Lantheus Holdings, Inc.
Form 10-K
February 23, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2016

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

Commission File Number 001-36569

LANTHEUS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**35-2318913**
(State or other jurisdiction of incorporation or organization)	**(I.R.S 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)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $0.01 par value per share	NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act:

None

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

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

Large accelerated filer Accelerated filer

Non-accelerated filer (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

The aggregate market value of the registrant s common stock held by non-affiliates of the registrant on June 30, 2016 was approximately $49.1 million based on the last reported sale price of the registrant s common stock on the NASDAQ Global Market on June 30, 2016 of $ 3.67 per share.

As of February 21, 2017 the registrant had 36,840,138 shares of common stock, $0.01 par value, issued and outstanding.

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 27, 2017, portions of which are incorporated by reference into Parts II and III of this Form 10-K. The 2017 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, 2016.

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LANTHEUS HOLDINGS, INC.

ANNUAL REPORT ON FORM 10-K

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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.

Some of the statements contained in this Annual Report on Form 10-K 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, predict 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 increased competition; (iii) our outlook and expectations related to products manufactured at Jubilant HollisterStier (JHS) and global isotope supply; (iv) our ability to finalize our previously announced collaboration and license transaction with GE Healthcare Ltd. (GE Healthcare) and our outlook and expectations related to the development and commercialization of flurpiridaz F 18 through that collaboration; and (v) our liquidity, including our belief that our existing cash, cash equivalents, anticipated revenues and availability under our revolving credit facility (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 on Form 10-K 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 segment competition from other echocardiography contrast agents, including Optison from GE Healthcare and Lumason from Bracco Diagnostics Inc. (Bracco);

Risks associated with revenues and unit volumes for Xenon in pulmonary studies and the competition in this generic segment from IBA Molecular/Mallinckrodt (IBAM);

Our dependence on key customers for our medical imaging products, and our ability to maintain and profitably renew our contracts with those key customers, including Cardinal Health (Cardinal), United Pharmacy Partners (UPPI), GE Healthcare and Triad Isotopes (Triad);

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

Risks associated with the technology transfer programs to secure production of our products at alternate contract manufacturer sites, including our next generation DEFINITY product at Samsung BioLogics (SBL);

Risks associated with the manufacturing and distribution of our products and the regulatory requirements related thereto;

The instability of the global Molybdenum-99 (Moly) supply;

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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;

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 finalize our previously announced collaboration and license transaction with GE Healthcare;
- The ability to obtain Food and Drug Administration (FDA) approval; and
- The ability to gain post-approval market acceptance and adequate reimbursement;

The extensive costs, time and uncertainty associated with new product development, including further product development potentially relying on external development partners;

Our inability to introduce new products and adapt to an evolving technology and diagnostic landscape;

Our inability to identify and in-license or acquire additional products to grow our business;

Our inability to protect our intellectual property and the risk of claims that we have infringed on the intellectual property of others;

Risks associated with prevailing economic 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 Part I, Item 1A. Risk Factors, beginning on page 30.

Factors that could cause or contribute to such differences include, but are not limited to, those that are discussed in other documents we file with the Securities and Exchange Commission (SEC). Any forward-looking statement made by us in this Annual Report on Form 10-K 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.

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Trademarks

We own or have the rights to various trademarks, service marks and trade names, including, among others, the following: DEFINITY®, TechneLite®, Cardiolite®, Neurolite®, Vialmix®, Quadramet® (U.S. only) and Lantheus Medical Imaging® referred to in this Annual Report on Form 10-K. Solely for convenience, we refer to trademarks, service marks and trade names in this Annual Report on Form 10-K 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 on Form 10-K, such as Lumason®, Myoview®, Optison® and SonoVue® are, to our knowledge, owned by that other company.

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PART I

Item 1. Business

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. Clinicians use our imaging agents and products across a range of imaging modalities, including echocardiography and nuclear imaging. We believe that the resulting improved diagnostic information enables healthcare providers to better detect and characterize, or rule out, disease, potentially achieving improved patient outcomes, reducing patient risk and limiting overall costs for payers and the entire healthcare system. Our commercial products are used by cardiologists, nuclear physicians, radiologists, internal medicine physicians, sonographers and technologists working in a variety of clinical settings.

We sell our products globally and operate our business in two reportable segments, which are further described below:

U.S. Segment produces and markets our medical imaging agents and products throughout the U.S. In the U.S., we primarily sell our products to radiopharmacies, integrated delivery networks, hospitals, clinics and group practices.

International Segment operations consist of production and distribution activities in Puerto Rico and direct distribution activities in Canada. Additionally, within our International Segment, we have established and maintain third-party distribution relationships under which our products are marketed and sold in Europe, Canada, Australia, Asia Pacific and Latin America.

During the year ended December 31, 2016, we sold certain business units that were part of our International Segment business. In January 2016, we entered into an asset purchase agreement pursuant to which we sold substantially all of our Canadian radiopharmacy business and Gludef manufacturing and distribution business. In August 2016, we entered into a share purchase agreement pursuant to which we sold all of the stock of our Australian radiopharmacy servicing subsidiary. See Footnote 5, Sales of Certain International Segment Assets included in the consolidated financial statements located elsewhere in this Annual Report on Form 10-K.

For further information on our products and segments, see Our Product Portfolio within this Item 1. Business.

Our Product Portfolio

Our portfolio of nine commercial products is diversified across a range of imaging modalities. Our products include an ultrasound contrast agent and medical radiopharmaceuticals (including technetium generators).

Ultrasound contrast agents are compounds that are used in diagnostic procedures such as cardiac ultrasounds, or echocardiograms that are used by physicians to improve the clarity of the diagnostic image.

Medical 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.

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Radioisotopes are most commonly manufactured in a nuclear research reactor, where a target is bombarded with subatomic particles, or in 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 (SPECT) which measures gamma rays emitted by a SPECT radiopharmaceutical, and positron emission tomography (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 cardiovascular disease, a typical diagnostic progression could include an electrocardiogram, followed by an echocardiogram (possibly using our agent DEFINITY), and then a nuclear myocardial perfusion imaging (MPI) study using either SPECT or PET imaging (possibly using our technetium generator and our SPECT-based MPI agent). 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 in the U.S., and 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 U.S. over 31.8 million in 2016 a third party source estimates that approximately 20%, or approximately 6.4 million echocardiograms in 2016, 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 a 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 U.S. 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 8.1 million patients throughout the world. In 2016, DEFINITY was the leading ultrasound imaging agent based on revenue and usage, used by echocardiologists and sonographers. We estimate that DEFINITY had an approximately 80% share of the U.S. market for contrast agents in echocardiography procedures as of December 2016. DEFINITY currently competes with Optison, a GE Healthcare product, Lumason, a Bracco product (known as SonoVue outside the U.S.) as well as other non-echocardiography 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 Part I, Item 1A. Risk Factors Ultrasound contrast agents may cause side

effects which could limit our ability to sell DEFINITY.

