities			
Accounts receivable, net	(14)	(3,563)	2,627
Inventory	(2,609)	1,500	(4,741)
Other current assets	(132)	(865)	1,026
Accounts payable	(1,680)	(4,047)	(1,147)
Income taxes	187	68	410
Accrued expenses and other liabilities	(3,986)	(4,937)	(9,633)
Cash provided by (used in) operating activities	21,762	11,590	(15,572)
Cash flows from investing activities			
Capital expenditures	(13,151)	(8,137)	(5,010)
Proceeds from sale of property, plant and equipment		227	1,527
Redemption of certificate of deposit restricted		228	
Cash used in investing activities	(13,151)	(7,682)	(3,483)
Cash flows from financing activities			
Proceeds from issuance of common stock in initial public offering	73,539		
Payments for initial public offering costs	(6,362)		
Proceeds from issuance of long-term debt	360,438		
Payments on long-term debt	(1,900)	(71)	(1,310)
Payments on senior notes	(400,000)		
Payment for call premium on senior notes	(9,752)		
Payments for offering costs	(563)	(2,064)	

Deferred financing costs	(6,304)	(175)	(1,249)
Proceeds from line of credit		5,500	8,000
Payments on line of credit	(8,000)	(5,500)	
Proceeds from issuance of common stock, other		13	400
Payments for common stock repurchase			(106)
Payments for tax withholding related to net share settlement of equity awards	(97)		
Payments of dividend			(123)
Cash provided by (used in) financing activities	999	(2,297)	5,612
Effect of foreign exchange rate on cash	(753)	(450)	(1,300)
Increase (decrease) in cash and cash equivalents	8,857	1,161	(14,743)
Cash and cash equivalents, beginning of year	19,739	18,578	33,321
Cash and cash equivalents, end of year	$ 28,596	$ 19,739	$ 18,578
Supplemental disclosure of cash flow information			
Interest paid	$ 40,788	$ 39,214	$ 39,150
Income taxes paid, net	$ 174	$ 508	$ 118
Noncash investing and financing activities			
Property, plant and equipment included in accounts payable and accrued expenses and other liabilities	$ 1,125	$ 2,916	$ 1,243
Deferred offering cost included in accounts payable and accrued expenses and other liabilities	$	$ 132	$

See notes to consolidated financial statements

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Lantheus Holdings, Inc. and subsidiaries

Notes to Consolidated Financial Statements

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

1. Description of Business

Overview

Holdings, a Delaware corporation, is the parent company of LMI, also a Delaware corporation.

The Company develops, manufactures and commercializes innovative diagnostic medical imaging agents and products that assist clinicians in the diagnosis and treatment of cardiovascular and other diseases. The Company s commercial products are used by cardiologists, nuclear physicians, 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, Canada, Puerto Rico 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 contrast agents and medical radiopharmaceuticals (including technetium generators), 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.

TechneLite 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, or Xenon, is a radiopharmaceutical gas that is inhaled and used to assess pulmonary function and also cerebral 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 commercial radiopharmacies owned or controlled by third parties. In Puerto Rico and Australia, the Company owns three radiopharmacies and sells

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its own radiopharmaceuticals, as well as others, directly to end users. In Canada, 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 $14.7 million during the year ended December 31, 2015 and had an accumulated deficit of $359.2 million at December 31, 2015.

On June 25, 2015, in conjunction with its initial public offering, or IPO, the Company effected a corporate reorganization, whereby Lantheus MI Intermediate, Inc. (formerly the direct parent of LMI and the direct subsidiary of Holdings) was merged with and into Holdings, or the Merger.

On June 30, 2015, the Company completed an IPO of its common stock at a price to the public of $6.00 per share. The Company s common stock is now traded on the NASDAQ under the symbol LNTH . The Company issued and sold 12,256,577 shares of common stock in the IPO, including 1,423,243 shares that were offered and sold pursuant to the underwriters exercise in full of their overallotment option. The IPO resulted in proceeds to the Company of approximately $67.2 million, after deducting $6.4 million in underwriting discounts, commissions and related expenses.

On June 30, 2015, the Company also entered into a $365.0 million senior secured term loan facility, or the Term Facility. The net proceeds of the Term Facility, together with the net proceeds from the IPO and cash on hand of $10.9 million were used to repay in full the aggregate principal amount of LMI s $400.0 million 9.750% Senior Notes due 2017, or the Notes, pay related premiums, interest and expenses and pay down the $8.0 million of outstanding borrowings under LMI s $50.0 million revolving credit facility, or the Revolving Facility.

The Company currently relies on Jubilant HollisterStier, or 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, which is currently approved for manufacture by a single manufacturer. In addition, the Company has ongoing technology transfer activities at Pharmalucence for the manufacture and supply of DEFINITY.

The Company has historically been dependent on key customers and group purchasing organizations for the majority of the sales of its medical imaging products. The Company s 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 Cardinal Health, or Cardinal, relating to TechneLite, Xenon, Neurolite, Cardiolite and certain other products expired in accordance with contract terms on December 31, 2014. Following extended discussions with Cardinal, on November 19, 2015, the Company entered into a new contract for the distribution of TechneLite, Xenon, Neurolite and other products beginning in 2015 through 2017. The agreement specifies pricing levels and requirements to purchase minimum volumes of certain products

during certain periods. The agreement, which expires on December 31, 2017, may be terminated upon the occurrence of specified events, including a material breach by the other party and certain force majeure events. From January 1, 2015 until the signing of the new agreement on November 19, 2015, the Company continued to accept and fulfill product orders from Cardinal on a purchase order basis at supply price.

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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 utilized its Revolving Facility as a source of liquidity from time to time. Borrowing capacity under the Revolving Facility is calculated by reference to a borrowing base consisting of a percentage of certain eligible accounts receivable, inventory and machinery and 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, 2015, the aggregate Borrowing Base was approximately $48.2 million, which was reduced by the $8.8 million unfunded Standby Letter of Credit and

$0.1 million in accrued interest, resulting in a net Borrowing Base availability of approximately $39.3 million. The Company s new Term Facility contains a number of affirmative, negative, reporting and financial covenants, in each case subject to certain exceptions and materiality thresholds. Incremental borrowings under the Revolving Facility may affect the Company s ability to comply with the covenants in the Term Facility, including the financial covenant restricting total net leverage. Accordingly, the Company may be limited in utilizing its net Borrowing Base availability as a source of liquidity.

Based on the Company s current operating plans, the Company believes its existing cash and cash equivalents, results of operations and availability under the Revolving 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, asset retirement obligations, income tax liabilities and related indemnification receivable, deferred tax assets and liabilities and accrued expenses. Actual results could materially differ from those estimates or assumptions.

Stock Split

In conjunction with the Merger, the Company effected a 0.355872-for-1 reverse stock split for its common stock. Upon consummation of the Merger, the par value of the common stock changed from $0.001 to $0.01. Accordingly, all references to share and per share information in the consolidated financial statements have been adjusted to reflect the stock split and new par value for all periods presented.

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.

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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.

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 $2.3 million and $2.2 million at December 31, 2015 and 2014, respectively. Rebate and allowance charges against gross revenues totaled $5.9 million, $5.2 million and $4.8 million for the years ended December 31, 2015, 2014 and 2013, respectively.

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

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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 classifies interest and penalties within the provision for income taxes.

Loss per Share

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

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, 2015 and 2014, the Company had allowances for doubtful accounts of approximately $0.9 million and $0.6 million, respectively.

Also included in accounts receivable are miscellaneous receivables of approximately $1.0 million and $2.0 million as of December 31, 2015 and 2014, respectively.

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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 three customers that represented greater than 10% of the total net accounts receivable balance at either December 31, 2015 or 2014. The same three customers contributed revenues of 12%, 11% and 10% during the year ended December 31, 2015, which is included in the U.S. segment. No other customers contributed more than 10% of revenue in any of the years ended December 31, 2015, 2014 and 2013.

