

Lantheus Holdings, Inc.  
Form S-1/A  
July 09, 2014  
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As filed with the Securities and Exchange Commission on July 9, 2014

Registration No. 333-196998

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

Amendment No. 1 to

## FORM S-1

REGISTRATION STATEMENT UNDER THE  
SECURITIES ACT OF 1933

# Lantheus Holdings, Inc.

(Exact name of registrant as specified in its charter)

<b>Delaware</b>	<b>2835</b>	<b>35-2318913</b>
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(IRS Employer Identification No.)

**331 Treble Cove Road**  
**North Billerica, Massachusetts 01862**

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(978) 671-8001

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Michael P. Duffy**

**Vice President, General Counsel and Secretary**

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, or the Securities Act, check the following box. "

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

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If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

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 the definitions of "accelerated filer," "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer "

Accelerated filer "

Non-accelerated filer

Smaller reporting company "

(Do not check if a smaller

reporting company)

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Commission acting pursuant to said Section 8(a), may determine.**

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**EXPLANATORY NOTE**

Upon consummation of this offering, we will enter into a corporate reorganization, whereby our direct, wholly-owned subsidiary, Lantheus MI Intermediate, Inc. will merge with and into us. See Prospectus Summary Corporate Reorganization in the accompanying prospectus.

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**The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

**SUBJECT TO COMPLETION, DATED JULY 9, 2014**

**PRELIMINARY PROSPECTUS**

**Shares**

**Lantheus Holdings, Inc.**

**Common Stock**

**\$            per share**

This is the initial public offering of our common stock. We are selling            shares of our common stock. We currently expect the initial public offering price to be between \$            and \$            per share of common stock. No public market currently exists for our common stock.

We have granted the underwriters an option to purchase up to            additional shares of common stock solely to cover over-allotments.

We intend to apply to have our common stock listed on The NASDAQ Global Market under the symbol LNTH.

We are an emerging growth company as defined under the federal securities laws and, as such, will be subject to reduced public company reporting requirements. See Prospectus Summary Implications of Being an Emerging Growth Company.

**Investing in our common stock involves a high degree of risks. See Risk Factors beginning on page 16.**

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	<b>PER SHARE</b>	<b>TOTAL</b>
Public Offering Price	\$	\$
Underwriting Discount(1)	\$	\$
Proceeds to Lantheus Holdings, Inc. (before expenses)	\$	\$

(1) We refer you to Underwriting beginning on page 166 of this prospectus for additional information regarding total underwriting compensation.

The underwriters expect to deliver the shares to purchasers on or about \_\_\_\_\_, 2014 through the book-entry facilities of The Depository Trust Company.

**Citigroup**

**Jefferies**

**RBC Capital Markets**

**Wells Fargo Securities**

**Baird**

, 2014

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You should rely only on the information contained in this prospectus. We and the underwriters have not authorized any other person to provide you with any additional information or different information. If anyone provides you with additional, different or inconsistent information, you should not rely on it. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is only accurate as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

**TRADEMARKS**

We own or have the rights to various trademarks, service marks and trade names, including, among others, the following: DEFINITY®, TechneLite®, Cardiolute®, Neurolite®, Ablavar®, Vialmix®, Quadramet® (United States only) and Lantheus Medical Imaging® referred to in this prospectus. Solely for convenience, we refer to trademarks, service marks and trade names in this prospectus 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 prospectus, such as Myoview®, Optison® and SonoVue® are, to our knowledge, owned by that other company.

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**MARKET AND INDUSTRY INFORMATION**

Market data and industry information used throughout this prospectus is based on management's knowledge of the industry and the good faith estimates of management. We also relied, to the extent available, upon management's review of independent industry surveys and publications, including Global Industry Analysts, Inc. and Frost & Sullivan, and other publicly available information prepared by a number of sources, including American Heart Association. All of the market data and industry information used in this prospectus involves a number of assumptions and limitations, and you are cautioned not to give undue weight to these estimates. While we believe the estimated market position, market opportunity and market size information included in this prospectus is reliable, that information, which is derived in part from management's estimates and beliefs, is inherently uncertain and imprecise. Projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in Risk Factors, Cautionary Note Regarding Forward-Looking Statements and elsewhere in this prospectus. Those and other factors could cause results to differ materially from those expressed in our estimates and beliefs and in the estimates prepared by independent parties.



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**PROSPECTUS SUMMARY**

*This summary provides an overview of selected key information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and consolidated financial statements included elsewhere in this prospectus. You should carefully review the entire prospectus, including the risk factors, the consolidated financial statements and the notes thereto, and the other documents to which this prospectus refers before making an investment decision. 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, after giving effect to the corporate reorganization described below; references to Lantheus Holdings refer to Lantheus Holdings, Inc. (previously named Lantheus MI Holdings, Inc.), our predecessor; references to Lantheus Intermediate refer to Lantheus MI Intermediate, Inc.; and references to LMI refer to Lantheus Medical Imaging, Inc., our wholly-owned subsidiary.*

**Overview**

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

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

For the three months ended March 31, 2014, we recorded revenues, net income (loss) and Adjusted EBITDA of \$73.3 million, \$(1.3) million and \$16.0 million, respectively. For the year ended December 31, 2013, we recorded revenues, net income (loss) and Adjusted EBITDA of \$283.7 million, \$(61.6) million and \$47.4 million, respectively. Our products are sold in 30 countries and we generated approximately 23% and 25% of our revenues outside of the United States for the three months ended March 31, 2014 and the year ended December 31, 2013, respectively. For an explanation of Adjusted EBITDA and a reconciliation of Adjusted EBITDA to net income (loss) as calculated under generally accepted accounting principles, or GAAP, see footnote (1) of Summary Consolidated Financial and Other Data.

Our portfolio of 10 commercial products is diversified across a range of imaging modalities. Our imaging agents include radiopharmaceuticals and contrast agents.

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.

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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 radioactive target is bombarded with subatomic particles, or on a cyclotron, which is a type of particle accelerator that also creates radioisotopes.

Two common forms of nuclear imaging procedures are single-photon emission computed tomography, or SPECT, which measures gamma rays emitted by a SPECT radiopharmaceutical, and positron emission tomography, or PET, which measures positrons emitted by a PET radiopharmaceutical.

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

As an example of the procedures in which our products may be used, in the diagnosis of coronary artery disease, a typical diagnostic progression could include an electrocardiogram, followed by an echocardiogram (possibly using our agent DEFINITY), and then a nuclear myocardial perfusion imaging, or MPI, study using either SPECT or PET imaging (possibly using our technetium generator or one of our MPI agents). An MPI study assesses blood flow distribution to the heart. MPI is also used for diagnosing the presence of coronary artery disease. See Diagnostic Medical Imaging Overview.

### *Leading Products*

Our leading commercial products are:

**DEFINITY** the leading ultrasound contrast imaging agent used by cardiologists and sonographers during echocardiography exams based on revenue and usage. DEFINITY is an injectable agent that is indicated in the United States for use in patients with suboptimal echocardiograms to assist in the visualization of the left ventricle, the main pumping chamber of the heart. The use of DEFINITY in echocardiography allows physicians to significantly improve their assessment of the function of the left ventricle. Since its launch in 2001, DEFINITY has been used to image approximately five million patients.

Of the approximately 28 million echocardiograms performed each year in the United States, a third party source estimates that approximately 20%, or approximately six million echocardiograms, produce suboptimal images. We believe that in 2013, 3.1% of the total echocardiography procedures performed in the United States used a contrast agent (which translates to only approximately 15% of all echocardiograms considered suboptimal). We believe that through April 2014, the average contrast penetration rate increased to 3.5%. Contrast penetration rates in echocardiography procedures have increased over the past six years and we believe will continue to increase in the future as clinicians continue to adopt the use of contrast as an important tool to assist their clinical decision-making. Of the echocardiograms in which a contrast agent is used, we estimate that DEFINITY had an approximate 75% share of these procedures in the United States in December 2013.

We believe that DEFINITY has this leading position because of its preferred product functionality and composition derived from a synthetic rather than a blood-based product. As a result, we believe DEFINITY will be a key driver of the future growth of our business, both in the United States and in international markets as we continue to grow contrast penetration through sales and marketing efforts focused on the appropriate use of contrast and maintain our leading position. DEFINITY currently has patent or other exclusivity protection until 2021 in the United States and until 2019 outside of the United States.

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***TechneLite*** a self-contained system, or generator, of technetium (Tc99m), a radioisotope with a six hour half-life, used by radiopharmacists at radiopharmacies to prepare patient-specific radiolabeled imaging agents. Technetium results from the radioactive decay of Molybdenum-99, or Moly, itself a radioisotope

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with a 66-hour half-life produced in nuclear research reactors around the world from enriched uranium. Because of the short half-lives of Moly and technetium, radiopharmacies typically replace TechnoLite generators on a weekly basis pursuant to standing orders made with us. In addition, the supply chain for Moly is global and, because of the 66-hour half-life, we utilize just-in-time inventory management. We believe that we have the most balanced and diversified supply chain in the industry, buying Moly from four out of the five major global Moly processors, which are supplied by seven of the eight major global Moly reactors.

We are one of two principal technetium generator manufacturers in the United States and Canada. We are also the leading and most consistent U.S. manufacturer of low-enriched uranium, or LEU, technetium generators. Governments and policy-makers are encouraging the increased use of technetium generators made with Moly derived from LEU rather than highly-enriched uranium, or HEU, which may present greater proliferation and security risks. In the United States, nuclear imaging agent unit doses prepared with LEU technetium generators are reimbursed by Medicare in the hospital outpatient setting at a higher rate.

We believe that our substantial capital investments in our highly automated TechnoLite 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. We estimate that in 2013, we had an approximately 40% share of generator sales in the United States. Certain TechnoLite generator components currently have U.S. patent protection until 2029.

### ***Other Commercial Products***

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

*Xenon Xe 133 Gas* is a radiopharmaceutical gas that is inhaled and used to assess pulmonary function and also to image blood flow. Our Xenon is manufactured by a third party as part of the Moly production process and packaged by us. We are currently the leading provider of Xenon in the United States.

*Cardiolite* is an injectable, technetium-labeled imaging agent, also known by its generic name sestamibi, used with SPECT technology in MPI procedures that assess blood flow to the muscle of the heart. Launched in 1991, Cardiolite has the highest cumulative revenue of any branded radiopharmaceutical in history.

*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.

*Thallium Tl 201* is an injectable radiopharmaceutical imaging agent used in MPI studies to detect coronary artery disease and is manufactured by us using cyclotron-based technology.

*Gallium Ga67* is an injectable radiopharmaceutical imaging agent used to detect certain infections and cancerous tumors, especially lymphoma, and is manufactured by us using cyclotron technology.

*Gludef* is an injectable, fluorine-18-labeled imaging agent used with PET technology to identify and characterize tumors in patients undergoing oncologic diagnostic procedures. Gludef is our branded version of fludeoxyglucose F 18 injection, or FDG.

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*Quadramet*, our only therapeutic product, is an injectable radiopharmaceutical used to treat severe bone pain associated with certain kinds of cancer, and is manufactured by us.

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*Ablavar* is an injectable, gadolinium-based contrast agent used with magnetic resonance angiography, or MRA, a type of MRI scan, to image the iliac arteries that start at the aorta and go through the pelvis into the legs, in order to diagnose narrowing or blockage of these arteries in known or suspected peripheral vascular disease.

In the United States, we sell DEFINITY through our sales team of approximately 80 employees that call on healthcare providers in the echocardiography space, as well as group purchasing organizations and integrated delivery networks. Our radiopharmaceutical products are primarily distributed through over 350 radiopharmacies, the majority of which are controlled by or associated with Cardinal Health, or Cardinal, United Pharmacy Partners, or UPPI, GE Healthcare and Triad Isotopes, Inc., or Triad.

In Canada, Puerto Rico and Australia, we own nine radiopharmacies and sell our radiopharmaceuticals, as well as others, directly to end users. In Europe, Asia Pacific and Latin America, we utilize distributor relationships to market, sell and distribute our products. We have entered into a partnership with Double-Crane Pharmaceutical Company, or Double-Crane, to complete confirmatory clinical trials necessary for Chinese regulatory approval and to distribute DEFINITY in China. We believe that international markets, particularly China, represent significant growth opportunities for our products.

### ***Our Agents in Development***

We have established a portfolio of three internally-discovered imaging agents in clinical and preclinical development, each of which we believe could represent a large market opportunity and has the potential to significantly enhance current imaging modalities and fulfill unmet diagnostic medical imaging needs. We are currently seeking strategic partners to pursue the further development of each of these agents, which include:

***Flurpiridaz F 18 Myocardial Perfusion Imaging Agent.*** Flurpiridaz F 18 is a small molecule imaging agent radiolabeled with fluorine-18 and designed for use in PET MPI to assess blood flow to the muscle of the heart. We believe that in comparison to SPECT MPI, the current standard of care, PET MPI with flurpiridaz F 18 potentially provides higher image quality, increased diagnostic certainty, more accurate risk stratification and reduced patient radiation exposure. This agent could be particularly useful in difficult to image heart patients, including women and obese patients. In the first of two planned Phase 3 studies, flurpiridaz F 18 outperformed SPECT in a highly statistically significant manner in the co-primary endpoint of sensitivity (that is, its ability to identify disease) and in the secondary endpoints of image quality and diagnostic certainty. However, flurpiridaz F 18 did not meet its other co-primary endpoint of non-inferiority for specificity (that is, its ability to rule out disease). Consequently, we have initiated discussions about potential next steps in the flurpiridaz F 18 development process with the U.S. Food and Drug Administration, or FDA. At the same time, we are seeking strategic partners to further develop and, if approved, commercialize flurpiridaz F 18. This compound currently has U.S. patent protection until 2028 before taking into account any potential regulatory extensions.

***18F LMI 1195 Cardiac Neuronal Imaging Agent.*** 18F LMI 1195 is a small molecule imaging agent also radiolabeled with fluorine-18 and designed to assess cardiac sympathetic nerve function with PET imaging. We believe that PET imaging with 18F LMI 1195 could allow for better identification of patients at risk of heart failure progression and fatal arrhythmias, which would better inform pharmaceutical therapy or implantable device use. This compound has completed a Phase 1 study and currently has U.S. patent protection until 2030 before taking into account any potential regulatory extensions.

***LMI 1174 Vascular Remodeling Imaging Agent.*** LMI 1174 is a gadolinium-based MRI agent designed to identify elastin in the arterial walls and atherosclerotic plaques. We believe that this agent could allow for the minimally-invasive assessment of plaque location, burden and composition and,

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accordingly, could be used to risk stratify patients for potential vascular events, including heart attack or stroke. This compound is in late-stage preclinical studies and currently has U.S. patent protection until 2031 before taking into account any potential regulatory extensions.

### **Diagnostic Medical Imaging Agent Overview**

Medical imaging is commonly employed as a critical aid in the diagnosis of numerous medical conditions, including heart disease and cancer. Selection of treatment options and monitoring of disease progression are also facilitated by the use of imaging procedures. Diagnostic medical imaging procedures often employ imaging agents to highlight specific tissues and organs, or physiological or pathological processes. Imaging agents can be used in a range of imaging modalities, including x-ray, computed tomography, or CT, ultrasound, SPECT, PET and MRI.

#### ***Nuclear Imaging***

Nuclear imaging uses small amounts of radioactive materials, called radiopharmaceuticals, taken by injection, inhalation, or orally to diagnose and treat disease. Radiopharmaceutical imaging agents consist of a radioisotope (such as technetium) paired with a molecular agent designed to localize in specific organs and tissues (such as Cardiolite and Neurolite). Clinicians utilize specialized cameras, either SPECT or PET, designed to capture radiation emitted by the agent. Computers are then used to generate detailed images of the area of interest. The resulting images provide clinicians with important information on both the structure and function of the internal organ or tissue.

#### ***Echocardiography***

Cardiac ultrasound, also known as echocardiography, is a non-invasive test that uses sound waves to create moving images of the heart. These images allow an assessment of the heart's size, shape and function. For example, echocardiography can be used to detect areas of the heart that are not functioning properly due to poor blood supply, as seen in patients with coronary artery disease. Echocardiography is considered to be one of the safest, most reliable and cost-effective ways to diagnose certain cardiac abnormalities, and it is the most widely used technique for non-invasive imaging of the heart. Echocardiography may, however, yield images of limited diagnostic value in certain situations due to signal attenuation, such as in women and patients who are obese or have lung disease. It is estimated that suboptimal image quality occurs in approximately 20% of all patients undergoing echocardiography in the United States. Uninterpretable images may lead to misdiagnosis or the need for additional, often unnecessary and costly tests. Use of contrast agents in echocardiography increases sensitivity (the ability to identify the disease) and specificity (the ability to rule out the disease), particularly in hard to image patients, by improving the delineation of the edges of the heart wall. In 2013, according to a third party source, there were 28.3 million echocardiography procedures performed in the United States.

#### ***Imaging Agents Market***

We believe that the demand for imaging agents in developed and developing markets will continue to be driven by an aging and increasingly obese population, and bolstered by long-term initiatives focused on improving healthcare and the supporting infrastructure, with a particular emphasis on expanding access to rural areas and small towns and cities. According to a research report dated February 2012 released by Global Industry Analysts, Inc., or GIA, the worldwide diagnostic imaging market is projected to reach \$15.5 billion by 2015, reflecting a compound annual growth rate of 6.9% over the period from 2007 through 2015.



Heart disease is a key driver of growth in the market for diagnostic medical imaging procedures and agents. Heart disease is currently the leading cause of death for both women and men in the United States and worldwide. According to the American Heart Association, or AHA, an estimated 83.6 million American adults, greater than one in three, have one or more types of heart disease. Heart disease refers to a number of disease

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states including coronary artery disease and structural defects of the heart. Coronary artery disease is the most common form of heart disease, with an estimated prevalence of approximately 6% in the United States. Many of our imaging agents and products are used in connection with diagnostic imaging for heart disease.

### **Our Competitive Strengths**

We believe that our business model provides us with a strong platform to reach our strategic goal of providing cost-effective, clinically-beneficial diagnostic medical imaging agents and products that enable clinicians either to identify and characterize, or rule out, disease and consequently improve patient care. We believe our competitive strengths include:

***Leading Position Across a Range of Imaging Modalities.*** We are a global leader in the diagnostic medical imaging industry with over 50 years of experience in developing and bringing to market differentiated products critical to healthcare decision making, including radiopharmaceutical imaging agents, contrast imaging agents and other products. Our key brands include: DEFINITY, the leading echocardiology contrast imaging agent based on revenue and usage; and TechnoLite, our technetium-based generator used by radiopharmacies to radiolabel technetium-based imaging agents, such as our own SPECT products Cardiolite and Neurolite, that are used in combination with nuclear imaging technologies. We also sell a broad portfolio of other commercial agents and products, diversified across a range of imaging modalities.

***DEFINITY is a Uniquely-Positioned Growth Opportunity in the United States and Globally.*** We believe that DEFINITY will be a key driver of the future growth of our business, both in the United States and globally. In echocardiography procedures in which a contrast agent is used, we estimate that DEFINITY had approximately 75% share of these procedures in the United States in December 2013. We are actively pursuing international growth opportunities, such as our partnership with Double-Crane in China. If the regulatory and required clinical trial processes in China are both timely and successful, we currently estimate the commercialization of DEFINITY in China could begin as soon as 2017. We are also pursuing additional product registrations internationally to maximize the global potential of DEFINITY. We also believe our intellectual property for DEFINITY currently gives us patent or other market exclusivity protection in the United States until 2021 and outside of the United States until 2019.

***Significant Investment in Complex Manufacturing and Regulatory Capabilities.*** We believe that our expertise in the design, development and validation of complex manufacturing systems and processes that many of our radiopharmaceutical products require due to their limited half-lives, as well as our strong track record of on-time delivery and reputation as a high-quality, reliable provider, has enabled us to become a leader in the diagnostic medical imaging industry. 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 create significant and sustainable competitive advantages.

***Diversified Supply Chain.*** We are establishing a strong and diversified supply chain for our key products. For TechnoLite, we have a strong, reliable and durable position in the technetium generator market because of our balanced and diversified Moly supply and our favorable access to Moly derived from LEU. We believe we have the most balanced and diversified Moly supply chain in the industry. We receive finished Moly from four of the five main processing sites in the world. These processing sites are, in turn, supplied by seven of the eight main Moly-producing reactors in the world. We are also the leading and most consistent manufacturer of LEU generators in North America, and we believe that in 2014, up to 40% of our Moly supply will be derived from LEU. For DEFINITY, we have already successfully completed a technology transfer from Ben Venue Laboratories, or BVL, our former manufacturing partner, to Jubilant HollisterStier, or JHS. We are also now in the process of our technology transfer activities with Phamalucence Inc., or Phamalucence, an additional manufacturing partner for DEFINITY.

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***Established Global Distribution Network and Experienced Direct Sales Force.*** We have an established global distribution network including long-term relationships with Cardinal and UPPI, who together distributed an estimated 71% of SPECT doses sold by radiopharmacies in the United States in 2013. In the United States, our radiopharmaceuticals (including technetium generators) are primarily distributed through radiopharmacies, the majority of which are controlled by or associated with Cardinal, UPPI, GE Healthcare and Triad. In the United States, we sell DEFINITY through our sales team of approximately 80 employees, which we believe is the largest dedicated sales force in the industry serving the echocardiography market. The majority of our sales team has over a decade of experience selling diagnostic imaging agents. In Canada, Puerto Rico and Australia, we own radiopharmacies and sell directly to end users. In Europe, Asia Pacific and Latin America, we utilize distributor relationships to market, sell and distribute our products.

***Experienced Management Team.*** Our senior management team has an average of more than 25 years of healthcare industry experience and consists of industry leaders with significant expertise in product development, operations and commercialization. We believe that the depth and experience of our management team demonstrates our expertise within the diagnostic medical imaging industry and our ability to operate successfully in a highly regulated environment.

### **Our Business Strategy**

Our objective is to enhance our position as a global leader in developing, manufacturing, selling and distributing innovative diagnostic medical imaging agents and products. The key elements of this strategy are to:

continue to grow U.S. sales of our existing commercial products, which are diversified across a range of imaging modalities;

enhance the position of our portfolio of commercial products in international markets, obtaining additional regulatory approvals where necessary;

create strategic partnerships to further advance our agents in development to maximize their value in potentially large domestic and international markets; and

pursue select strategic licenses or acquisitions to further strengthen and diversify our portfolios of commercial products while leveraging core competencies.

### **Implications of Being an Emerging Growth Company**

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

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

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

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

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reduced disclosure about executive compensation arrangements.

We will remain an emerging growth company for five years unless, prior to that time, we have (i) more than \$1 billion in annual revenue, (ii) have a market value for our common stock held by non-affiliates of more than \$700 million as of the last day of our second fiscal quarter of the fiscal year when a determination is made that we are deemed to be a large accelerated filer, as defined in Rule 12b-2 promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act, or (iii) issue more than \$1 billion of non-convertible debt over a three-year period. We have availed ourselves of the reduced reporting obligations with respect to executive compensation disclosure in this prospectus, and expect to continue to avail ourselves of the reduced reporting obligations available to emerging growth companies in future filings.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, or the Securities Act, for complying with new and revised accounting standards. An emerging growth company can, therefore, delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we are choosing to opt out of that extended transition period and, as a result, we plan to comply with new and revised accounting standards on the relevant dates on which adoption of those standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new and revised accounting standards is irrevocable.

As a result of our decision to avail ourselves of certain provisions of the JOBS Act, the information that we provide may be different than what you may receive from other public companies in which you hold an equity interest. In addition, it is possible that some investors will find our common stock less attractive as a result of our elections, which may cause a less active trading market for our common stock and more volatility in our stock price.

### **Risks Associated With Our Business**

Our business is subject to numerous risks, as discussed more fully in the section entitled **Risk Factors** beginning on page 16 of this prospectus, which you should read in its entirety. In particular:

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;

the global supply of Moly is fragile and not stable and 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;

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;

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

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we face potential supply and demand challenges for Xenon;

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

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our history of net losses and ability to achieve sustained profitability;

we face continued pricing pressures from our competitors, large customers and group purchasing organizations;

certain of our customers are highly dependent on payments from third party payors, including government sponsored programs, particularly Medicare, in the United States and other countries in which we operate, and reductions in third party coverage and reimbursement rates for our products could adversely affect our business and results of operations; and

we have a substantial amount of indebtedness that may limit our financial and operating activities and adversely affect our ability to incur additional debt to fund future needs, and we may not be able to generate sufficient cash flow to meet our debt service requirements.

**Corporate Reorganization**

Prior to the consummation of this offering, we will effect a corporate reorganization, whereby our direct, wholly-owned subsidiary, Lantheus MI Intermediate, Inc. (the direct parent of LMI) will merge with and into us, and we will be the surviving entity of the merger, and each share of our common stock outstanding immediately prior to the merger will be converted into the right to receive \_\_\_\_\_ share of our newly issued common stock, with any fractional shares rounded down. In addition, as part of our corporate reorganization, shares of our common stock underlying stock options outstanding immediately prior to the merger will be ratably adjusted. The corporate reorganization will not affect our operations, which we will continue to conduct through our operating subsidiaries, including LMI.

The diagram below reflects a simplified overview of our organizational structure following the corporate reorganization and this offering (including the application of the net proceeds therefrom):

- (1) Guarantor of LMI's \$50.0 million revolving credit facility and \$ \_\_\_\_\_ million of LMI's 9.750% senior notes due 2017, or the Notes.
- (2) For a description of our revolving credit facility and the Notes, see Description of Material Indebtedness Revolving Credit Facility and Description of Material Indebtedness Senior Notes.

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**History and Principal Stockholder**

Founded in 1956 as New England Nuclear Corporation, our medical imaging business was purchased by E. I. du Pont de Nemours and Company, or DuPont, in 1981. Bristol-Myers Squibb Company, or BMS, subsequently acquired our medical imaging business from DuPont 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, or collectively Avista, formed Lantheus Holdings and its subsidiary, Lantheus Intermediate, and, through Lantheus Intermediate, acquired our medical imaging business from BMS, or the Acquisition, in an entity which is now known as LMI. After this offering, Avista is expected to collectively own approximately % of our outstanding common stock.

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

**Corporate Information**

Lantheus is a Delaware corporation, which was incorporated in 2007 and is headquartered in North Billerica, Massachusetts. LMI, our wholly-owned principal operating subsidiary, was founded in 1956 and incorporated as a Delaware corporation in 1999. Our principal executive offices are located at 331 Treble Cove Road, North Billerica, Massachusetts 01862, and our telephone number at that address is (978) 671-8001. Our web site is located at [www.lantheus.com](http://www.lantheus.com). The information on our web site is not part of, and is not incorporated by reference into, this prospectus.



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**THE OFFERING**

<b>Common stock offered by us</b>	_____ shares (_____ shares, if the Underwriters exercise their option to purchase additional shares in full).
<b>Common stock to be outstanding after this offering</b>	_____ shares (_____ shares, if the Underwriters exercise their option to purchase additional shares in full).
<b>Option to purchase additional shares of common stock</b>	The underwriters may also purchase up to _____ additional shares of common stock from us, solely to cover over-allotments, at the public offering price, less the underwriting discount, within 30 days from the date of this prospectus.
<b>Use of proceeds</b>	We estimate that the net proceeds to us from this offering, after deducting underwriting discounts and commissions and estimated expenses, will be approximately \$ _____ million, assuming the shares are offered at \$ _____ (the midpoint of the price range set forth on the cover of this prospectus). We intend to use these net proceeds to reduce our outstanding indebtedness and for working capital and other general corporate purposes. See <b>Use of Proceeds</b> for a more complete description of our intended use of the net proceeds from this offering.
<b>Dividend policy</b>	We do not anticipate paying any dividends on our common stock; however, we may change this policy in the future. See <b>Dividend Policy</b> .
<b>Proposed NASDAQ symbol</b>	LNTH.
<b>Risk factors</b>	Investing in our common stock involves a high degree of risk. You should carefully read this entire prospectus, including the more detailed information set forth under the caption <b>Risk Factors</b> and the historical consolidated financial statements, and the related notes thereto, included elsewhere in this prospectus, before investing in our common stock.