DEFINITY is currently patent protected in the U.S. with a composition of matter patent expiring in 2019 and a manufacturing patent expiring in 2021. In addition, DEFINITY is protected in numerous foreign

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jurisdictions with patent or regulatory protection until 2019. We also have an active next generation development program for this agent. DEFINITY generated revenues of $131.6 million, $111.9 million and $95.8 million for the years ended December 31, 2016, 2015 and 2014, respectively. DEFINITY represented approximately 44%, 38% and 32% of our revenues in 2016, 2015 and 2014, respectively.

TechneLite

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

The technetium produced by our TechneLite generator is the medical radioisotope that can be attached to a number of imaging agents, including our own Cardiolite products and Neurolite, during the radiolabeling 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 below.

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 U.S., we have supply contracts with significant radiopharmacy chains, including Cardinal, UPPI, GE Healthcare and Triad. We also supply generators on a purchase order basis with other customers. We estimate that TechneLite had an approximately 40% share of the U.S. generator market as of December 31, 2016, competing primarily with technetium-based generators produced by IBAM. In Puerto Rico, we also supply TechneLite to our 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 Isologic Supply Agreement), the buyer of those radiopharmacies. Under the Isologic Supply Agreement, we will supply Isologic with certain of our products on commercial terms, including certain product purchase commitments by Isologic. The agreement expires in January 2021 and may be terminated upon the occurrence of specified events, including a material breach by the other party, bankruptcy by either party or certain force majeure events. In Australia, where we sold our radiopharmacy servicing business in August 2016, we have a supply agreement with Global Medical Solutions (GMS), the buyer of that business (the GMS Supply Agreement). Under the GMS Supply Agreement, we supply GMS with certain of our products on commercial terms, including certain minimum product purchase commitments by GMS. The agreement expires in August 2020 and may be terminated in whole or in part on a product-by-product basis upon the occurrence of specified events, including a material breach by the other party, bankruptcy by either party or certain force majeure events.

The Moly used in our TechneLite generators can be produced using targets made of either highly-enriched uranium (HEU) or low-enriched uranium (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

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January 2, 2013, President Obama signed into law the American Medical Isotopes Production Act of 2012 (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 U.S. 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 (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.

TechneLite has patent protection in the U.S. 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 $99.2 million, $72.6 million and $93.6 million for the years ended December 31, 2016, 2015 and 2014, respectively. TechneLite represented approximately 33%, 25% and 31% of our revenues in 2016, 2015 and 2014, 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 a bi-product of Moly production and is processed and finished by us. We are currently the leading provider of Xenon in the U.S. During the years ended December 31, 2016, 2015 and 2014, Xenon Xe 133 Gas represented approximately 10%, 17% and 12% of our revenues, respectively.

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, specialized workforce, technical know-how and supplier and customer relationships.

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.

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.

Thallium Tl 201 is an injectable radiopharmaceutical imaging agent used in MPI studies to detect cardiovascular disease. We have marketed Thallium since 1977 and manufacture the agent using cyclotron technology.

FDG is an injectable, fluorine-18-radiolabeled imaging agent used with PET technology to identify and characterize tumors in patients undergoing oncologic diagnostic procedures. We manufacture and distribute FDG from our Puerto Rico radiopharmacy.

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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.

Quadramet, our only therapeutic product, is an injectable radiopharmaceutical used to treat severe bone pain associated with metastatic bone lesions. We serve as the direct manufacturer and supplier of Quadramet in the U.S.

For consolidated revenues and other consolidated financial information for our U.S. and International segments, see Footnote 18, Segment Information to our accompanying 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, United Kingdom, Netherlands, Germany	Europe[1], Israel, India[2], 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[3]	South Korea, Taiwan, Mexico, Europe[4]
Thallium Tl 201	United States, Canada, Australia,	New Zealand

	South Korea, Pakistan, Panama, Taiwan	
	United States, Canada, Colombia, Mexico,	
Gallium Ga67	Pakistan, Australia, Costa Rica, South Korea,	None
	Panama, Taiwan, New Zealand	
FDG	Puerto Rico	None
Quadramet	United States	None

(1) Other than the United Kingdom, Netherlands, Germany and Austria.
(2) JHS is pending approval in India.
(3) Excluding Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Italy, Luxembourg, Norway, Slovenia, Spain and Sweden.
(4) JHS has regulatory approval pending for Neurolite in Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Italy, Luxembourg, Norway, Slovenia, Spain and Sweden.

In the U.S. and Canada, we sell DEFINITY through our sales team of 78 employees that call on healthcare providers in the echocardiography space, as well as group purchasing organizations and integrated delivery networks.

Our radiopharmaceutical products are sold in the U.S. through a small nuclear products sales team, primarily to radiopharmacies. We sell a majority of our radiopharmaceutical products in the U.S. to four

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radiopharmacy groups namely 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 U.S. We estimate that Cardinal s radiopharmacies distributed approximately 44% of the aggregate U.S. SPECT doses sold in the first half of 2016 (the latest information currently available to us). Our written supply agreement with Cardinal relating to TechneLite, Xenon, Neurolite and other products expires on December 31, 2017. The agreement specifies pricing levels and requirements to purchase minimum shares of certain products during certain periods. The agreement may be terminated upon the occurrence of specified events, including a material breach by the other party and certain force majeure events.

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 U.S. 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 approximately 26% of the aggregate U.S. SPECT doses sold in the first half of 2016. 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, 2019.

GE Healthcare maintains 31 radiopharmacies in the U.S. that purchase our TechneLite generators. We estimate that GE Healthcare distributed approximately 11% of the aggregate U.S. SPECT doses sold in the first half of 2016. 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 from us. Our agreement, which expires on December 31, 2017, may be terminated by either party on 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 or force majeure events.

Triad maintains approximately 56 radiopharmacies in the U.S. that purchase a range of our products. We estimate that Triad distributed approximately 10% of the aggregate U.S. SPECT doses sold in the first half of 2016. 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 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, Australia, 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 multi-country regional basis.

In March 2012, we entered into a development and distribution arrangement for DEFINITY in China, Hong Kong and Macau with Double-Crane Pharmaceutical Company (Double-Crane). Double-Crane is currently

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pursuing the Chinese regulatory approval required to commercialize DEFINITY. 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 (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 three small confirmatory clinical trials one for abdominal (liver and kidney), one for cardiac and the third a pharmacokinetic study. 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 2018.

We believe that international markets, particularly China, represent significant growth opportunities for our products. The Double-Crane distribution agreement did not have a meaningful impact our revenues during the years ended December 31, 2016 or 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 operated in Australia and the one radiopharmacy we own and operate in Puerto Rico. Currently in Canada, we sell our products through our Isologic Supply Agreement, which we entered into in connection with the sale of our Canadian radiopharmacies in January 2016. We also sell our products directly to hospitals with in-house radiopharmacy capabilities. In Australia, we sell our products through our GMS Supply Agreement, which we entered into in connection with the sale of our Australian subsidiary in August 2016.