	Accounts Receivable as of December 31,		Revenue for the year ended December 31,		
	2015	2014	2015	2014	2013
Company A	5.8%	16.5%	11.3%	18.0%	18.8%
Company B	12.9%	13.4%	11.9%	11.1%	10.2%
Company C	10.3%	9.8%	9.7%	8.8%	9.8%

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. The Company has agreements with Nordion and NTP/ANSTO, the Company s Moly suppliers, with an expiration dates of October 31, 2016 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, or IRE, who had previously been supplying the Company with Moly under the previous agreement with NTP, and this agreement expires on December 31, 2017. In January 2015, the Company 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.

The Company currently relies on JHS as its sole source manufacturer of DEFINITY, Neurolite and evacuation vials. 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 approved for manufacture by a single manufacturer.

Based on current projections, the Company believes that it will have sufficient supply of DEFINITY, Neurolite and evacuation vials from JHS to meet expected demand and sufficient Cardiolite product supply and saline from the Company s current suppliers to meet expected demand.

The Company is 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.

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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, 2015, 2014 and 2013.

	Year Ended December 31,		
	2015	2014	2013
DEFINITY	38.1%	31.8%	27.5%
TechneLite	24.7%	31.0%	32.5%
Xenon	16.7%	12.1%	11.3%

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, 2015, the Company expensed $0.6 million of such product costs in cost of goods sold relating to Cardiolite that was manufactured by JHS. 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, 2015 and 2014, the Company had no capitalized inventories associated with product that did not have regulatory approval.

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 operations.

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

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projects that are not significant are expensed as incurred. Capitalized software development costs, net of accumulated amortization, were $9.1 million and $2.4 million at December 31, 2015 and 2014, respectively. Amortization expense related to the capitalized software was $1.1 million, $0.7 million and $1.5 million for the years ended December 31, 2015, 2014 and 2013, respectively. Future amortization expense for all capitalized software placed in service as of December 31, 2015 is estimated to be $2.2 million, $2.0 million, $2.0 million, $1.7 million and $1.2 million for the years ending December 31, 2016, 2017, 2018, 2019 and 2020, 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 2015 and 2014, 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.

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 2015, 2014 and 2013 and determined that at each of those periods, the Company s fair value was substantially in excess of its carrying value.

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

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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.

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 was 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 operations 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 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 operations.

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 operations. During the fourth quarter of 2013, the Company sold the excess land for net proceeds of $1.1 million.

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. Fixed assets dedicated to R&D activities, which were impacted by the March 2013 R&D strategic shift, have a carrying value of $4.6 million as of December 31, 2015. 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.

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.

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Deferred Financing Costs

During 2015, the Company early adopted ASU No. 2015-03, *Interest Imputation of Interest (Topic 835): Simplifying the Presentation of Debt Issuance Costs,* or ASU 2015-03. Adoption of this standard has resulted in the reclassification of $5.5 million and $6.4 million from other long-term assets to long-term debt, net on the balance sheet at December 31, 2015 and 2014, respectively. Deferred financing costs related to the Revolving Facility of $1.1 million and $0.9 million are presented in other long-term assets at December 31, 2015 and 2014, respectively. Deferred financing costs are amortized to interest expense using the effective interest rate method. The expense associated with the amortization of deferred financing costs was $1.9 million, $2.5 million and $2.4 million for the years ended December 31, 2015, 2014 and 2013, respectively. In connection with the redemption of the Notes, the Company wrote off $5.8 million of existing unamortized debt issuance costs, which is included in loss on extinguishment of debt in the accompanying consolidated statements of operations during the year ended December 31, 2015. 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 operations.

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 Company s Term Facility at December 31, 2015, approximates carrying value because the interest rate is subject to change with market interest rates. 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.

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 $17.4 million, $19.4 million and $20.5 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Advertising and Promotion Costs

Advertising and promotion costs are expensed as incurred and totaled $3.1 million, $2.8 million and $2.7 million for the years ended December 31, 2015, 2014 and 2013, 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.

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Foreign Currency

The consolidated statements of operations 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 accumulated other comprehensive loss.

For the years ended December 31, 2015, 2014 and 2013, losses arising from foreign currency transactions totaled approximately $1.8 million, $0.3 million and $0.3 million, respectively. Transaction gains and losses are reported as a component of other income (expense), net.

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, 2015 and 2014 were $8.1 million and $7.4 million, respectively.

Self Insurance Reserves

The Company s consolidated balance sheet at both December 31, 2015 and 2014 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

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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 at both December 31, 2015 and 2014, and is included in other current assets.

Recent Accounting Standards

In May 2014, the FASB issued ASU 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. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606), Deferral of the Effective Date*, which defers the effective date of ASU 2014-09 to annual reporting periods beginning after December 15, 2017 with early adoption permitted as of its original effective date of December 15, 2016. The new guidance requires either a retrospective or a modified retrospective approach to adoption. The Company is currently evaluating the impact this ASU will have on our financial position, results of operations, cash flows, and disclosures.

In August 2014, the FASB issued ASU 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 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, 2015 and 2014, 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).

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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, 2015 and 2014:

(in thousands)	Total fair value at December 31, 2015	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Money market	$ 1,586	$ 1,586	$	$
Certificates of deposit restricted	74		74	
	$ 1,660	$ 1,586	$ 74	$

(in thousands)	Total fair value at December 31, 2014	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Money market	$ 2,737	$ 2,737	$	$
Certificates of deposit restricted	89		89	
	$ 2,826	$ 2,737	$ 89	$

At both December 31, 2015 and December 31, 2014, the Company has a $0.1 million certificate of deposit which 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, 2015, the Company had total cash and cash equivalents of $28.6 million, which included approximately $1.6 million of money market funds and $27.0 million of cash on-hand. At December 31, 2014, the Company had total cash and cash equivalents of $19.7 million, which included approximately $2.7 million of money market funds and $17.0 million of cash on-hand.

4. Income Taxes

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

(in thousands)	2015	2014	2013
United States	$ (2,670)	$ 2,201	$ (57,970)
International	(9,108)	(4,567)	(2,571)

	$ (11,778)	$ (2,366)	$ (60,541)

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The provision for income taxes as of December 31 was:

(in thousands)	2015	2014	2013
Current			
Federal	$ 265	$ (208)	$ (782)
State	2,386	1,285	1,712
International	218	325	356
	2,869	1,402	1,286
Deferred			
Federal		(277)	
State			
International	99	70	(272)
	99	(207)	(272)
	$ 2,968	$ 1,195	$ 1,014

The Company s provision for income taxes in the years ended December 31, 2015, 2014 and 2013 was different from the amount computed by applying the statutory U.S. Federal income tax rate to loss from operations before income taxes, as a result of the following:

(in thousands)	2015	2014	2013
U.S. statutory rate	$ (4,122)	$ (828)	$ (21,181)
Permanent items and foreign tax credits	(476)	149	292
Uncertain tax positions	2,523	817	809
Research credits	(120)	(1,204)	(1,346)
State and local taxes	478	234	(1,780)
Impact of rate change on deferred taxes	749	61	31
True-up of prior year tax	1,191	1,065	(1,465)
Foreign tax rate differential	46	437	92
Valuation allowance	2,704	958	25,631
Tax on repatriation		(500)	(18)
Other	(5)	6	(51)
	$ 2,968	$ 1,195	$ 1,014

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

(in thousands)	2015	2014
Deferred Tax Assets		

Federal benefit of state tax liabilities	$ 11,112	$ 10,950
Reserves, accruals and other	30,564	38,285
Capitalized research and development	22,431	26,471
Amortization of intangibles other than goodwill	20,553	36,523
Net operating loss carryforwards	72,416	46,843
Depreciation	2,301	
Deferred tax assets	159,377	159,072
Deferred Tax Liabilities		
Reserves, accruals and other	(399)	(642)
Customer relationships	(4,558)	(6,012)
Depreciation		(95)
Deferred tax liability	(4,957)	(6,749)
Less: Valuation allowance	(154,252)	(152,138)
	$ 168	$ 185

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(in thousands)	2015	2014
Recorded in the accompanying consolidated balance sheet as:		
Current deferred tax assets	$ 95	$ 256
Current deferred tax liabilities	(194)	(152)
Noncurrent deferred tax assets	320	328
Noncurrent deferred tax liability	(53)	(247)

The Company files separate federal income tax returns for Lantheus Holdings and its subsidiaries.