Unless otherwise indicated, the number of shares of common stock to be outstanding after this offering excludes:

\_\_\_\_\_ shares of our common stock issuable upon exercise of outstanding stock options as of March 31, 2014, with a weighted average exercise price of \$ \_\_\_\_\_ per share;

\_\_\_\_\_ shares of restricted stock issued under our 2014 Equity Incentive Plan;

\_\_\_\_\_ shares of our common stock reserved for the future issuance of grants under our 2014 Equity Incentive Plan.

In addition, except where otherwise stated, the information in this prospectus:

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gives effect to our corporate reorganization (see Prospectus Summary Corporate Reorganization );

gives effect to our amended and restated certificate of incorporation and our amended and restated bylaws, which will be in effect prior to the consummation of this offering;

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assumes no exercise of the underwriters' over-allotment option to purchase up to \_\_\_\_\_ additional shares from us.

Unless otherwise indicated, this prospectus assumes an initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover of this prospectus.

**Table of Contents****SUMMARY CONSOLIDATED FINANCIAL AND OTHER DATA**

The following tables set forth our summary consolidated financial and other data for the periods ended and as of the dates indicated. The summary consolidated statements of operations data for each of the three fiscal years in the period ended December 31, 2013 have been derived from our audited consolidated financial statements and related notes included elsewhere in this prospectus. The summary consolidated balance sheet data as of March 31, 2014 and statements of operations data for the three months ended March 31, 2014 and 2013 have been derived from our unaudited consolidated financial statements and related notes included elsewhere in this prospectus. We have prepared the unaudited consolidated financial information set forth below on the same basis as our audited consolidated financial statements and have included all adjustments, consisting of only normal recurring adjustments, that we consider necessary for a fair presentation of our financial position and operating results for such periods. The results for any interim period are not necessarily indicative of the results that may be expected for a full year.

The summary consolidated financial data set forth below and elsewhere in this prospectus are not necessarily indicative of our future performance. You should read this information together with Capitalization, Selected Consolidated Financial Data, Management's Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and the related notes thereto included elsewhere in this prospectus.

For a discussion on our quarterly results of operations for 2014 and 2013, see Management's Discussion and Analysis of Financial Condition and Results of Operations Quarterly Results of Operations.

	Three Months ended March 31,		Year ended December 31,		
	2014	2013	2013	2012	2011
	(dollars in thousands except share and per share data)				
Revenues	\$ 73,336	\$ 71,018	\$ 283,672	\$ 288,105	\$ 356,292
Cost of goods sold	43,275	48,206	206,311	211,049	255,466
Loss on firm purchase commitment				1,859	5,610
Total cost of goods sold	43,275	48,206	206,311	212,908	261,076
Gross profit	30,061	22,812	77,361	75,197	95,216
Operating expenses					
Sales and marketing expenses	9,498	9,797	35,227	37,437	38,689
General and administrative expenses	8,852	10,253	33,036	32,520	32,862
Research and development expenses	3,222	11,998	30,459	40,604	40,945
Proceeds from manufacturer			(8,876)	(34,614)	
Impairment on land			6,406		
Total operating expenses	21,572	32,048	96,252	75,947	112,496
Operating income (loss)	8,489	(9,236)	(18,891)	(750)	(17,280)
Interest expense	(10,552)	(10,669)	(42,915)	(42,014)	(37,658)
Interest income			104	252	333
Other income (expense), net	(414)	721	1,161	(44)	1,429

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Loss before income taxes	(2,477)	(19,184)	(60,541)	(42,556)	(53,176)
Provision (benefit) for income taxes	(1,192)	628	1,014	(555)	84,082
Net income (loss)	\$ (1,285)	\$ (19,812)	\$ (61,555)	\$ (42,001)	\$ (137,258)
Net income (loss) per common share:					
Basic and diluted	\$ (0.03)	\$ (0.39)	\$ (1.21)	\$ (0.84)	\$ (2.73)
Common shares:					
Basic and diluted	50,803,484	50,333,927	50,670,274	50,250,957	50,237,490
Pro forma net income (loss) per common share (unaudited)(2):					
Basic					
Diluted					
Pro forma common shares (unaudited)(2):					
Basic					
Diluted					

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	Three Months ended March 31,		Year ended December 31,		
	2014	2013	2013	2012	2011
(dollars in thousands)					
(unaudited)					
<b>Other Financial Data:</b>					
Adjusted EBITDA(1)	\$ 16,018	\$ 4,750	\$ 47,359	\$ 56,212	\$ 79,978
<b>As of March 31, 2014</b>					
			<b>Actual</b>	<b>Pro forma(3)</b>	<b>Pro forma as adjusted(4)</b>
(dollars in thousands)					
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents			\$ 17,010	\$	\$
Total assets			260,960		
Total liabilities			497,736		
Current portion of long-term debt					
Total long-term debt, net			399,098		
Total stockholders' deficit			(236,776)		

- (1) Adjusted EBITDA is defined as EBITDA (GAAP net income (loss), plus interest expense, net, provision of income taxes, depreciation and amortization), further adjusted to exclude unusual items that management does not believe are indicative of its core operating performance. Adjusted EBITDA is used by management to measure operating performance and by investors to measure a company's ability to service its debt and meet its other cash needs. Management believes that the inclusion of the adjustments to EBITDA applied in presenting Adjusted EBITDA is appropriate to provide additional information to investors about our performance across reporting periods on a consistent basis by excluding items that it does not believe are indicative of its core operating performance. See Non-GAAP Financial Measures.

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

	Three Months ended March 31,		Year ended December 31,		
	2014	2013	2013	2012	2011
(dollars in thousands)					
(unaudited)					
Net income (loss)	\$ (1,285)	\$ (19,812)	\$ (61,555)	\$ (42,001)	\$ (137,258)
Interest expense, net	10,552	10,669	42,811	41,762	37,325
Provision for income taxes(a)	(1,017)	189	(127)	(901)	82,702
Depreciation and amortization	4,516	6,568	25,783	27,955	33,258
EBITDA	12,766	(2,386)	6,912	26,815	16,027
Non-cash stock-based compensation	284	257	578	1,240	(969)
Legal fees(b)	234	268	660	1,455	2,017
Loss on firm purchase commitment(c)				1,859	5,610
Asset write-off(d)	420	1,100	28,349	13,095	52,973
Severance and recruiting costs(e)	85	4,091	5,239	1,761	1,995
Sponsor fee and other(f)	251	257	1,457	1,042	1,719
New manufacturer costs(g)	1,978	1,163	4,164	8,945	606
Adjusted EBITDA(h)	\$ 16,018	\$ 4,750	\$ 47,359	\$ 56,212	\$ 79,978

(a)

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Represents provision for income taxes, less tax indemnification associated with an agreement with BMS, and, in the year ended December 31, 2011, includes the establishment of a full valuation allowance against the U.S. deferred tax assets.

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- (b) Represents legal services expenses incurred in connection with our business interruption claim associated with the NRU reactor shutdown in 2009 to 2010.
  - (c) Represents a loss associated with a portion of the committed purchases of Ablavar that we do not believe we will be able to sell prior to expiration.
  - (d) Represents non-cash losses incurred associated with the write-down of land, intangible assets, inventory and write-off of long-lived assets. The March 31, 2014 and 2013 amounts consist primarily of non-cash losses incurred associated with the write-down of inventory. The December 31, 2013 amount consists primarily of a \$6.4 million write-down of land, a \$15.4 million impairment charge on the Cardiolite trademark intangible asset, a \$1.7 million impairment charge on a customer relationship intangible asset and a \$1.6 million inventory write-down related to Ablavar. The December 31, 2012 amount consists primarily of a \$10.6 million inventory write-down related to Ablavar. The December 31, 2011 amount consists primarily of a \$25.8 million inventory write-down related to Ablavar and a \$23.5 million impairment charge to adjust the carrying value of the Ablavar patent portfolio asset to its fair value of zero.
  - (e) Represents primarily severance and recruitment costs related to employees, executives and directors.
  - (f) Represents annual sponsor monitoring fee and related expenses, non-recurring professional fees and certain non-recurring charges relating to a customer relationship.
  - (g) Represents internal and external costs associated with establishing new manufacturing sources for our commercial products and agents in development.
  - (h) Does not include run-rate cost savings, operating expense reductions and other expense and cost-savings of \$14.4 million, \$2.9 million and \$6.6 million, which were realized for the years ended December 31, 2013 and 2012 and the three months ended March 31, 2013, respectively, primarily relating to our strategic shift from in-house research and development, or R&D, to an external partnering model of R&D.
- (2) Pro forma net income (loss) assumes \$       million of the net offering proceeds are used to redeem a portion of our Notes based on an assumed initial public offering price of \$       per share (the midpoint of the price range set forth on the cover of this prospectus) and assumes a reduction of interest expense, net of tax, of approximately \$       million related to such redemption, assuming that the offering and the related application of net proceeds was completed on January 1, 2013. Pro forma net income (loss) per common share and number of common shares gives effect to our corporate reorganization immediately prior to the consummation of this offering and the sale of       shares of our common stock in this offering at an assumed initial public offering price of \$       per share (the midpoint of the price range set forth on the cover of this prospectus).
- (3) Pro forma information gives effect to our corporate reorganization described above, which had no impact on our historical results.
- (4) Pro forma as adjusted information gives effect to our corporate reorganization described above and our capitalization to reflect the sale of       shares of our common stock in this offering by us at an assumed initial public offering price of \$       per share (the midpoint of the price range set forth on the cover of this prospectus) after deducting underwriting discounts and commissions and estimated offering expenses payable by us, and the application of the net proceeds from this offering as described under Use of Proceeds.



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**RISK FACTORS**

*An investment in our common stock involves a high degree of risk. You should carefully consider the following risks, as well as the other information contained in this prospectus, before making an investment decision. If any of the following risks, as well as other risks and uncertainties that are not identified or that we currently think are immaterial, actually occur, our business, results of operations or financial condition could be materially and adversely affected. In such an event, the trading price of our common stock could decline and you could lose part or all of your investment.*

**Risks Relating to our Business and Industry**

*Our dependence upon third parties for the manufacture and supply of a substantial portion of our products could prevent us from delivering our products to our customers in the required quantities, within the required timeframes, or at all, which could result in order cancellations and decreased revenues.*

We obtain a substantial portion of our products from third party manufacturers and suppliers. Historically, we relied on BVL in Bedford, Ohio as our sole manufacturer of DEFINITY, Neurolite and evacuation vials, an ancillary component for our TechnoLite generators, and as one of two manufacturers of Cardiolite. Our products were manufactured at BVL's south complex facility, or the South Complex, where BVL also manufactured products for a number of other pharmaceutical customers. In July 2010, BVL temporarily shutdown the South Complex, in order to upgrade the facility to meet certain regulatory requirements. BVL had originally planned for the shutdown of the South Complex to run through March 2011 and to resume production of our products in April 2011. In anticipation of the shutdown, BVL manufactured for us additional inventory of these products to meet our expected needs during this period. A series of unexpected delays at BVL, however, resulted in a stockout for Neurolite from the third quarter 2011 until the third quarter 2013, product outages and shortages for DEFINITY in much of 2012 and product outages and shortages for Cardiolite in 2012 and 2013.

Although we entered into new agreements with BVL in March 2012, which provided, among other things, \$35.0 million of cash payments to us, and BVL was able to resume some manufacturing under the new agreement, BVL continued to face regulatory issues and supply challenges. In October 2013, BVL announced that it would cease manufacturing further new batches of our products in its Bedford, Ohio facility and, in November 2013, BVL terminated our arrangement, and, among other things, paid us an additional \$8.9 million.

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

Based on our current estimates, we believe that we will have sufficient supply of DEFINITY from JHS and remaining BVL inventory to meet expected demand, sufficient Cardiolite product supply from our current manufacturer to meet expected demand, sufficient supply of evacuation vials from JHS to meet expected demand and sufficient Ablavar product supply to meet expected demand. We also currently anticipate that we will have sufficient BVL-manufactured Neurolite supply for the U.S. market to last until Neurolite technology transfer and U.S. regulatory approval at JHS are completed. However, we can give no assurances that JHS or our other manufacturing partners will be able to manufacture and distribute our products in a high quality and timely manner and in sufficient quantities to allow us to avoid product stock-outs and shortfalls.

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Currently, the regulatory authorities in certain countries prohibit us from marketing products previously manufactured by BVL, and JHS has not yet obtained approval of some of those regulatory authorities that would permit us to market all of our products manufactured by JHS. 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.

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Our manufacturing agreement for Ablavar runs until 2014, although we do not foresee the need to order any additional active pharmaceutical ingredients, or APIs, or finished drug product under this agreement, other than our outstanding purchase commitment. We do not have any current plans to initiate technology transfer activities for Ablavar. If we do not engage in Ablavar technology transfer activities in the future with a new manufacturing partner for Ablavar, then our existing Ablavar inventory will expire in 2016 and we will have no further Ablavar inventory that we will be able to sell.

In addition to the products described above, for reasons of quality assurance or cost-effectiveness, we purchase certain components and raw materials from sole suppliers (including, for example, the lead casing for our TechneLite generators and the evacuation vials for our TechneLite generators manufactured by JHS). 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. If we or one of our manufacturing partners experiences an event, including a labor dispute, natural disaster, fire, power outage, 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. For example, on November 12, 2013, we entered into a Manufacturing and Supply Agreement with Pharmalucence to manufacture and supply DEFINITY. We cannot assure you, however, that these supply diversification activities will be successful, or that before those alternate manufacturers or sources of product are fully functional and qualified, that we will be able to avoid or mitigate interim supply shortages. In addition, we cannot assure you that our existing manufacturers or suppliers or any new manufacturers or suppliers can adequately maintain either their financial health or regulatory compliance to allow continued production and supply. A reduction or interruption in manufacturing, or an inability to secure alternative sources of raw materials or components, could eventually have a material adverse effect on our business, results of operations, financial condition and cash flows.

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

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

Quality, regulatory and recall challenges could cause us to incur significant costs, including costs to replace products, lost revenue, damage to customer relationships, time and expense spent investigating the cause and costs of any possible settlements or judgments related thereto and potentially cause similar losses with respect to other products. These challenges could also divert the attention of our management and employees from operational, commercial or other business efforts. If we deliver products with defects, or if there is a perception that our products or the processes related to our products contain errors or defects, we could incur additional recall and product liability costs, and our credibility and the market acceptance and sales of our products could be



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

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

As part of the conditions for the relicensing of the NRU reactor through October 2016, the Canadian government has asked AECL to shut down the reactor for at least four weeks at least once a year for inspection and maintenance. The most recent shutdown period ran from April 13, 2014 until May 13, 2014, and we were able to source sufficient Moly to satisfy all of our standing-order customer demand for our TechneLite generators during this time period from our other suppliers. During this shutdown period, however, because Xenon is a by-product of the Moly production process and is currently captured only by NRU, we were not able to supply all of our standing-order customer demand for Xenon. There can be no assurance that in the future these off-line periods will last for the stated time or that the NRU will not experience other unscheduled shutdowns. Further prolonged scheduled or unscheduled shutdowns would limit the amount of Moly and Xenon available to us and limit the quantity of TechneLite that we could manufacture, sell and distribute and the amount of Xenon that we could sell and distribute, resulting in a further substantial negative effect on our business, results of operations, financial condition and cash flows.

In the face of the NRU reactor operating challenges and licensure risks, we entered into Moly supply agreements with NTP, ANSTO and IRE to augment our supply of Moly. While we believe this additional Moly supply now gives us the most balanced and diversified Moly supply chain in the industry, a prolonged disruption of service from only one of our significant Moly suppliers could have a material adverse effect on our business, results of operations, financial condition and cash flows. We are also pursuing additional sources of Moly from potential new producers around the world to further augment our current supply, but we cannot assure you that these 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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Although our agreements with NTP, ANSTO and IRE run until December 31, 2017, our agreement with Nordion runs only until December 31, 2015 and can be terminated by Nordion upon the occurrence of certain events, including if we fail to purchase a minimum percentage of Moly or if Nordion incurs certain cost increases, and in the latter case, as soon as October 1, 2014.

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 2016 or later. 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.

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

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

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

***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



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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 nearly 28 million echocardiograms performed each year in the United States, a third party source estimates that 20%, or approximately six million echocardiograms, produce suboptimal images. We estimate that DEFINITY had approximately 75% share of the market for contrast agents in the United States in December 2013. 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 continue to fund our other growth initiatives at planned levels, which could have a negative effect on our prospects.

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

Currently, Nordion is our sole supplier, and we believe the principal supplier on a global basis, of Xenon, which is captured by the NRU reactor as a by-product of the Moly production process. We are currently pursuing alternative sources of Xenon on a global basis. If we are not able to secure a new producer of Xenon prior to the expiration of the NRU reactor's license in October 2016 and obtain regulatory approval to sell Xenon from that new producer, we will no longer be able to offer Xenon in our portfolio of commercial products, which would have a negative effect on our business, results of operations, financial condition and cash flows. For the three months ended March 31, 2014 and 2013 and the year ended December 31, 2013, Xenon represented approximately 13%, 12% and 11%, respectively, of our revenues.

Currently, we obtain Xenon from Nordion on a purchase order basis. Nordion recently announced that it has entered into a definitive agreement to be acquired by Sterigenics. As a result of this transaction, our supplier could change the terms on which we obtain Xenon. If we are not able to pass along to our customers any change of terms from our supplier, there could be a negative effect on our business, results of operations, financial condition and cash flows.

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

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



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

In the United States, we rely on a limited number of radiopharmacy customers, primarily Cardinal, GE Healthcare, UPPI and Triad, to distribute our current largest volume nuclear imaging products and generate a majority of our revenues. Three customers accounted for approximately 39% of our revenues in the fiscal year ended December 31, 2013, with Cardinal, UPPI and GE Healthcare accounting for 19%, 10% and 10%, respectively. Among the existing radiopharmacies in the United States, continued consolidations, divestitures and reorganizations may have a negative effect on our business, results of operations, financial condition or cash flows. We generally have distribution arrangements with our major radiopharmacy customers pursuant to multi-year contracts, each of which is subject to renewal. Our current contract with Cardinal expires in December 2014. If these contracts are terminated prior to expiration of their term, or are not renewed, or are renewed on terms that are less favorable to us, then such an event could have a material adverse effect on our business, results of operations, financial condition and cash flows.

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

Outside of the United States, Canada, Australia and Puerto Rico, we have no radiopharmacies or sales force and, consequently, rely on third party distributors, either on a country-by-country basis or on a multicountry, regional basis, to market, sell and distribute our products. These distributors accounted for approximately 13%, 16% and 19% of non-U.S. revenues for the fiscal years ended December 31, 2013, 2012 and 2011, respectively. In certain circumstances, these distributors may also sell competing products to our own or products for competing diagnostic modalities and may have incentives to shift sales towards those competing products. As a result, we cannot assure you that our international distributors will increase or maintain our current levels of unit sales or increase or maintain our current unit pricing, which, in turn, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

***We have a history of net losses and total 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. For the three months ended March 31, 2014, we incurred net loss of \$1.3 million and total stockholders' deficit of \$236.8 million. We incurred net loss for the years ended December 31, 2013, 2012 and 2011 of \$61.6 million, \$42.0 million and \$137.3 million, respectively, and as of December 31, 2013, we had a total stockholders' deficit of \$235.5 million. We cannot assure you that we will be able to achieve or sustain profitability on a quarterly or annual basis in the future. If we cannot improve our profitability, the value of our enterprise may decline.

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

The market for diagnostic medical imaging agents is highly competitive and continually evolving. Our principal competitors in existing diagnostic modalities include large, global companies with substantial financial, manufacturing, sales and marketing and logistics resources that are more diversified than ours, such as Mallinckrodt, GE Healthcare, Bayer Schering Pharma AG, or Bayer, Bracco Diagnostics Inc., or Bracco, and DRAXIS Specialty Pharmaceuticals Inc. (an affiliate of JHS), or Draxis, as well as other competitors. We cannot anticipate their actions in the same or competing diagnostic modalities, such as significant price reductions on products that are comparable to our own, development or introduction of new products that are more cost-effective or have superior performance than our current products, the introduction of generic

versions when our proprietary products lose their patent protection or the new entry into a generic market in which we are already a

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participant. Our current or future products could be rendered obsolete or uneconomical as a result of this competition. 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.

For example, Bracco may be seeking FDA approval in the United States for its echocardiography agent, SonoVue, which is already approved for sale in Europe and certain Asian markets, including China, Japan and Korea. If Bracco receives U.S. regulatory approval, Bracco will have one of three FDA-approved echocardiography contrast agents in the United States, together with GE Healthcare's Optison and our DEFINITY. If Bracco receives U.S. regulatory approval and successfully commercializes SonoVue in the United States without otherwise increasing the overall usage of ultrasound contrast agents, our current and future sales volume could suffer, which would have a material adverse effect on our business, results of operations, financial condition and cash flows.

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

We are currently aware of four separate, third party generic offerings of sestamibi, the first of which launched in September 2008. Cardiolite products accounted for approximately 6% and 15% of our revenues in the three months ended March 31, 2014 and 2013, respectively, and 9%, 12% and 19% of our revenues in the fiscal years ended December 31, 2013, 2012, and 2011, respectively. Included in Cardiolite is branded Cardiolite and generic sestamibi, some of which we produce and some of which we procure from third parties. With the advent of generic competition in September 2008, we have faced significant pricing and unit volume pressures on Cardiolite. To the extent generic competitors further reduce their prices, we may be forced to further reduce the price of our Cardiolite products as well as lose additional market share, which would have an adverse effect on our business, results of operations, financial condition and cash flows.

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

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



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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.

For example, in 2013, although Medicare generally does not provide separate payment to hospitals for the use of diagnostic radiopharmaceuticals administered in an outpatient setting, the Centers for Medicare and Medicaid Services, or CMS, finalized a policy to make an additional payment to hospitals that utilize products with non-HEU, meaning the product is 95% derived from non-HEU sources. This payment policy continues in 2014. Although some of our TechneLite generators are manufactured using non-HEU, not all of our TechneLite generators meet CMS's definition of non-HEU, and therefore this payment will not be available for 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 believe that Medicare changes to payment policies for imaging procedures will continue to result in certain physicians practices ceasing to provide these services and a further shifting of where certain medical imaging procedures are performed, from the physician office and free-standing imaging facility settings to the hospital outpatient setting, which we believe may incrementally reduce the overall number of diagnostic medical imaging procedures performed. In recent legislation, Congress expanded CMS' authority to review and revalue the codes used for reimbursement under the Medicare Physician Fee Schedule. Changes applicable to Medicare payment in the hospital outpatient setting could influence the decisions by hospital outpatient physicians to perform procedures that involve our products. These changes overall could slow the acceptance and introduction of next-generation imaging equipment into the marketplace, which, in turn, could adversely impact the future market adoption of certain of our imaging agents already in the market or currently in clinical or preclinical development. We expect that there will continue to be proposals to reduce or limit Medicare and Medicaid payment for diagnostic services.

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

See Business Regulatory Matters.



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

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

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

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

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

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

The implementation of the Healthcare Reform Act could potentially reduce the aggregate number of diagnostic medical imaging procedures performed in the United States. Under the Healthcare Reform Act, referring physicians under the federal self-referral law must inform patients that they may obtain certain services, including MRI, CT, PET and certain other diagnostic imaging services from a provider other than that physician, another physician in his or her group practice, or another individual under the direct supervision of the physician or another physician in the group practice. The referring physician must provide each patient with a written list of other suppliers which furnish those services in the area in which the patient resides. These new requirements could have the effect of shifting where certain diagnostic medical imaging procedures are performed. In addition, they could potentially reduce the overall number of diagnostic medical imaging procedures performed. We cannot predict the full impact of the Healthcare Reform Act on our business. The reform law substantially changed the way healthcare is financed by both governmental and private insurers. Although certain provisions may negatively affect payment rates for certain imaging services, the Healthcare Reform Act also extended coverage to approximately 25 million previously uninsured people (based on April 2014 estimates from the Congressional Budget Office), which may result in an increase in the demand for our services, but we cannot be assured of a proportional, or any, increase in the use of our products.

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Further, we expect that there will continue to be proposals to reduce or limit Medicare and Medicaid payment for services. Rates paid by some private third party payors are based, in part, on established physician,

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clinic and hospital charges and are generally higher than Medicare payment rates. Reductions in the amount of reimbursement paid for diagnostic medical imaging procedures and changes in the mix of our patients between non-governmental payors and government sponsored healthcare programs and among different types of non-government payor sources, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

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

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

Under U.S. law, for example, we are required to report certain adverse events and production problems, if any, to the FDA. We also have similar adverse event and production reporting obligations outside of the United States, including to the EMA and MHRA. Additionally, we must comply with requirements concerning advertising and promotion for our products, including the prohibition on the promotion of our products for indications that have not been approved by the FDA or a so-called off-label use. If the FDA determines that our promotional materials constitute the unlawful promotion of an off-label use, it could request that we modify our promotional materials or subject us to regulatory or enforcement actions. Also, quality control and manufacturing procedures at our own facility and at third party suppliers must conform to cGMP regulations and other applicable law after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMPs and other applicable law, and, from time to time, makes those cGMPs more stringent. Accordingly, we and others with whom we work must expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control. For example, we currently rely on JHS as our sole manufacturer of DEFINITY and, later in 2014, we will rely on JHS as our sole manufacturer of NeuroLite. JHS has recently received a warning letter from the FDA in connection with their manufacturing facility in Spokane, Washington where our products are, or will be, manufactured. If JHS cannot resolve the issues in their facility underlying the warning letter or if the issues become worse, then the FDA could take additional regulatory action which could limit or suspend the ability of JHS to manufacture our products and 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 certain of our products, which requires us to report certain price information to the federal government that could subject us to potential liability under the False Claims Act, civil monetary penalties or liability under other laws and regulations in connection with the covered products as well as the products not covered by the agreement. Determination of the rebate amount that we pay to state Medicaid programs for our products, as well as determination of payment amounts under Medicare and certain other third party payers, including government payers, depends upon

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information reported by us to the government. If we provide customers or government officials with inaccurate information about the products pricing or eligibility for coverage, or the products fail to satisfy coverage requirements, we could be terminated from the rebate program, be excluded from participation in government healthcare programs, or be subject to potential liability under the False Claims Act or other laws and regulations. See Business Regulatory Matters Healthcare Fraud and Abuse Laws.

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

substantial modifications to our business practices and operations;

significantly reduced demand for our products (if products become ineligible for reimbursement under federal and state healthcare programs);

a total or partial shutdown of production in one or more of the facilities where our products are produced while the alleged violation is being remediated;

delays in or the inability to obtain future pre-market clearances or approvals; and

withdrawals or suspensions of our current products from the market.

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

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

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

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

Separately, the Healthcare Reform Act requires manufacturers to submit information on the identity and quantity of drug samples requested and distributed by a manufacturer during each year. The first report (covering

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2011) was to be submitted by April 1, 2012, but the FDA indicated that it would exercise enforcement discretion until October 1, 2012, and would issue a notice prior to its decision to begin enforcing this decision. At this time, the FDA has not published a notice to begin enforcement of this provision. We have not voluntarily submitted reports and are awaiting the FDA notice. State laws may also require disclosure of pharmaceutical pricing information and marketing expenditures, compliance with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and/or the tracking and reporting of gifts, compensation, and other remuneration to physicians and other healthcare providers. We believe we have developed appropriate protocols to implement these state requirements. Any irregularities or mistakes in our reporting, however, could result in a finding that we have been non-compliant with these requirements, which could subject us to the penalty provisions of applicable federal and state laws and regulations.