In Puerto Rico, we own and operate one of two radiopharmacies on the island and sell our own products as well as products of third parties to end-users.

Seasonality

Our business has modest seasonality as patients may seek to schedule diagnostic imaging procedures less frequently during the summer vacation months and over the year-end holidays.

Customers

Total revenues from customers that accounted for 10% or more of our total consolidated revenues are as follows:

	Year Ended December 31,		
	2016	**2015**	**2014**
Cardinal	10.3%	11.3%	18.0%
UPPI	11.4%	11.9%	11.1%

Backlog

Our backlog consists of orders for which a delivery schedule within the next twelve months has been specified. Orders included in backlog may be canceled or rescheduled by customers at any time with the exception of TechneLite orders. For TechneLite, customers must provide us with four weeks advanced notice to cancel an order. We do not believe that our backlog at any particular time is meaningful because it has historically been immaterial relative to our total revenue and is not necessarily indicative of future revenues at any given period.

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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 currently include IBAM, GE Healthcare, Bayer AG (Bayer), Bracco and DRAXIS Specialty 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, or bundle the sale of a portfolio of products to the detriment of our specific products. Our current or future products could be rendered obsolete or uneconomical as a result of these activities.

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, 2016, our largest suppliers of raw materials and supplies were NTP Radioisotopes (NTP), acting for itself and on behalf of ANSTO, and Nordion, accounting for approximately 15% and 14%, respectively, of our total purchases.

Molybdenum-99

Our TechneLite, Cardiolite and Neurolite products all rely on Moly, the radioisotope which is produced by bombarding uranium 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 three of the four main processing sites in the world, namely, NTP in South Africa; ANSTO in Australia; and Institute for Radioelements (IRE) in Belgium. These processing sites are, in turn, supplied by five of the six main Moly-producing reactors in the world, namely, SAFARI in South Africa; OPAL in Australia; BR2 in Belgium; LVR-15 in the Czech Republic; and High Flux Reactor (HFR) in The Netherlands.

Historically, our largest supplier of Moly was Nordion, which relied on the NRU reactor in Canada for its supply of Moly. Our agreement with Nordion expired on October 31, 2016, and from November 2016, the NRU reactor transitioned from providing regular supply of medical isotopes to providing only emergency back-up supply of HEU based Moly through March 2018.

Our agreement with NTP includes their partner, ANSTO. ANSTO has significantly increased its Moly production capacity from its existing facility in August 2016 and has a new Moly processing facility under construction, in cooperation with NTP, that ANSTO believes will expand its production capacity up to

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approximately 3,500 six-day Curies/week, which is expected to be in commercial operation in the first half of 2018. 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 or 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 (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 favorable allocations 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 or force majeure events. The IRE Agreement expires on December 31, 2017.

In addition, IRE 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 and exceed the NRU s most recent routine production. The NTP/ANSTO agreement contains minimum percentage volume requirements and provides for the increased supply of Moly derived from LEU targets from NTP and ANSTO.

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 entered into a strategic agreement with SHINE Medical Technologies, Inc. (SHINE), a Wisconsin-based company, 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. See Part I, 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

Historically, Nordion was our sole supplier of Xenon, and a principal supplier on a global basis, of Xenon, which is captured as a by-product of the Moly production process. Our agreement with Nordion expired on October 31, 2016. In January 2015, we entered into a new strategic agreement with IRE for the future supply of Xenon. We are now receiving bulk unprocessed Xenon from IRE, which we are processing and finishing for our customers at our North Billerica, Massachusetts manufacturing facility. Until we can qualify an additional source of bulk unprocessed Xenon, we will rely on IRE as a sole source provider. See Part I, 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 Thallium and Gallium using our cyclotron technology,

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

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

Manufacturing and Supply Arrangements

We currently have the following technology transfer and manufacturing and supply agreements in place for some of our major products:

DEFINITY In February 2012, we entered into a Manufacturing and Supply Agreement with JHS, for the manufacture of DEFINITY. Under the agreement, JHS manufactures DEFINITY for us for an initial term of five years. In September 2016, we extended the agreement through January 2022, including a commitment by JHS to provide us 100% of our DEFINITY volume until July 2018. We have the right to extend the agreement 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. Our technology transfer activities with Pharmalucence have been repeatedly delayed, and we are now in the process of negotiating an exit to that arrangement. On May 3, 2016, we entered into a Manufacturing and Supply Agreement with SBL to perform technology transfer and process development services to manufacture and supply our next generation DEFINITY product. There are no minimum purchase requirements under this agreement, which has an initial term of five years from the date of first commercial sale and is renewable at our option for an additional five years. This agreement allows for termination upon the occurrence of certain events, including material breach or bankruptcy of either party. We cannot give any assurances as to when that technology transfer will be completed and when we will actually receive supply of next generation DEFINITY product from SBL. 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 s (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. In the third quarter of 2016, we completed the technology transfer process and received FDA approval to manufacture Cardiolite at JHS. Under the agreement, JHS has agreed to manufacture products for an initial term of five years from the effective date. 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

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place orders for a minimum percentage of our requirements for Cardiolite products with JHS during such term. Based on our current projections, we believe that we will have sufficient Cardiolite products supply 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 manufacture Neurolite at JHS. Under the agreement, JHS has agreed to manufacture Neurolite for an initial term of five years from the effective date. We have the contractual 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 during such term. Based on our current projections, we believe that we will have sufficient supply of Neurolite from JHS to meet expected demand.

Although we are pursuing new manufacturing relationships to establish and secure additional long-term or alternative suppliers as described above, we are uncertain of the timing as to when these arrangements could provide meaningful quantities of product. See Part I, Item 1A. Risk Factors The global supply of Moly is fragile and not stable. Our dependence on a limited number of third party suppliers for Moly could prevent us from delivering some of our products to our customers in the required quantities, within the required timeframes, or at all, which could result in order cancellations and decreased revenues, Part I, 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 Part I, 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 either one of our clinical-stage PET cardiac imaging agents - flurpiridaz F 18 and 18F LMI 1195 - are ultimately successful in clinical trials, a new manufacturing model will be required in which 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. 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 the relevant agent, each of the radiopharmacies will have to be included in the agent s New Drug Application (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 and 18F LMI 1195 Cardiac Neuronal Imaging Agent.

Research and Development

For the years ended December 31, 2016, 2015 and 2014, we invested $12.2 million, $14.4 million and $13.7 million in research and development (R&D), respectively. 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 U.S. and numerous foreign jurisdictions.