A reconciliation of the Company s changes in uncertain tax positions for 2015, 2014 and 2013 is as follows:

(in thousands)	
Beginning balance of uncertain tax positions as of January 1, 2013	$ 14,781
Additions related to current year tax positions	18
Reductions related to prior year tax positions	
Settlements	(34)
Lapse of statute of limitations	(763)
Balance of uncertain tax positions as of December 31, 2013	14,002
Additions related to current year tax positions	
Reductions related to prior year tax positions	(8)
Settlements	(1,434)
Lapse of statute of limitations	(416)
Balance of uncertain tax positions as of December 31, 2014	12,144
Additions related to current year tax positions	
Reductions related to prior year tax positions	
Settlements	(694)
Lapse of statute of limitations	
Balance of uncertain tax positions as of December 31, 2015	$ 11,450

As of December 31, 2015 and 2014, the total amount of unrecognized tax benefits was $11.5 million and $12.1 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 $0.6 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, 2015.

As of December 31, 2015 and 2014, total liabilities for tax obligations and associated interest and penalties were $33.8 million and $33.2 million, respectively, consisting of income tax provisions for uncertain tax benefits of $11.7 million and $12.4 million, interest accruals of $19.9 million and $18.6 million, respectively, and penalty accruals of $2.2 million, which were included in other long-term liabilities on the consolidated balance sheets. Included in the 2015,

2014 and 2013 tax provision is $2.5 million, $1.2 million and $1.9 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

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obligation. The tax indemnification receivable is recognized within other noncurrent assets. The total noncurrent asset related to the indemnification was $17.6 million and $17.8 million at December 31, 2015 and 2014, respectively. The changes in the tax indemnification asset are recognized within other income (expense), net in the consolidated statement of operations. In accordance with the Company s accounting policy, the change in the tax liability and penalties and interest associated with these obligations (net of any offsetting federal or state benefit) is recognized within 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, 2015 and 2014, BMS, on behalf of the Company, made payments totaling $1.9 million and $6.3 million, respectively to a number of states in connection with prior year state income tax filings. The amount due from BMS, included within other long-term assets, decreased by $1.6 million and $2.9 million for the year ended December 31, 2015 and 2014, 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 years ended December 31, 2015 and 2014, is an expense of $0.4 million and $1.1 million, respectively, relating to the reduction in the indemnification receivable from BMS associated with the expiration of statute of limitations and income of $2.1 million and $1.9 million at December 31, 2015 and 2014, respectively, 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, 2015, 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 $154.3 million and $152.1 million at December 31, 2015 and 2014, respectively.

The following is a reconciliation of the Company s valuation allowance for the years ended December 31, 2015, 2014, and 2013.

(in thousands)	
Balance at January 1, 2013	$ 125,782
Charged to provision for income taxes	25,557
Deductions	
Balance at December 31, 2013	151,339
Charged to provision for income taxes	958
Foreign currency	(159)
Deductions	
Balance at December 31, 2014	152,138
Charged to provision for income taxes	2,704

Foreign currency	(590)
Deductions	
Balance at December 31, 2015	$ 154,252

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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, 2015, the Company has federal net operating loss carryovers of $175.5 million, which will begin to expire in 2031 and completely expire in 2034. The Company has $2.4 million of federal research credits, which begin to expire in 2029. The Company has foreign tax credits of approximately $4.4 million that will begin to expire in 2020. The Company has state research credits of $1.8 million, which will expire between 2024 and 2029. The Company has Massachusetts investment tax credits of approximately $0.3 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 immaterial in 2015.

5. Assets Held for Sale

During the fourth quarter of 2015, the Company committed to a plan to sell certain assets and liabilities associated with the Company s international business. This event qualified for held for sale accounting and the Company has determined that the fair value of the net assets being sold significantly exceeds the carrying value as of December 31, 2015. The transaction was finalized in the first quarter of 2016.

Effective January 7, 2016, the Canadian subsidiary of the Company, entered into an asset purchase agreement, the Purchase Agreement, pursuant to which it would sell substantially all of the assets of its Canadian radiopharmacies and Gludef manufacturing and distribution business to one of its existing Canadian radiopharmacy customers.

The purchase price for the asset sale was $9.0 million in cash, which is subject to certain working capital adjustment calculations. The Purchase Agreement contained customary representations, warranties and covenants by each of the parties. Subject to certain limitations, the buyer will be indemnified for damages resulting from breaches or inaccuracies of the Company s representations, warranties and covenants in the Purchase Agreement.

As part of the transaction, the Company and the buyer also entered into a customary transition services agreement and a long-term supply contract under which the Company will supply the buyer with the Company s products on commercial terms and under which the buyer has agreed to certain product purchase commitments.

The Company does not believe the sale of certain net assets in the international business constitute a strategic shift that would have a major effect on its operations or financial results. As a result, this transaction has not been classified as discontinued operations in the Company s financial statements and has been classified as assets and liabilities held for sale as of December 31, 2015.

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The following table summarizes the major classes of assets and liabilities classified as held for sale as of December 31, 2015.

(in thousands)	
Current Assets:	
Accounts receivable, net	$ 2,512
Inventory	806
Other current assets	26
Total current assets	3,344
Non-Current Assets:	
Property, plant and equipment, net	791
Intangibles, net	480
Other long-term assets	29
Total assets held for sale	$ 4,644
Current Liabilities:	
Accounts payable	$ 430
Accrued expense and other liabilities	1,285
Total liabilities held for sale	$ 1,715

6. 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:

(in thousands)	December 31, 2015	December 31, 2014
Raw materials	$ 7,506	$ 6,043
Work in process	2,407	1,788
Finished goods	5,709	7,751
Inventory	15,622	15,582
Other long-term assets	1,156	1,156
Total	$ 16,778	$ 16,738

At both December 31, 2015 and 2014, inventories reported as other long-term assets included $1.2 million of raw materials, respectively.

7. Property, Plant and Equipment, net

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

(in thousands)	2015	2014
Land	$ 14,950	$ 14,950
Buildings	68,941	67,571
Machinery, equipment and fixtures	60,787	65,179
Construction in progress	9,099	9,746
Accumulated depreciation	(67,260)	(61,432)
Property, plant and equipment, net	$ 86,517	$ 96,014

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Depreciation expense related to property, plant and equipment was $11.8 million, $9.9 million and $9.3 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Included within machinery, equipment and fixtures are spare parts of approximately $2.4 million and $2.5 million as of December 31, 2015 and 2014, 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. During the years ended December 31, 2015 and 2014, $7.9 million and $1.7 million, respectively, of capitalized software development costs were placed into service and removed out of construction in progress.

8. 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, 2015, the liability is measured at the present value of the obligation expected to be incurred, of approximately $26.6 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.