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

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

DEFINITY is an ultrasound contrast agent based on perflutren lipid microspheres. In 2007, the FDA received reports of deaths and serious cardiopulmonary reactions following the administration of ultrasound micro-bubble contrast agents used in echocardiography. Four of the 11 reported deaths were caused by cardiac arrest occurring either during or within 30 minutes following the administration of the contrast agent; most of the serious but non-fatal reactions also occurred in this time frame. As a result, in October 2007, the FDA requested that we and GE Healthcare, which distributes Optison, a competitor to DEFINITY, add a boxed warning to these products emphasizing the risk for serious cardiopulmonary reactions and that the use of these products was contraindicated in certain patients. In a strong reaction by the cardiology community to the FDA's new position, a letter was sent to the FDA, signed by 161 doctors, stating that the benefit of these ultrasound contrast agents outweighed the risks and urging that the boxed warning be removed. In May 2008, the FDA substantially modified the boxed warning. On May 2, 2011, the FDA held an advisory committee meeting to consider the status of ultrasound micro-bubble contrast agents and the boxed warning. In October 2011, we received FDA approval of further modifications to the DEFINITY label, including: further relaxing the boxed warning; eliminating the sentence in the Indication and Use section "The safety and efficacy of DEFINITY with exercise 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. If additional safety issues arise, this may result in further changes in labeling or result in restrictions on the approval of our product, including removal of the product from the market. Lingering safety concerns about DEFINITY among some healthcare providers or future unanticipated side effects or safety concerns associated with DEFINITY could limit expanded use of DEFINITY and have a material adverse effect on the unit sales of this product and our financial condition and results of operations.

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

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

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

the availability of alternative products from our competitors, such as, in the case of DEFINITY, GE Healthcare's Optison, Bracco's SonoVue and other imaging modalities;

the price of our products relative to those of our competitors;

the timing of our market entry;

our ability to market and distribute our products effectively;

market acceptance of our products; and

our ability to obtain adequate reimbursement.

The field of diagnostic medical imaging is dynamic, with new products, including equipment and agents, continually being developed and existing products continually being refined. Our own diagnostic imaging agents compete not only with other similarly administered imaging agents but also with imaging agents employed in different and often competing diagnostic modalities. New imaging agents in a given diagnostic modality may be developed that provide benefits superior to the then-dominant agent in that modality, resulting in commercial displacement. Similarly, changing perceptions about comparative efficacy and safety including, among other things, comparative radiation exposure, as well as changing availability of supply may favor one agent over another or one modality over another. In addition, new or revised professional society appropriate use criteria, which are developed 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.

Our current portfolio of commercial products primarily focuses on heart disease and vascular disease. This particular focus, however, may not be in our long-term best interest if the incidence and prevalence of heart disease and vascular disease decrease over time. Despite the aging

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population in the affluent parts of the world where diagnostic medical imaging is most frequently used, government and private efforts to promote preventative cardiac care through exercise, diet and improved medications could decrease the overall demand for our products, which could have a material adverse effect on our business, results of operations, financial condition and cash flows.



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*Because market acceptance of Ablavar has been slower than we anticipated, we have had a series of asset write-downs.*

Given the lower market demand for Ablavar than we initially anticipated and the magnitude of the required purchase minimums originally contained in the manufacturing agreement with Mallinckrodt, we entered into two separate amendments to the agreement in August 2010 and October 2011 to reduce the minimum purchase requirements. In the fourth quarter of 2010, we recorded an inventory write-down of approximately \$10.9 million for Ablavar finished good product that had already been manufactured by Mallinckrodt that would likely expire prior to its sale to and use by customers. In the second quarter of 2011, we recorded an impairment charge of \$23.5 million, the full remaining value of the product's intellectual property. In addition, in the second and fourth quarters of 2011, we recorded a further inventory write-down of approximately \$13.5 million and \$12.3 million, respectively, and a loss of \$1.9 million and \$3.7 million, respectively, for the portion of committed purchases of Ablavar that we did not believe we would be able to sell prior to product expiry. In the third quarter of 2012, we recorded an additional inventory write-down of approximately \$10.6 million and a loss of \$1.9 million for the portion of committed purchases of Ablavar that we do not believe we will be able to sell prior to product expiry. Finally, in the fourth quarter of 2013, we recorded an additional inventory write-down of approximately \$1.6 million related to the API that the Company would not be able to convert or be able to sell prior to its expiration.

There are no remaining future purchase commitments under the agreement with Mallinckrodt. In 2013, we transitioned the sales and marketing efforts for Ablavar from our direct sales force to our customer service team in order to allow our direct sales force to drive our DEFINITY sales growth. If we do not meet our current sales goals or cannot sell the product we have committed to purchase prior to its expiration, we could incur additional inventory losses and/or losses on our purchase commitments.

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

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

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



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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 a special protocol assessment, or SPA, with the FDA. Although flurpiridaz F 18 appeared to be well-tolerated from a safety perspective and outperformed SPECT in a highly statistically significant manner in the co-primary endpoint of sensitivity and in the secondary endpoints of image quality and diagnostic certainty, the agent did not meet its other co-primary endpoint of non-inferiority for identifying subjects without disease. We can give no assurances that our SPA agreement will be deemed binding on the FDA or will result in any particular outcome from regulatory review of the study or the agent, that any of the data generated thus far in the 301 trial can be used for a New Drug Application, or NDA, approval, that a strategic partner will have to conduct only one additional clinical trial, the planned 302 trial, prior to filing an NDA, or that flurpiridaz F 18 will ever be approved as a PET MPI imaging agent by the FDA. See Business Regulatory Matters Food and Drug Laws.

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

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. For example, rather than being manufactured at our own facilities, flurpiridaz F 18 would require the creation of a complex, field-based network involving PET cyclotrons located at radiopharmacies where the agent would need to be manufactured and distributed rapidly to end-users, given the agent's 110-minute half-life. In addition, in the case of flurpiridaz F 18, obtaining adequate reimbursement is critical, including not only coverage from Medicare, Medicaid, other government payors as well as private payors but also appropriate payment levels which adequately cover the substantially higher manufacturing and distribution costs associated with a PET MPI agent in comparison to, for example, sestamibi.

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

In March 2013, we implemented a strategic shift in how we intend to fund our important R&D programs. We have reduced our internal R&D resources, while at the same time we are seeking to engage strategic partners to further develop and commercialize our important agents in development, including flurpiridaz F 18, 18F LMI 1195 and LMI 1174. However, different strategic partners may have different time horizons, risk profiles, return expectations and amounts of capital to deploy, and we may not be able to negotiate relationships with potential strategic partners on acceptable terms, or at all. In addition, because we failed to meet one of our two co-primary

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endpoints in the first of our two flurpiridaz F 18 Phase 3 trials, we have initiated discussions about potential next steps in the flurpiridaz F 18 development process with the FDA. If we are unable to establish or maintain these strategic partnerships, we will have to limit the size or scope of, or delay, our development programs.

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

the inability to control the amount or timing of resources that our partners may devote to developing the agents;

the possibility that we may be required to relinquish important rights, including economic, intellectual property, marketing and distribution rights;

the receipt of lower revenues than if we were to commercialize those agents ourselves;

our failure to receive future milestone payments or royalties if a partner fails to commercialize one of our agents successfully;

the possibility that a partner could separately move forward with competing agents developed either independently or in collaboration with others, including our competitors;

the possibility that our strategic partners may experience financial or operational difficulties;

business combinations or significant changes in a partner's business strategy that may adversely affect that partner's willingness or ability to complete its obligations under any arrangement with us; and

the possibility that our partners may operate in countries where their operations could be negatively impacted by changes in the local regulatory environment or by political unrest.

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

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

We believe that there has been heightened public and regulatory focus on radiation exposure, including the concern that repeated doses of radiation used in diagnostic imaging procedures pose the potential risk of long-term cell damage, cancer and other diseases. For example, starting in January 2012, the CMS required the accreditation of facilities providing the technical component of advanced imaging services, including CT, MRI, PET and nuclear medicine, in non-hospital free-standing settings. In August 2011, the Joint Commission (an independent, not-for-profit organization that accredits and certifies more than 20,500 healthcare organizations and programs in the United States) issued an alert on the radiation risks of diagnostic imaging and recommended specific actions for providing the right test and the right dose through effective processes, safe technology and a culture of safety. In January 2014, the Joint Commission published revised accreditation standards for diagnostic imaging. These standards were originally scheduled to take effect in July 2014, but implementation has been delayed to 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.

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

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

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

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

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

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

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



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

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

we might not have been the first to make the inventions covered by each of our pending patent applications and issued patents, and we could lose our patent rights as a result;

we might not have been the first to file patent applications for these inventions or our patent applications may not have been timely filed, and we could lose our patent rights as a result;

others may independently develop similar or alternative technologies or duplicate any of our technologies;

it is possible that none of our pending patent applications will result in any further issued patents;

our issued patents may not provide a basis for commercially viable drugs, may not provide us with any protection from unauthorized use of our intellectual property by third parties, and may not provide us with any competitive advantages;

our patent applications or patents may be subject to interferences, oppositions, post-grant review, reexaminations or similar administrative proceedings;

while we generally apply for patents in those countries where we intend to make, have made, use or sell patented products, we may not be able to accurately predict all of the countries where patent protection will ultimately be desirable and may be precluded from doing so at a later date;

we may fail to seek patent protection in certain countries where the actual cost outweighs the perceived benefit at a certain time;

patents issued in foreign jurisdictions may have different scopes of coverage as our United States patents and so our products may not receive the same degree of protection in foreign countries as they would in the United States;

we may not develop additional proprietary technologies that are patentable; or

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

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



may be brought in U.S. or non-U.S. jurisdictions to challenge the validity of a patent.

The defense and prosecution of intellectual property suits, interferences, oppositions and related legal and administrative proceedings are costly, time consuming to pursue and result in diversion of resources. The outcome of these proceedings is uncertain and could significantly harm our business. If we are not able to defend the patents of our technologies and products, then we will not be able to exclude competitors from marketing products that directly compete with our products, which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

We will also rely on trade secrets and other know-how and proprietary information to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We use reasonable efforts to protect our trade secrets, but our employees,

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consultants, contractors, outside scientific partners and other advisors may unintentionally or willfully disclose our confidential information to competitors or other third parties. Enforcing a claim that a third party improperly obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. We often rely on confidentiality agreements with our collaborators, employees, consultants and other third parties and invention assignment agreements with our employees to protect our trade secrets and other know-how and proprietary information concerning our business. These confidentiality agreements may not prevent unauthorized disclosure of trade secrets and other know-how and proprietary information, and there can be no guarantee that an employee or an outside party will not make an unauthorized disclosure of our trade secrets, other technical know-how or proprietary information, or that we can detect such an unauthorized disclosure. We may not have adequate remedies for any unauthorized disclosure. This might happen intentionally or inadvertently. It is possible that a 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, Cardiolute, TechneLite, Ablavar, 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 the current economic environment.***

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

business.

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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. In addition, if economic challenges in the United States result in widespread and prolonged unemployment, either regionally or on a national basis, prior to the effectiveness of certain provisions of the Healthcare Reform Act, a substantial number of people may become uninsured or underinsured. In turn, this may lead to fewer individuals pursuing or being able to afford diagnostic medical imaging procedures. To the extent economic challenges 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 three months ended March 31, 2014 and 2013, 23% and 24%, respectively, of our revenues were derived outside of the United States. For the years ended December 31, 2013, 2012 and 2011, 25%, 27% and 25%, respectively, of our revenues were derived from countries outside the United States. We anticipate that revenue from non-U.S. operations will grow. 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;

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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.

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

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

We generate significant revenue from export sales, as well as from operations conducted outside the United States. During the three months ended March 31, 2014 and 2013, the net impact of foreign currency changes on transactions was a loss of \$238,000 and \$85,000, respectively. During the years ended December 31, 2013, 2012 and 2011, the net impact of foreign currency changes on transactions was a loss of \$349,000, \$579,000 and \$156,000, respectively. Operations outside the United States expose us to risks including fluctuations in currency values, trade restrictions, tariff and trade regulations, U.S. export controls, non-U.S. tax laws, shipping delays and economic and political instability. For example, violations of U.S. export controls, including those administered by the U.S. Treasury Department's Office of Foreign Assets Control, could result in fines, other civil or criminal penalties and the suspension or loss of export privileges which could have a material adverse effect on our business, results of operations, financial conditions and cash flows.

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

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

As of March 31, 2014, we had approximately \$408.0 million of total principal indebtedness consisting of \$400.0 million of Notes issued May 10, 2010 and March 16, 2011 and due May 15, 2017 and our revolving credit facility, with an outstanding balance of \$8.0 million. In addition to the \$8.0 million outstanding under our revolving credit facility, there is an \$8.8 million unfunded Standby Letter of Credit as of March 31, 2014. As of March 31, 2014, our revolving credit facility had \$25.7 million of remaining availability. In June 2014, we amended our revolving credit facility to increase the size from \$42.5 million to \$50.0 million. During periods of volatility and disruption in the U.S., European, or global credit markets, obtaining additional or replacement financing may be more difficult and the cost of issuing new debt or replacing our revolving credit facility could be higher than under our current revolving credit facility. Higher cost of new debt may limit our ability to have cash on hand for working capital, capital expenditures and acquisitions on terms that are acceptable to us. Additionally, our revolving credit facility has a variable interest rate. By its nature, a variable interest rate will move up or down based on changes in the economy and other factors, all of which are beyond our control. If interest rates increase, our interest expense could increase, affecting earnings and reducing cash flows available for working capital, capital expenditures and acquisitions.

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

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

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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

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accurately and fairly reflect our transactions. Because of the predominance of government-sponsored healthcare systems around the world, many of our customer relationships outside of the United States are, either directly or indirectly, with governmental entities and are therefore subject to the FCPA and similar anti-bribery laws in non-U.S. jurisdictions. In addition, the Bribery Act has been enacted, and its provisions extend beyond bribery of foreign public officials and are more onerous than the FCPA in a number of other respects, including jurisdiction, non-exemption of facilitation payments and penalties.

Our policies mandate compliance with these anti-bribery laws. We operate in many parts of the world that have experienced governmental corruption to some degree, and in certain circumstances strict compliance with anti-bribery laws may conflict with local customs and practices. Despite our training and compliance programs, 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 infrastructure ages and becomes subject to increasing maintenance and repair and our systems generally are vulnerable to potential damage or interruptions from fires, natural disasters, power outages, blackouts, telecommunications failures and other unexpected events, as well as to break-ins, sabotage, increasingly sophisticated intentional acts of vandalism or cyber threats. As these threats continue to evolve, we may be required to expend additional resources to enhance our information security measures or to investigate and remediate any information security vulnerabilities. Given the extensive reliance of our business on technology, any substantial disruption or resulting loss of data that is not avoided or corrected by our backup measures could harm our business, operations and financial condition.

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

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

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

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



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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.

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

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

exposure to unknown liabilities;

disruption of our business, customer base and diversion of our management's time and attention to develop acquired products or technologies;

a reduction of our current financial resources;

difficulty or inability to secure financing to fund development activities for those acquired or in-licensed technologies;

incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions; and

higher than expected acquisition and integration costs.

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

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

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

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require us to dedicate a substantial portion of cash flow from operations to the payment of interest on and principal of our indebtedness, thereby reducing the funds available for other purposes;

make it more difficult for us to satisfy and comply with our obligations with respect to the Notes, namely the payment of interest and principal;

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;

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reduce our flexibility in planning for or responding to changing business, industry and economic conditions; and

place us at a competitive disadvantage to competitors that have relatively less debt than we have.

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

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

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

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

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

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

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

incur additional debt;

pay dividends or make other distributions;

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redeem stock;

issue stock of subsidiaries;

make certain investments;

create liens;

enter into transactions with affiliates; and

merge, consolidate or transfer all or substantially all of our assets.

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

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

As of December 31, 2013, we had federal income tax loss carryforwards of \$84.8 million, which will begin to expire in 2031 and will completely expire in 2034. We have had significant financial losses in previous years and as a result we currently maintain a full valuation allowance for our deferred tax assets including our federal and state tax loss carryforwards.

**Risks Relating to Our Company and Ownership Structure**

*As a NASDAQ-listed public company, we will become subject to additional financial and other reporting and corporate governance requirements that may be difficult for us to satisfy.*

As a publicly traded company, we will incur significant legal, accounting and other expenses, particularly after we are no longer an emerging growth company as defined under the JOBS Act. After this offering, we will be required to file with the SEC annual and quarterly information and other reports that are specified in Section 13 of the Exchange Act. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the Dodd-Frank Wall Street Reform Act and Consumer Protection Act of 2010, or the Dodd-Frank Act, as well as rules subsequently implemented by the SEC, have imposed various requirements on public companies, including the establishment and maintenance of effective disclosure controls and procedures, internal controls and corporate governance practices.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting to be

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compliant with the Sarbanes-Oxley Act, significant resources and management oversight will be required. As a result, our management's attention might be diverted from other business concerns. We are also required to evaluate our internal controls systems in order to allow management to report on, and, once we are no longer an emerging growth company, our independent auditors to audit, our internal control over financial reporting. We are required to perform the system and process evaluation and testing (and any necessary remediation) required to comply with the management certification (and, once we are no longer an emerging growth company, auditor attestation) requirements of Section 404 of the Sarbanes-Oxley Act. We incur significant legal, accounting and other expenses in order to comply with these requirements and the other requirements of the Sarbanes-Oxley Act and the Dodd-Frank Act.

After this offering, we will also be required to ensure that we have the ability to prepare financial statements that are fully compliant with all SEC reporting requirements on a timely basis. We will also become subject to other reporting and corporate governance requirements, including the requirements of The NASDAQ Global

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Market, or NASDAQ, and certain additional provisions of the Sarbanes-Oxley Act and the regulations promulgated thereunder, which will impose significant compliance obligations upon us. As a NASDAQ-listed public company, we will be required to:

prepare and distribute additional periodic public reports and other stockholder communications in compliance with our obligations under the federal securities laws and NASDAQ rules;

create or expand the roles and duties of our Board of Directors and committees of the Board of Directors;

supplement our internal accounting, auditing and tax functions, including hiring additional staff with expertise in accounting and financial reporting for a public company;

enhance our investor relations function; and

involve and retain to a greater degree outside counsel and accountants in the activities listed above.

These changes will require a commitment of additional resources. We may not be successful in implementing these requirements and implementing them could adversely affect our business or operating results. In addition, if we fail to implement the requirements with respect to our internal accounting and audit functions, our ability to report our results of operations on a timely and accurate basis could be impaired and we could suffer adverse regulatory consequences or violate NASDAQ listing standards. There could also be a negative reaction in the financial markets due to a loss of investor confidence in us and the reliability of our financial statements, which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

If we fail to maintain an effective internal control environment or to comply with the numerous legal and regulatory requirements imposed on public companies, we could make material errors in, and be required to restate, our financial statements. Any such restatement could result in a loss of public confidence in the reliability of our financial statements and sanctions imposed on us by the SEC, which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

*Our management team currently manages a private company and the transition to managing a public company will present new challenges.*

Following the consummation of this offering, we will be subject to various additional regulatory requirements, including those of the SEC and NASDAQ. These requirements include record keeping, financial reporting and corporate governance rules and regulations. Certain members of our management team do not have experience managing a public company. Our internal infrastructure may not be adequate to support our increased reporting obligations, and we may be unable to hire, train or retain necessary staff and may be reliant on engaging outside consultants or professionals to overcome our lack of experience or employees. If our internal infrastructure is inadequate, we are unable to engage outside consultants or are otherwise unable to fulfill our public company obligations, it could have a material adverse effect on our business, financial condition, results of operations and cash flows.

*We have not been required to evaluate our internal control over financial reporting in a manner that meets the standards of publicly traded companies required by Section 404 of the Sarbanes-Oxley Act. In connection with the implementation of the necessary procedures and practices related to internal control over financial reporting, we may identify deficiencies that we may not be able to remediate in time to meet the deadline imposed by the Sarbanes-Oxley Act for compliance with the requirements of Section 404.*



We have not been required to evaluate our internal control over financial reporting in a manner that meets the standards of publicly traded companies required by Section 404 of the Sarbanes-Oxley Act. Section 404 of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting, starting with the second annual report that we file with the SEC as a public company, and generally requires in the same report a report by our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, under the recently enacted JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal

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control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act until we are no longer an emerging growth company. We could be an emerging growth company for up to five years after becoming a public company. Once we are no longer an emerging growth company, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting on an annual basis. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation of our existing controls and the incurrence of significant additional expenditures.

In connection with the implementation of the necessary procedures and practices related to internal control over financial reporting, we may identify deficiencies that we may not be able to remediate in time to meet the deadline imposed by the Sarbanes-Oxley Act for compliance with the requirements of Section 404. In addition, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation in connection with the attestation provided by our independent registered public accounting firm. We will be unable to issue securities in the public markets through the use of a shelf registration statement if we are not in compliance with Section 404. Furthermore, failure to achieve and maintain an effective internal control environment could limit our ability to report our financial results accurately and timely and have a material adverse effect on our business, results of operations, financial condition and cash flows.

***We are an emerging growth company, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.***

As an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to obtain an assessment of the effectiveness of our internal controls over financial reporting from our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile.

***We are a controlled company within the meaning of NASDAQ rules and, as a result, we will qualify for, and intend to rely on, exemptions from certain corporate governance requirements. Our stockholders will not have the same protections afforded to stockholders of companies that are subject to those requirements.***

After the consummation of this offering, Avista will collectively beneficially own approximately % of our outstanding common stock and will collectively beneficially own approximately % of our outstanding common stock if the underwriters' over-allotment option to purchase additional shares is exercised in full. As a consequence, Avista will be able to exert a significant degree of influence or actual control over our management and affairs and will control matters requiring stockholder approval, including the election of directors, a merger, consolidation or sale of all or substantially all of our assets, and any other significant transaction. The interests of this stockholder may not always coincide with our interests or the interests of our other stockholders. For instance, this concentration of ownership may have the effect of delaying or preventing a change in control of us otherwise favored by our other stockholders and could depress our stock price.

Following this offering, Avista will continue to control a majority of the voting power of our outstanding common stock. As a result, we are a controlled company within the meaning of the corporate governance standards of NASDAQ. Under these rules, a company of which more than 50% of the voting power is held by an individual, group or another company is a controlled company and may elect not to comply with certain corporate governance requirements, including:

the requirement that a majority of the Board of Directors consist of independent directors;

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the requirement that we have a nominating/corporate governance committee that is composed entirely of independent directors;

the requirement that we have a compensation committee that is composed entirely of independent directors; and

the requirement for an annual performance evaluation of the nominating/corporate governance and compensation committees.

Following this offering, we intend to utilize these exemptions. As a result, our nominating and corporate governance committee and compensation committee will not consist entirely of independent directors and those committees will not be subject to annual performance evaluations. Additionally, we only are required to have one independent audit committee member upon the listing of our common stock on NASDAQ, a majority of independent audit committee members within 90 days from the date of listing and all independent audit committee members within one year from the date of listing. Accordingly, you will not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of NASDAQ.

Avista, however, is not subject to any contractual obligation to retain their controlling interest, except that they have agreed, subject to certain exceptions, not to sell or otherwise dispose of any shares of our common stock or other capital stock or other securities exercisable or convertible therefor for a period of at least 180 days after the date of this prospectus without the prior written consent of the representatives of the underwriters in this initial public offering. Except for this brief period, there can be no assurance as to the period of time during which Avista will maintain their ownership of our common stock following the offering. As a result, there can be no assurance as to the period of time during which we will be able to avail ourselves of the controlled company exemptions.

***Anti-takeover provisions in our amended and restated certificate of incorporation and amended and restated by-laws could prohibit a change of control that our stockholders may favor and could negatively affect our stock price.***

Upon the closing of this offering, provisions in our amended and restated certificate of incorporation and by-laws may make it more difficult and expensive for a third party to acquire control of us even if a change of control would be beneficial to the interests of our stockholders. These provisions could discourage potential takeover attempts and could adversely affect the market price of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. For example, our amended and restated certificate of incorporation and by-laws:

permit our Board of Directors to issue preferred stock with such terms as they determine, without stockholder approval;

provide that only one-third of the members of the Board are elected at each stockholders meeting and prohibit removal without cause;

require advance notice for stockholder proposals and director nominations; and

contain limitations on convening stockholder meetings and stockholder action by written consent.

These provisions make it more difficult for stockholders or potential acquirers to acquire us without negotiation and could discourage potential takeover attempts and could adversely affect the market price of our common stock. In addition, we have opted out of Section 203 of the Delaware General Corporation Law, or the DGCL. Our amended and restated certificate of incorporation will provide that we will not be

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governed by Section 203 until there occurs a transaction following the consummation of which Avista holds beneficial ownership of less than 5% of the voting power of our then-outstanding shares of common stock.

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*Conflicts of interest may arise because some of our directors are principals of our principal stockholder.*

Upon the consummation of this offering, representatives of Avista will occupy two of the seats on our Board of Directors. Avista could invest in entities that directly or indirectly compete with us or companies in which Avista is currently invested may already compete with us. As a result of these relationships, when conflicts arise between the interests of Avista and the interests of our stockholders, these directors may not be disinterested. Neither Avista nor the representatives of Avista on our Board of Directors, by the terms of our amended and restated certificate of incorporation, are required to offer us any transaction opportunity of which they become aware, and any of them could take any such opportunity for themselves or offer it to other companies in which they have an investment, unless that opportunity is expressly offered to a person serving as our director solely in his or her capacity as our director.

## **Risks Relating to Our Common Stock and this Offering**

*There may not be an active, liquid trading market for our common stock.*

Prior to this offering, there has been no public market for shares of our common stock. We cannot predict the extent to which investor interest in our company will lead to the development of a trading market on NASDAQ, or how liquid that market may become. If an active trading market does not develop, you may have difficulty selling any of our common stock that you purchase. The initial public offering price of shares of our common stock will be determined by negotiation between us and the underwriters and may not be indicative of prices that will prevail following the consummation of this offering. The market price of shares of our common stock may decline below the initial public offering price, and you may not be able to resell your shares of our common stock at or above the initial offering price.

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

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

market conditions in the broader stock market;

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

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

anticipated and reported clinical trial results;

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issuance of new or changed securities analysts' reports or recommendations;

investor perceptions of us and the specialty pharmaceutical industry;

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

additions or departures of key personnel;

regulatory or political developments;

litigation and governmental investigations; and

changing economic conditions.

These and other factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, in the past, when the market price of a

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stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management from our business, which could significantly harm our profitability and reputation.

*Management may invest or spend our net proceeds from this offering in ways that may not yield an acceptable return to you.*

Although we plan to use a portion of our net proceeds from this offering to reduce our outstanding indebtedness and to pay fees and expenses associated with the offering, we also may use a portion of the net proceeds for general corporate purposes. We will have broad discretion as to how we will spend those proceeds, and you will have no advance opportunity to evaluate our decisions and may not agree with the manner in which we spend those proceeds. We may not be successful investing the proceeds from this offering in either our operations or external investments.