In March 2013, we began to implement a strategic shift in how we fund our important R&D programs, reducing our internal R&D resources. On February 21, 2017, we announced entering into a term sheet with

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GE Healthcare relating to the continued development and commercialization of flurpiridaz F 18. In the future, we may also seek to engage strategic partners for our 18F LMI 1195 and LMI 1174 programs. See Part I, Item 1A. Risk Factors We may 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 (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 3 Program

To date, our Phase 3 program for flurpiridaz F 18 has included a phase 3 trial (301 Trial), which was an open-label, multicenter, international study with 755 subjects with known or suspected coronary artery disease (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 imaging 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 (SPA) for our 301 Trial. See Regulatory Matters Food and Drug Laws below. In June 2011, we enrolled our first patient, and we completed patient enrollment in the third quarter of 2013.

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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 imaging in a highly statistically significant manner on sensitivity. In addition, flurpiridaz F 18 showed statistically significant improvements in image quality and diagnostic certainty in comparison to SPECT imaging. 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 imaging results were skewed with low sensitivity and high specificity when compared to coronary angiography. When the flurpiridaz F 18 imaging results were compared to the SPECT imaging results, flurpiridaz F 18 imaging substantially outperformed SPECT imaging 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 multi-vessel disease. A significantly higher percentage of images were rated as either excellent or good with flurpiridaz F 18 imaging as compared to SPECT imaging, leading to a greater diagnostic certainty of interpretation. Importantly, radiation exposure associated with flurpiridaz F 18 imaging was reduced to approximately 50% of SPECT imaging. 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. See Part I, 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.

Proposed GE Healthcare Transaction

On February 21, 2017, we announced entering into a term sheet with GE Healthcare relating to the continued development and worldwide commercialization of flurpiridaz F 18. Under the proposed transaction, GE Healthcare would fund the second Phase III flurpiridaz F 18 clinical study, worldwide regulatory approvals and its worldwide launch and commercialization, with us collaborating in both development and commercialization through a joint steering committee. We would also maintain the option to co-promote the agent in the U.S. GE Healthcare s development plan would focus on obtaining regulatory approval in the U.S., Japan, Europe and Canada. We would receive a $5 million upfront cash payment and, if successful, up to $60 million in regulatory and sales milestones payments, plus tiered double-digit royalties on U.S. sales and mid-single-digit royalties on sales outside of the U.S. Subject to satisfactory due diligence and necessary approvals, we anticipate entering into a definitive agreement for the proposed transaction in the second quarter of 2017. However, there is no assurance that we will enter into a definitive agreement on these terms or at all. See Part I, Item 1A. Risk Factors We may not be able to further develop or commercialize our agents in development without successful strategic partners.

18F LMI 1195 Cardiac Neuronal 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 U.S. alone, there are over five million patients living with congestive heart failure, and over a half million new diagnoses each year.

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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 (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 U.S., Canada and Europe to develop additional clinical data which may allow us to enter into pivotal clinical trials.

LMI 1174 Vascular Remodeling Imaging Agent

We have developed LMI 1174, an internally discovered gadolinium-based magnetic resonance imaging (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 currently working closely with investigators in the U.S. and Europe to develop additional preclinical data which may allow us to enter into clinical trials.

Intellectual Property

Patents, trademarks and other intellectual property rights, both in the U.S. 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

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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 U.S., 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. See Part I, Item 1A. Risk Factors 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.

Trademarks, Service Marks and Trade Names

We own various trademarks, service marks and trade names, including DEFINITY, TechneLite, Cardiolite, Neurolite, Vialmix, Quadramet (U.S. only) and Lantheus Medical Imaging. We have registered these trademarks, as well as others, in the U.S. 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 U.S., 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, 2017, our patent portfolio included a total of 34 issued U.S. patents, 205 issued foreign patents, 23 pending patent applications in the U.S. and 161 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 U.S., 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. In the U.S., we have a composition of matter patent expiring in 2019 and a manufacturing patent expiring in 2021. Outside of the U.S., we have patent or regulatory extension protection in Canada, Europe and parts of Asia until 2019. We also have an active next generation development program for this agent. TechneLite currently has patent protection in the U.S. 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 U.S. or the rest of the world. Xenon, Thallium and Gallium have no patent protection; however, we are pursuing patent protections for an improved container for Xenon.

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 U.S. 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 U.S. 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

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remodeling imaging agent, including in the U.S. 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 provide assurances that an employee or an outside party will not make an unauthorized disclosure of our trade secrets, other technical know-how or proprietary information. We may not have adequate monitoring abilities to discover, or adequate remedies for, any unauthorized disclosure. This might happen intentionally or inadvertently. It is possible that a competitor will make use of such information, and that our competitive position will be compromised, in spite of any legal action we might take against persons making such unauthorized disclosures. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

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

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 U.S. 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 related to the development, manufacture, packaging or repackaging of our pharmaceutical and medical device products subject 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 (NRC), the U.S. Department of Health and Human Services (HHS), Health Canada, the European Medicines Agency (EMA), the U.K. Medicines and Healthcare Products Regulatory Agency (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

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and sales and distribution of pharmaceutical products in the U.S. Prior to marketing a pharmaceutical product, we must first receive FDA approval. In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (FDCA) and implementing regulations. The process of obtaining regulatory approvals and compliance with appropriate federal, state, local, and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Currently, the process required by the FDA before a drug product may be marketed in the U.S. 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 an 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 (cGMPs) regulations; and
- FDA review and approval of the NDA.

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

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.

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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 (IRB), serving any of the institutions participating in the clinical trial can suspend or terminate approval of a clinical study at a relevant institution if the clinical study is not being conducted in accordance with the IRB s requirements or if the agent has been associated with unexpected serious harm to patients. Failure to register a clinical trial or disclose study results within the required time periods could result in penalties, including civil monetary penalties.

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

The results of product development, preclinical studies and clinical studies, along with descriptions of the manufacturing process, analytical tests conducted on the drug product, proposed labeling, and other relevant information, are submitted to the FDA as part of an NDA for a new drug, requesting approval to market the agent. The submission of an NDA is subject to the payment of a substantial user fee, pursuant to the Prescription Drug User Fee Act (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 (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 December 2016, Congress enacted and President Obama signed the 21st Century Cures bill into law. That law contains a number of provisions that may change regulatory requirements for drugs and medical devices. Given its recent enactment, as well as the change in the federal Administration, it is uncertain how the law will be implemented. Therefore, it is also uncertain whether or to what extent any changes or additions to regulatory requirements authorized by the new law will have an impact on the regulation of drugs or medical devices.

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

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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 (REMS) to ensure that the benefits of a product outweigh its risks. A REMS could add training requirements for healthcare professionals, safety communications efforts and limits on channels of distribution, among other things. The sponsor would be required to evaluate and monitor the various REMS activities and adjust them if need be. Whether a REMS would be imposed on any of our products and any resulting financial impact is uncertain at this time.

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

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

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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 U.S. 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, 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)

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

Healthcare Reform and Other Laws Affecting Payment

We operate in a highly-regulated industry. The U.S. and state governments continue to propose and pass legislation that may affect the availability and cost of healthcare. For example, 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: (which tax applied to applicable sales made from January 1, 2013 through December 31, 2015, but is currently suspended for 2016 and 2017).