The following is a reconciliation of the Company s asset retirement obligations for the years ended December 31, 2015, 2014 and 2013:

(in thousands)	
Balance at January 1, 2013	$ 5,416
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	7,435
Net decrease due to changes in estimated future cash flows	(37)
Accretion expense	747
Balance at December 31, 2015	$ 8,145

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9. Intangibles, net

Intangibles, net consisted of the following:

	December 31, 2015			
(in thousands)	**Cost**	**Accumulated amortization**	**Net**	**Amortization Method**
Trademarks	$ 13,540	$ 6,934	$ 6,606	Straight-line
Customer relationships	100,737	88,564	12,173	Accelerated
Other patents	42,780	41,063	1,717	Straight-line
	$ 157,057	$ 136,561	$ 20,496	

	December 31, 2014			
(in thousands)	**Cost**	**Accumulated amortization**	**Net**	**Amortization Method**
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
	$ 161,693	$ 134,502	$ 27,191	

The Company recorded amortization expense for its intangible assets of $6.0 million, $7.6 million and $14.4 million for the years ended December 31, 2015, 2014 and 2013, respectively.

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

Years ended December 31,	
2016	$ 5,165
2017	3,386
2018	2,683
2019	1,832
2020	1,592
2021 and thereafter	5,838
	$ 20,496

Changes in the gross carrying amount of intangible assets for the year ended December 31, 2015 and 2014, were as follows (in thousands):

(in thousands)	
Balance at December 31, 2013	$ 162,618
Effect of currency translation	(925)
Balance at December 31, 2014	161,693
Intangible assets held for sale	(3,188)
Effect of currency translation	(1,448)
Balance at December 31, 2015	$ 157,057

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10. Accrued Expenses and Other Liabilities

Accrued expenses are comprised of the following at December 31:

(in thousands)	2015	2014
Compensation and benefits	$ 10,525	$ 11,198
Accrued interest	94	4,994
Accrued professional fees	1,493	1,508
Research and development services	360	248
Freight, distribution and operations	2,962	3,069
Marketing expense	490	978
Accrued rebates, discounts and chargebacks	2,085	2,164
Other	687	704
	$ 18,696	$ 24,863

11. Financing Arrangements

Term Facility

On June 30, 2015, LMI entered into a new $365.0 million seven-year Term Facility, which was issued net of a 1.25% discount of $4.6 million. LMI has a right to request an increase of the Term Facility in an aggregate amount up to $37.5 million plus additional amounts subject to certain leverage ratios. The net proceeds of the Term Facility, together with the net proceeds of the IPO and cash on hand, were used to refinance in full the aggregate principal amount of the Notes and pay related premiums, interest and expenses.

The term loans under the Term Facility bear interest, with pricing based from time to time at LMI s election at (i) LIBOR plus a spread of 6.00% (with a LIBOR rate floor of 1.00%) or (ii) the Base Rate (as defined in our Term Facility) plus a spread of 5.00%. Interest under term loans based on (i) the LIBOR rate is payable at the end of each interest period (as defined in our Term Facility) and (ii) the Base Rate is payable at the end of each quarter. At December 31, 2015, the Company s interest rate under the Term Facility was 7.00%.

LMI is permitted to voluntarily prepay the Term Facility, in whole or in part, with a premium applicable for the first six months of the Term Facility in connection with a repricing transaction. LMI is required to make quarterly payments, which began on September 30, 2015, in an amount equal to a quarter of a percent (0.25%) per annum of the original principal amount of the Term Facility. The remaining unpaid principal amount of the Term Facility will be payable on the maturity date, or June 30, 2022.

The Term Facility will require LMI to prepay outstanding term loans, subject to certain exceptions, with:

100% of the net cash proceeds of all non-ordinary course sales or other dispositions of assets (including as a result of casualty or condemnation, subject to certain exceptions); the Company may reinvest or commit to reinvest certain of those proceeds in assets useful in our business within twelve months;

100% of the net cash proceeds from issuances or incurrence of debt, other than proceeds from debt permitted under the Term Facility and Revolving Facility;

50% (with two leverage-based stepdowns) of the Company s excess cash flow; and

50% of net payments from the Zurich insurance settlement (as defined therein).

The foregoing mandatory prepayments will be applied to the scheduled installments of principal of the Term Facility in direct order of maturity.

The Term Facility is guaranteed by the Company and Lantheus Real Estate, and obligations under the Term Facility are secured by substantially all the property and assets and all interests of the Company, LMI and Lantheus Real Estate.

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The Company s minimum payments of principal obligations under the Term Facility are as follows as of December 31, 2015:

(in thousands)	
2016	$ 3,650
2017	3,650
2018	3,650
2019	3,650
2020	3,650
2021 and thereafter	344,925
Total debt	363,175
Unamortized debt discount	(4,210)
Unamortized debt issuance costs	(5,457)
Total	353,508
Less current portion	(3,650)
Total long-term debt	$ 349,858

Term Facility Covenants

The Term Facility contains a number of affirmative, negative, reporting and financial covenants, in each case subject to certain exceptions and materiality thresholds. The Term Facility requires the Company to be in quarterly compliance, measured on a trailing four quarter basis. The financial covenants are displayed in the table below:

Term Facility Financial Covenants

Period	Total Net Leverage Ratio
Q3 2015 to Q1 2016	6.25 to 1.00
Q2 2016 to Q4 2016	6.00 to 1.00
Q1 2017 to Q2 2017	5.50 to 1.00
Thereafter	5.00 to 1.00

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

Senior Notes

LMI had $400.0 million in aggregate principal amount of the Notes outstanding. The interest on the Notes was at a rate of 9.750% per year, payable on May 15 and November 15 of each year. The net proceeds of the Term Facility, together with the net proceeds of the IPO and cash on hand, were used to refinance in full the aggregate principal

amount of the Notes and pay related premiums, interest and expenses. The Company satisfied and discharged its obligations under the Notes as of June 30, 2015. The notes and accrued interest were redeemed in full on July 30, 2015.

The Company recorded a loss on extinguishment of debt totaling $15.5 million, which included a redemption premium of $9.7 million and a $5.8 million write-off of unamortized debt issuance costs associated

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with the Senior Notes. On June 30, 2015, the Company also paid the accrued interest to the redemption date totaling $3.3 million, which is included in interest expense for the twelve months ended December 31, 2015 on the consolidated statement of operations.

Revolving Line of Credit

At December 31, 2015, LMI has a Revolving Facility with an aggregate principal amount not to exceed $50.0 million. The loans under the Revolving Facility bear interest subject to a pricing grid based on average historical excess availability, with pricing based from time to time at the election of LMI at (i) LIBOR plus a spread ranging from 2.00% or (ii) the Reference Rate (as defined in the agreement) plus 1.00%. The Revolving Facility also includes an unused line fee of 0.375% and expires on June 30, 2020.

As of December 31, 2015, the Company has an unfunded Standby Letter of Credit of $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 expired during February 2016. It automatically renewed for a one year period and will continue to 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 such expiration.

The Revolving Facility is guaranteed by Holdings and Lantheus Real Estate and is secured by a pledge of substantially all of the assets of each of the loan parties including accounts receivable, inventory and machinery and equipment. 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, 2015, the aggregate Borrowing Base was approximately $48.2 million, which was reduced by an outstanding $8.8 million unfunded Standby Letter of Credit and $0.1 million in accrued interest, resulting in a net Borrowing Base availability of approximately $39.3 million.

Revolving Line of Credit Covenants

The Revolving 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 Revolving 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 Revolving Facility or excess availability under the Revolving Facility falls below (i) the greater of $7.5 million or 15% of the then-current line cap (as defined in the Revolving Facility) for a period of more than five consecutive Business Days or (ii) $5.0 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 Holdings 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. Upon an event of default, the lender has the right to declare the loans and other obligations outstanding immediately due and payable and all commitments immediately terminated or reduced, and the lender may, after such events of default, require LMI to make deposits with respect to any outstanding letters of credit in an amount equal to 105% of the greatest amount for which such letter of credit may be drawn.