*If a substantial number of shares become available for sale and are sold in a short period of time, the market price of our common stock could decline.*

Our directors, executive officers and certain of our significant stockholders will be subject to (i) the lock-up agreements described in Underwriting, (ii) the Rule 144 holding period requirements described in Shares Eligible for Future Sale Rule 144, and (iii) the transfer restrictions in certain shareholders agreements, described in Shares Eligible for Future Sale Lock-Up Agreements. After these restrictions have elapsed, additional shares, some of which will be subject to vesting, will be eligible for sale in the public market. If our existing stockholders sell substantial amounts of our common stock in the public market following this offering, the market price of our common stock could decrease significantly. The perception in the public market that our existing stockholders might sell shares of common stock could also depress the market price of our common stock. Upon the consummation of this offering, % of our common stock will be outstanding. In addition, we have reserved shares of common stock for issuance under our equity compensation plans. See Executive and Director Compensation 2014 Equity Incentive Plan. Upon consummation of this offering, we expect to have shares of common stock issuable upon exercise of outstanding options ( of which will be fully vested). A decline in the price of shares of our common stock caused by the lapse of resale restrictions by our existing stockholders or the sale of common stock issued pursuant to our equity incentive plans might impede our ability to raise capital through the issuance of additional shares of our common stock or other equity securities.

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

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

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

We currently intend to retain our future earnings, if any, for the foreseeable future, to repay indebtedness and to fund the development and growth of our business. We do not intend to pay any dividends to holders of our common stock and the indenture governing the Notes and the



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agreement governing our revolving credit facility limit our ability to pay dividends. As a result, capital appreciation in the price of our common stock, if any, will be your only source of gain on an investment in our common stock. See Dividend Policy.

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*New investors in our common stock will experience immediate and substantial book value dilution after this offering.*

The initial public offering price of our common stock will be substantially higher than the pro forma net tangible book value per share of the outstanding common stock immediately after the offering. Based on an assumed initial public offering price of \$        per share (the midpoint of the price range set forth on the cover of this prospectus) and our net tangible book value as of March 31, 2014, if you purchase our common stock in this offering, you will suffer immediate dilution in net tangible book value per share of approximately \$        per share. See Dilution.

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**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

Some of the statements contained in this prospectus are forward-looking statements. These forward-looking statements, including, in particular, statements about our plans, strategies, prospects and industry estimates are subject to risks and uncertainties. These statements identify prospective information and include words such as anticipates, intends, plans, seeks, believes, estimates, expects, should, could, and similar expressions. Examples of forward-looking statements include, but are not limited to, statements we make regarding: (i) outlook and expectations related to the global isotope supply and products manufactured at BVL, JHS and Pharmeducence; (ii) our outlook and expectations including, without limitation, in connection with continued market expansion and penetration for our commercial products, particularly DEFINITY; (iii) our outlook and expectations related to our intention to seek to engage strategic partners to assist in developing and potentially commercializing development candidates; and (iv) our liquidity, including our belief that our existing cash, cash equivalents, anticipated revenues and availability under our revolving credit facility are sufficient to fund our existing operating expenses, capital expenditures and liquidity requirements for at least the next twelve months. Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. The matters referred to in the forward-looking statements contained in this prospectus may not in fact occur. We caution you therefore against relying on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include regional, national or global political, economic, business, competitive, market and regulatory conditions and the following:

our dependence upon third parties for the manufacture and supply of a substantial portion of our products;

risks associated with the technology transfer programs to secure production of our products at alternate contract manufacturer sites;

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

the instability of the global Moly supply;

our ability to continue to increase segment penetration for DEFINITY in suboptimal echocardiograms;

risks associated with supply and demand for Xenon;

our dependence on key customers and group purchasing organization arrangements for our medical imaging products, and our ability to maintain and profitably renew our contracts and relationships with those key customers and group purchasing organizations;

our ability to compete effectively, including in connection with pricing pressures and new market entrants;

the dependence of certain of our customers upon third party healthcare payors and the uncertainty of third party coverage and reimbursement rates;

uncertainties regarding the impact of U.S. healthcare reform on our business, including related reimbursements for our current and potential future products;

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;

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

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

obtain FDA approval; and

gain post-approval market acceptance and adequate reimbursement;

risks associated with being able to negotiate in a timely manner relationships with potential strategic partners to advance our other development programs on acceptable terms, or at all;

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

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

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

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

risks associated with the current economic environment, including the U.S. credit markets;

risks associated with our international operations;

our inability to adequately protect our facilities, equipment and technology infrastructure;

our inability to hire or retain skilled employees and key personnel;

costs and other risks associated with the Sarbanes-Oxley Act and the Dodd-Frank Act risks related to the ownership of our common stock; and

other factors that are described in Risk Factors, beginning on page 16 of this prospectus.

Any forward-looking statement made by us in this prospectus 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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**USE OF PROCEEDS**

We estimate that the net proceeds to us from our sale of \_\_\_\_\_ shares of our common stock in this offering will be \$ \_\_\_\_\_ million, after deducting underwriting discounts and commissions and estimated expenses payable by us in connection with this offering. The underwriters also have the option to purchase up to an additional \_\_\_\_\_ shares of common stock. We estimate that the net proceeds, if the underwriters exercise their right to purchase the maximum of \_\_\_\_\_ additional shares of common stock from us, will be approximately \$ \_\_\_\_\_ million, after deducting underwriting discounts and commissions and estimated expenses payable by us in connection with this offering. This assumes an initial public offering price of \$ \_\_\_\_\_ per share (the midpoint of the price range set forth on the cover of this prospectus).

We expect to use net proceeds from this offering primarily for the following purposes:

approximately \$ \_\_\_\_\_ million to redeem a portion of our outstanding 9.750% Senior Notes due 2017; and

the remainder for general corporate purposes.

For further disclosure on the Notes, see [Description of Material Indebtedness](#) Senior Notes.

This expected use of net proceeds from this offering represents our current intentions based upon our present plans and business conditions. The amounts and timing of our actual expenditures depend on numerous factors, including the ongoing status of and results from our current development and commercialization activities, and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Assuming no exercise of the underwriters' option to purchase additional shares, a \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share (the midpoint of the price range set forth on the cover page of this prospectus) would increase (decrease) the net proceeds to us from this offering by \$ \_\_\_\_\_ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated expenses payable by us.

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**DIVIDEND POLICY**

After this offering, we intend to retain all available funds and any future earnings to reduce debt and for general corporate purposes. However, in the future, subject to the factors described below and our future liquidity and capitalization, we may change this policy and choose to pay dividends. Our business is conducted through our principal operating subsidiary, LMI. Dividends from, and cash generated by, LMI will be our principal source of cash to repay indebtedness, fund operations and pay dividends. Accordingly, our ability to pay dividends to our stockholders is dependent on the earnings and distributions of funds from LMI. LMI's ability to pay dividends to us and, therefore, our ability to pay dividends on our common stock, is currently restricted by the terms of the indenture governing the Notes and the agreement governing our revolving credit facility and may be further restricted by any future indebtedness we incur.

Any future determination to pay dividends will be at the discretion of our Board of Directors and will take into account:

restrictions in the indenture governing the Notes, the agreement governing our revolving credit facility and the instruments or agreements governing any future indebtedness we incur;

general economic and business conditions;

our financial condition, results of operations and cash flows;

our capital requirements;

the ability of LMI to pay dividends and make distributions to us; and

those other factors that our Board of Directors may deem relevant.

See Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources.



**Table of Contents****CAPITALIZATION**

The following table sets forth our cash and cash equivalents and our capitalization as of March 31, 2014:

on an actual basis;

on a pro forma basis to give effect to our corporate reorganization immediately prior to the consummation of this offering; and

on a pro forma as adjusted basis to give effect to (1) our corporate reorganization and (2) the sale of \_\_\_\_\_ shares of our common stock in this offering by us at an assumed initial public offering price of \$ \_\_\_\_\_ per share (the midpoint of the price range set forth on the cover of this prospectus) after deducting underwriting discounts and commissions and estimated offering expenses payable by us, and the application of the net proceeds from this offering to reduce our indebtedness as described in Use of Proceeds.

The following table should be read in conjunction with Use of Proceeds, Selected Consolidated Financial Data, Management's Discussion and Analysis of Financial Condition and Results of Operations, Description of Capital Stock, and our financial statements and notes thereto included elsewhere in this prospectus.

	As of March 31, 2014		
	Actual	Pro forma(1)	Pro forma as adjusted(2)
	(dollars in thousands)		
Cash and cash equivalents	\$ 17,010	\$	\$
Long-term debt, including current portion:			
Revolving credit facility(3)	\$ 8,000	\$	\$
Senior notes(4)	399,098		
Total long-term debt, including current portion	407,098		
Stockholders' (deficit) equity:			
Common stock (\$ _____ par value, _____ shares authorized, _____ shares issued and _____ outstanding, on a pro forma as			
adjusted basis)	51		
Treasury stock ( _____ shares, at cost, on a pro forma as adjusted basis)	(106)		
Additional paid-in capital	106,082		
Accumulated deficit	(342,138)		
Accumulated other comprehensive income	(665)		
Total stockholders' (deficit) equity	(236,776)		
Total capitalization	\$ 170,322	\$	\$

(1)

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Pro forma information gives effect to our corporate reorganization described in Prospectus Summary Corporate Reorganization, which had no impact on our historical results.

- (2) Assuming the number of shares sold by us in the offering remains the same as set forth on the cover page of this prospectus, a \$1.00 increase or decrease in the assumed public offering price would increase or decrease, as applicable, our total capitalization by approximately \$ million.
- (3) The senior secured credit facilities provide for a \$42.5 million revolving credit facility as of March 31, 2014, under which we had borrowings of \$8.0 million and a letter of credit commitment of \$8.8 million as of such date, giving us approximately \$25.7 million of remaining revolver availability outstanding as of such date. On June 24, 2014, we amended our revolving credit facility to increase revolving credit commitments to \$50.0 million. See Description of Material Indebtedness Revolving Credit Facility.
- (4) The senior notes consist of \$400.0 million in aggregate principal amount of the Notes issued May 10, 2010 and March 16, 2011, net of approximately \$3.8 million in consent solicitation fees and \$2.3 million premium on debt, which will be amortized as an adjustment to interest expense over the remaining term of the debt. Interest is payable entirely in cash. See Description of Material Indebtedness Senior Notes.

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**DILUTION**

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share and the pro forma as adjusted net tangible book value per share of common stock as of the consummation of this offering. Dilution results from the fact that the per share offering price of our common stock exceeds the pro forma net tangible book value per share purchased by new investors in this offering.

Our pro forma net tangible book value as of March 31, 2014 was \$       million, or \$       per share of common stock. Pro forma net tangible book value represents the amount of total tangible assets less total liabilities, and net tangible book value per share represents net tangible book value divided by the number of shares of common stock outstanding, in each case, after giving effect to our corporate reorganization but before giving effect to this offering. The corporate reorganization had no impact on our historical net tangible book value as of March 31, 2014.

After giving effect to (i) the sale by us of       shares of common stock in this offering at an assumed public offering price of \$       per share (the midpoint of the price range set forth on the cover page of this prospectus) and (ii) the application of the net proceeds of the offering, our pro forma as adjusted net tangible book value as of March 31, 2014 would have been \$       million, or \$       per share. This represents an immediate increase in pro forma net tangible book value of \$       per share to existing stockholders and an immediate dilution in pro forma net tangible book value of \$       per share to new investors purchasing common stock in this offering. The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share	\$
Pro forma net tangible book value per share as of March 31, 2014	\$
Increase in pro forma net tangible book value per share attributable to the sale of shares in this offering	
Pro forma as adjusted net tangible book value per share after this offering	
Dilution in pro forma net tangible book value per share to new investors purchasing in this offering	\$

A \$1.00 increase (decrease) in the assumed initial public offering price of \$       per share (the midpoint of the price range set forth on the cover page of this prospectus) would increase (decrease) our pro forma as adjusted net tangible book value after this offering by \$       million and increase (decrease) the dilution per share to new investors purchasing in this offering by \$       per share, assuming no other change to the number of shares of common stock offered by us as set forth on the cover page of this prospectus.

The following table summarizes the differences between the existing stockholders and new investors purchasing shares in this offering with respect to the number of shares purchased from us, the total consideration paid and the average price paid per share as of March 31, 2014, as adjusted to give effect to our sale of       shares in this offering at an assumed initial public offering price of \$       per share, which is the midpoint of the range set forth on the cover page of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses:

	Shares purchased		Total consideration		Average price per share
	Number	Percent	Amount	Percent	share
Existing stockholders		%	\$	%	\$
New investors					

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Total	%	\$	%	\$
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A \$1.00 increase (decrease) in the assumed initial public offering price of \$      per share (the midpoint of the price range set forth on the cover page of this prospectus) would increase (decrease) the total consideration paid by new investors purchasing in this offering by \$      million and the total consideration paid by all stockholders by \$      million.

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In addition, we may choose to raise additional capital based on market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

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**NON-GAAP FINANCIAL MEASURES**

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

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

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

they do not reflect our cash expenditures, or future requirements, for capital expenditures or contractual commitments;

they do not reflect changes in, or cash requirements for, our working capital needs;

they do not reflect the significant interest expense or the cash requirements necessary to service interest or principal payments, on our debt;

although depreciation is a non-cash charge, the assets being depreciated will often have to be replaced in the future, and our Non-GAAP Measures do not reflect any cash requirements for those replacements;

they are not adjusted for all non-cash income or expense items that are reflected in our statements of cash flows; and

other companies in our industry may calculate these measures differently than we do, limiting their usefulness as comparative measures.

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

Please see the consolidated financial statements included elsewhere in this prospectus for our GAAP results. Additionally, for a presentation of net income as calculated under GAAP and reconciliation to our calculation of Adjusted EBITDA, see Prospectus Summary Summary Consolidated Financial and Other Data in this prospectus. For our definition of EBITDA as used in our equity incentive plans and a summary of the differences between such EBITDA definition and Adjusted EBITDA, see Executive and Director Compensation Elements of Compensation Long-Term Equity Incentive Awards.



**Table of Contents****SELECTED CONSOLIDATED FINANCIAL DATA**

The following selected consolidated financial data should be read in conjunction with, and are qualified by reference to, Capitalization, Management's Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and notes thereto included elsewhere in this prospectus. The summary consolidated statement of operations data for the years ended December 31, 2013, 2012 and 2011 and the summary consolidated balance sheet data as of December 31, 2013 and 2012 has been derived from, and is qualified by reference to, our audited consolidated financial statements included elsewhere in this prospectus and should be read in conjunction with those consolidated financial statements and notes thereto. The summary consolidated balance sheet data as of March 31, 2014 and statements of operations data for the three months ended March 31, 2014 and 2013 have been derived from our unaudited consolidated financial statements and related notes included elsewhere in this prospectus. Balance sheet data as of March 31, 2013 have been derived from our unaudited consolidated financial statements that are not included in this prospectus. We have prepared the unaudited consolidated financial information set forth below on the same basis as our audited consolidated financial statements and have included all adjustments, consisting of only normal recurring adjustments, that we consider necessary for a fair presentation of our financial position and operating results for such periods. The results for any interim period are not necessarily indicative of the results that may be expected for a full year. The results indicated below and elsewhere in this prospectus are not necessarily indicative of our future performance. You should read this information, together with Capitalization, Management's Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and related notes included elsewhere in this prospectus.

	Three Months ended March 31,		Year ended December 31,		
	2014	2013	2013	2012	2011
	(dollars in thousands, except share and per share numbers)				
<b>Statement of Comprehensive Loss Data:</b>					
Revenues	\$ 73,336	\$ 71,018	\$ 283,672	\$ 288,105	\$ 356,292
Cost of goods sold	43,275	48,206	206,311	211,049	255,466
Loss on firm purchase commitment				1,859	5,610
Sales and marketing expenses	9,498	9,797	35,227	37,437	38,689
General and administrative expenses	8,852	10,253	33,036	32,520	32,862
Research and development expenses	3,222	11,998	30,459	40,604	40,945
Proceeds from manufacturer			(8,876)	(34,614)	
Impairment of land			6,406		
Operating income (loss)	8,489	(9,236)	(18,891)	(750)	(17,280)
Interest expense	(10,552)	(10,669)	(42,915)	(42,014)	(37,658)
Interest income			104	252	333
Other income (expense), net	(414)	721	1,161	(44)	1,429
Loss before income taxes	(2,477)	(19,184)	(60,541)	(42,556)	(53,176)
Provision (benefit) for income taxes	(1,192)	628	1,014	(555)	84,082
Net income (loss)	(1,285)	(19,812)	(61,555)	(42,001)	(137,258)
Foreign currency translation, net of taxes	(271)	(597)	(1,729)	964	(337)
Total comprehensive loss	\$ (1,556)	\$ (20,409)	\$ (63,284)	\$ (41,037)	\$ (137,595)
Net loss per common share:					
Basic and diluted	\$ (0.03)	\$ (0.39)	\$ (1.21)	\$ (0.84)	\$ (2.73)
Common shares:					
Basic and diluted	50,803,484	50,333,927	50,670,274	50,250,957	50,237,490



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	As of March 31,		As of December 31,	
	2014	2013	2013	2012
	(dollars in thousands)			
<b>Balance Sheet Data:</b>				
Cash and cash equivalents	\$ 17,010	\$ 30,640	\$ 18,578	\$ 33,321
Total assets	260,960	314,307	261,311	324,652
Total liabilities	497,736	507,625	496,828	497,757
Total long-term debt, net	399,098	398,876	399,037	398,822
Total stockholders' deficit	(236,776)	(193,318)	(235,517)	(173,105)

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### **MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

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

#### **Overview**

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

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

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

#### ***Our Products***

Our principal products include the following:

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

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

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

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

Sales of our contrast agent, DEFINITY, are made through our sales team of approximately 80 employees. In the United States, our nuclear imaging products, including TechnoLite and Cardiolite, are primarily distributed through over 350 radiopharmacies that are controlled by or associated with Cardinal, GE Healthcare, UPPI and Triad. A small portion of our nuclear imaging product sales in the United States are made through our direct sales

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force to hospitals and clinics that maintain their own in-house radiopharmaceutical capabilities. Outside the United States, we own five radiopharmacies in Canada and two radiopharmacies in each of Puerto Rico and Australia. We also maintain a direct sales force in each of these countries. In Europe, Asia Pacific and Latin America, we rely on third party distributors to market, sell and distribute our nuclear imaging and contrast agent products, either on a country-by-country basis or on a multicountry regional basis.

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

	Three Months ended March 31,				Year ended December 31,					
	2014		2013		2013		2012		2011	
	\$	%	\$	%	\$	%	\$	%	\$	%
	(dollars in thousands)									
DEFINITY	\$ 22,359	30.5	\$ 17,030	24.0	\$ 78,094	27.5	\$ 51,431	17.9	\$ 68,503	19.2
TechneLite	23,041	31.4	22,426	31.5	92,195	32.5	114,249	39.7	131,241	36.9
Xenon	9,709	13.2	8,321	11.7	32,125	11.3	30,075	10.4	26,761	7.5
Cardiolite	4,680	6.4	10,910	15.4	26,137	9.2	34,995	12.1	66,127	18.6
Other	13,547	18.5	12,331	17.4	55,121	19.5	57,355	19.9	63,660	17.8
Revenues	\$ 73,336	100.0	\$ 71,018	100.0	\$ 283,672	100.0	\$ 288,105	100.0	\$ 356,292	100.0

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

**Key Factors Affecting Our Results**

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

***Inventory Supply***

Our products consist of radiopharmaceuticals and other imaging agents. The radiopharmaceuticals are decaying radioisotopes with half-lives ranging from a few hours to several days. These products cannot be kept in inventory because of their limited useful lives and are subject to just-in-time manufacturing, processing and distribution. We obtain a substantial portion of our other imaging agents from third party suppliers. JHS is currently our sole source manufacturer of DEFINITY, and we have ongoing technology transfer activities at JHS for our Neurolite supply. In the meantime, we have no other currently active supplier of Neurolite, and our Cardiolite product supply is manufactured by a single manufacturer.

Historically, we relied on BVL in Bedford, Ohio as our sole manufacturer of DEFINITY, Neurolite and evacuation vials, an ancillary component for our TechneLite generators, and as one of two manufacturers of Cardiolite. Our products were manufactured at the South Complex, where BVL also manufactured products for a number of other pharmaceutical customers. In July 2010, BVL temporarily shutdown the South Complex, in order to upgrade the facility to meet certain regulatory requirements. BVL had originally planned for the shutdown of the South Complex to run through March 2011 and to resume production of our products in April 2011. In anticipation of the shutdown, BVL manufactured for us

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additional inventory of these products to meet our expected needs during this period. A series of unexpected delays at BVL, however, resulted in a stockout for Neurolite from the third quarter 2011 until the third quarter 2013, product outages and shortages for DEFINITY in much of 2012 and product outages and shortages for Cardiolite in 2012 and 2013. Until JHS is approved by certain foreign regulatory authorities to manufacture our products, we will also face continued limitations on where we can sell our products outside the United States.

Because of BVL's ongoing regulatory issues and our mutual desire to enter into a new contractual relationship to replace the original arrangement, in March 2012 we terminated the original manufacturing agreement and entered into a new set of contracts with BVL which provided, among other things, cash payments to us of \$35 million and an undertaking by BVL to continue to manufacture for us through December 2013.

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Although BVL was able to resume some manufacturing under the new agreements, BVL continued to face regulatory and supply challenges and, in October 2013, it announced that it would cease to manufacture further new batches of our products in its Bedford, Ohio facility. In November 2013, in connection with the termination of our manufacturing agreement, we and BVL entered into a settlement agreement, or the Settlement Agreement, which provided, among other things, that BVL pay us an additional \$8.9 million. BVL was also obligated to use commercially reasonable efforts to finalize specific batches of DEFINITY, Cardiolite and saline manufactured and not yet released by the BVL quality function for commercial distribution. BVL has since released for commercial distribution all of our remaining manufactured product that was awaiting quality approval.

We are also currently working to secure additional alternative suppliers for our key products as part of our ongoing supply chain diversification strategy. For example, on November 12, 2013, we entered into a Manufacturing and Supply Agreement with Pharmeducence to manufacture and supply DEFINITY.

## ***Growth of DEFINITY***

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

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

## ***Global Isotope Supply***

Currently, our largest supplier of Moly and our only supplier of Xenon is Nordion, which relies on the NRU reactor in Chalk River, Ontario. For Moly, we currently have a supply agreement with Nordion that runs through December 31, 2015, subject to certain early termination provisions (that cannot be effective prior to October 1, 2014) and supply agreements with NTP of South Africa, ANSTO of Australia, and IRE of Belgium, each running through December 31, 2017. For Xenon, we have a purchase order relationship with Nordion. The Canadian government requires the NRU reactor to shut down for at least four weeks at least once a year for inspection and maintenance. The 2014 shutdown period ran from April 13, 2014 until May 13, 2014, and we were able to source all of our standing order customer demand for Moly during this time period from our other suppliers. However, because Xenon is a by-product of the Moly production process and is currently captured only by NRU, during this shutdown period, we were not able to supply all of our standing order customer demand for Xenon during the outage. Because the month-long

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NRU shutdown was fully anticipated in our 2014 budgeting process, we do not believe the shutdown will have a material adverse effect on our results of operations, financial condition and cash flows.

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We believe we are well-positioned with our current supply partners to have a secure supply of Moly, including LEU Moly, when the NRU reactor commercial operations cease in 2016. We are currently pursuing alternative sources of Xenon on a global basis. If we are not able to secure a new producer of Xenon prior to the 2016 and obtain regulatory approval to sell Xenon from that new producer, we will no longer be able to offer Xenon. In addition, Nordion recently announced that it has entered into a definitive agreement to be acquired by Sterigenics. As a result of this transaction, our supplier could change the terms on which we obtain Xenon. See Risk Factors Risks Related to our Business and Industry We face potential supply and demand challenges for Xenon.

### ***Demand for TechneLite***

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

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

In November 2013, CMS announced the 2014 final Medicare payment rules for hospital outpatient settings. Under the final rules, each technetium dose produced from a generator for a diagnostic procedure in a hospital outpatient setting is reimbursed by Medicare at a higher rate if that technetium dose is produced from a generator containing Moly sourced from at least 95 percent LEU. We currently understand that CMS expects to continue this incentive program for the foreseeable future. In January 2013, we began to offer a TechneLite generator which contains Moly sourced from at least 95 percent LEU and which satisfies the requirements for reimbursement under this incentive program. Although demand for LEU generators appears to be growing, it is too early to tell whether this incremental reimbursement for LEU Moly generators will result in a material increase in our generator sales.

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

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

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



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

**Table of Contents****Research and Development Expenses**

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

**Segments**

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

**Operating Results****Three Months Ended March 31, 2014 and 2013**

	<b>For the Three Months ended March 31, 2014                      2013 (dollars in thousands)</b>	
Revenues	\$ 73,336	\$ 71,018
Cost of goods sold	43,275	48,206
<b>Gross profit</b>	<b>30,061</b>	<b>22,812</b>
Operating expenses		
Sales and marketing expenses	9,498	9,797
General and administrative expenses	8,852	10,253
Research and development expenses	3,222	11,998
<b>Total operating expenses</b>	<b>21,572</b>	<b>32,048</b>
<b>Operating income (loss)</b>	<b>8,489</b>	<b>(9,236)</b>
Interest expense, net	(10,552)	(10,669)
Other income (expense), net	(414)	721
<b>Loss before income taxes</b>	<b>(2,477)</b>	<b>(19,184)</b>
Provision (benefit) for income taxes	(1,192)	628

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Net income (loss)	(1,285)	(19,812)
Foreign currency translation, net of taxes	(271)	(597)
Total comprehensive loss	\$ (1,556)	\$ (20,409)

The following are reflected in our results as of and for the three months ended March 31, 2014:

increased revenues and segment penetration for DEFINITY in the suboptimal echocardiogram segment as a result of sustained availability of product supply;

decreased revenues from our Cardiolite products resulting from continued generic competition;

increased revenues resulting from the return of Neurolite product supply in the third quarter of 2013;

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under-absorption of manufacturing overhead due to lower production and low lot yields resulting from the continued supply challenges with BVL during 2013;

the impact of certain cost savings actions taken in March 2013 as we finish implementing the strategic shift in how we fund our research and development, or R&D, programs; and

lower material costs incurred for the production of TechneLite.

**Comparison of the Three Months Ended March 31, 2014 and 2013****Revenues**

Revenues are summarized as follows:

	Three Months ended March 31,		2014 compared to 2013	
	2014	2013	Change \$	Change %
	(dollars in thousands)			
United States				
DEFINITY	\$ 21,984	\$ 16,746	\$ 5,238	31.3%
TechneLite	20,100	19,572	528	2.7
Xenon	9,705	8,306	1,399	16.8
Cardiolite	521	6,430	(5,909)	(91.9)
Other	4,501	3,201	1,300	40.6
Total U.S. revenues	\$ 56,811	\$ 54,255	\$ 2,556	4.7%
International				
DEFINITY	\$ 375	\$ 284	\$ 91	32.0%
TechneLite	2,941	2,854	87	3.0
Xenon	4	15	(11)	(73.3)
Cardiolite	4,159	4,480	(321)	(7.2)
Other	9,046	9,130	(84)	(0.9)
Total International revenues	\$ 16,525	\$ 16,763	\$ (238)	(1.4)%
Revenues	\$ 73,336	\$ 71,018	\$ 2,318	3.3%

Revenues increased \$2.3 million, or 3.3%, to \$73.3 million in the three months ended March 31, 2014, as compared to \$71.0 million in the three months ended March 31, 2013. U.S. segment revenue increased \$2.6 million, or 4.7%, to \$56.8 million in the three months ended March 31, 2014, as compared to \$54.3 million in the prior year. The increase in the U.S. segment over the prior year is primarily driven by a \$5.2 million increase in DEFINITY as a result of higher unit volumes, a \$1.8 million increase in NeuroLite as the product returned to market in September 2013 and a \$1.4 million increase in Xenon primarily due to favorable pricing. Offsetting these increases was a decrease in Cardiolite revenues of \$5.9 million over the prior period as a result of a contract with a significant customer that reduced unit pricing and volume commitments and a \$1.0 million decrease in Quadramet revenues due to less unit volume since we transitioned to being the direct manufacturer at the end of 2013.