The Healthcare Reform Act also establishes an Independent Payment Advisory Board (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 through 2016, so no adjustments will be made under the IPAB until 2019 (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 (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.

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The Healthcare Reform Act has been subject to political and judicial challenges. In 2012, the U.S. Supreme Court considered the constitutionality of certain provisions of the law. The U.S. 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.

Modification to or repeal of all or certain provisions of the Healthcare Reform Act are expected as a result of the outcome of the recent presidential election and Republicans maintaining control of Congress, consistent with statements made by Donald Trump and members of Congress during the presidential campaign and following the election. We cannot predict the ultimate content, timing or effect of any changes to the Healthcare Reform Act or other federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future 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.

General legislative cost control measures may also affect reimbursement for our products. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect through 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 could have an adverse impact on our results of operations.

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 criminal or civil sanctions, including fines and civil monetary penalties, and/or exclusion from federal health care programs (including Medicare and Medicaid). Federal and state authorities are paying increased attention to enforcement of these laws within the pharmaceutical industry, and private individuals have been active in alleging violations of the laws and bringing suits on behalf of the government under the federal False Claims Act (FCA). Violations of international fraud and abuse laws could result in similar penalties, including exclusion from participation in health programs outside the U.S. 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. The Healthcare Reform Act clarifies the intent requirements of the federal Anti-Kickback Statute, providing that a person or entity does not need to have actual knowledge of the statute or a specific intent to violate the statute. 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. 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. 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 willfully, 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

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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 $10,781 to $21,563 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). The Healthcare Reform Act 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. 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 activities could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

Other Healthcare Laws

Our operations may be affected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations (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 (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 (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

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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 U.S. 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 U.S. 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 Part I, Item 1A. Risk Factors We use hazardous materials in our business and must comply with environmental laws and regulations, which can be expensive.

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

We are required to maintain a number of environmental permits and nuclear licenses for our North Billerica, Massachusetts 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 (D&D) the Billerica site at the end of its use as a nuclear facility. In addition, we have a radioactive production facility in San Juan, Puerto Rico. As of December 31, 2016, we currently estimate the D&D cost to be approximately $26.9 million. As of December 31, 2016 and 2015, we have a liability recorded associated with the fair value of the asset retirement obligations of approximately $9.4 million and $8.1 million, respectively. We have recorded accretion expense of $0.9 million, $0.7 million and $0.8 million during the years ended December 31, 2016, 2015 and 2014, 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 below regulatory limits, 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

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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, 2017, we had 465 employees, of which 421 were located in the U.S. and 44 were located internationally, and approximately 78 contractors. None of our employees are represented by a collective bargaining agreement, 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 E.I. du Pont de Nemours and Company (DuPont) in 1981. BMS subsequently acquired our diagnostic medical imaging business as part of its acquisition of DuPont Pharmaceuticals in 2001. In January 2008, Avista Capital Partners, L.P., Avista Capital Partners (Offshore), L.P. and ACP-Lantern Co-Invest, LLC (collectively Avista) formed Lantheus Holdings and its subsidiary, Lantheus Intermediate, and, through Lantheus Intermediate, acquired our medical imaging business from BMS. On June 30, 2015, the Company completed an initial public offering (IPO) of its common stock. Immediately prior to the consummation of the Company s IPO, Lantheus MI Intermediate merged with and into Lantheus Holdings, Inc., which was the survivor of the merger. The Company s common stock is now traded on the NASDAQ Global Market under the symbol LNTH .

Executive Officers of the Registrant

The following table sets forth information regarding our executive officers, including their ages as of the date of this report:

Name	Age	Position
Mary Anne Heino	57	Chief Executive Officer, President and Director
Jack Crowley	53	Chief Financial Officer and Treasurer
William Dawes	45	Vice President, Manufacturing and Operations
Michael Duffy	56	Senior Vice President, Strategy and Business Development, General Counsel and Secretary
Timothy Healey	51	Senior Vice President, Commercial
Dr. Cesare Orlandi	66	Chief Medical Officer
Dr. Simon Robinson	57	Vice President, Research and Development
Carol Walker	54	Vice President, Quality

Mary Anne Heino has served as our Chief Executive Officer and Director since August 2015. She previously served as our Chief Operating Officer, a position she held since March 2015, and our Chief Commercial Officer, a position she held since joining the Company in April 2013. Ms. Heino brings more than 25 years of diverse pharmaceutical industry experience. Prior to joining Lantheus, Ms. Heino led Angelini Labopharm LLC and Labopharm USA in the roles of President and Senior Vice President of World Wide Sales and Marketing from February 2007 to March 2012.

From May 2000 until February 2007, Ms. Heino served in numerous capacities at Centocor, Inc., a Johnson & Johnson Company, including Vice President Strategic Planning and Competitive Intelligence, Vice President Sales, Executive Director Customer Relationship Management and Senior Director Immunology Marketing. Ms. Heino began her professional career with Janssen

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Pharmaceutica as a Sales Representative in June 1989 and worked her way up to the role of Field Sales Director in 1999. Ms. Heino received her Master in Business Administration from New York University Stern School of Business. She earned a Bachelor of Science in Nursing from the City University of New York and a Bachelor of Science in Biology from the State University of New York at Stony Brook. Ms. Heino was chosen as a Director because of her role as President and Chief Executive Officer, which gives her an extensive understanding of our business and operations, and because of her strong commercial experience in the pharmaceutical industry.

Jack Crowley has served as our Chief Financial Officer and Treasurer since March 2016. Mr. Crowley previously served as our interim Chief Financial Officer from December 2015 to March 2016 and as our Vice President, Chief Accounting Officer from March 2015 to December 2015. Mr. Crowley held the position of Vice President, Finance from April 2013 until March 2015 and was Director, Accounting from September 2010 until April 2013. Prior to joining Lantheus, Mr. Crowley was the Assistant Corporate Controller of Biogen Idec, the Director of Accounting at Thermo Fischer Scientific and a Senior Manager in the Audit practice of PricewaterhouseCoopers LLP. Mr. Crowley holds a Master of Business Administration degree from the University of Massachusetts and a Bachelor of Science in Business Administration from Westfield State University and is a Certified Public Accountant (Massachusetts licensure, current status inactive).

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

Michael Duffy has served as our Senior Vice President, Strategy and Business Development since October 2015 and our Vice President, General Counsel and Secretary since January 2008. From 2002 to 2008, he served as Senior Vice President, General Counsel and Secretary of Point Therapeutics, Inc., a Boston-based biopharmaceutical company. Between 1999 and 2001, Mr. Duffy served as Senior Vice President, General Counsel and Secretary of Digital Broadband Communications, Inc., a competitive local exchange carrier. From 1996 to 1999, Mr. Duffy served as Senior Vice President, General Counsel and Secretary of ETC w/tci, a sub-portfolio of TCI Ventures, Inc./Liberty Media Corporation. Mr. Duffy began his legal career with the law firm Ropes & Gray and holds law degrees from the University of Pennsylvania and Oxford University and a Bachelor of Arts degree in History of Science from Harvard College. From 2013 to 2015, Mr. Duffy also served as the Chairman of the Board of Directors of CORAR, the Council on Radionuclides and Radiopharmaceuticals, a trade association for the radiopharmaceutical industry.