Financing Costs

On June 30, 2015, LMI incurred and capitalized approximately $5.9 million in debt issuance costs, consisting primarily of underwriting fees and expenses and legal fees in connection with the issuance of the Term Facility.

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During the years ended December 31, 2015 and 2014, LMI incurred approximately $0.4 million and $0.2 million in fees and expenses, in connection with amendments under the previous facility, which are being amortized on a straight-line basis over the term of the Revolving Facility.

12. Stockholders Equity

As of December 31, 2015, the authorized capital stock of the Company consisted of 250,000,000 shares of common stock, par value $0.01 per share, and 25,000,000 shares of preferred stock, par value $0.01 per share. The common stockholders are entitled to one vote per share and will share equally on a per share basis in any dividend declared by the Board of Directors, subject to any preferential rights of the holders of any outstanding preferred stock.

13. Stock-Based Compensation

As of June 24, 2015, the Company adopted the 2015 Equity Incentive Plan, or the 2015 Plan.

The Company s employees are eligible to receive awards under the 2015 Plan. The 2015 Plan is administered by the Board of Directors and permits the granting of stock options, stock appreciation rights, or SARs, restricted stock, restricted stock units and dividend equivalent rights (DERs) to employees, officers, directors and consultants of the Company. The Board of Directors may, at its sole discretion, grant DERs with respect to any award and such DER is treated as a separate award. The number of shares authorized for issuance under the 2015 Plan is 2,190,320. Option awards under the 2015 Plan are granted with an exercise price equal to the fair value of the Company s common stock at the date of grant. Time based option awards vest based on time, typically four 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 for the entire award. 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.

	Years Ended December 31,					
	2015		2014		2013	
Expected volatility	26	30%	27	35%	30	37%
Expected dividends						
Expected life (in years)	4.1	6.3	3.1	7.0	3.6	6.3
Risk-free interest rate	1.3	1.9%	1.1	2.0%	0.5	1.7%

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A summary of option activity for 2015 is presented below:

	Time Based	Performance Based	Total	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2015	1,146,509	384,601	1,531,110	$ 13.57	6.4	$ 3,979,000
Options granted	281,474		281,474	12.11		
Options cancelled	(34,498)	(4,934)	(39,432)	19.78		
Options exercised						
Options forfeited and expired	(448,442)	(143,737)	(592,179)	17.71		
Outstanding at December 31, 2015	945,043	235,930	1,180,973	10.95	4.5	$
Vested and expected to vest at December 31, 2015	919,115	231,338	1,150,453	10.87	4.4	$
Exercisable at December 31, 2015	668,425	208,793	877,218	10.05	3.9	$

The weighted average grant-date fair value of options granted during the years ended December 31, 2015, 2014 and 2013 was $1.44, $1.70 and $2.45, respectively.

No stock options were exercised during the year ended December 31, 2015. During the year ended December 31, 2014, 6,237 options were exercised. The intrinsic value for the options exercised during the year ended December 31, 2014 was approximately $25,000.

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

	Years Ended December 31,		
(in thousands)	2015	2014	2013
Cost of goods sold	$ 192	$ 135	$ 41
Sales and marketing	254	154	93
General and administrative	1,330	621	429
Research and development	226	121	15
Total stock-based compensation expense	$ 2,002	$ 1,031	$ 578

Stock-based compensation expense recognized in the consolidated statement of operations for the years ended December 31, 2015, 2014, and 2013 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, the Company 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 the Company will exercise its call right. The Company did not reclassify any equity awards to liability-based awards as of December 31, 2015 and 2014. There were no liability awards paid out during the years ended December 31, 2015, 2014 and 2013.

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A summary of restricted stock awards activity for 2015 is presented below:

	Time Based	Weighted Average Grant Date Fair Value Per Share
Issued and unvested at January 1, 2015		$
Granted	1,368,700	5.97
Vested		
Forfeited	(280,532)	6.01
Issued and unvested at December 31, 2015	1,088,168	$ 5.96

The Company did not recognize an income tax benefit for the years ended December 31, 2015, 2014 and 2013. As of December 31, 2015, there was approximately $5.6 million of total unrecognized compensation costs related to stock options and restricted stock awards granted under the 2015, 2013 and 2008 Plans. These costs are expected to be recognized over a weighted-average remaining period of 3.1 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.

14. Net Loss Per Share

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

	Years Ended December 31,		
(in thousands, except share and per share amounts)	**2015**	**2014**	**2013**
Net loss	$ (14,746)	$ (3,561)	$ (61,555)
Basic and diluted weighted average common shares outstanding	24,439,845	18,080,615	18,032,131
Basic and diluted loss per common share	$ (0.60)	$ (0.20)	$ (3.42)

The weighted average number of common shares for the years ended December 31, 2015, 2014, and 2013 did not include 2,269,141, 1,531,110 and 1,373,119 options and unvested restricted stock awards, respectively, because of their antidilutive effect.

15. Other Income (Expense), net

Other income, net consisted of the following:

	Years Ended December 31,		
(in thousands)	**2015**	**2014**	**2013**
Foreign currency losses	$ (1,752)	$ (279)	$ (349)
Tax indemnification income	1,655	754	1,141
Other income	8	3	369
Total other income (expense), net	$ (89)	$ 478	$ 1,161

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16. 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):

Years ended December 31,	Operating Leases
2016	$ 481
2017	387
2018	371
2019	370
2020	295
2021 and thereafter	883
	$ 2,787

Lease expense was $0.9 million, $1.0 million and $0.9 million for the years ended December 31, 2015, 2014 and 2013, 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.

17. 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. The Company did not contribute any additional non-elective discretionary match during the years ended December 31, 2015, 2014 and 2013. 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 $1.6 million, $1.5 million and $1.2 million for the years ended December 31, 2015, 2014 and 2013, respectively.

18. 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, 2015, 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

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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. On March 25, 2015, the United States District Court for the Southern District of New York granted defendant s motion for summary judgment. On September 4, 2015, the Company filed an appeal of the District Court decision with the United States Court of Appeals for the Second Circuit. On December 4, 2015, the defendant filed an answer brief to the Company s appeal, and on December 18, 2015, the Company filed a reply brief to the defendant s answer. 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.

19. Related Party Transactions

Avista, the Company s majority shareholder, provided certain advisory services to the Company pursuant to an advisory services and monitoring agreement. The Company was 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 was seven years. On June 25, 2015, the Company exercised its right to terminate its advisory services and monitoring agreement with Avista. In connection with such termination, the Company has paid Avista Capital Holdings, L.P. an aggregate termination fee of $6.5 million, which is included in general and administrative expenses in the consolidated statement of operations. The Company incurred costs associated with this agreement totaling $7.0 million for the year ended December 31, 2015 and $1.0 million for each of the years ended December 31, 2014 and 2013. There were no amounts outstanding as of December 31, 2015. At December 31, 2014, $10,000, 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 during the year ended December 31, 2013. At December 31, 2015 and 2014, there was no balance outstanding. In the first quarter of 2016, the Company entered into a services agreement with INC to provide pharmacovigilance services. The agreement has a term of three years.

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 $0.3 million, $0.5 million and $0.3 million during each of the years ended December 31, 2015, 2014 and 2013, respectively. At December 31, 2015 and 2014, $10,000 and $21,000, respectively, was included in accounts payable and accrued expenses.

The Company retains Marsh USA, Inc., or Marsh, for insurance brokering and risk management. In November 2013, Donald Bailey, brother of the Company s former President and Chief Executive Officer, Jeffrey Bailey, was appointed head of sales for Marsh s U.S. and Canada division. In 2015, the Company paid Marsh approximately $0.2 million in consulting fees. At December 31, 2015, there was an accrual of $22,000 included in accrued expenses. At December 31, 2014, there was a prepaid of $43,000 included in other current assets.