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The International segment revenues decreased \$0.2 million, or 1.4%, to \$16.5 million in the three months ended March 31, 2014, as compared to \$16.8 million in the three months ended March 31, 2013. The decrease in the International segment over the prior year period is due to \$1.3 million unfavorable foreign exchange. Offsetting this decrease, in part, was a \$0.6 million increase relating to other marketed products, which is driven by the return of Neurolite finished product to certain international markets and increased Thallium sales in Asia Pacific. In addition, TechnLite revenues increased \$0.3 million primarily driven by increased volume.

**Table of Contents***Rebates and Allowances*

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

An analysis of the amount of, and change in, reserves for the period from January 1, 2013 through March 31, 2014 is summarized as follows:

	<b>Rebates</b>	<b>Allowances</b>	<b>Total</b>
	<b>(dollars in thousands)</b>		
Balance, as of January 1, 2013	\$ 1,542	\$ 66	\$ 1,608
Current provisions relating to revenues in current year	4,696	243	4,939
Adjustments relating to prior years' estimate	(21)		(21)
Payments/credits relating to revenues in current year	(3,438)	(220)	(3,658)
Payments/credits relating to revenues in prior years	(1,040)	(69)	(1,109)
Balance, as of December 31, 2013	1,739	20	1,759
Current provisions relating to revenues in current year	1,637	76	1,713
Adjustments relating to prior years' estimate	42		42
Payments/credits relating to revenues in current year	(443)	(51)	(494)
Payments/credits relating to revenues in prior years	(652)	(20)	(672)
Balance, as of March 31, 2014	\$ 2,323	\$ 25	\$ 2,348

Accrued sales rebates were approximately \$2.3 million and \$1.7 million at March 31, 2014 and December 31, 2013, respectively. The \$0.6 million increase in accruals is primarily associated with the Quadramet product.

*Costs of Goods Sold*

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

Cost of goods sold is summarized as follows:

<b>Three Months ended</b>	<b>2014 compared</b>
<b>March 31,</b>	<b>to 2013</b>

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	2014	2013	Change \$	Change %
	(dollars in thousands)			
United States	\$ 31,265	\$ 34,063	\$ (2,798)	(8.2)%
International	12,010	14,143	(2,133)	(15.1)
<b>Total Cost of Goods Sold</b>	<b>\$ 43,275</b>	<b>\$ 48,206</b>	<b>\$ (4,931)</b>	<b>(10.2)%</b>

Total cost of goods sold decreased \$4.9 million, or 10.2%, to \$43.3 million in the three months ended March 31, 2014, as compared to \$48.2 million in the three months ended March 31, 2013. U.S. segment cost of goods sold decreased approximately \$2.8 million, or 8.2%, to \$31.3 million in the three months ended March 31,

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2014, as compared to \$34.1 million in the prior year period. The decrease in the U.S. segment cost of goods sold was primarily due to a decrease of \$3.7 million in cost of goods associated with Cardiolite as a result of lower unit volumes sold and lower amortization expense due to a write-down in the Cardiolite trademark intangible asset in the fourth quarter of 2013. Offsetting these decreases was a \$1.0 million increase in NeuroLite cost of goods due to higher technology transfer costs.

For the three months ended March 31, 2014, the International segment cost of goods sold decreased \$2.1 million, or 15.1%, to \$12.0 million, as compared to \$14.1 million in the prior year period. Cost of goods sold in our International segment decreased primarily due to \$1.0 million favorable foreign exchange impact. Additionally, cost of goods sold decreased by \$1.0 million as compared to the prior year period primarily due to lower volume of the more expensive substitute products being sold in the current period as a result of the return of supply and reduced costs associated with increased operating efficiencies.

**Gross Profit**

	Three Months ended March 31,		2014 compared to 2013	
	2014	2013	Change \$	Change %
United States	\$ 25,546	\$ 20,192	\$ 5,354	26.5%
International	4,515	2,620	1,895	72.3
<b>Total Gross Profit</b>	<b>\$ 30,061</b>	<b>\$ 22,812</b>	<b>\$ 7,249</b>	<b>31.8%</b>

Total gross profit increased \$7.2 million, or 31.8%, to \$30.1 million in the three months ended March 31, 2014, as compared to \$22.8 million in the three months ended March 31, 2013. U.S. segment gross profit increased \$5.4 million, or 26.5%, to \$25.5 million, as compared to \$20.2 million in the prior year period. The increase in the U.S. segment gross profit primarily due to a \$4.7 million increase for DEFINITY gross profit due to higher unit volumes. In addition, Xenon gross profit increased by \$1.6 million due to favorable pricing and NeuroLite gross profit increased by \$1.8 million since the product returned to market in September 2013. Technelite gross profit increased by \$0.6 million primarily due to lower material costs and Ablavar gross profit increased by \$0.4 million due to higher unit volumes. Offsetting these increases was a decrease in Cardiolite gross profit of \$2.2 million primarily due to lower unit volumes, a \$1.1 million decrease in Quadramet gross profit due to lower unit volumes and a \$1.0 million decrease in NeuroLite gross profit due to higher technology transfer costs.

For the three months ended March 31, 2014, the International segment gross profit increased \$1.9 million, or 72.3%, to \$4.5 million, as compared to \$2.6 million in the prior year period. Gross profit in the International segment increased due to the return of NeuroLite finished product to certain international markets, lower volume of the more expensive substitute products sold in the current period as a result of the return of supply and reduced costs associated with increased operating efficiencies. These increases were partially offset by unfavorable foreign exchange impact of \$0.3 million.

**Sales and Marketing**

Three Months ended March 31,	2014 compared to 2013
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	2014	2013	Change \$	Change %
	(dollars in thousands)			
United States	\$ 8,300	\$ 8,711	\$ (411)	(4.7)%
International	1,198	1,086	112	10.3
Total Sales and Marketing	\$ 9,498	\$ 9,797	\$ (299)	(3.1)%

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

Total sales and marketing expenses decreased \$0.3 million, or 3.1%, to \$9.5 million in the three months ended March 31, 2014, as compared to \$9.8 million in the three months ended March 31, 2013. In the U.S. segment, sales and marketing expense decreased \$0.4 million, or 4.7%, to \$8.3 million in the same period, as compared to \$8.7 million in the prior year. The decrease in the U.S. segment was primarily due to lower variable compensation and other employee related costs.

For the three months ended March 31, 2014, the International segment sales and marketing expenses increased \$0.1 million or 10.3%, to \$1.2 million as compared to \$1.1 million in the prior year period primarily due to increased headcount and employee related expenses.

**General and Administrative**

	Three Months ended March 31,		2014 compared to 2013	
	2014	2013	Change \$	Change %
	(dollars in thousands)			
United States	\$ 8,281	\$ 9,698	\$ (1,417)	(14.6)%
International	571	555	16	2.9
<b>Total General and Administrative</b>	<b>\$ 8,852</b>	<b>\$ 10,253</b>	<b>\$ (1,401)</b>	<b>(13.7)%</b>

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

Total general and administrative expenses decreased approximately \$1.4 million, or 13.7%, to \$8.9 million in the three months ended March 31, 2014, as compared to \$10.3 million in the three months ended March 31, 2013. In the U.S. segment, general and administrative expenses decreased \$1.4 million, or 14.6%, to \$8.3 million, as compared to \$9.7 million in the prior year period. The decrease in the U.S. segment was primarily due to higher severance expense in the prior year period related to the reduction in force in the first quarter of 2013, lower legal expense due to a reduced amount of services and cost savings achieved through the renegotiation of certain information technology related contracts.

For the three months ended March 31, 2014, general and administrative expenses in the International segment remained flat as compared to the prior year period.

**Research and Development**

	Three Months ended March 31,		2014 compared to 2013	
	2014	2013	Change \$	Change %
United States	\$ 3,114	\$ 11,950	\$ (8,836)	(73.9)%
International	108	48	60	125.0
<b>Total Research and Development</b>	<b>\$ 3,222</b>	<b>\$ 11,998</b>	<b>\$ (8,776)</b>	<b>(73.1)%</b>

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

Total research and development expense decreased \$8.8 million, or 73.1%, to \$3.2 million for the three months ended March 31, 2014, as compared to \$12.0 million in the three months ended March 31, 2013. In the U.S. segment, research and development expense decreased approximately \$8.8 million, or 73.9%, to \$3.1 million, as compared to \$12.0 million in the prior year period. The decrease in the U.S. segment was driven by lower headcount related to the reduction in force in the first quarter of 2013 as a result of a strategic shift to use fewer internal resources and lower external expense as we seek strategic partners to assist in the future development and commercialization of our development candidates. Additionally, we had a decline in external expense associated with Phase 3 clinical trial for flurpiridaz F 18 as we completed patient enrollment during the third quarter of 2013.

For the three months ended March 31, 2014, research and development expenses in the International segment remained flat as compared to the prior year period.

***Other (Expense) Income, Net***

	Three Months ended March 31,		2014 compared to 2013	
	2014	2013	Change \$	Change %
	(dollars in thousands)			
Interest expense	\$ (10,560)	\$ (10,711)	\$ 151	(1.4)%
Interest income	8	42	(34)	(81.0)
Other income (expense), net	(414)	721	(1,135)	(157.4)
Total Other Expense, net	\$ (10,966)	\$ (9,948)	\$ (1,018)	10.2%

***Interest Expense***

For the three months ended March 31, 2014, compared to the same period in 2013, interest expense decreased by \$151,000 as a result of decreased amortization related to the capitalization of deferred financing costs.

***Interest Income***

For the three months ended March 31, 2014, compared to the same period in 2013, interest income decreased by \$34,000 as a result of the change in balances in interest bearing accounts.

*Other (Expense) Income, net*

For the three months ended March 31, 2014, compared to the same period in 2013, other expense increased by \$1.1 million primarily due to a net \$1.2 million impact associated with a state tax settlement indemnified by BMS. In addition, during the three months ended March 31, 2013, we received \$0.4 million in consideration from the extinguishment of our membership interests in a mutual insurance company.

*Provision (Benefit) for Income Taxes*

	Three Months ended March 31,		2014 compared to 2013	
	2014	2013 (dollars in thousands)	Change \$	Change %
Provision (benefit) for income taxes	\$ (1,192)	\$ 628	\$ (1,820)	(289.8)%

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For the three months ended March 31, 2014 and 2013, our effective tax rate was 48.1% and (3.3)%, respectively. The \$1.8 million decrease in the tax provision for the three months ended March 31, 2014, as compared to the same period in 2013, was impacted primarily by discrete events which included a reversal of an uncertain tax position resulting in a \$1.8 million tax benefit attributable to a state tax settlement and a \$0.7 million tax expense for current year additions. Our tax rate is also affected by recurring items, such as tax rates in foreign jurisdictions, which we expect to be fairly consistent in the near term, as well as other discrete events that may not be consistent from year-to-year. The following items had the most significant impact on the differences between our statutory U.S. federal income tax rate of 35% and our effective tax rate during the three months ended:

*March 31, 2014*

A \$1.1 million decrease in our uncertain tax positions relating to a state tax settlement and state tax nexus and transfer pricing matters.

*March 31, 2013*

A \$6.6 million increase to our valuation allowance against net domestic deferred tax assets.

A \$0.7 million increase in our uncertain tax positions relating to state tax nexus and transfer pricing matters.

*Years Ended December 31, 2013, 2012 and 2011*

	Year ended December 31,			2013 compared to 2012		2012 compared to 2011	
	2013	2012	2011	Change \$	Change %	Change \$	Change %
	(dollars in thousands)						
Revenues	\$ 283,672	\$ 288,105	\$ 356,292	\$ (4,433)	(1.5)%	\$ (68,187)	(19.1)%
Cost of goods sold	206,311	211,049	255,466	(4,738)	(2.2)	(44,417)	(17.4)
Loss on firm purchase commitment		1,859	5,610	(1,859)	(100.0)	(3,751)	(66.9)
Total cost of goods sold	206,311	212,908	261,076	(6,597)	(3.1)	(48,168)	(18.4)
Gross profit	77,361	75,197	95,216	2,164	2.9	(20,019)	(21.0)
Operating expenses							
Sales and marketing expenses	35,227	37,437	38,689	(2,210)	(5.9)	(1,252)	(3.2)
General and administrative expenses	33,036	32,520	32,862	516	1.6	(342)	(1.0)
Research and development expenses	30,459	40,604	40,945	(10,145)	(25.0)	(341)	(0.8)
Proceeds from manufacturer	(8,876)	(34,614)		25,738	(74.4)	(34,614)	(100.0)
Impairment on land	6,406			6,406	100.0		
Total operating expenses	96,252	75,947	112,496	20,305	26.7	(36,549)	(32.5)
Operating income (loss)	(18,891)	(750)	(17,280)	(18,141)	2,418.8	16,530	95.7
Interest expense	(42,915)	(42,014)	(37,658)	(901)	2.1	(4,356)	11.6

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Interest income	104	252	333	(148)	(58.7)	(81)	(24.3)
Other income (expense), net	1,161	(44)	1,429	1,205	2,738.6	(1,473)	(103.1)
Loss before income taxes	(60,541)	(42,556)	(53,176)	(17,985)	42.3	10,620	20.0
Provision (benefit) for income taxes	1,014	(555)	84,082	1,569	282.7	(84,637)	(100.7)
Net income (loss)	(61,555)	(42,001)	(137,258)	(19,554)	46.6	95,257	69.4
Foreign currency translation, net of taxes	(1,729)	964	(337)	(2,693)	(279.4)	1,301	386.1
Total comprehensive loss	\$ (63,284)	\$ (41,037)	\$ (137,595)	\$ (22,247)	54.2%	\$ 96,558	70.2%

The following are reflected in our results as of and for the year ended December 31, 2013:

increased revenues and segment penetration for DEFINITY in the suboptimal echocardiogram segment as a result of sustained availability of product supply from BVL and JHS;

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decreased revenues due to limited supply of Neurolite product inventory as a result of the BVL production challenges, and a higher cost of goods sold for Cardiolite because of more expensive sourcing from our current manufacturer of Cardiolite and from our third party manufacturers of generic sestamibi;

decreased revenues for TechneLite due to a contract that took effect at the beginning of 2013 with a significant customer that reduced unit pricing;

decreased revenues resulting from continued generic competition to Cardiolite;

under-absorption of manufacturing overhead due to lower production and low lot yields resulting from the continued supply challenges with BVL during 2013;

the impact of certain cost saving actions taken in March 2013 as we continue to implement a strategic shift in how we fund our R&D programs;

lower material costs incurred for the production of TechneLite;

an impairment charge on certain excess land held for sale;

an impairment charge on the Cardiolite trademark intangible asset;

an impairment charge on customer relationship intangible assets; and

a total of \$8.9 million received from BVL to compensate us for business losses.

During the year ended December 31, 2013, we incurred a net income (loss) of \$(61.6) million and an operating income (loss) of \$(18.9) million. We have developed plans and taken steps that we believe will enable us to strengthen our operations and meet our operating and financing requirements. In March 2013, we implemented a strategic shift in how we intend to fund our important R&D programs. We have reduced our internal R&D resources while at the same time seeking to engage strategic partners to assist us in the further development and commercialization of our important agents in development, including flurpiridaz F 18, 18F LMI 1195 and LMI 1174.

**Comparison of the Years Ended December 31, 2013, 2012, and 2011**

***Revenues***

Revenues are summarized as follows:



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	Year ended December 31,			2013 compared to 2012		2012 compared to 2011	
	2013	2012	2011	Change \$	Change %	Change \$	Change %
(dollars in thousands)							
United States							
DEFINITY	\$ 76,539	\$ 50,377	\$ 67,442	\$ 26,162	51.9%	\$ (17,065)	(25.3)%
TechneLite	80,609	101,049	114,833	(20,440)	(20.2)	(13,784)	(12.0)
Cardiolite	8,612	13,851	39,214	(5,239)	(37.8)	(25,363)	(64.7)
Xenon	32,086	30,048	26,728	2,038	6.8	3,320	12.4
Other	15,793	14,686	20,148	1,107	7.5	(5,462)	(27.1)
<b>Total U.S. revenues</b>	<b>\$ 213,639</b>	<b>\$ 210,011</b>	<b>\$ 268,365</b>	<b>\$ 3,628</b>	<b>1.7%</b>	<b>\$ (58,354)</b>	<b>(21.7)%</b>
International							
DEFINITY	\$ 1,555	\$ 1,054	\$ 1,061	\$ 501	47.5%	\$ (7)	(0.7)%
TechneLite	11,586	13,200	16,408	(1,614)	(12.2)	(3,208)	(19.6)
Cardiolite	17,525	21,144	26,913	(3,619)	(17.1)	(5,769)	(21.4)
Xenon	39	27	33	12	44.4	(6)	(18.2)
Other	39,328	42,669	43,512	(3,341)	(7.8)	(843)	(1.9)
<b>Total International revenues</b>	<b>\$ 70,033</b>	<b>\$ 78,094</b>	<b>\$ 87,927</b>	<b>\$ (8,061)</b>	<b>(10.3)</b>	<b>\$ (9,833)</b>	<b>(11.2)</b>
<b>Revenues</b>	<b>\$ 283,672</b>	<b>\$ 288,105</b>	<b>\$ 356,292</b>	<b>\$ (4,433)</b>	<b>(1.5)%</b>	<b>\$ (68,187)</b>	<b>(19.1)%</b>

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*2013 v. 2012*

Revenues decreased \$4.4 million, or 1.5%, to \$283.7 million in the year ended December 31, 2013, as compared to \$288.1 million in the year ended December 31, 2012. U.S. segment revenue increased \$3.6 million, or 1.7%, to \$213.6 million in the same period, as compared to \$210.0 million in the prior year. The increase of \$3.6 million in U.S. segment revenue during the year ended December 31, 2013, as compared to the prior year period is primarily driven by a \$26.2 million increase in DEFINITY revenue given product supply shortages that impacted the prior year period. Offsetting this increase was a decrease in TechneLite revenues of \$20.4 million over the prior year period as a result of: (i) a contract that took effect at the beginning of 2013 with a significant customer that reduced unit pricing, resulting in lower revenues of \$16.9 million as compared to the prior year period; (ii) a decline in a significant customer's market share which lowered its share of product purchases from us and decreased revenues by \$5.7 million; and (iii) loss of a customer resulting in lower revenue of \$1.3 million. Offsetting these decreases in TechneLite revenues was a higher share volume with a group of customers resulting in a \$3.3 million increase in sales over the prior year period. Additionally, Cardiolite revenues were \$5.2 million lower than the prior year period as a result of a contract with a significant customer that reduced unit pricing and volume commitments.

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

*2012 v. 2011*

Revenues decreased \$68.2 million, or 19.1%, to \$288.1 million in the year ended December 31, 2012, as compared to \$356.3 million in the year ended December 31, 2011. U.S. segment revenue decreased \$58.4 million, or 21.7%, to \$210.0 million in the same period, as compared to \$268.4 million in the prior year. The decrease in the U.S. segment over the prior year is primarily due to the BVL production challenges impacting our supply of DEFINITY, Cardiolite, and NeuroLite, which represented \$35.5 million of unit volume revenue decreases. We also experienced lower pricing on Cardiolite and DEFINITY products in 2012, which represented \$11.1 million of the decrease in U.S. segment revenues. We experienced lower TechneLite revenues due to the loss of a significant customer during the second quarter of 2012, resulting in lower revenues of \$8.0 million. A decline in a significant customer's market share resulted in lower revenues of \$4.1 million in 2012. Offsetting these decreases were increases in revenue for the U.S. segment of Xenon, with price increases of \$5.1 million offset in part by lower unit volumes of \$1.8 million.

The International segment revenues decreased \$9.8 million, or 11.2%, to \$78.1 million in the year ended December 31, 2012, as compared to \$87.9 million in the year ended December 31, 2011. The decrease was primarily due to the BVL production challenges impacting our supply of Cardiolite and NeuroLite in the international markets and TechneLite decreases due to lower unit volume and pricing in certain markets.

*Rebates and Allowances*

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Estimates for rebates and allowances represent our estimated obligations under contractual arrangements with third parties. Rebate accruals and allowances are recorded in the same period the related revenue is recognized, resulting in a reduction to revenue and the establishment of a liability which is included in accrued expenses. These rebates result from performance-based offers that are primarily based on attaining contractually

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specified sales volumes and growth, Medicaid rebate programs for certain products, administration fees of group purchasing organizations and certain distributor related commissions. The calculation of the accrual for these rebates and allowances is based on an estimate of the third party buying patterns and the resulting applicable contractual rebate or commission rate(s) to be earned over a contractual period.

An analysis of the amount of, and change in, reserves for the period from January 1, 2011 through December 31, 2013 is summarized as follows:

	<b>Rebates</b>	<b>Allowances</b>	<b>Total</b>
	<b>(dollars in thousands)</b>		
Balance, as of January 1, 2011	\$ 910	\$ 101	\$ 1,011
Current provisions relating to revenues in current year	3,672	474	4,146
Adjustments relating to prior years estimate	(116)		(116)
Payments/credits relating to revenues in current year	(2,617)	(441)	(3,058)
Payments/credits relating to revenues in prior years	(493)	(101)	(594)
Balance, as of December 31, 2011	1,356	33	1,389
Current provisions relating to revenues in current year	3,224	291	3,515
Adjustments relating to prior years estimate	(145)		(145)
Payments/credits relating to revenues in current year	(2,232)	(223)	(2,455)
Payments/credits relating to revenues in prior years	(661)	(35)	(696)
Balance, as of December 31, 2012	1,542	66	1,608
Current provisions relating to revenues in current year	4,696	243	4,939
Adjustments relating to prior years estimate	(21)		(21)
Payments/credits relating to revenues in current year	(3,438)	(220)	(3,658)
Payments/credits relating to revenues in prior years	(1,040)	(69)	(1,109)
Balance, as of December 31, 2013	\$ 1,739	\$ 20	\$ 1,759

Accrued sales rebates were approximately \$1.7 million and \$1.5 million at December 31, 2013 and December 31, 2012, respectively. The increase in rebate provisions as compared to 2012 and 2011 is primarily related to the increase in DEFINITY revenues. In October 2010, we entered into a Medicaid Drug Rebate Agreement for certain of our products, which did not have a material impact on our results of operations in 2011, 2012 or 2013. If the demand for these products through the Medicaid program increases in the future, our rebates associated with this program could increase and could have a material impact on future results of operations.

**Cost of Goods Sold**

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

Cost of goods sold is summarized as follows:

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	Year ended December 31,		2011 (dollars in thousands)	2013 compared to 2012		2012 compared to 2011	
	2013	2012		Change \$	Change %	Change \$	Change %
United States	\$ 149,018	\$ 156,098	\$ 206,450	\$ (7,080)	(4.5)%	\$ (50,352)	(24.4)%
International	57,293	56,810	54,626	483	0.9	2,184	4.0
<b>Total Cost of Goods Sold</b>	<b>\$ 206,311</b>	<b>\$ 212,908</b>	<b>\$ 261,076</b>	<b>\$ (6,597)</b>	<b>(3.1)%</b>	<b>\$ (48,168)</b>	<b>(18.4)%</b>

The Ablavar product was commercially launched in January 2010. The revenues for this product through December 31, 2013 have not been significant and have resulted in charges to cost of goods sold for inventory

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write downs, intangible asset impairments and expected losses on future contractual commitments in 2011, 2012 and 2013. During 2011, we recorded an inventory write-down of \$25.8 million, a contract loss of \$5.6 million and a full impairment of the Ablavar intellectual property intangible asset of \$23.5 million. During 2012, we recorded an additional inventory write-down of \$10.6 million and an additional contract loss of \$1.9 million. In 2013, we recorded an additional inventory write-down of \$1.6 million. See Note 5 to our consolidated financial statements, which are included elsewhere in this prospectus. After giving effect to these adjustments, as of December 31, 2013 and 2012, we have a total of \$1.5 million and \$2.8 million, respectively, of Ablavar inventory on hand and approximately \$1.8 million and \$9.4 million, respectively, of remaining committed Ablavar purchase obligations, of which \$1.3 million and \$7.5 million, respectively, is included in our accrued contract loss. If we do not meet our current sales goals or cannot sell the product we have committed to purchase prior to its expiration, we could incur additional inventory write-downs and/or losses on our purchase commitments.

*2013 v. 2012*

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

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

*2012 v. 2011*

Total cost of goods sold decreased \$48.2 million, or 18.4%, to \$212.9 million in the year ended December 31, 2012, as compared to \$261.1 million in the year ended December 31, 2011. U.S. segment cost of goods sold decreased approximately \$50.4 million, or 24.4%, to \$156.1 million in same period, as compared to \$206.5 million in the prior year period. The primary contributing factor to the decrease in the U.S. segment cost of goods sold was the prior period write-off for Ablavar intangible assets of \$23.5 million and the decrease of \$18.9 million in amounts recorded for Ablavar inventory write-down and contract loss reserves associated with Ablavar inventory purchase commitments. We also incurred lower TechneLite material costs of \$12.6 million due to lower unit volumes and lower cost with our primary supplier beginning in November 2012. These decreases were partially offset by higher DEFINITY technology transfer costs of \$4.9 million, take or pay losses of \$4.3 million on purchase commitments for Moly (prior to a Moly supply contract amendment which changed purchase requirements from unit volume to percentage) and higher Cardiolite manufacturing costs of \$1.5 million due to increased material expenses as a result of sourcing material from an alternate higher cost manufacturer due to the BVL outage.

For the year ended December 31, 2012, the International segment cost of goods sold increased \$2.2 million, or 4.0%, to \$56.8 million, as compared to \$54.6 million in the prior year period. Cost of goods sold in our



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International segment increased primarily due to temporary increases in costs for third party sestamibi and a substitute product for Neurolite. These increases were partially offset by lower Cardiolite, Neurolite and TechneLite unit volumes in certain markets.

**Gross Profit**

	Year ended December 31,			2013 compared to 2012		2012 compared to 2011	
	2013	2012	2011	Change \$	Change %	Change \$	Change %
	(dollars in thousands)						
United States	\$ 64,621	\$ 53,913	\$ 61,915	\$ 10,708	19.9%	\$ (8,002)	(12.9)%
International	12,740	21,284	33,301	(8,544)	(40.1)	(12,017)	(36.1)
<b>Total Gross Profit</b>	<b>\$ 77,361</b>	<b>\$ 75,197</b>	<b>\$ 95,216</b>	<b>\$ 2,164</b>	<b>2.9%</b>	<b>\$ (20,019)</b>	<b>(21.0)%</b>

**2013 v. 2012**

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

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

**2012 v. 2011**

Total gross profit decreased \$20.0 million, or 21.0%, to \$75.2 million in the year ended December 31, 2012, as compared to \$95.2 million in the year ended December 31, 2011. U.S. segment gross profit decreased \$8.0 million, or 12.9%, to \$53.9 million, as compared to \$61.9 million in the prior year period. Gross profit in the U.S. segment decreased primarily due to lower profits of \$40.9 million from Cardiolite, DEFINITY, and Neurolite caused by supply issues resulting from the BVL production challenges. We also experienced decreased profits of \$5.5 million from TechneLite, driven by \$4.3 million of take or pay losses on purchase commitments for Moly, \$4.1 million in lower margins from lower unit sales, offset by \$2.9 million in higher selling price given the customer mix. Additionally, we incurred increased DEFINITY technology transfer costs of \$4.9 million and higher Cardiolite manufacturing costs of \$1.5 million in 2012 due to increased material expenses as a result of sourcing material from an alternate higher cost manufacturer due to the BVL production challenges, contributing to a lower gross profit in comparison to



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the prior period. These decreases were partially offset by the prior period write-off for Ablavar intangible assets of \$23.5 million and the decrease of \$18.9 million in amounts recorded for Ablavar inventory write-down and contract loss reserves associated with Ablavar inventory purchase commitments and higher Xenon gross profit due to price increases of \$5.1 million offset by lower unit volumes reducing gross profit by \$2.0 million.