Timothy Healey has served as our Senior Vice President, Commercial since November 2015. Previously, Mr. Healey spent nearly three years with Abbott Laboratories and then AbbVie, Inc., a spinoff of Abbott, as Vice President, U.S. Virology. Before joining Abbott/AbbVie, he served as Senior Vice President, Commercial Operations at AMAG Pharmaceuticals and Executive Director, CNS Marketing at Sepracor. Earlier in his career, Mr. Healey held positions at Aventis, Hoechst Marion Roussel, Marion Merrell Dow and Marion Laboratories, including sales and sales management roles. He received a Bachelor of Science from Boston College and a Master of Business Administration from Babson College, Franklin W. Olin Graduate School of Business.

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

company developing hospital products for cardiovascular indications. From 1998 until 2007, Dr. Orlandi served, among other positions, as Vice President, Global Clinical Development of Otsuka Pharmaceuticals, a large Japanese pharmaceutical company. Earlier in his career, Dr. Orlandi served in

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increasing roles of clinical research responsibility at Medco Research, Inc. and the Radiopharmaceutical Division of The DuPont Merck Pharmaceutical Company, a predecessor organization to Lantheus, and The Upjohn Company. Dr. Orlandi received his medical degree from the University of Pavia Medical School in Pavia, Italy. He is currently an Adjunct Assistant Professor of Medicine at Tufts University School of Medicine in Boston, Massachusetts, and he is a founding member of the American Society of Nuclear Cardiology and a Fellow of the American College of Cardiology, the European Society of Cardiology and the American Society of Nuclear Cardiology.

Dr. Simon Robinson has served as our Vice President, Research and Pharmaceutical Development, a position he has held since February 2010. Dr. Robinson was our Senior Director, Discovery Research from 2008 to 2010 and our Director, Discovery Biology and Veterinary Sciences from 2001 to 2008. Prior to joining us, he held research positions at Bristol-Myers Squibb, Sphinx Pharmaceuticals, BASF and DuPont Pharmaceuticals. He holds a Ph.D. and Bachelor of Science Pharmacology from the University of Leeds, England and did post-doctoral training at the University of Wisconsin Clinical Cancer Center.

Carol Walker has served as our Vice President, Quality since February 2015. Ms. Walker brings more than 30 years of industry experience in quality and medical technology primarily in the medical device area. Prior to joining Lantheus, Ms. Walker served as Vice President of Quality for Intelligent Medical Devices, Inc. from 2012 to 2015. Previously she held a number of successive Quality management roles at Siemens Healthcare Diagnostics (formerly Bayer Healthcare Diagnostics), including Vice President, Quality Assurance from 2007 to 2011 and Director, Quality Assurance from 2001 to 2007. Ms. Walker received a Bachelor of Science degree in Medical Technology from the Rochester Institute of Technology.

Available information

The Company maintains a global internet site at www.lantheus.com. The Company makes available for free on its website its Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as soon as reasonably practicable after such reports are electronically filed with, or furnished to the SEC. The public may read and copy any materials the Company files with the SEC at the SEC s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. 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 on Form 10-K.

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, Cardiolite and evacuation vials. Our technology

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transfer activities with Pharmalucence for the manufacture and supply of DEFINITY have been repeatedly delayed, and we are now in the process of negotiating an exit to that arrangement. We currently have additional on-going technology transfer activities for our next generation DEFINITY product with SBL, but we cannot give any assurances as to when that technology transfer will be completed and when we will actually receive supply of next generation DEFINITY product from SBL. Currently, our DEFINITY, Neurolite, Cardiolite, evacuation vial and saline product supplies are approved for manufacture by a single manufacturer.

Based on our current estimates, we believe that we will have sufficient supply of DEFINITY, Neurolite, Cardiolite and evacuation vials from JHS, and sufficient supply of saline from our sole manufacturer, to meet expected demand. However, we can give no assurances that JHS or our other manufacturing partner 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, regulatory authorities in certain countries have not yet approved JHS as a manufacturer of certain 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.

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 and Quadramet using our hot cell infrastructure. As with all manufacturing facilities, equipment and infrastructure age and become subject to increasing maintenance and repair. If we or one of our manufacturing partners experiences an event, including a labor dispute, natural disaster, fire, power outage, machinery breakdown, security problem, failure to meet regulatory requirements, product quality issue, technology transfer issue or other issue, we may be unable to manufacture the relevant products at previous levels or on the forecasted schedule, if at all. Due to the stringent regulations and requirements of the governing regulatory authorities regarding the manufacture of our products, we may not be able to quickly restart manufacturing at a third party or our own facility or establish additional or replacement sources for certain products, components or materials.

In addition to our existing manufacturing relationships, we are also pursuing new manufacturing relationships to establish and secure additional or alternative suppliers for our commercial products. Our technology transfer activities with Pharmalucence for the manufacture and supply of DEFINITY have been repeatedly delayed, and we are now in the process of negotiating an exit to that arrangement. We currently have additional on-going technology transfer activities for our next generation DEFINITY product with SBL, but we cannot assure you that these activities or any of our additional supply activities will be successful or that we will be able to avoid or mitigate interim supply shortages before those new manufacturers or sources of product are fully functional and qualified. 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 revenues, 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

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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 shut down production lines based on internal safety and quality monitoring and testing data.

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

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

A critical ingredient of TechneLite, historically our largest product by annual revenues, is Moly. We currently purchase finished Moly from three of the four main processing sites in the world, namely NTP in South Africa; ANSTO in Australia; and IRE in Belgium. These processing sites are, in turn, supplied by five of the six main Moly-producing reactors in the world, namely, OPAL in Australia; BR2 in Belgium; LVR-15 in the Czech Republic; HFR in The Netherlands; and SAFARI in South Africa.

Historically, our largest supplier of Moly was Nordion, which has relied on the NRU reactor owned by Atomic Energy of Canada Limited (AECL), a Crown corporation of the Government of Canada, located in Chalk River, Ontario. As a result of a decision by the Government of Canada, the NRU reactor is exiting the medical isotope business and beginning in November 2016 will provide only emergency back-up Moly supply 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 commercial production planned to start in the first half of 2018. In addition, IRE received approval from its regulator to expand its production capability by up to 50% of its former capacity. This new ANSTO and IRE production capacity is expected to replace the NRU s most recent 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 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 entered into a 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 will result in commercial quantities of Moly for our business, or that these new suppliers together with our current suppliers will be able to deliver a sufficient quantity of Moly to meet our needs.

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U.S., Canadian and international governments have encouraged the development of a number of alternative Moly production projects with existing reactors and technologies as well as new technologies. However, the Moly produced from these projects will likely not become available until at least 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 (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.