20. 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,

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marketing, selling and distribution of medical imaging products, focused primarily on cardiovascular diagnostic imaging. The U.S. segment comprises 80.4%, 78.4% and 75.3% of consolidated revenues in 2015, 2014 and 2013, respectively, and 86.7% and 90.1% of consolidated assets at December 31, 2015 and 2014, respectively. All goodwill has been allocated to the U.S. operating segment.

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

(in thousands)	2015	2014	2013
Revenues			
U.S.	$ 258,349	$ 258,148	$ 234,567
International	57,637	65,080	70,033
Total revenue, including inter-segment	315,986	323,228	304,600
Inter-segment revenue	(22,525)	(21,628)	(20,928)
	$ 293,461	$ 301,600	$ 283,672
Revenues from external customers			
U.S.	$ 235,824	$ 236,520	$ 213,639
International	57,637	65,080	70,033
	$ 293,461	$ 301,600	$ 283,672
Revenues by product			
DEFINITY	$ 111,859	$ 95,760	$ 78,094
TechneLite	72,562	93,588	92,195
Xenon	48,898	36,549	32,125
Other	60,142	75,703	81,258
	$ 293,461	$ 301,600	$ 283,672
Geographical revenue			
U.S.	$ 235,824	$ 236,520	$ 213,639
Canada	28,340	31,363	35,502
All other	29,297	33,717	34,531
	$ 293,461	$ 301,600	$ 283,672
Operating income/(loss)			
U.S.	$ 49,131	$ 38,410	$ (18,781)
International	(6,535)	353	703
Total operating income (loss), including inter-segment	42,596	38,763	(18,078)
Inter-segment operating income (loss)	(66)	654	(813)
Operating income (loss)	42,530	39,417	(18,891)

Interest expense	(38,715)	(42,288)	(42,915)
Interest income	24	27	104
Loss on extinguishment of debt	(15,528)		
Other income (expense), net	(89)	478	1,161
Loss before income taxes	$ (11,778)	$ (2,366)	$ (60,541)
Depreciation and amortization			
U.S.	$ 17,054	$ 16,055	$ 22,146
International	1,850	2,196	3,009
	$ 18,904	$ 18,251	$ 25,155
Capital expenditures			
U.S.	$ 13,040	$ 7,811	$ 4,903
International	111	326	107
	$ 13,151	$ 8,137	$ 5,010

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	2015	2014
Assets		
U.S.	$ 210,183	$ 219,129
International	32,196	24,024
	$ 242,379	$ 243,153

	2015	2014
Long-lived assets		
U.S.	$ 84,241	$ 91,346
International	2,276	4,668
	$ 86,517	$ 96,014

21. Valuation and Qualifying Accounts

(in thousands)	Balance at Beginning of Fiscal Year	Charge to Costs and Expenses (Recovery of write-offs)	Deductions From Reserves	Balance at End of Fiscal Year
Year ended December 31, 2015:				
Allowance for doubtful accounts	$ 585	$ 773	$ (477)	$ 881
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

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

22. Quarterly Financial Data (Unaudited)

Summarized quarterly financial data for 2015 and 2014 are as follows (in thousands):

(in thousands)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2015				
Net Sales	$ 74,823	$ 73,314	$ 74,123	$ 71,201
Gross Profit	35,769	32,667	33,705	33,381
Net (loss) income	375	(24,423)*	5,386	3,916
Basic and diluted income (loss) per share	$ 0.02	$ (1.29)	$ 0.18	$ 0.13

2014				
Net Sales	$ 73,336	$ 75,613	$ 75,682	$ 76,969
Gross Profit	30,061	31,059	31,638	32,761
Net (loss) income	(1,285)	(1,636)	(867)	227
Basic and diluted income (loss) per share	$ (0.07)	$ (0.09)	$ (0.05)	$ 0.01

* Included in the net loss for the second quarter of 2015 is a $15.5 million loss on extinguishment of debt related to the redemption of the Company s Senior Notes, a $6.5 million payment for the termination of our advisory services and monitoring agreement with Avista and $3.3 million interest payment made for interest through the redemption date (July 30, 2015) on the Company s Senior Notes.

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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, 2015. 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, 2015, 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 pursuant to the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As a company with less than $1 billion in revenue during our last fiscal year, we qualify as an emerging growth company, as defined in the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other regulatory requirements or up to five years that are otherwise applicable generally to public companies. These provisions include, among other matters:

- exemption from the auditor attestation requirement on the effectiveness of our system of internal control over financial reporting;

- exemption from compliance with any new requirements adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation or a supplement to the auditor s report in which the auditor would be required to provide additional information about the audit and the financial statements of the issuer;

exemption from the requirement to seek non-binding advisory votes on executive compensation and golden parachute arrangements; and

reduced disclosure about executive compensation arrangements.

We will remain an emerging growth company for five years unless, prior to that time, we have (i) more than $1 billion in annual revenue, (ii) have a market value for our common stock held by non-affiliates of more than $700 million as of the last day of our second fiscal quarter of the fiscal year when a determination is made that we are deemed to be a large accelerated filer, as defined in Rule 12b-2 promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act, or (iii) issue more than $1 billion of non-convertible

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debt over a three-year period. 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, 2015 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.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

Pursuant to Section 406 of the Sarbanes-Oxley Act of 2002, we have adopted 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*. 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 SEC.

The additional information required with respect to this item is incorporated herein by reference to our Definitive Proxy Statement for our 2016 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission no later than 120 days after the close of our year ended December 31, 2015.

Item 11. Executive Compensation

The information required with respect to this item is incorporated herein by reference to our Definitive Proxy Statement for our 2016 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission no later than 120 days after the close of our year ended December 31, 2015.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required with respect to this item is incorporated herein by reference to our Definitive Proxy Statement for our 2016 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission no later than 120 days after the close of our year ended December 31, 2015.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required with respect to this item is incorporated herein by reference to our Definitive Proxy Statement for our 2016 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission no later than 120 days after the close of our year ended December 31, 2015.

Item 14. Principal Accountant Fees and Services

The information required with respect to this item is incorporated herein by reference to our Definitive Proxy Statement for our 2016 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission no later than 120 days after the close of our year ended December 31, 2015.

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PART IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1) Financial Statements

Included in Part II of this annual report:

(a)(2) Schedules

None.

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(a)(3) Exhibits

Exhibit Number	Description of Exhibits	Incorporated by Reference			
		Form	File Number	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of Lantheus Holdings, Inc.	8-K	001-36569	3.1	June 30, 2015
3.2	Amended and Restated Bylaws of Lantheus Holdings, Inc.	8-K	001-36569	3.2	June 30, 2015
4.1	Common Stock Certificate.	8-K	001-36569	4.1	June 30, 2015
4.2	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.	S-4	333-169785	4.1	October 6, 2010
4.3	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.	8-K	333-169785	4.1	March 16, 2011
4.4	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.	8-K	333-169785	4.1	March 21, 2011
4.5	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.	S-4	333-169785	4.2	October 6, 2010
4.6	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.	8-K	333-169785	4.2	March 21, 2011
4.7	Form of 9.750% Senior Notes due 2017 (included in Exhibit 4.2).	S-4	333-169785	4.1	October 6, 2010

4.8	Third Supplemental Indenture, dated as of June 25, 2015, among Lantheus Medical Imaging, Inc., Lantheus MI Intermediate, Inc. and Lantheus MI Real Estate, LLC as guarantors, and Wilmington Trust FSB, as trustee.	8-K	001-36569	4.2	June 30, 2015