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For the year ended December 31, 2012, the International segment gross profit decreased \$12.0 million, or 36.1%, to \$21.3 million, as compared to \$33.3 million in the prior year period. Gross profit in our International segment decreased due to lower Cardiolite and NeuroLite unit sales volumes related to the product shortage issues resulting from the BVL production challenges, higher material expenses as we sourced material from alternate higher cost manufacturers and lower units sales volumes given competitive pressures in certain markets. These decreases were partially offset by higher profits from sales of NeuroLite ligand, which was unaffected by the BVL production challenges.

**Sales and Marketing**

	Year ended December 31,			2013 compared to 2012		2012 compared to 2011	
	2013	2012	2011	Change \$	Change %	Change \$	Change %
	(dollars in thousands)						
United States	\$ 31,024	\$ 33,638	\$ 34,040	\$ (2,614)	(7.8)%	\$ (402)	(1.2)%
International	4,203	3,799	4,649	404	10.6	(850)	(18.3)
<b>Total Sales and Marketing</b>	<b>\$ 35,227</b>	<b>\$ 37,437</b>	<b>\$ 38,689</b>	<b>\$ (2,210)</b>	<b>(5.9)%</b>	<b>\$ (1,252)</b>	<b>(3.2)%</b>

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

**2013 v. 2012**

Total sales and marketing expenses decreased \$2.2 million, or 5.9%, to \$35.2 million in the year ended December 31, 2013, as compared to \$37.4 million in the year ended December 31, 2012. In the U.S. segment, sales and marketing expense decreased \$2.6 million, or 7.8%, to \$31.0 million in the same period, as compared to \$33.6 million in the prior year. The decrease in the U.S. segment was primarily due to lower headcount and employee related expenses, including contractors, due to a reduction in workforce and reduced marketing expenses related to Ablavar. Offsetting the decreases were increases in variable compensation and marketing expenses related to DEFINITY. As a percentage of total U.S. revenues, sales and marketing expenses in the U.S. segment were 14.5%, 16.0% and 12.7% for the years ended December 31, 2013, 2012 and 2011, respectively.

For the year ended December 31, 2013, the International segment sales and marketing expense increased \$0.4 million or 10.6%, to \$4.2 million as compared to \$3.8 million in the prior year period due to increased headcount and higher variable compensation. Offsetting the increases was a decrease in professional services. As a percentage of total International revenues, sales and marketing expenses in the International segment were 6.0%, 4.9% and 5.3% for the years ended December 31, 2013, 2012 and 2011, respectively.

**2012 v. 2011**

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Total sales and marketing expenses decreased \$1.3 million, or 3.2%, to \$37.4 million in the year ended December 31, 2012, as compared to \$38.7 million in the year ended December 31, 2011. In the U.S. segment, sales and marketing expense decreased \$0.4 million, or 1.2%, to \$33.6 million in the same period, as compared to \$34.0 million in the prior year. Overall, there were lower expenses on sales and marketing activities as a result of \$1.6 million of reductions in discretionary spending due to the prolonged BVL outage. Additionally, salary and other personnel costs in 2012 were \$1.3 million lower primarily due to the workforce reductions during the second quarter of 2011 and March 2012. These decreases were offset by a \$1.1 million reversal of stock-based compensation expense in the first quarter of 2011 and \$1.4 million of increased sales incentive compensation related to the return of DEFINITY product to the market in June 2012.

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For the year ended December 31, 2012, the International segment sales and marketing expense decreased \$0.9 million or 18.3%, to \$3.8 million as compared to \$4.6 million in the prior year period. The decrease in sales and marketing expenses in the International segment was primarily due to lower headcount and expenses on sales and marketing activities as a result of reductions in discretionary spending due to the prolonged BVL outage.

**General and Administrative**

	Year ended December 31,			2013 compared to 2012		2012 compared to 2011	
	2013	2012	2011	Change \$	Change %	Change \$	Change %
	(dollars in thousands)						
United States	\$ 30,742	\$ 30,192	\$ 30,220	\$ 550	1.8%	\$ (28)	(0.1)%
International	2,294	2,328	2,642	(34)	(1.5)	(314)	(11.9)
<b>Total General and Administrative</b>	<b>\$ 33,036</b>	<b>\$ 32,520</b>	<b>\$ 32,862</b>	<b>\$ 516</b>	<b>1.6%</b>	<b>\$ (342)</b>	<b>(1.0)%</b>

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

*2013 v. 2012*

Total general and administrative expenses increased approximately \$0.5 million, or 1.6%, to \$33.0 million in the year ended December 31, 2013, as compared to \$32.5 million in the year ended December 31, 2012. In the U.S. segment, general and administrative expenses increased \$0.5 million, or 1.8%, to \$30.7 million, as compared to \$30.2 million in the prior year period. The increase was primarily due to additional variable compensation in the current period and severance expense from a reduction in workforce in the first quarter of 2013. Offsetting these increases were cost savings over the prior period through the renegotiation of certain information technology related contracts as support provided by certain vendors was reduced and reduced legal expense. In addition, compensation for performance-based awards was lower in the current period due to adjustments made based on the probability of achievement.

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

*2012 v. 2011*

Total general and administrative expenses decreased approximately \$0.3 million, or 1.0%, to \$32.5 million in the year ended December 31, 2012, as compared to \$32.9 million in the year ended December 31, 2011. In the U.S. segment, general and administrative expenses remained

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relatively flat from 2011 to 2012. However, there was an overall reduction in costs associated with external support primarily related to information technology. Offsetting this decrease was a \$0.9 million increase in stock compensation driven by the reversal of stock-based compensation expense in 2011 relating to the determination that the achievement of certain performance targets was no longer probable and current year modifications to stock option agreements. In addition, there was an increase in professional services and depreciation expense increased approximately \$0.3 million over the prior year as a result of certain capital spending projects occurring in late 2011 and early 2012 related primarily to information technology improvements.

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For the year ended December 31, 2012, general and administrative expenses in the International segment decreased \$0.3 million or 11.9%, to \$2.3 million as compared to \$2.6 million in the prior year period. This decrease was primarily due to a recovery of previously reserved accounts receivable during 2012 and reduced headcount in 2012 as compared to 2011.

**Research and Development**

	Year ended December 31,			2013 compared to 2012		2012 compared to 2011	
	2013	2012	2011	Change \$	Change %	Change \$	Change %
	(dollars in thousands)						
United States	\$ 30,138	\$ 40,457	\$ 40,387	\$ (10,319)	(25.5)%	\$ 70	0.2%
International	321	147	558	174	118.4	(411)	(73.7)
<b>Total Research and Development</b>	<b>\$ 30,459</b>	<b>\$ 40,604</b>	<b>\$ 40,945</b>	<b>\$ (10,145)</b>	<b>(25.0)%</b>	<b>\$ (341)</b>	<b>(0.8)%</b>

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

*2013 v. 2012*

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

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

*2012 v. 2011*

Total research and development expense decreased \$0.3 million, or 0.8%, to \$40.6 million for the year ended December 31, 2012, as compared to \$40.9 million in the year ended December 31, 2011. In the U.S. segment, research and development expense increased approximately

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\$0.1 million, or 0.2%, to \$40.4 million, as compared to \$40.3 million in the prior year period. Research and development expense in the U.S. segment remained relatively flat from 2011 to 2012. We continued to actively enroll patients and activate sites for our flurpiridaz F 18 Phase 3 program. In the first half of 2011, we were primarily in the planning and preparation stage for our flurpiridaz F 18 Phase 3 program. We enrolled our first patient in this Phase 3 program during the second quarter of 2011. The resulting increase in clinical activity in 2012 was related to our clinical research organization, investigator expenses, drug products, lab supplies, and consultants by \$5.3 million. These increases were offset by a reduction in workforce in the second quarter of 2011 by \$4.4 million and the decrease in depreciation expense of \$0.9 million.

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For the year ended December 31, 2012, the International segment research and development expenses decreased approximately \$0.4 million, or 73.7%, to \$0.1 million, as compared to \$0.6 million in the prior year period. The decrease in research and development expenses for the International segment was primarily due to a reduction in workforce in the second quarter of 2011.

***Impairment of Land***

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

***Proceeds from Manufacturer***

For the year ended December 31, 2013, as compared to the same period in 2012, proceeds from manufacturer decreased by \$25.7 million as a result of the receipt of the \$30.0 million from BVL in 2012 to compensate us for business losses and an additional \$5.0 million under the Transition Services Agreement compared to proceeds of \$8.9 million from BVL under a 2013 Settlement and Release Agreement.

During the fourth quarter of 2013, BVL and LMI entered into a Settlement and Release Agreement. Pursuant to the Settlement and Release Agreement, BVL and LMI agreed to a broad mutual waiver and release for all matters that occurred prior to the date of the Settlement Agreement, a covenant not to sue and settlement payments to us in the aggregate amount of \$8.9 million. In addition, the Settlement and Release Agreement provides that the Manufacturing and Service Contract terminates as of November 15, 2013, subject to BVL's obligations to use commercially reasonable efforts to finalize specific batches of DEFINITY, Cardiolite product and saline manufactured and not yet released by the BVL quality function for commercial distribution. BVL has now released for commercial distribution all of our remaining manufactured product.

***Other Income (Expense), Net***

	Year ended December 31,			2013 compared to 2012		2012 compared to 2011	
	2013	2012	2011	Change \$	Change %	Change \$	Change %
	(dollars in thousands)						
Interest expense	\$ (42,915)	\$ (42,014)	\$ (37,658)	\$ (901)	2.1%	\$ (4,356)	11.6%
Interest income	104	252	333	(148)	(58.7)	(81)	(24.3)
Other income (expense), net	1,161	(44)	1,429	1,205	2,738.6	(1,473)	(103.1)
Total Other Expense, net	\$ (41,650)	\$ (41,806)	\$ (35,896)	\$ 156	(0.4)%	\$ (5,910)	16.5%



*Interest Expense*

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

For the year ended December 31, 2012 compared to the same period in 2011, interest expense increased by 11.6% to \$42.0 million from \$37.7 million, as a result of the issuance of \$150.0 million of new Notes in the first quarter of 2011. See Note 10 to our consolidated financial statements, which are included elsewhere in this prospectus.

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*Interest Income*

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

For the year ended December 31, 2012, as compared to the same period in 2011, interest income decreased by 24.3% to \$252,000 from \$333,000, primarily as a result of a decrease in cash in interest bearing accounts.

*Other Income (Expense), net*

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

For the year ended December 31, 2012, as compared to the same period in 2011, other income (expense), net decreased by 103.1% to \$(44,000) from \$1.4 million primarily due to a decrease in the tax indemnification asset and changes in foreign currency exchange rates.

*Provision (Benefit) for Income Taxes*

	Year ended December 31,			2013 compared to 2012		2012 compared to 2011	
	2013	2012	2011	Change \$	Change %	Change \$	Change %
	(dollars in thousands)						
Provision (benefit) for income taxes	\$ 1,014	\$ (555)	\$ 84,082	\$ 1,569	282.7%	\$ (84,637)	(100.7)%

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

For the year ended December 31, 2012, as compared to the same period in 2011, provision (benefit) for income taxes decreased by 100.7% to \$(0.6) million from \$84.1 million due primarily to the valuation allowance that was recorded in 2011 and the release of the prior year's uncertain tax positions due to the lapse of statutes in 2012.

We have generated domestic pre-tax losses for the past three years. This loss history demonstrates negative evidence concerning our ability to utilize our gross deferred tax assets. In order to overcome the presumption of recording a valuation allowance against our net deferred tax assets,

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we must have sufficient positive evidence that we can generate sufficient taxable income to utilize these deferred tax assets within the carryover or forecast period. Although we have no history of expiring net operating losses or other tax attributes, based on our pre-tax loss of \$60.5 million in 2013, and the cumulative domestic loss incurred over the three-year period ended December 31, 2013, management has determined that all of the net U.S. deferred tax assets are not more-likely-than-not recoverable. As a result of this analysis, we have recorded an additional valuation allowance in the amount of \$25.6 million in 2013.

The valuation allowance was initially recorded in 2011 as a result of generating domestic pre-tax losses for the prior two years. The loss history demonstrated negative evidence concerning our ability to utilize our gross deferred tax assets. In order to overcome the presumption of recording a valuation allowance against our net deferred tax assets, we must have sufficient positive evidence that we can generate sufficient taxable income to utilize these deferred tax assets within the carryover or forecast period. Although we had no history of expiring net operating losses or other tax attributes, with our pre-tax loss of \$53.2 million in 2011 and the cumulative loss

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incurred over the three-year period ended December 31, 2011, management determined that all of the net U.S. deferred tax assets were not more likely than not recoverable. As a result of this analysis, we recorded a valuation allowance in the amount of \$103.0 million in 2011.

Our effective tax rates for the years ended December 31, 2013, 2012, and 2011 were, (1.7) %, 1.3%, and (158.1) %, respectively. Our tax rate is affected by recurring items, such as tax rates in foreign jurisdictions, which we expect to be fairly consistent in the near term. It is also affected by discrete events that may not occur in any given year, but are not consistent from year-to-year. The following items had the most significant impact on the difference between our statutory U.S. federal income tax rate of 35% and our effective tax rate during the years ended:

*December 31, 2013*

A \$25.6 million increase to our valuation allowance against net domestic deferred tax assets.

A \$1.5 million reduction relating primarily to prior year uncertain tax positions for a closed tax year.

A \$1.8 million reduction primarily relating to a state income tax benefit related to state NOL s.

*December 31, 2012*

A \$20.2 million increase to our valuation allowance against net domestic deferred tax assets.

A \$2.3 million reduction relating to prior year uncertain tax positions for a closed tax year.

A \$1.8 million reduction relating to a state income tax benefit consisting of \$1.1 million related to state NOL s, \$0.3 million related to research credits, and \$0.4 million to other changes to state deferred taxes.

*December 31, 2011*

A \$103.0 million increase to our valuation allowance against net domestic deferred tax assets.

A \$1.1 million increase in our uncertain tax positions relating to state tax nexus and transfer pricing.

A \$2.6 million increase relating to the establishment of a deferred tax liability for foreign subsidiary earnings that are no longer considered permanently reinvested.

A \$1.8 million reduction relating to a state income tax benefit associated with changes to deferred taxes.

**Liquidity and Capital Resources****Cash Flows**

The following table provides information regarding our cash flows:

	Three Months ended March 31,		% Change 2014 Compared to 2013	Year ended December 31,			% Change	
	2014	2013		2013	2012	2011	2013 Compared to 2012	2012 Compared to 2011
<b>Cash provided by (used in):</b>								
Operating activities	\$ (60)	\$ (150)	60%	\$ (15,572)	\$ (372)	\$ 23,209	(4,622.1)%	(101.6)%
Investing activities	(1,462)	(1,449)	(0.9)%	(3,483)	(8,145)	(7,694)	(57.2)%	5.9%
Financing activities	(5)	(644)	(99.2)%	5,612	(5,114)	(2,210)	209.7%	(131.4)%

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

Cash provided by operating activities is primarily driven by our earnings and changes in working capital. The decrease in cash used in operating activities for the three months ended March 31, 2014 as compared to 2013 was primarily driven by the decrease in net loss. This increase was offset by cash flow decreases in accrued expenses and other liabilities primarily for the payment of variable compensation and severance during the first quarter of 2014 and cash flow decreases in accounts receivable primarily due to an increase in revenues.

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

The decrease in cash provided by operating activities for the year ended December 31, 2012 as compared to 2011 was primarily driven by the impact of decreased unit sales due to the BVL production challenges. These decreases were offset by: (1) the receipt of the \$35.0 million BVL settlement in 2012; (2) an amended purchase agreement for one of our products of which \$1.7 million of required purchases were made during the year ended December 31, 2012, versus \$24.8 million for the year ended December 31, 2011; and (3) the timing of payments made to vendors.

### ***Net Cash Used in Investing Activities***

Our primary uses of cash in investing activities are for the purchase of property and equipment. The increase in net cash used in investing activities in the three months ended March 31, 2014 as compared to 2013 primarily reflects increased spending on the purchase of property and equipment. Net cash used in investing activities in 2013, 2012 and 2011 reflected the purchase of property and equipment for \$5.0 million, \$7.9 million and \$7.7 million, respectively.

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

Our primary historical uses of cash in financing activities are principal payments on our term loan and financing costs. The decrease in net cash used in financing activities in the three months ended March 31, 2014 as compared to 2013 was primarily driven by a decrease in payments on a note payable.

Net cash provided by financing activities during 2013 was in the form of an \$8.0 million draw against our outstanding line of credit. Net cash used in financing activities during 2012 was primarily associated with a \$3.5 million dividend. On March 21, 2011, we issued \$150.0 million of our Notes and paid associated financing costs. Net cash used in 2012 and 2011 included the results of these activities as well as the draw down and repayment in 2011 of \$10.0 million on our line of credit.

Our primary source of cash flows from financing activities is draws against our outstanding line of credit. Going forward, we expect our primary source of cash flows from financing activities to be similar draws against our line of credit, issuances of securities or other financing

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arrangements into which we may enter. Our primary historical uses of cash in financing activities are principal payments on our term loan and line of credit as well as dividends to Holdings, our parent. See External Sources of Liquidity.

### *External Sources of Liquidity*

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

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

The Exchange Notes and the New Exchange Notes, or together, the Notes, mature on May 15, 2017. Interest on the Notes accrues at a rate of 9.750% per year and is payable semiannually in arrears on May 15 and November 15 commencing on November 15, 2010 for the Notes issued on May 10, 2010 and May 15, 2011 for the Notes issued on March 21, 2011. Our annual interest expense increased from \$24.4 million to \$39.0 million as a result of the March 21, 2011 issuance of Notes.

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

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

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

As of March 31, 2014 and December 31, 2013, we had an unfunded Standby Letter of Credit for up to \$8.8 million. The unfunded Standby Letter of Credit requires annual fees, payable quarterly, which, subsequent to the amendment, is set at LIBOR plus a spread of 2.00% and expires on February 5, 2015, which will automatically renew for a one year period at each anniversary date, unless we elect not to renew in writing within 60 days prior to such expiration.

Our revolving credit facility is secured by a pledge of substantially all of the assets of LMI, together with the assets of Lantheus Intermediate (or, upon consummation of the corporate reorganization, our assets) and assets of Lantheus MI Real Estate, LLC, or Lantheus Real Estate, including each such entity's accounts receivable, inventory and machinery and equipment, and is guaranteed by each of Lantheus Intermediate (or, upon consummation of the corporate reorganization, us) and Lantheus Real Estate. Borrowing capacity is determined by reference to a borrowing base, or the Borrowing Base, which is based on (i) a percentage of certain eligible accounts receivable, inventory and machinery and equipment minus (ii) any reserves. As of March 31, 2014, the aggregate borrowing base was approximately \$42.5 million, which was reduced by (i) an





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outstanding \$8.8 million unfunded Standby Letter of Credit and (ii) an \$8.0 million outstanding loan balance, resulting in a net borrowing base availability of approximately \$25.7 million as of such date.

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

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

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

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

### ***Funding Requirements***

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

our ability to have product manufactured and released from JHS and other manufacturing sites in a timely manner in the future;

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the pricing environment and the level of product sales of our currently marketed products, particularly DEFINITY, and any additional products that we may market in the future;

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

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

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

the extent to which we acquire or invest in products, businesses and technologies;

the extent to which we choose to establish collaboration, co- promotion, distribution or other similar arrangements for our marketed products;

the legal costs relating to maintaining, expanding and enforcing our intellectual property portfolio, pursuing insurance or other claims and defending against product liability, regulatory compliance or other claims; and

the cost of interest on any additional borrowings which we may incur under our financing arrangements.

If JHS is not able to continue to manufacture and release product supply on a timely and consistent basis, or we are unable to continue to grow DEFINITY sales, then we will need to implement certain additional expense reductions, such as a delay or elimination of discretionary spending in all functional areas, as well as other operating and strategic initiatives. See Risk Factors Risks Relating to our Business and Industry We may not be able to generate sufficient cash flow to meet our debt service obligations.

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

At March 31, 2014, our only current committed external source of funds is our borrowing availability under our revolving credit facility. We generated a net loss of \$1.3 million during the three months ended March 31, 2014 and had \$17.0 million of cash and cash equivalents at March 31, 2014. Availability under our revolving credit facility is calculated by reference to the Borrowing Base. If we are not successful in achieving our forecasted results, our accounts receivable and inventory could be negatively affected, reducing the Borrowing Base and limiting our borrowing availability.

We took actions during March 2013 to substantially reduce our discretionary spending in order to reposition us to focus our resources on our higher growth products. In particular, we implemented a strategic shift in how we intend to fund our important R&D programs. We have reduced our internal R&D resources during 2013 while at the same time we seek to engage one or more strategic partners to assist us in the further development and commercialization of our important agents in development, including flurpiridaz F 18, 18F LMI 1195 and LMI 1174. Based on our current operating plans, we believe that our existing cash and cash equivalents, results of operations and availability under our revolving credit facility will be sufficient to continue to fund our liquidity requirements for at least the next twelve months.

**Quarterly Results of Operations**

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The following tables set forth selected unaudited quarterly consolidated statements of operations data for each of the four quarters for the period ended March 31, 2014. The unaudited quarterly statement of operations data have been prepared on the same basis as our audited consolidated financial statements and, in the opinion of our management, reflect all adjustments, consisting of normal recurring adjustments, necessary for a fair

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presentation of this data. The summary consolidated financial data set forth below and elsewhere in this prospectus are not necessarily indicative of our future performance. The following quarterly financial data should be read in conjunction with our audited consolidated financial statements and the related notes thereto included elsewhere in this prospectus.

	June 30,	Three Months ended		March 31,
		September 30,	December 31,	2014
		2013		
		(dollars in thousands)		
		(unaudited)		
<b>Statement of Comprehensive Loss Data:</b>				
Revenues(1)	\$ 70,601	\$ 70,385	\$ 71,668	\$ 73,336
Cost of goods sold	49,654	46,664	61,787	43,275
Sales and marketing expenses	8,993	8,476	7,961	9,498
General and administrative expenses	8,170	7,132	7,481	8,852
Research and development expenses	7,537	5,893	5,031	3,222
Impairment on land		6,788	(382)	
Proceeds from manufacturer			(8,876)	
Operating income (loss)	(3,753)	(4,568)	(1,334)	8,489
Interest expense	(10,647)	(11,052)	(10,505)	(10,552)
Interest income	28	17	17	
Other income (expense), net	(87)	260	267	(414)
Loss before income taxes	(14,459)	(15,343)	(11,555)	(2,477)
Provision (benefit) for income taxes	(82)	(279)	747	(1,192)
Net income (loss)	\$ (14,377)	\$ (15,064)	\$ (12,302)	\$ (1,285)
<b>Statement of Cash Flows Data:</b>				
Net cash flows provided by (used in):				
Operating activities	\$ (15,840)	\$ 4,291	\$ (3,873)	\$ (60)
Investing activities	(1,347)	(915)	228	(1,462)
Financing activities	7,948	(1,495)	(197)	(5)
<b>Other Financial Data:</b>				
EBITDA(2)	\$ 2,857	\$ 1,731	\$ 4,710	\$ 12,766
Adjusted EBITDA(2)	6,668	11,908	24,033	16,018
Capital expenditures	1,347	915	1,299	1,482

(1) The following table provides detail of revenues:

	June 30,	Three Months ended		March 31,
		September 30,	December 31,	2014
		2013		
		(dollars in thousands)		
		(unaudited)		
DEFINITY	\$ 18,742	\$ 20,161	\$ 22,161	\$ 22,359
TechneLite	25,254	22,422	22,093	23,041
Xenon	7,647	8,182	7,975	9,709
Cardiolite	5,188	4,640	5,399	4,680
Other	13,770	14,980	14,040	13,547
Revenues	\$ 70,601	\$ 70,385	\$ 71,668	\$ 73,336

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- (2) Adjusted EBITDA is defined as EBITDA (GAAP net income (loss), plus interest expense, net, provision of income taxes, depreciation and amortization), further adjusted to exclude unusual items that management does not believe are indicative of its core operating performance. Adjusted EBITDA is used by management to measure operating performance and by investors to measure a company's ability to service its debt and meet its other cash needs. Management believes that the inclusion of the adjustments to EBITDA applied in presenting Adjusted EBITDA are appropriate to provide additional information to investors about our

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performance across reporting periods on a consistent basis by excluding items that it does not believe are indicative of its core operating performance. See Non-GAAP Financial Measures.

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

	June 30,	Three Months ended		March 31,
		September 30,	December 31,	2014
		2013		
		(dollars in thousands)		
		(unaudited)		
Net income (loss)	\$ (14,377)	\$ (15,064)	\$ (12,302)	\$ (1,285)
Interest expense, net	10,619	11,035	10,488	10,552
Provision for income taxes(a)	85	(713)	312	(1,017)
Depreciation and amortization	6,530	6,473	6,212	4,516
<b>EBITDA</b>	<b>2,857</b>	<b>1,731</b>	<b>4,710</b>	<b>12,766</b>
Non-cash stock-based compensation	306	172	(157)	234
Legal fees(b)	119	165	108	660
Asset write-off(c)	958	8,200	18,091	420
Severance and recruiting costs(d)	400	478	270	85
Sponsor fee and other(e)	681	259	260	251
New manufacturer costs(f)	1,347	903	751	1,978
<b>Adjusted EBITDA(g)</b>	<b>\$ 6,668</b>	<b>\$ 11,908</b>	<b>\$ 24,033</b>	<b>\$ 16,018</b>

- (a) Represents provision for income taxes, less tax indemnification associated with an agreement with BMS.
- (b) Represents legal services expenses incurred in connection with our business interruption claim associated with the NRU reactor shutdown in 2009 to 2010.
- (c) Represents non-cash losses incurred associated with the write-down of land, intangible assets, inventory and write-off of long-lived assets.
- (d) Represents primarily severance and recruitment costs related to employees, executives and directors.
- (e) Represents annual sponsor monitoring fee and related expenses, non-recurring professional fees and certain non-recurring charges relating to a customer relationship.
- (f) Represents internal and external costs associated with establishing new manufacturing sources for our commercial products and agents in development.
- (g) Does not include run-rate cost savings, operating expense reductions and other expense and cost-savings of \$1.4 million, \$2.4 million and \$4.0 million, respectively, which were realized for the three months ended December 31, 2013, September 30, 2013 and June 30, 2013, respectively, primarily relating to our strategic shift from in-house R&D to an external partnering model of R&D.





**Table of Contents****Contractual Obligations**

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent contractual liabilities for which we cannot reasonably predict future payment, including contingencies related to potential future development, financing, certain suppliers, contingent royalty payments and/or scientific, regulatory, or commercial milestone payments under development agreements. The following table summarizes our contractual obligations as of December 31, 2013:

	Total	Payments Due by Period			
		Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
		(dollars in thousands)			
Debt obligations (principal)	\$ 400,000	\$	\$	\$ 400,000	\$
Interest on debt obligations	136,500	39,000	78,000	19,500	
Operating leases(1)	2,509	898	881	467	263
Purchase obligations(2)	3,416	3,416			
Asset retirement obligation	6,385				6,385
Other long-term liabilities(3)	34,898				34,898
<b>Total contractual obligations</b>	<b>\$ 583,708</b>	<b>\$ 43,314</b>	<b>\$ 78,881</b>	<b>\$ 419,967</b>	<b>\$ 41,546</b>

- (1) Operating leases include minimum payments under leases for our facilities and certain equipment.
- (2) Purchase obligations include fixed or minimum payments under manufacturing and service agreements with third parties.
- (3) Due to the uncertainty related to the timing of the reversal of uncertain tax positions, the liability is not subject to fixed payment terms and the amount and timing of payments, if any, which we will make related to this liability are not known.