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 U.S., over 31.8 million in 2016, based on medical literature, a third party source estimates that 20%, or approximately 6.4 million echocardiograms in 2016, produced suboptimal images. We estimate that DEFINITY had an approximately 80% share of the U.S. market for contrast agents in echocardiography procedures as of December 2016. 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.

Historically, Nordion was our sole supplier, and a principal supplier on a global basis, of Xenon, which is captured as a by-product of the Moly production process. In January 2015, we entered into a strategic agreement

with IRE for the supply of Xenon. We are now receiving bulk unprocessed Xenon from IRE, which we are processing and finishing for our customers. We believe we will have sufficient supply of Xenon to meet our customers needs. However, until we can qualify an additional source of bulk unprocessed Xenon, we will rely on IRE as a sole source provider. For the year ended December 31, 2016, Xenon represented approximately 9.6% of our revenues.

Historically, several companies, including IBAM, sold packaged Xenon as a pulmonary imaging agent in the U.S., but from 2010 through the first quarter of 2016 we were the only supplier of this imaging agent in the U.S. In March 2016, IBAM received regulatory approval from the FDA to again sell packaged Xenon in the U.S. and has begun to do so. Depending upon the pricing, extent of availability and market penetration of IBAM s offering, we believe we are at risk for volume loss and price erosion from those customers which are not subject to price or volume commitments with us.

In addition to IBAM again selling 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 (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. Since 2014, Draxis has instituted multiple and 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 U.S., we are heavily dependent on a few large customers and group purchasing organization arrangements to generate a majority of our revenues for our medical imaging products. Outside of the U.S., we rely primarily on distributors to generate a substantial portion of our revenue.

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

In Puerto Rico, we own and operate one of two radiopharmacies on the island and sell our own products as well as products of third parties to end users.

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

Outside of the U.S., Canada and Puerto Rico, we have no sales force and, consequently, rely on third party distributors, either on a country-by-country basis or on a multi-country, regional basis, to market, sell and distribute our products. This is the case in both Canada and Australia, where we formerly owned or operated

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radiopharmacies and are now distributing products under the Isologic Agreement and the GMS Agreement, respectively. Distributors accounted for approximately 34%, 15% and 17% of International segment revenues for the years ended December 31, 2016, 2015 and 2014, respectively. In certain circumstances, distributors may also sell competing products to our own or products for competing diagnostic modalities and may have incentives to shift sales towards those competing products. As a result, we cannot assure you that our international distributors will increase or maintain 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 stockholders 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 and 2014 of $14.7 million and $3.6 million, respectively, and as of December 31, 2016, we had a total stockholders deficit of $106.5 million. Although we had net income of $26.8 million for the year ended December 31, 2016, we cannot assure you that we will be able to sustain profitability on a quarterly or annual basis in the future. If we cannot improve our profitability, the value of our enterprise may decline.

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

The market for diagnostic medical imaging agents is highly competitive and continually evolving. Our principal competitors in existing diagnostic modalities include large, global companies with substantial financial, manufacturing, sales and marketing and logistics resources that are more diversified than ours, such as GE Healthcare, Bracco, IBAM, 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.

Xenon for lung ventilation diagnosis is our third largest product by revenue. Historically, several companies, including IBAM, sold packaged Xenon as a pulmonary imaging agent in the U.S., but from 2010 through the first quarter of 2016, we were the only supplier of this imaging agent in the U.S. In March 2016, IBAM received regulatory approval from the FDA to again sell packaged Xenon in the U.S. and has begun to do so. Depending upon the pricing, extent of availability and market penetration of IBAM s 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 U.S. 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

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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 (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 certain alternative payment models designated as advanced by CMS. 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

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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 are not separately payable by Medicare, although new drug products are eligible for separate payment for a portion of the drug products costs and certain products may trigger an additional nominal payment. 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 a nominal additional payment ($10) to hospitals that utilize products with non-HEU, meaning the product is 95% derived from non-HEU sources. This payment policy continues in 2017. Although some of our TechneLite generators are manufactured using non-HEU, not all of our TechneLite generators meet CMS s definition of non-HEU, and therefore this payment is not 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. Federal legislation requires CMS to develop appropriate use criteria (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 2018, 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 U.S., our business, results of operations, financial condition and cash flows would be adversely affected. See Part I, Item I. Business Regulatory Matters.

Reforms to the U.S. healthcare system may adversely affect our business.

A significant portion of our patient volume is derived from U.S. government healthcare programs, principally Medicare, which are highly regulated and subject to frequent and substantial changes. For example, in March 2010, the President signed one of the most significant healthcare reform measures in decades, the Healthcare Reform Act. The Healthcare Reform Act 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 U.S. See Part I, Item 1. Business Regulatory Matters Healthcare Reform and Other Laws Affecting Payment. 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

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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 2024, and a 4% reduction in payment to providers during 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.

Further, changes in payor mix and reimbursement by private third party payors may also affect our business. 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.

The full impact on our business of healthcare reforms and other new laws, or changes in existing laws, is uncertain. Nor is it clear whether additional legislative changes will be adopted or how those changes would affect our industry in general or our ability to successfully commercialize our products or develop new products.

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 U.S. as well as non-U.S. and transnational laws and regulations, with regulations differing from country to country. In the U.S., 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 U.S., including to the EMA and MHRA. Additionally, we must comply with requirements concerning advertising and promotion for our products, including the prohibition on the promotion of our products for indications that have not been approved by the FDA or a so-called off-label use. If the FDA determines that our promotional materials constitute the unlawful promotion of an off-label use, it could request that we modify our promotional materials or subject us to regulatory or enforcement actions. Also, quality control and manufacturing procedures at our own facility and at third party suppliers must conform to cGMP regulations and other applicable law after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMPs and other applicable law, and, from time to time, makes those cGMPs more stringent. Accordingly, we and others with whom we work must expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control. For example, we currently rely on JHS as our sole manufacturer of DEFINITY, Neurolite, Cardiolite 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

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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, and in 2016 entered into a separate Medicaid Drug Rebate Agreement for the balance of our products. These agreements require 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 at the time covered by the agreements. 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. In 2016, CMS 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 Part I, Item 1. Business Regulatory Matters Healthcare Fraud and Abuse Laws.

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

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

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

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

We are subject to 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 U.S., and even alleged violations can result in the imposition of corporate integrity agreements that could severely restrict or limit our business practices. See Part I, Item 1. Business-Regulatory Matters-Healthcare Fraud and Abuse Laws and Laws Relating to Foreign Trade. These

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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.

If our operations are found to be in violation of these laws or any other government regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, imprisonment, the curtailment or restructuring of our operations, or exclusion from state and federal healthcare programs including Medicare and Medicaid, any of which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

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

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

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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.