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Exhibit Number	Description of Exhibits	Incorporated by Reference			
		Form	File Number	Exhibit	Filing Date
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.	S-4	333-169785	10.3	October 6, 2010
10.2	Amended and Restated Shareholders Agreement, dated as of February 26, 2008 among Lantheus Holdings, Inc., Avista Capital Partners, L.P., Avista Capital Partners (Offshore), L.P., ACP-Lantern Co-Invest, LLC and certain management shareholders named therein.	S-4	333-169785	10.4	October 6, 2010
10.3	Employee Shareholders Agreement, dated as of May 8, 2008, among Lantheus Holdings, Inc., Avista Capital Partners, L.P., Avista Capital Partners (Offshore), L.P., ACP-Lantern Co-Invest, LLC and certain employee shareholders named therein.	S-4	333-169785	10.5	October 6, 2010
10.4	Sales Agreement, dated as of April 1, 2009, between Lantheus Medical Imaging, Inc. and NTP Radioisotopes (Pty) Ltd.	S-4	333-169785	10.9	December 23, 2010
10.5	Amendment No. 1 to Sales Agreement, dated as of January 1, 2010, between Lantheus Medical Imaging, Inc. and NTP Radioisotopes (Pty) Ltd.	S-4	333-169785	10.10	December 1, 2010
10.6	Amendment No. 2 to Sales Agreement, dated as of January 1, 2010, between Lantheus Medical Imaging, Inc. and NTP Radioisotopes (Pty) Ltd.	10-Q	333-169785	10.1	May 13, 2011
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.).	S-4	333-169785	10.12	December 23, 2010
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.	10-K	333-169785	10.13	March 8, 2011
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.	S-4	333-169785	10.26	December 1, 2010

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Exhibit Number	Description of Exhibits	Incorporated by Reference			
		Form	File Number	Exhibit	Filing Date
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.	S-4	333-169785	10.14	December 23, 2010
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.	S-4	333-169785	10.16	December 29, 2010
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.	S-4	333-169785	10.17	December 1, 2010
10.13	Lantheus Holdings, Inc. 2008 Equity Incentive Plan.	S-4	333-169785	10.18	October 6, 2010
10.14	Amendment No. 1 to Lantheus Holdings, Inc. 2008 Equity Incentive Plan.	S-4	333-169785	10.19	October 6, 2010
10.15	Amendment No. 2 to Lantheus Holdings, Inc. 2008 Equity Incentive Plan.	S-4	333-169785	10.20	October 6, 2010
10.16	Form of Option Grant Award Agreement.	S-4	333-169785	10.21	October 6, 2010
10.17	Lantheus Medical Imaging, Inc. Severance Plan Policy.	S-4	333-169785	10.24	October 6, 2010
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.	10-Q	333-169785	10.1	May 15, 2012
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.	10-Q	333-169785	10.2	May 15, 2012
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	10-Q	333-169785	10.1	August 14, 2012

HollisterStier LLC.

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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.	10-K	333-169785	10.52	March 29, 2013
10.22	Amendment No. 3, effective as of October 1, 2012, to Sales Agreement between Lantheus Medical Imaging, Inc. and NTP Radioisotopes (Pty) Ltd.	10-K	333-169785	10.53	March 29, 2013
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.	10-K	333-169785	10.54	March 29, 2013
10.24	Separation Agreement, dated February 19, 2013, by and between Lantheus Medical Imaging, Inc. and Don Kiepert.	10-K	333-169785	10.57	March 29, 2013
10.25	Fission Mo-99 Supply Agreement, effective January 1, 2013, by and between Lantheus Medical Imaging, Inc. and the Institut National des Radioelements.	10-Q	333-169785	10.1	May 10, 2013
10.26	Lantheus Holdings, Inc. 2013 Equity Incentive Plan.	8-K	333-169785	10.1	May 6, 2013
10.27	Form of Employee Option Grant Award Agreement.	8-K	333-169785	10.2	May 6, 2013
10.28	Form of Non-Employee Director Option Grant Award Agreement.	8-K	333-169785	10.3	May 6, 2013
10.29	Employment Agreement, dated May 8, 2013, by and between Lantheus Medical Imaging, Inc. and Jeffrey Bailey.	10-Q	333-169785	10.1	November 12, 2013
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 Wells Fargo Bank, National Association, as collateral agent and administrative agent and as sole lead arranger, book runner and syndication agent.	10-Q	333-169785	10.1	August 7, 2013
10.31	Employment Agreement, dated June 4, 2014, by and between Lantheus Medical Imaging, Inc.	S-1	333-196998	10.31	June 24, 2015

	and John K. Bakewell.				
10.32	Employment Agreement, effective August 12, 2013, by and between Lantheus Medical Imaging, Inc. and Mary Anne Heino.	10-K	333-169785	10.47	March 11, 2014

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Exhibit Number	Description of Exhibits	Incorporated by Reference			
		Form	File Number	Exhibit	Filing Date
10.33	Employment Agreement, effective August 12, 2013, by and between Lantheus Medical Imaging, Inc. and Cesare Orlandi.	10-K	333-169785	10.48	March 11, 2014
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, as collateral agent and administrative agent and as sole lead arranger, book runner and syndication agent.	S-1	333-196998	10.34	June 24, 2015
10.35	Amendment, dated June 25, 2015, to Amended and Restated Shareholders Agreement, among Lantheus Holdings, Inc., Avista Capital Partners, L.P., Avista Capital Partners (Offshore), L.P., ACP-Lantern Co-Invest, LLC and certain management shareholders named therein.	8-K	001-36569	10.2	June 30, 2015
10.36	Amendment, dated June 25, 2015, to Employee Shareholders Agreement, among Lantheus Holdings, Inc., Avista Capital Partners, L.P., Avista Capital Partners (Offshore), L.P., ACP-Lantern Co-Invest, LLC and certain employee shareholders named therein.	8-K	001-36569	10.3	June 30, 2015
10.37	2015 Equity Incentive Plan of Lantheus Holdings, Inc.	S-1	333-196998	10.37	June 24, 2015
10.38	Form of 2015 Restricted Stock Agreement of Lantheus Holdings, Inc.	S-1	333-196998	10.38	June 24, 2015
10.39	Form of 2015 Option Award Agreement of Lantheus Holdings, Inc.	S-1	333-196998	10.39	June 24, 2015
10.40	Form of Amendment to the Lantheus Holdings, Inc. 2013 Equity Incentive Plan.	S-1	333-196998	10.40	June 24, 2015
10.41	Form of Amendment to the Lantheus Holdings, Inc. 2008 Equity Incentive Plan.	S-1	333-196998	10.41	June 24, 2015
10.42	Amended and Restated Employment Agreement, effective March 16, 2015, by and between Lantheus Medical Imaging, Inc. and Mary Anne Heino.	10-Q	333-169785	10.1	May 5, 2015

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Exhibit Number	Description of Exhibits	Incorporated by Reference			
		Form	File Number	Exhibit	Filing Date
10.43	Affirmation and Assumption Agreement, dated June 25, 2015, to Amended and Restated Credit Agreement, dated July 3, 2013, 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, as collateral agent and administrative agent and as sole lead arranger, book runner and syndication agent.	8-K	001-36569	10.1	June 30, 2015
10.46	Term Loan Agreement, dated as of June 30, 2015, among Lantheus Medical Imaging, Inc., as borrower, Credit Suisse AG, Cayman Islands Branch, as administrative agent and collateral agent, each of the lenders party thereto, and Lantheus Holdings, Inc. and Lantheus MI Real Estate, LLC, each as guarantors in respect thereto.	8-K	001-36569	10.4	June 30, 2015
10.47	Second Amended and Restated Credit Agreement, dated as of June 30, 2015, among Lantheus Medical Imaging, Inc., as borrower, Wells Fargo Bank, National Association, as administrative agent and collateral agent, each of the lenders party thereto and Lantheus Holdings, Inc. and Lantheus MI Real Estate, LLC, each as guarantors in respect thereto.	8-K	001-36569	10.5	June 30, 2015
10.48	Amendment, dated June 25, 2015, to the Employment Agreement, dated May 8, 2013, by and between Lantheus Medical Imaging, Inc. and Jeffrey Bailey.	8-K	001-36569	10.6	June 30, 2015
10.49	Amendment, dated June 25, 2015, to the Amended and Restated Employment Agreement, effective March 16, 2015, by and between Lantheus Medical Imaging, Inc. and Mary Anne Heino.	8-K	001-36569	10.7	June 30, 2015
10.50	Amendment, dated June 25, 2015, to the Employment Agreement, dated August 12, 2013, by and between Lantheus Medical Imaging, Inc. and Cesare Orlandi.	8-K	001-36569	10.8	June 30, 2015