**Off-Balance Sheet Arrangements**

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

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

**Effects of Inflation**

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

### **Recent Accounting Standards**

We have elected to opt out of the extended transition period for complying with new and revised accounting standards pursuant to Section 107 of the JOBS Act, and the election is irrevocable. See Prospectus Summary Implications of Being an Emerging Growth Company.

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

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

## **Critical Accounting Policies and Estimates**

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

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

### ***Revenue Recognition***

Our revenue is generated from the sales of our diagnostic imaging agents to wholesalers, distributors, and radiopharmacies and directly to hospitals and clinics. We recognize revenue when evidence of an arrangement exists, title has passed, substantially all the risks and rewards of ownership have transferred to the customer, the selling price is fixed or determinable and collectability is reasonably assured. For transactions for which revenue recognition criteria have not yet been met, the respective amounts are recorded as deferred revenue until that point in time when criteria are met and revenue can be recognized. Revenue is recognized net of reserves, which consist of allowances for returns and sales rebates. The estimates of these allowances are based on historical sales volumes and mix and require assumptions and judgments to be made in order to make those estimates. In the event that the sales mix is different from our estimates, we may be required to pay higher or lower returns and sales rebates than we previously estimated. Any changes to these estimates are recorded in the current period. In 2013, 2012 and 2011, these changes in estimates were not material to our results.

Revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer. The arrangement's consideration is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value; (ii) third party evidence of selling price; and (iii) best estimate of selling

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price. The best estimate of selling price reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis. The consideration allocated to each

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unit of accounting is then recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. Supply or service transactions may involve the charge of a nonrefundable initial fee with subsequent periodic payments for future products or services. The up-front fees, even if nonrefundable, are earned (and revenue is recognized) as the products and/or services are delivered and performed over the term of the arrangement.

### ***Inventory***

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

Inventory costs associated with product that has not yet received regulatory approval are capitalized if we believe there is probable future commercial use of the product and future economic benefit of the asset. If future commercial use of the product is not probable, then inventory costs associated with that product are expensed during the period the costs are incurred. At December 31, 2012, we had \$1.5 million of those product costs included in inventories. Subsequent to the year ended December 31, 2012, the contract manufacturer received regulatory approval to manufacture this product. At December 31, 2013, we had no such inventories.

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

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

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

In performing the annual goodwill impairment test, we bypassed the option to perform a qualitative assessment and proceeded directly to performing the first step of the two-step goodwill impairment test. We completed our required annual impairment test for goodwill in the fourth quarter of 2013, 2012 and 2011 and determined that at each of those periods the carrying amount of goodwill was not impaired. In each year, our fair value, which includes goodwill, was substantially in excess of our carrying value.

In addition, as a result of the continued supply challenges with BVL, we performed an interim impairment test for goodwill as of December 31, 2011. The interim impairment test did not indicate that there was any impairment as of December 31, 2011. There were no events at December 31, 2012 that triggered an interim

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impairment test. During the first quarter of 2013, the strategic shift in how we intend to fund our R&D programs significantly altered the expected future costs and revenues associated with our agents in development. Accordingly, this action was deemed to be a triggering event for an evaluation of the recoverability of our goodwill as of March 31, 2013. We performed an interim impairment test and determined that there was no impairment of goodwill as of March 31, 2013. Furthermore, we performed our annual impairment test for goodwill as of October 31, 2013, and there were no events through December 31, 2013 that triggered an interim impairment test. At each annual and interim impairment test date, the fair value of our reporting unit, which includes goodwill, was substantially in excess of our carrying value.

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

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

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

In the third quarter of 2013, we were in negotiations with a new distributor for the sale of certain products within certain international markets. This agreement was signed in October 2013 and as a result we did not renew the agreements with our former distributors in these international markets. We determined the customer relationship intangible related to these former distributors was no longer recoverable and recorded an impairment charge of \$1.0 million in the third quarter of 2013. In the fourth quarter of 2013, we updated our strategic plan to reflect the non-renewal of these agreements and the uncertainty in the timing of product availability in this region. As a result, we reviewed the recoverability of certain of our customer relationship intangible assets in the International segment that were impacted by our revised strategic plan. We conducted an impairment analysis and concluded that the estimate



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

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

Fixed assets dedicated to R&D activities, which were impacted by the recent R&D strategic shift, have a carrying value of \$6.3 million as of December 31, 2013. We believe these fixed assets will be utilized for either internally funded ongoing R&D activities or R&D activities funded by a strategic partner. If we are not successful in finding a strategic partner, and there are no alternative uses for those fixed assets, they could be subject to impairment in the future.

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

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

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

Prior to the consummation of this offering, our employees were eligible to receive awards from our Old Equity Plans (as defined below). Following the consummation of this offering, employees are eligible to receive awards from our 2014 Equity Plan. Our stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service period, which generally represents the vesting period, and includes an estimate of the awards that will be forfeited. We use the Black Scholes valuation model for estimating the fair value on the date of grant of stock options. The fair value of stock option awards is affected by our valuation assumptions, including the estimated fair value of our common stock, the volatility of equity comparables, the expected term of the options, the risk-free interest rate, expected dividends and other objective and subjective variables.

Each award is approved by our Board of Directors (or its compensation committee) at a per share exercise price not less than the per share fair value determined by the Board of Directors (or its compensation committee) in effect as of that award date. Historically for all periods prior to this initial public offering, our Board of Directors (or its compensation committee) has determined the fair value of the common stock underlying our stock options with assistance from management and based upon information available at the time of grant. Given the absence of a public trading market for our common stock, estimating the fair value of our common stock has required complex and subjective judgments

assumptions, including:

quarterly valuations of our common stock based on our actual operational and financial performance, current business conditions and cash flow projections; and

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the trading and exit multiples of companies that we consider peers based on a number of factors, including similarity to us with respect to industry, products and business model.

We considered a combination of valuation methodologies, including discounted cash flows, comparable trading multiples and comparable transactions. Any material change to the assumptions used in estimating the fair value of the options could have a material impact on our results of operations. When a contingent cash settlement of vested options becomes probable, we reclassify the vested awards to a liability and account for any incremental compensation cost in the period in which the settlement becomes probable.

For valuations after the consummation of this offering, our Board of Directors (or its compensation committee) will determine the fair value of each share of underlying common stock based on the closing price of our common stock as reported on the date of grant.

## ***Income Taxes***

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

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

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

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

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

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### **Quantitative and Qualitative Disclosures About Market Risk**

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

#### ***Interest Rate Risk***

We are subject to interest rate risk in connection with our revolving credit facility, which is variable rate indebtedness. As of March 31, 2014, there was \$8.0 million outstanding under our revolving credit facility and an \$8.8 million unfunded Standby Letter of Credit. Any increase in the interest rate under our revolving credit facility would increase interest rate payments, which could have a negative impact on our future earnings and cash flow to the extent we have outstanding borrowings under our revolving credit facility. The effect of a 100 basis point adverse change in market interest rates, sustained for one year, on our interest expense would be approximately \$20,000. Historically, we have not used derivative financial instruments or other financial instruments to hedge these economic exposures.

#### ***Foreign Currency Risk***

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

During the three months ended March 31, 2014 and 2013, the net impact of foreign currency changes on transactions was a loss of \$0.2 million and \$0.1 million, respectively. Historically, we have not used derivative financial instruments or other financial instruments to hedge such economic exposures.

Gross margins of products we manufacture at our U.S. plants and sell in currencies other than the U.S. Dollar are also affected by foreign currency exchange rate movements. Our gross margin on revenues for the three month periods ended March 31, 2014 and 2013 was 41.0% and 32.1%, respectively. If the U.S. Dollar had been stronger by 1%, 5% or 10%, compared to the actual rates during the three months ended March 31, 2014, we estimate our gross margin on revenues would have been 41.0%, 41.2% and 41.5%, respectively. If the U.S. Dollar had been stronger by 1%, 5% or 10%, compared to the actual rates during the three months ended March 31, 2013, we estimate our gross margin on revenues would have been 32.2%, 32.3% and 32.6%, respectively.

During years ended December 31, 2013, 2012 and 2011, the net impact of foreign currency changes on transactions was a loss of \$349,000, \$579,000 and \$156,000, respectively. Historically, we have not used derivative financial instruments or other financial instruments to hedge these economic exposures.

Gross margins for our products that are manufactured in the United States and are sold in currencies other than the U.S. Dollar are also affected by foreign currency exchange rate movements. Our gross margin on revenues was 27.3%, 26.1% and 26.7% during the years ended

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December 31, 2013, 2012 and 2011, respectively. If the U.S. Dollar had been stronger by 1%, 5% or 10%, compared to the actual exchange rates during 2013, our gross margin on revenues would have been 27.3%, 27.5% and 27.7%, respectively. If the U.S. Dollar had been stronger by 1%, 5% or 10%, compared to the actual exchange rates during 2012, our gross margin on revenues would have been 26.1%, 26.3% and 26.4%, respectively. If the U.S. Dollar had been stronger by 1%, 5% or 10%, compared to the actual exchange rates during 2011, our gross margin on revenues would have been 26.7%, 26.9% and 27.0%, respectively.

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

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

<b>Increase in U.S. Dollar to Applicable Foreign Currency Exchange Rate</b>	<b>Approximate Decrease in Revenues (dollars in thousands)</b>	<b>Approximate Decrease in Net Loss</b>
1%	\$ (112)	\$ (5)
5%	(558)	(24)
10%	(1,116)	(49)

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

<b>Increase in U.S. Dollar to Applicable Foreign Currency Exchange Rate</b>	<b>Approximate Decrease in Revenues (dollars in thousands)</b>	<b>Approximate Decrease in Net Loss</b>
1%	\$ (122)	\$ (5)
5%	(609)	(24)
10%	(1,218)	(48)

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

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

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

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

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1%	\$ (519)	\$ 3
5%	(2,593)	17
10%	(5,187)	34

If the U.S. Dollar had been uniformly stronger by 1%, 5% or 10%, compared to the actual average exchange rates used to translate the financial results of our foreign subsidiaries, our revenues and net income for the year ended December 31, 2011 would have been impacted by approximately the following amounts:

<b>Increase in U.S. Dollar to Applicable Foreign Currency Exchange Rate</b>	<b>Approximate Change in Revenues (dollars in thousands)</b>	<b>Approximate Change in Net Income</b>
1%	\$ (608)	\$ (24)
5%	(3,041)	(118)
10%	(6,082)	(236)



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### **BUSINESS**

#### **Overview**

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

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

Our portfolio of 10 commercial products is diversified across a range of imaging modalities. Our imaging agents include radiopharmaceuticals and contrast agents.

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

In certain circumstances, a 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. Our products include both the chemical compounds that are radiolabeled as well as generators containing radioisotopes that radiolabel.

In other circumstances, a radioisotope can be used as a radiopharmaceutical without attaching any additional chemical compound. Our products also include this type of radiopharmaceutical.

Radioisotopes are most commonly manufactured in a nuclear research reactor, where a radioactive target is bombarded with subatomic particles, or on a cyclotron, which is a type of particle accelerator that also creates radioisotopes. Our products include radioisotopes produced in research reactors and in cyclotrons, and we own seven cyclotrons.

Two common forms of nuclear imaging procedures are SPECT and PET. In both SPECT and PET procedures, a radiopharmaceutical is injected into a patient, and it localizes in a specific organ or system within the body. The radiopharmaceutical emits small amounts of measurable radiation that are captured by a specialized camera that generates an image of the specific organ or system for the physician to read. The type of radiation the radiopharmaceutical emits will determine the type of camera that can be used a SPECT radiopharmaceutical emits gamma rays captured with a SPECT camera, and a PET radiopharmaceutical emits positrons captured with a PET camera.

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

As an example of the procedures in which our products may be used, in the diagnosis of coronary artery disease, a typical diagnostic progression could include an electrocardiogram, followed by an echocardiogram (possibly using our agent DEFINITY), and then a MPI study using either SPECT or PET imaging (possibly using our technetium generator or one of our MPI agents). An MPI study assesses blood flow distribution to the heart. An MPI imaging agent is injected into a patient intravenously, and the imaging agent deposits in the patient s

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heart muscle based on how much blood reaches the various areas. A heart with normal blood flow will show the imaging agent taken up uniformly, while a scar from a previous heart attack that blocks or restricts blood flow will not show any uptake of the imaging agent. MPI is also used for diagnosing the presence of coronary artery disease. See Diagnostic Medical Imaging Overview.

**Leading Products.** Our leading commercial products are:

*DEFINITY* the leading ultrasound contrast imaging agent used by cardiologists and sonographers during echocardiography exams based on revenue and usage. *DEFINITY* is an injectable agent that is indicated in the United States for use in patients with suboptimal echocardiograms to assist in the visualization of the left ventricle, the main pumping chamber of the heart. The use of *DEFINITY* in echocardiography allows physicians to significantly improve their assessment of the function of the left ventricle. Since its launch in 2001, *DEFINITY* has been used to image approximately five million patients.

Of the approximately 28 million echocardiograms performed each year in the United States, a third party source estimates that approximately 20%, or approximately six million echocardiograms, produce suboptimal images. We believe that in 2013, 3.1% of the total echocardiography procedures performed in the United States used a contrast agent (which translates to only approximately 15% of all echocardiograms considered suboptimal). Contrast penetration rates in echocardiography procedures have increased over the past six years and, we believe, will continue to increase in the future as clinicians continue to adopt the use of contrast as an important tool to assist their clinical decision-making. Of the echocardiograms in which a contrast agent is used, we estimate that *DEFINITY* had an approximate 75% share of these procedures in the United States in December 2013.

We believe that *DEFINITY* has this leading position because of its preferred product functionality and composition derived from a synthetic rather than a blood-based product. As a result, we believe *DEFINITY* will be a key driver of the future growth of our business, both in the United States and in international markets, as we continue to grow contrast penetration through sales and marketing efforts focused on the appropriate use of contrast and maintain our leading position. *DEFINITY* currently has patent or other exclusivity protection until 2021 in the United States and until 2019 outside of the United States.

*TechneLite* a self-contained system, or generator, of technetium (Tc99m), a radioisotope with a six hour half-life, used by radiopharmacists at radiopharmacies to prepare patient-specific radiolabeled 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. Because of the short half-lives of Moly and technetium, radiopharmacies typically replace *TechneLite* generators on a weekly basis pursuant to standing orders made with us. In addition, the supply chain for Moly is global and, because of the 66-hour half-life, we utilize just-in-time inventory management. We believe that we have the most balanced and diversified supply chain in the industry, buying Moly from four out of the five major global Moly processors, which are supplied by seven of the eight major global Moly reactors.

We are one of two principal technetium generator manufacturers in the United States and Canada. We are also the leading and most consistent U.S. manufacturer of LEU technetium generators. Governments and policy-makers are encouraging the increased use of technetium generators made with Moly derived from LEU rather than HEU, which may present greater proliferation and security risks. In the United States, nuclear imaging agent unit doses prepared with LEU technetium generators are reimbursed by Medicare in the hospital outpatient setting at a higher rate.

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. We estimate that in 2013, we had an approximately 40% share of generator sales in the United States. Certain *TechneLite* generator components currently have U.S. patent protection until 2029.



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### ***Other Commercial Products***

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

*Xenon Xe 133 Gas* is a radiopharmaceutical gas that is inhaled and used to assess pulmonary function and also to image blood flow. Our Xenon is manufactured by a third party as part of the Moly production process and packaged by us. We are currently the leading provider of Xenon in the United States.

*Cardiolite* is an injectable, technetium-labeled imaging agent, also known by its generic name sestamibi, used with SPECT technology in MPI procedures that assess blood flow to the muscle of the heart. Launched in 1991, Cardiolite has the highest cumulative revenue of any branded radiopharmaceutical in history.

*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.

*Thallium Tl 201* is an injectable radiopharmaceutical imaging agent used in MPI studies to detect coronary artery disease and is manufactured by us using cyclotron-based technology.

*Gallium Ga67* is an injectable radiopharmaceutical imaging agent used to detect certain infections and cancerous tumors, especially lymphoma, and is manufactured by us using cyclotron technology.

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

*Quadramet*, our only therapeutic product, is an injectable radiopharmaceutical used to treat severe bone pain associated with certain kinds of cancer, and is manufactured by us. Previously, we served as a contract manufacturer of Samarium 153, the radioisotope used to prepare Quadramet. Effective December 13, 2013, we purchased the rights to Quadramet in the United States and now serve as the direct manufacturer and supplier of Quadramet in the United States.

*Ablavar* is an injectable, gadolinium-based contrast agent used with MRA, a type of MRI scan, to image the iliac arteries that start at the aorta and go through the pelvis into the legs, in order to diagnose narrowing or blockage of these arteries in known or suspected peripheral vascular disease.

For revenue and other financial information for our U.S. and International segments, see Note 18 to our consolidated financial statements, which are included elsewhere in this prospectus.

In the United States, we sell DEFINITY through our sales team of approximately 80 employees that call on healthcare providers in the echocardiography space, as well as group purchasing organizations and integrated delivery networks. Our radiopharmaceutical products are primarily distributed through over 350 radiopharmacies, the majority of which are controlled by or associated with Cardinal, UPPI, GE Healthcare and Triad.

In Canada, Puerto Rico and Australia, we own nine radiopharmacies and sell our radiopharmaceuticals, as well as others, directly to end users. In Europe, Asia Pacific and Latin America, we utilize distributor relationships to market, sell and distribute our products. We have entered into a partnership with Double-Crane to complete confirmatory clinical trials necessary for Chinese regulatory approval and to distribute DEFINITY in China. We believe that international markets, particularly China, represent significant growth opportunities for our products.

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### ***Our Agents in Development***

We have established a portfolio of three internally-discovered imaging agents in clinical and preclinical development, each of which we believe could represent a large market opportunity and has the potential to significantly enhance current imaging modalities and fulfill unmet diagnostic medical imaging needs. We are currently seeking strategic partners to pursue the further development of each of these agents, which include:

***Flurpiridaz F 18 Myocardial Perfusion Imaging Agent.*** Flurpiridaz F 18 is a small molecule imaging agent radiolabeled with fluorine-18 and designed for use in PET MPI to assess blood flow to the muscle of the heart. We believe that, in comparison to SPECT MPI, the current standard of care, PET MPI with flurpiridaz F 18 potentially provides higher image quality, increased diagnostic certainty, more accurate risk stratification and reduced patient radiation exposure. This agent could be particularly useful in difficult to image heart patients, including women and obese patients. In the first of two planned Phase 3 studies, flurpiridaz F 18 outperformed SPECT in a highly statistically significant manner in the co-primary endpoint of sensitivity (that is, its ability to identify disease) and in the secondary endpoints of image quality and diagnostic certainty. However, flurpiridaz F 18 did not meet its other co-primary endpoint of non-inferiority for specificity (that is, its ability to rule out disease). Consequently, we have initiated discussions about potential next steps in the flurpiridaz F 18 development process with the FDA. At the same time, we are seeking strategic partners to further develop and, if approved, commercialize flurpiridaz F 18. This compound currently has U.S. patent protection until 2028 before taking into account any potential regulatory extensions.

***18F LMI 1195 Cardiac Neuronal Imaging Agent.*** 18F LMI 1195 is a small molecule imaging agent also radiolabeled with fluorine-18 and designed to assess cardiac sympathetic nerve function with PET imaging. We believe that PET imaging with 18F LMI 1195 could allow for better identification of patients at risk of heart failure progression and fatal arrhythmias, which would better inform pharmaceutical therapy or implantable device use. This compound has completed a Phase 1 study and currently has U.S. patent protection until 2030 before taking into account any potential regulatory extensions.

***LMI 1174 Vascular Remodeling Imaging Agent.*** LMI 1174 is a gadolinium-based MRI agent designed to identify elastin in the arterial walls and atherosclerotic plaques. We believe that this agent could allow for the minimally-invasive assessment of plaque location, burden and composition and, accordingly, could be used to risk stratify patients for potential vascular events, including heart attack or stroke. This compound is in late-stage preclinical studies and currently has U.S. patent protection until 2031 before taking into account any potential regulatory extensions.

### **Diagnostic Medical Imaging Agents Overview**

Medical imaging is commonly employed as a critical aid in the diagnosis of numerous medical conditions, including heart disease and cancer. Selection of treatment options and monitoring of disease progression are also facilitated by the use of imaging procedures. Diagnostic medical imaging procedures often employ imaging agents to highlight specific tissues and organs, or physiological or pathological processes. Imaging agents can be used in a range of imaging modalities, including x-ray, CT, ultrasound, SPECT, PET and MRI.

### ***Nuclear Imaging***

Nuclear imaging uses small amounts of radioactive materials, called radiopharmaceuticals, taken by injection, inhalation or orally to diagnose and treat disease. Radiopharmaceutical imaging agents consist of a radioisotope (such as technetium) paired with a molecular agent designed to localize in specific organs and tissues (such as Cardiolite and Neurolite), and are used in combination with imaging techniques for clinical diagnostic applications.

Clinicians utilize specialized cameras, either SPECT or PET, designed to capture radiation emitted by the agent. Computers are then used to generate detailed images of the area of interest. The resulting images provide clinicians with important information on both the structure and function of the internal organ or tissue.



**Table of Contents*****Echocardiography***

Echocardiography is a non-invasive test that uses sound waves to create moving images of the heart. These images allow an assessment of the heart's size, shape and function. For example, echocardiography can be used to detect areas of the heart that are not functioning properly due to poor blood supply, as seen in patients with coronary artery disease. Echocardiography is considered to be one of the safest, most reliable and cost-effective ways to diagnose certain cardiac abnormalities, and it is the most widely used technique for non-invasive imaging of the heart. Echocardiography may, however, yield images of limited diagnostic value in certain situations due to signal attenuation, such as in women and patients who are obese or have lung disease. It is estimated that suboptimal image quality occurs in approximately 20% of all patients undergoing echocardiography in the United States. Uninterpretable images may lead to misdiagnosis or the need for additional, often unnecessary and costly tests. Use of contrast agents in echocardiography increases sensitivity (the ability to identify the disease) and specificity (the ability to rule out the disease), particularly in hard to image patients by improving the delineation of the edges of the heart wall. In 2013, according to a third party source, there were 28.3 million echocardiography procedures performed in the United States with a compound annual growth rate of 2.2% over the period 2007 through 2013. In the United States, from 2007 through 2013, contrast enhanced echocardiography procedures grew at a compound annual growth rate of 6.9% with 880,000 contrast enhanced echocardiography procedures performed in 2013, up from 589,000 in 2007.

***Imaging Agents Market***

We believe that the demand for imaging agents in developed and developing markets will continue to be driven by an aging and increasingly obese population, and bolstered by long-term initiatives focused on improving healthcare and the supporting infrastructure, with a particular emphasis on expanding access to rural areas and small towns and cities. According to a research report dated February 2012 released by GIA, the worldwide diagnostic imaging market is projected to reach approximately \$18.0 billion by 2017, reflecting a compound annual growth rate of 7.2% over the period from 2013 through 2017. The worldwide diagnostic imaging market can be analyzed on a major market basis as follows:

Market	2013 Sales Projections	Share of Total Global Diagnostic Imaging Market	2017 Sales Projections	CAGR (2013-2017)
United States	\$6.5	48%	\$8.9	8.1%
Japan	\$3.1	23%	\$3.9	5.4%
Europe	\$2.6	19%	\$3.6	8.0%
Asia-Pacific (excluding Japan)	\$0.6	5%	\$0.8	7.0%
Canada	\$0.3	2%	\$0.4	4.4%

In terms of specific imaging modalities, the worldwide market can be analyzed as between contrast agents and diagnostic radiopharmaceuticals as follows:

Imaging Modality	2013 Sales Projections	Share of Total Global Diagnostic Imaging Market	2017 Sales Projections	CAGR (2013-2017)
Contrast Agents*	\$ 7.6	56%	\$9.4	5.2%
Diagnostic Radiopharmaceuticals	\$ 6.0	44%	\$8.6	9.7%

\* Includes imaging agents for echocardiography, MRI, CTA, CT and x-ray procedures.

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The United States diagnostic imaging markets can be further analyzed as follows:

U.S. Ultrasound Contrast Agent Market	2013 Sales Projections	2014 Sales Projections	2015 Sales Projections	2016 Sales Projections	2017 Sales Projections	CAGR (2013-2017)
Ultrasound Contrast Agents	\$ 149.3	\$ 170.8	\$ 195.7	\$ 224.5	\$ 257.9	14.6%

*Source: GIA Report, February 2012*

U.S. Radiopharmaceutical Market	2013 Sales Projections	2014 Sales Projections	2015 Sales Projections	2016 Sales Projections	2017 Sales Projections	CAGR (2013-2017)
SPECT	\$ 857.2	\$ 850.8	\$ 882.9	\$ 923.8	\$ 973.6	3.2%
PET	\$ 257.5	\$ 280.9	\$ 311.0	\$ 360.8	\$ 430.6	13.7%
Radiotherapy Agents	\$ 58.4	\$ 65.0	\$ 74.0	\$ 86.1	\$ 98.3	13.9%
Total	\$ 1,173.1	\$ 1,196.7	\$ 1,267.9	\$ 1,370.7	\$ 1,502.5	6.4%

*Source: Frost & Sullivan Report, September 2013*

Heart disease is a key driver of growth in the market for diagnostic medical imaging procedures and agents. Heart disease is currently the leading cause of death for both women and men in the United States and worldwide. According to the AHA, an estimated 83.6 million American adults, greater than one in three, have one or more types of heart disease. The AHA also reports that the total number of inpatient cardiovascular operations and procedures increased 28%, from more than 5.9 million in 2000 to more than 7.5 million in 2010. The total direct and indirect cost of heart disease and stroke in the United States for 2010 was estimated to be \$315.4 billion. Heart disease costs more than any other diagnostic group and these costs are rising. Coronary artery disease alone costs the United States \$108.9 billion each year. This total includes the cost of health care services, medications and lost productivity.

Heart disease refers to a number of disease states, including coronary artery disease and structural defects of the heart. Coronary artery disease is the most common form of heart disease, with an estimated prevalence of approximately 6% in the United States. The clinical approach to the diagnosis of this condition varies among clinicians based on clinical presentation, test availability and physicians' preferences. However, a typical diagnostic progression includes an electrocardiogram, followed by an echocardiogram and then a nuclear MPI study using either SPECT or PET. This diagnostic progression would typically be followed until the point at which coronary artery disease could be credibly identified or ruled out and prior to when more invasive procedures are considered. Some clinicians may also favor MRI or computed tomography angiography, or CTA, to augment or replace a nuclear MPI study in the minimally invasive diagnostic progression. To evaluate structural defects of the heart, a typical diagnostic progression would start with an echocardiogram, followed by MRI, CT or CTA, again until that point at which a structural defect could be credibly identified or ruled out and an appropriate benefit/risk assessment for more invasive intervention can be made. These imaging methods are not mutually exclusive. Rather, they can provide complementary information, and physicians may select one or more modalities based on a variety of criteria, including the physician's preference, available imaging equipment and overall clinical presentation. Our imaging agents and products are used in connection with diagnostic imaging for heart disease.