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 Part I, Item 1. Business Regulatory Matters. Satisfaction of all regulatory requirements typically takes many years and requires the expenditure of substantial resources. A number of other factors may cause significant delays in the completion of our clinical trials, including unexpected delays in the

initiation of clinical sites, slower than projected enrollment, competition with ongoing clinical trials and scheduling conflicts with participating clinicians, regulatory requirements, limits on manufacturing capacity and failure of an agent to meet required standards for administration to humans. In addition, it may take longer than we project to achieve study endpoints and complete data analysis for a trial or we may decide to slow down the enrollment in a trial in order to conserve financial resources.

Our agents in development are also subject to the risks of failure inherent in drug development and testing. The results of preliminary studies do not necessarily predict clinical success, and larger and later stage clinical trials may not produce the same results as earlier stage trials. Sometimes, agents that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials. Agents in later stage clinical trials may fail to show desired safety and efficacy traits, despite having progressed through initial

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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 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 an NDA approval, that only one additional clinical trial will have to be conducted prior to filing an NDA, or that flurpiridaz F 18 will ever be approved as a PET MPI imaging agent by the FDA. See Part I, Item 1. Business Regulatory Matters Food and Drug Laws.

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

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

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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 may 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 fund our important R&D programs, reducing our internal R&D resources. On February 21, 2017, we announced entering into a term sheet with GE Healthcare related to the continued development and commercialization of flurpiridaz F 18. Subject to satisfactory due diligence and necessary approvals, we anticipate entering into a definitive agreement for the proposed transaction in the second quarter of 2017. However, there is no assurance that we will enter into a definitive agreement with GE Healthcare on the proposed terms or at all. See Part I, Item 1. Business Research and Development Proposed GE Healthcare Transaction .

In the future, we may also seek to engage strategic partners for our 18F LMI 1195 and LMI 1174 programs. 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 may have to limit the size or scope of, or delay, our development programs.

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

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

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;

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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.

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 U.S.) 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

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date, claims that could be brought against us might not be covered by our insurance policies. Furthermore, although we currently have product liability insurance coverage with policy limits that we believe are customary for pharmaceutical companies in the diagnostic medical imaging industry and adequate to provide us with insurance coverage for foreseeable risks, even where the claim is covered by our insurance, our insurance coverage might be inadequate and we would have to pay the amount of any settlement or judgment that is in excess of our policy limits. We may not be able to obtain insurance on terms acceptable to us or at all, since insurance varies in cost and can be difficult to obtain. Our failure to maintain adequate insurance coverage or successfully defend against product liability claims could have a material adverse effect on our business, results of operations, financial condition and cash flows.

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 U.S. and in foreign countries. We will only be able to protect our intellectual property from unauthorized use by third parties to the extent that we maintain the secrecy of our trade secrets and can enforce our valid patents and trademarks.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. In addition, changes in either the patent laws or in interpretations of patent laws in the U.S. or other countries may diminish the value of our intellectual

property and we may not receive the same degree of protection in every jurisdiction.

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Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third party patents.

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

- We might not have been the first to make the inventions covered by each of our pending patent applications and issued patents, and we could lose our patent rights as a result;
- We might not have been the first to file patent applications for these inventions or our patent applications may not have been timely filed, and we could lose our patent rights as a result;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies;
- It is possible that none of our pending patent applications will result in any further issued patents;
- Our issued patents may not provide a basis for commercially viable drugs, may not provide us with any protection from unauthorized use of our intellectual property by third parties, and may not provide us with any competitive advantages;
- Our patent applications or patents may be subject to interferences, oppositions, post-grant review, 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 U.S. patents and so our products may not receive the same degree of protection in foreign countries as they would in the U.S.;
- We may not develop additional proprietary technologies that are patentable; or

The patents of others may have an adverse effect on our business.

Moreover, the issuance of a patent is not conclusive as to its validity or enforceability. A third party may challenge the validity or enforceability of a patent even after its issuance by the 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

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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 U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. We often rely on confidentiality agreements with our collaborators, employees, consultants and other third parties and invention assignment agreements with our employees to protect our trade secrets and other know-how and proprietary information concerning our business. These confidentiality agreements may not prevent unauthorized disclosure of trade secrets and other know-how and proprietary information, and there can be no guarantee that an employee or an outside party will not make an unauthorized disclosure of our trade secrets, other technical know-how or proprietary information, or that we can detect such an unauthorized disclosure. We may not have adequate remedies for any unauthorized disclosure. This might happen intentionally or inadvertently. It is possible that a 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, 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 U.S. and inflationary pressures. We cannot anticipate all the ways in which the current economic climate and financial market conditions could adversely impact our business.

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We are exposed to risks associated with reduced profitability and the potential financial instability of our customers, many of which may be adversely affected by volatile conditions in the financial markets. For example, unemployment and underemployment, and the resultant loss of insurance, may decrease the demand for healthcare services and pharmaceuticals. If fewer patients are seeking medical care because they do not have insurance coverage, our customers may experience reductions in revenues, profitability and/or cash flow that could lead them to modify, delay or cancel orders for our products. If customers are not successful in generating sufficient revenue or are precluded from securing financing, they may not be able to pay, or may delay payment of, accounts receivable that are owed to us. This, in turn, could adversely affect our financial condition and liquidity. 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, 2016, 2015 and 2014, we derived approximately 15%, 20% and 22% of our revenues from outside the fifty United States, respectively. We anticipate that revenue from non-U.S. operations will grow in the future from 2016 levels. 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, 2016, 2015 and 2014, the net impact of foreign currency changes on transactions was a loss of $0.9 million, $1.8 million and $0.3 million, respectively. Operations outside the U.S. 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.

With the exception of our United Kingdom subsidiary, the functional currencies of our International Segment subsidiaries are the respective local currencies of each entity. Exchange rates between some of these currencies and the 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 against economic exposures related to foreign currencies. During the year ended December 31, 2016, fluctuations in exchange rates had a $0.9 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 U.S. 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 U.S.

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 U.S. 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

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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. 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 which, due to the nature of such attacks, may remain undetected for a period of time. 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, reputation, 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. 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.

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, 2016, we had approximately $284.5 million of total principal indebtedness remaining under our seven-year senior secured term loan facility, which matures on June 30, 2022 (the Term Facility).

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Our aggregate Borrowing Base was approximately $44.6 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 $35.7 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;
- 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

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among restricted subsidiaries and us and indebtedness relating to hedging obligations. See Part II, Item 7. 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;

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, 2016, we had federal income tax loss carryforwards of $200.3 million, which will begin to expire in 2030 and will completely expire in 2036. We have had significant financial losses in previous years and as a result

we currently maintain a full valuation allowance for our net deferred tax assets including our federal and state tax loss carryforwards. We may be limited in our ability to use these tax loss carryforwards to reduce our future U.S. federal income tax liabilities if we were to experience another ownership change as specified in Section 382 of the Internal Revenue Code including if we were to issue a certain amount of equity securities, certain of our stockholders were to sell shares of our common stock, or we were to enter into certain strategic transactions.

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.