10.51	Retirement and Consulting Agreement, dated August 27, 2015, by and between Lantheus Medical Imaging, Inc. and Jeffrey Bailey.	10-Q	001-36569	10.1	November 4, 2015

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Exhibit Number	Description of Exhibits	Incorporated by Reference			
		Form	File Number	Exhibit	Filing Date
10.52	Amendment to Employment Agreement, dated August 31, 2015, by and between Lantheus Medical Imaging, Inc. and Mary Anne Heino.	10-Q	001-36569	10.2	November 4, 2015
10.53 *	Term Sheet for Supply Agreement, dated November 19, 2015, by and between Lantheus Medical Imaging, Inc. and Cardinal Health 414, LLC.				
21.1*	Subsidiaries of Lantheus Holdings, Inc.				
23.1*	Consent of Independent Registered Public Accounting Firm.				
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.				
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

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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 HOLDINGS, INC.

By: /s/ MARY ANNE HEINO
Name: Mary Anne Heino
Title: *President and Chief Executive Officer*
Date: March 2, 2016

We, the undersigned directors and officers of Lantheus Holdings, Inc., hereby severally constitute and appoint Mary Anne Heino, John W. Crowley 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.

Signature	Title	Date
/s/ MARY ANNE HEINO Mary Anne Heino	President, Chief Executive Officer and Director (Principal Executive Officer)	March 2, 2016
/s/ JOHN W. CROWLEY John W. Crowley	Interim Chief Financial Officer (Principal Financial Officer) and Vice President, Chief Accounting Officer	March 2, 2016
/s/ BRIAN MARKISON Brian Markison	Chairman of the Board of Directors	March 2, 2016
/s/ DAVID BURGSTAHLER David Burgstahler	Director	March 2, 2016
/s/ JAMES CLEMMER	Director	March 2, 2016

James Clemmer		
/s/ SAMUEL R. LENO	Director	March 2, 2016
Samuel R. Leno		
/s/ PATRICK J. O NEILL	Director	March 2, 2016
Patrick J. O Neill		
/s/ SRIRAM VENKATARAMAN	Director	March 2, 2016
Sriram Venkataraman		

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EXHIBIT INDEX

Exhibit Number	Description of Exhibits	Incorporated by Reference			
		Form	File Number	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of Lantheus Holdings, Inc.	8-K	001-36569	3.1	June 30, 2015
3.2	Amended and Restated Bylaws of Lantheus Holdings, Inc.	8-K	001-36569	3.2	June 30, 2015
4.1	Common Stock Certificate.	8-K	001-36569	4.1	June 30, 2015
4.2	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.	S-4	333-169785	4.1	October 6, 2010
4.3	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.	8-K	333-169785	4.1	March 16, 2011
4.4	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.	8-K	333-169785	4.1	March 21, 2011
4.5	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.	S-4	333-169785	4.2	October 6, 2010
4.6	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.	8-K	333-169785	4.2	March 21, 2011
4.7	Form of 9.750% Senior Notes due 2017 (included in Exhibit 4.2).	S-4	333-169785	4.1	October 6, 2010

4.8	Third Supplemental Indenture, dated as of June 25, 2015, among Lantheus Medical Imaging, Inc., Lantheus MI Intermediate, Inc. and Lantheus MI Real Estate, LLC as guarantors, and Wilmington Trust FSB, as trustee.	8-K	001-36569	4.2	June 30, 2015

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Exhibit Number	Description of Exhibits	Incorporated by Reference			
		Form	File Number	Exhibit	Filing Date
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.	S-4	333-169785	10.3	October 6, 2010
10.2	Amended and Restated Shareholders Agreement, dated as of February 26, 2008 among Lantheus Holdings, Inc., Avista Capital Partners, L.P., Avista Capital Partners (Offshore), L.P., ACP-Lantern Co-Invest, LLC and certain management shareholders named therein.	S-4	333-169785	10.4	October 6, 2010
10.3	Employee Shareholders Agreement, dated as of May 8, 2008, among Lantheus Holdings, Inc., Avista Capital Partners, L.P., Avista Capital Partners (Offshore), L.P., ACP-Lantern Co-Invest, LLC and certain employee shareholders named therein.	S-4	333-169785	10.5	October 6, 2010
10.4	Sales Agreement, dated as of April 1, 2009, between Lantheus Medical Imaging, Inc. and NTP Radioisotopes (Pty) Ltd.	S-4	333-169785	10.9	December 23, 2010
10.5	Amendment No. 1 to Sales Agreement, dated as of January 1, 2010, between Lantheus Medical Imaging, Inc. and NTP Radioisotopes (Pty) Ltd.	S-4	333-169785	10.10	December 1, 2010
10.6	Amendment No. 2 to Sales Agreement, dated as of January 1, 2010, between Lantheus Medical Imaging, Inc. and NTP Radioisotopes (Pty) Ltd.	10-Q	333-169785	10.1	May 13, 2011
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.).	S-4	333-169785	10.12	December 23, 2010
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.	10-K	333-169785	10.13	March 8, 2011
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10.47	Second Amended and Restated Credit Agreement, dated as of June 30, 2015, among Lantheus Medical Imaging, Inc., as borrower, Wells Fargo Bank, National Association, as administrative agent and collateral agent, each of the lenders party thereto and Lantheus Holdings, Inc. and Lantheus MI Real Estate, LLC, each as guarantors in respect thereto.	8-K	001-36569	10.5	June 30, 2015
10.48	Amendment, dated June 25, 2015, to the Employment Agreement, dated May 8, 2013, by and between Lantheus Medical Imaging, Inc. and Jeffrey Bailey.	8-K	001-36569	10.6	June 30, 2015
10.49	Amendment, dated June 25, 2015, to the Amended and Restated Employment Agreement, effective March 16, 2015, by and between Lantheus Medical Imaging, Inc. and Mary Anne Heino.	8-K	001-36569	10.7	June 30, 2015
10.50	Amendment, dated June 25, 2015, to the Employment Agreement, dated August 12, 2013, by and between Lantheus Medical Imaging, Inc. and Cesare Orlandi.	8-K	001-36569	10.8	June 30, 2015

10.51	Retirement and Consulting Agreement, dated August 27, 2015, by and between Lantheus Medical Imaging, Inc. and Jeffrey Bailey.	10-Q	001-36569	10.1	November 4, 2015

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Exhibit Number	Description of Exhibits	Incorporated by Reference			
		Form	File Number	Exhibit	Filing Date
10.52	Amendment to Employment Agreement, dated August 31, 2015, by and between Lantheus Medical Imaging, Inc. and Mary Anne Heino.	10-Q	001-36569	10.2	November 4, 2015
10.53 *	Term Sheet for Supply Agreement, dated November 19, 2015, by and between Lantheus Medical Imaging, Inc. and Cardinal Health 414, LLC.				
21.1*	Subsidiaries of Lantheus Holdings, Inc.				
23.1*	Consent of Independent Registered Public Accounting Firm.				
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.				
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