**Our Competitive Strengths**

We believe that our business model provides us with a strong platform to reach our strategic goal of providing cost-effective, clinically-beneficial diagnostic medical imaging agents and products that enable clinicians either to identify and characterize, or rule out, disease and consequently improve patient care. We believe our competitive strengths include:

***Leading Position Across a Range of Imaging Modalities.*** We are a global leader in the diagnostic medical imaging industry with over 50 years of experience in developing and bringing to market differentiated products critical to healthcare decision making, including radiopharmaceutical imaging agents, contrast imaging agents and other products. Our key brands include: DEFINITY, the leading

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echocardiology contrast imaging agent based on revenue and usage; and TechneLite, our technetium-based generator used by radiopharmacies to radiolabel technetium-based imaging agents, such as our own SPECT products Cardiolite and Neurolite. We also sell a broad portfolio of other commercial agents and products, diversified across a range of imaging modalities.

***DEFINITY is a Uniquely-Positioned Growth Opportunity in the United States and Globally.*** We believe that DEFINITY will be a key driver of the future growth of our business, both in the United States and globally. In echocardiography procedures in which a contrast agent is used, we estimate that DEFINITY had approximately 75% share of these procedures in the United States in December 2013. Contrast penetration rates in echocardiography procedures have increased over the past six years, and we believe will continue to increase in the future as clinicians continue to adopt the use of contrast as an important tool to assist their clinical decision-making.

We are actively pursuing international growth opportunities, such as our partnership with Double-Crane in China. Upon regulatory approval, we plan to commercialize DEFINITY in China with Double-Crane, a large Chinese pharmaceutical company that has extensive experience with the China FDA, or CFDA. We will be pursuing abdominal (liver and kidney) and cardiac indications for DEFINITY in China. In 2010, there were an estimated 48 million liver, 35 million renal and 18 million echocardiogram procedures performed in China which collectively represented approximately 50% of the total ultrasound procedures performed. Of these procedures, approximately 350,000 of the liver and renal studies and approximately 117,000 of the cardiac studies were enhanced with contrast agents. Chronic liver disease is one of the most common chronic diseases in China and provides us with what we believe to be a significant opportunity for improvement in patient diagnosis and care. If the regulatory and required clinical trial processes in China are both timely and successful, we currently estimate the commercialization of DEFINITY in China could begin as soon as 2017. We are also pursuing additional product registrations internationally to maximize the global potential of DEFINITY. We also believe our intellectual property for DEFINITY currently gives us patent or other market exclusivity protection in the United States until 2021 and outside of the United States until 2019.

***Significant Investment in Complex Manufacturing and Regulatory Capabilities.*** We believe that our expertise in the design, development and validation of complex manufacturing systems and processes that many of our radiopharmaceutical products require due to their limited half-lives, as well as our strong track record of on-time delivery and reputation as a high-quality, reliable provider, has enabled us to become a leader in the diagnostic medical imaging industry. 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 create significant and sustainable competitive advantages.

***Diversified Supply Chain.*** We are establishing a strong and diversified supply chain for our key products. For TechneLite, we have a strong, reliable and durable position in the technetium generator market because of our balanced and diversified Moly supply and our favorable access to Moly derived from LEU. We believe we have the most balanced and diversified Moly supply chain in the industry. We receive finished Moly from four of the five main processing sites in the world. These processing sites are, in turn, supplied by seven of the eight main Moly-producing reactors in the world. We are also the leading and most consistent manufacturer of LEU generators in North America, and we believe that in 2014, up to 40% of our Moly supply will be derived from LEU. In addition, we continue to assess opportunities to further diversify and strengthen our supply chain with non-HEU Moly-producing technologies. We believe we are well-positioned with our current supply partners to have a secure supply of Moly, including LEU Moly, when the NRU reactor in Canada ceases commercial operations in 2016. For DEFINITY, we have already successfully completed a technology transfer from BVL, our former manufacturing partner, to JHS. We are also now in the process of another technology transfer to Pharmedica as an additional manufacturing partner for DEFINITY, which, when completed, will give us further diversification and redundancy in our DEFINITY supply.

***Established Global Distribution Network and Experienced Direct Sales Force.*** We have an established global distribution network including long-term relationships with Cardinal and UPPI, who together

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distributed an estimated 71% of SPECT doses sold by radiopharmacies in the United States in 2013. In the United States, our radiopharmaceuticals (including technetium generators) are primarily distributed through radiopharmacies, the majority of which are controlled by or associated with Cardinal, UPPI, GE Healthcare and Triad. In the United States, we sell DEFINITY through our sales team of approximately 80 employees, which we believe is the largest dedicated sales force in the industry serving the echocardiography market. The majority of our sales team has over a decade of experience selling diagnostic imaging agents. In Canada, Puerto Rico and Australia, we own radiopharmacies and sell directly to end users. In Europe, Asia Pacific and Latin America, we utilize distributor relationships to market, sell and distribute our products.

***Experienced Management Team.*** Our senior management team has an average of more than 25 years of healthcare industry experience and consists of industry leaders with significant expertise in product development, operations and commercialization. We believe that the depth and experience of our management team demonstrates our expertise within the diagnostic medical imaging industry and our ability to operate successfully in a highly regulated environment.

## **Our Business Strategy**

Our objective is to enhance our position as a global leader in developing, manufacturing, selling and distributing innovative diagnostic medical imaging agents and products. The key elements of this strategy are to:

***Continue to grow U.S. sales of our existing commercial products, which are diversified across a range of imaging modalities.*** We will continue to drive the sales of our fastest growing and highest margin product, DEFINITY, through the growth of the appropriate use of contrast in echocardiography. As a strong, reliable and durable supplier of technetium generators, we expect to continue to grow our leading position in LEU generators. We will also focus on driving the growth of our other diagnostic imaging products.

***Enhance the position of our portfolio of commercial products in international markets, obtaining additional regulatory approvals where necessary.*** Through our development and commercialization arrangement with Double-Crane in China, once regulatory approval is obtained, we will seek to drive contrast adoption and DEFINITY sales for both abdominal (liver and kidney) and cardiac indications in one of the largest and most important markets in the world. We will also seek to enhance and expand our distribution relationships for DEFINITY and our other products with other national and regional partners. We will also pursue regulatory approvals and commercialization opportunities for DEFINITY and our other products in other important international markets.

***Create strategic partnerships to further advance our agents in development to maximize their value in potentially large domestic and international markets.*** We are determining next steps for our flurpiridaz F 18 Phase 3 development program and are continuing to seek to partner the further development and possible commercialization of the agent in potentially large domestic and international markets. We will seek to partner the further development and possible commercialization of our two earlier stage agents in development, 18F LMI 1195 and LMI 1174, both of which represent potential large market opportunities.

***Pursue select strategic licenses or acquisitions to further strengthen and diversify our portfolios of commercial products while leveraging core competencies.*** We will continue to evaluate, and where appropriate pursue, select opportunities to strengthen and diversify our portfolio of commercial products, whether those opportunities are tuck-in acquisitions, commercial stage in-licensing transactions or transformative transactions.

## **Our Products**

Our portfolio of 10 commercial products is diversified across a range of imaging modalities. Our products include medical radiopharmaceuticals (including technetium generators) and contrast agents. Radiopharmaceuticals, or nuclear imaging agents, are radiolabeled compounds that are

used by clinicians to

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perform nuclear imaging procedures, such as SPECT or PET. Technetium generators are used to prepare the radioactive Technetium (Tc99m) isotope that is combined with organ-localizing pharmaceuticals to create the most commonly used radiopharmaceuticals in diagnostic medicine. Contrast agents are typically non-radiolabeled compounds used by physicians to improve the clarity of the diagnostic image in diagnostic procedures such as echocardiograms or MRIs.

### ***DEFINITY***

DEFINITY is the leading ultrasound contrast imaging agent based on revenue and usage and, in the United States, is indicated for use in patients with suboptimal echocardiograms. Numerous patient conditions can decrease the quality of images of the left ventricle, the primary pumping chamber of the heart. Of the nearly 28 million echocardiograms performed each year in the United States, a third party source estimates that approximately 20%, or approximately six million echocardiograms, produce suboptimal images. The use of DEFINITY during echocardiography allows physicians to significantly improve their assessment of the function of the left ventricle.

DEFINITY is a clear, colorless, sterile liquid, which, upon activation in the Vialmix apparatus, a medical device specifically designed for DEFINITY, becomes a homogenous, opaque, milky white injectable suspension of perflutren-containing lipid microspheres. After activation and intravenous injection, DEFINITY improves the ultrasound delineation of the left ventricular endocardial border, or innermost layer of tissue that lines the chamber of the left ventricle. Better visualization of the ventricle wall allows clinicians to see wall motion abnormalities, namely that the heart muscle is not expanding and contracting in a normal, consistent and predictable way. We believe this allows clinicians to make more informed decisions about disease status. DEFINITY offers flexible dosing and administration through an IV bolus injection or continuous IV infusion. We believe DEFINITY's synthetic lipid-cased coating gives the compound a distinct competitive advantage, because it provides a strong ultrasound signal without using human albumin.

Since its launch in 2001, DEFINITY has been used in imaging procedures in approximately five million patients throughout the world. In 2013, DEFINITY was the leading ultrasound imaging agent based on revenue and usage, used by echocardiologists and sonographers. We estimate that DEFINITY had approximately 75% share of the market for contrast agents in the United States in December 2013. DEFINITY currently competes with Optison, a GE Healthcare product, as well as other non-echocardiography imaging modalities. DEFINITY and Optison both carry an FDA-required boxed warning, which has been modified over time, to notify physicians and patients about potentially serious safety concerns or risks posed by the products. See Risk Factors Risks Relating to our Business and Industry Ultrasound contrast agents may cause side effects which could limit our ability to sell DEFINITY.

We recently transferred our manufacturing of DEFINITY from BVL to JHS at its facility in Spokane, Washington. See Manufacturing BVL and Technology Transfer.

DEFINITY is currently patent protected in the United States until 2021 and in numerous foreign jurisdictions with patent or regulatory protection until 2019. For the three months ended March 31, 2014 and 2013, DEFINITY generated revenues of \$22.4 million and \$17.0 million, respectively, which represented approximately 30% and 24%, respectively, of our revenues. DEFINITY generated revenues of \$78.1 million, \$51.4 million and \$68.5 million for the years ended December 31, 2013, 2012 and 2011, respectively. DEFINITY represented approximately 28%, 18% and 19% of our revenues in 2013, 2012 and 2011, respectively.

### ***TechneLite***



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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

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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 the short half-lives of Moly and technetium, radiopharmacies typically purchase TechneLite generators on a weekly basis pursuant to standing orders.

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

TechneLite is produced in thirteen sizes and is currently marketed in North America, Latin America and Australia, largely to radiopharmacies that prepare unit doses of radiopharmaceutical imaging agents and that ship these preparations directly to hospitals for administration to patients. In the United States, we have supply arrangements with significant radiopharmacy chains, including Cardinal, UPPI and GE Healthcare. We believe TechneLite has approximately 40% of the U.S. generator market share, competing primarily with technetium-based generators produced by Mallinckrodt. In Canada and Puerto Rico, we also supply TechneLite to our Company-owned radiopharmacies to prepare radiopharmaceutical imaging agent unit doses.

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

TechneLite has patent protection in the United States and various foreign countries on certain component technology currently expiring in 2029. In addition, given the significant know-how and trade secrets associated with the methods of manufacturing and assembling the TechneLite generator, we believe we have a substantial amount of valuable and defensible proprietary intellectual property associated with the product. We believe that our substantial capital investments in our highly automated TechneLite production line and our extensive experience in complying with the stringent regulatory requirements for the handling of nuclear materials create significant and sustainable competitive advantages for us in generator manufacturing and distribution. For the three months ended March 31, 2014 and 2013, TechneLite generated revenues of \$23.0 million and \$22.4 million, respectively, which represented approximately 31% and 32%, respectively, of our revenues. TechneLite generated revenues of \$92.2 million, \$114.2 million and \$131.2 million for the years ended December 31, 2013, 2012 and 2011, respectively. TechneLite represented approximately 33%, 40% and 37% of our revenues in 2013, 2012 and 2011, respectively.

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### **Other Commercial Products**

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

*Xenon Xe 133 Gas* is a radiopharmaceutical gas that is inhaled and used to assess pulmonary function and also to image blood flow. Our Xenon is manufactured by a third party as part of the Moly production process and packaged by us. We are currently the leading provider of Xenon in the United States. In 2013, 2012 and 2011, Xenon Xe 133 Gas represented approximately 11%, 10% and 8%, respectively, of our revenues.

*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. With the advent of generic competition in September 2008, we have faced significant pricing and unit volume pressures on Cardiolite. We also sell Cardiolite in the form of a generic sestamibi at a lower price than branded Cardiolite. Since its launch in 1991, Cardiolite products have been used to image approximately 52 million patients in the United States. Cardiolite represented approximately 9%, 12% and 19% of our revenues in 2013, 2012 and 2011, respectively. Included in Cardiolite revenues are branded Cardiolite and generic sestamibi revenues, some of which we produce and some of which we procure from third parties from time to time.

*Neurolite* is an injectable, technetium-labeled imaging agent used with SPECT technology to identify the area within the brain where blood flow has been blocked or reduced due to stroke. We launched Neurolite in 1995. In 2013, 2012 and 2011, Neurolite represented approximately 2%, 2% and 3%, respectively, of our revenues.

*Thallium Tl 201* is an injectable radiopharmaceutical imaging agent used in MPI studies to detect coronary artery disease. We have marketed Thallium since 1977 and manufacture the agent using cyclotron technology. In 2013, 2012 and 2011, Thallium represented approximately 1%, 2% and 2%, respectively, of our revenues.

*Gallium Ga67* is an injectable radiopharmaceutical imaging agent used to detect certain infections and cancerous tumors, especially lymphoma. We manufacture Gallium using cyclotron technology. In each of 2013, 2012 and 2011, Gallium represented approximately 2% of our revenues.

*Gludex* is an injectable, fluorine-18-radiolabeled imaging agent used with PET technology to identify and characterize tumors in patients undergoing oncologic diagnostic procedures. Gludex is our branded version of FDG. In 2013, 2012 and 2011, Gludex represented approximately 3%, 2% and 2%, respectively, of our revenues.

*Quadramet*, our only therapeutic product, is an injectable radiopharmaceutical used to treat severe bone pain associated with certain kinds of cancer. Previously, we served as a contract manufacturer of Samarium 153, the radioisotope used to prepare Quadramet. Effective December 13, 2013, we purchased the rights to Quadramet in the United States and now serve as the direct manufacturer and supplier of Quadramet in the United States. In each of 2013, 2012 and 2011, Samarium 153 represented approximately 2% of our revenues.

*Ablavar* is an injectable, gadolinium-based contrast agent used with MRA, a type of MRI scan, to image the iliac arteries that start at the aorta and go through the pelvis into the legs, in order to diagnose narrowing or blockage of these arteries in known or suspected peripheral vascular disease. We launched Ablavar in January 2010. In 2013, 2012 and 2011, Ablavar represented approximately 0.9%, 0.9% and 0.5%, respectively, of our revenues.

For revenue and other financial information for our U.S. and International segments, see Note 18 to our consolidated financial statements, which are included elsewhere in this prospectus.

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**Distribution, Marketing and Sales**

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

<b>Product</b>	<b>Currently Marketed</b>	<b>Regulatory Approval, but Not Currently Marketed</b>
	United States, Canada,	
	Australia, New Zealand,	EU, Israel, India, South Korea, Singapore(1)
	Mexico	
	United States, Canada,	
	Caribbean Islands, Colombia,	Korea, Mexico, Panama
	Costa Rica, Taiwan	
	United States, Taiwan	Mexico, New Zealand, Australia, Panama
	United States, Canada, Certain	
	EU countries(2), Brazil, Costa	
	Rica, Israel, Japan, South Korea,	South Africa, India, Colombia, Denmark, Egypt, Hong Kong, Kuwait, Malta, Panama, Philippines, Slovenia, Thailand
	Lebanon, Mexico, Taiwan, Thailand, Japan, Australia,	
	New Zealand	
	United States, Canada, Japan, Colombia, Costa Rica, Hong Kong, Lebanon, Mexico, Philippines, Taiwan, Thailand	Australia, South Korea,  New Zealand(3)
	United States, Canada,	
	Australia, South Korea,	Colombia, Mexico, New Zealand
	Pakistan, Panama, Taiwan	
	United States, Canada,	
	Australia, Colombia, Costa	
	Rica, South Korea, Panama, Taiwan,	Mexico
	New Zealand	
	Puerto Rico, Canada	None

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United States	None
United States, Canada	Australia

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

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In the United States, we sell DEFINITY through our sales team of approximately 80 employees that call on healthcare providers in the echocardiography space, as well as group purchasing organizations and integrated delivery networks. In 2013, we transitioned the sales and marketing efforts for Ablavar from our sales team to our customer service team in order to allow our sales team to focus exclusively on driving our DEFINITY sales growth. For the three months ended March 31, 2014 and the year ended December 31, 2013, DEFINITY sales represented approximately 30% and 28%, respectively, of our revenues.

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

Cardinal maintains approximately 135 radiopharmacies that are typically located in large, densely populated urban areas in the United States. We estimate that Cardinal's radiopharmacies distributed approximately 45% of the aggregate U.S. SPECT doses sold in the first half of 2013 (the latest information currently available to us). We currently have two agreements with Cardinal, one for TechneLite generators, Gallium, Xenon, Thallium and Neurolite, or the TechneLite Agreement, and the other for Cardiolite products, or the Cardiolite Agreement, both of which require Cardinal to purchase minimum amounts of each of the products from us. The agreements contain provisions allowing for early termination by either party. The TechneLite Agreement allows for termination upon the occurrence of specified events, including a material breach by either party and force majeure events. The Cardiolite Agreement allows for termination upon the occurrence of specified events, including a material breach by either party, Cardinal's termination of its business operations in the nuclear medicine industry and force majeure events. The TechneLite and Cardiolite agreements both expire on December 31, 2014.

UPPI is a cooperative purchasing group (roughly analogous to a group purchasing organization) of over 80 independently owned or smaller chain radiopharmacies located in the United States. UPPI's radiopharmacies are typically broadly dispersed geographically, with some urban presence and a substantial number of radiopharmacies located in suburban and rural areas of the country. We estimate that these independent radiopharmacies, together with an additional 41 unofficial, independent radiopharmacies, distributed more than 25% of the aggregate U.S. SPECT doses sold in the first half of 2013. We currently have an agreement with UPPI for the distribution of both Cardiolite and TechneLite products to radiopharmacies or families of radiopharmacies within the UPPI cooperative purchasing group. The agreement contains specified pricing levels based upon specified purchase amounts for UPPI. We are entitled to terminate the UPPI agreement upon 60 days' written notice. The UPPI agreement expires on December 31, 2016.

GE Healthcare maintains 31 radiopharmacies in the United States that purchase our TechneLite generators. These radiopharmacies primarily distribute GE Healthcare's Myoview, a technetium-labeled MPI agent. We estimate that GE Healthcare distributed approximately 11% of the aggregate U.S. SPECT doses sold in the first half of 2013. We currently have one agreement with GE Healthcare for the distribution of TechneLite and other products. The agreement provides that GE Healthcare will purchase a minimum percentage of TechneLite generators as well as certain other products in the United States or Canada from us. Our agreement, which expires on December 31, 2017, may be terminated by either party on (i) two years' written notice relating to TechneLite on and after December 31, 2013 and (ii) six months' written notice relating to the other products. Our agreement also allows for termination upon the occurrence of specified events including a material breach by either party, bankruptcy by either party and force majeure events.

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

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

First, submission of a Clinical Trial Application which seeks Import Drug License approval. Double-Crane submitted the Clinical Trial Application to the CFDA in June 2013. The CFDA accepted the Clinical Trial Application for review in July 2013.

Second, approval of the Clinical Trial Application, at which point Double-Crane would conduct two small confirmatory clinical trials one for abdominal (liver and kidney) and one for cardiac.

Third, approval of the Import Drug License. If the regulatory and clinical trial processes are both successful, we currently estimate the commercialization of DEFINITY in China could begin as soon as 2017.

We believe that international markets, particularly China, represent significant growth opportunities for our products. The Mallinckrodt and Double-Crane distribution agreements did not have a significant impact on our revenue during 2013.

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

## **Customers**

For the year ended December 31, 2013, our largest customers were Cardinal, GE Healthcare and UPPI, accounting for approximately 19%, 10% and 10%, respectively, of our revenues.

## **Competition**

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

The market for diagnostic medical imaging agents is highly competitive and continually evolving. Our principal competitors in existing diagnostic modalities include large, global companies that are more diversified than we are and that have substantial financial, manufacturing, sales and marketing, distribution and other resources. These competitors include Mallinckrodt, GE Healthcare, Bayer, Bracco and Draxis, as well as other competitors. We cannot anticipate their competitive actions, 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



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generic versions after our proprietary products lose their current patent protection. Our current or future products could be rendered obsolete or uneconomical as a result of this competition.

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

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### **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 three months ended March 31, 2014 and the year ended December 31, 2013, our largest supplier of raw materials and supplies was Nordion, accounting for approximately 16% and 19%, 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-235 with neutrons in research reactors. Moly is the most common radioisotope used for medical diagnostic imaging purposes. With a 66-hour half-life, Moly degrades into technetium, another radioisotope with a half-life of six hours that is the isotope that is attached to radiopharmaceuticals, including our own Cardiolite and Neurolite, during the labeling process.

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

Historically, our largest supplier of Moly has been Nordion, which relies on the NRU reactor for its supply of Moly. Our agreement with Nordion contains minimum percentage purchase requirements for Moly. The agreement allows for termination upon the occurrence of certain events. Nordion can terminate if we fail to purchase a minimum percentage of Moly or if Nordion incurs certain cost increases, but in the latter case termination can occur no earlier than October 1, 2014. Either party may terminate if the other party fails to comply with material obligations, is bankrupt or experiences a force majeure event subject to a waiting period. The agreement expires on December 31, 2015.

Our agreement with NTP includes their consortium partner, ANSTO. The agreement contains minimum percentage volume requirements and provides for the increased supply of Moly derived from LEU targets from NTP and ANSTO. The agreement allows for termination upon the occurrence of certain events, including failure by NTP to provide our required amount of Moly, material breach of any provision by either party, bankruptcy by either party and force majeure events. Additionally, we have the ability to terminate the agreement with six months written notice prior to the expiration of the agreement. The agreement expires on December 31, 2017.

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

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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.

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### ***Xenon***

Currently, Nordion is our sole supplier of Xenon, and we believe it is currently the principal supplier of Xenon in the world. Xenon is captured by the NRU reactor as a by-product of the Moly production process. Our agreement with Nordion is on a purchase order basis. Nordion recently announced that it has entered into a definitive agreement to be acquired by Sterigenics. As a result of this transaction, our supplier could change the terms on which we obtain Xenon. We are also currently pursuing additional sources of Xenon from potential new producers around the world that seek to produce Xenon with existing or new reactors and technologies. If we are not able to secure a new producer of Xenon prior to the expiration of the NRU reactor's license in 2016 and obtain regulatory approval to sell Xenon from that new producer, we will no longer be able to offer Xenon in our portfolio of commercial products. See **Risk Factors** **Risks Relating to our Business and Industry** 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 believe are either in good standing or easily replaceable without any material disruption to our business.

### **Manufacturing**

We maintain manufacturing operations at our North Billerica, Massachusetts facility. We manufacture TechnLite on a highly automated production line and also manufacture Thallium and Gallium at this site using our cyclotron technology. 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 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, all raw materials used in those products are first sent to our North Billerica facility, where we test them prior to the third party manufacturing the final product. After the final products are manufactured, they are sent back to us for final quality control testing and then we ship them to our customers. We have expertise in the design, development and validation of complex manufacturing systems and processes, and our strong execution and quality control culture supports the just-in-time manufacturing model at our North Billerica facility.

### ***BVL and Technology Transfer***

We have undertaken technology transfers in response to supply challenges at our primary third party contract manufacturer. Historically, we relied on BVL as our sole manufacturer of DEFINITY, Neurolite and evacuation vials, an ancillary component for our TechnLite generators, and as one of our two manufacturers of Cardiolite. Following extended operational and regulatory challenges at BVL's Bedford, Ohio facility, in March 2012, we entered into the Settlement Agreement, under which we and BVL agreed to a broad mutual waiver and release for all matters that occurred prior to the date of the Settlement Agreement, a covenant not to sue and a settlement payment to us in the amount of \$30.0 million.

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We also entered into (i) the Transition Services Agreement, under which BVL manufactured for us certain products and made payments to us in the aggregate amount of \$5.0 million; and (ii) the Manufacturing Agreement, under which BVL manufactured for us certain products following the initial supply provided under the Transition Services Agreement. See Management's Discussion and Analysis of Financial Condition and Results of Operations Key Factors Affecting Our Results Inventory Supply.

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BVL continued to face supply challenges and, in October 2013, it announced that it would cease to manufacture further new batches of our products in its Bedford, Ohio facility. On November 12, 2013, in connection with the termination of the Manufacturing Agreement, we and BVL entered into the Second Settlement Agreement. Pursuant to the Second Settlement Agreement, we and BVL agreed to a broad mutual waiver and release for all matters that occurred prior to the date of the Second Settlement Agreement, a covenant not to sue and settlement payments to us in the aggregate amount of \$8.9 million. In addition, the Second Settlement Agreement provided that the Manufacturing Agreement terminated as of November 15, 2013, subject to BVL's obligations to use commercially reasonable efforts to finalize specific batches of DEFINITY, Cardiolite and saline manufactured and not yet released by the BVL quality function for commercial distribution. BVL has since released for commercial distribution all of our remaining manufactured product that was awaiting quality approval.

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

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

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

*Cardiolite* We currently have one manufacturer for our Cardiolite supply. We also entered into a Manufacturing and Supply Agreement, effective as of May 3, 2012, with JHS for the manufacture of Cardiolite products. Under the agreement, JHS has agreed to manufacture product for an initial term of five years. We have the right to extend the agreement for an additional five-year period, with automatic renewals for additional one year periods thereafter. The agreement allows for termination upon the occurrence of specified events, including material breach or bankruptcy by either party. The agreement requires us to place orders for a minimum percentage of our requirements for Cardiolite with JHS during such term. We are currently considering our product volume requirements and need for additional contract manufacturers for Cardiolite, including JHS. Based on our current projections, we believe that we will have sufficient Cardiolite product supply from our current supplier 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 we are currently in the technology transfer process. Under the agreement, JHS has agreed to manufacture product for an initial term of five years. We have the right to extend the agreement for an additional five-year period, with automatic renewals for additional one year periods thereafter. The agreement allows for termination upon the occurrence of specified events, including material breach or bankruptcy by either party. The agreement also requires us to place orders for a minimum percentage of our requirements for Neurolite with JHS during such term. We are also considering additional contract manufacturers for Neurolite. We currently anticipate JHS-manufactured Neurolite to be available in the United States by the second half of 2014 when the technology transfer and regulatory approval at JHS are completed.

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

### ***Mallinckrodt***

We rely on sole source manufacturing for Ablavar at Mallinckrodt. The agreement requires us to purchase a minimum amount of Ablavar and can be amended or terminated by mutual written agreement at any time. See **Risk Factors Risks Relating to Our Business and Industry** Our business depends on our ability to successfully introduce new products and adapt to a changing technology and diagnostic landscape. The agreement also allows for termination upon the occurrence of certain events such as a material breach or default by either party, or bankruptcy by either party. Currently, the agreement runs until September 30, 2014, although we do not foresee the need to order any additional API or finished drug product under this agreement other than our outstanding purchase commitment. As of March 31, 2014, there are no remaining future purchase commitments under the amended agreement. See **Risk Factors Risks Relating to Our Business and Industry** The global supply of Moly is fragile and not stable. Our dependence on a limited number of third party suppliers for Moly could prevent us from delivering some of our products to our customers in the required quantities within the required timeframe, or at all, which could result in order cancellations and decreased revenues.

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

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

### **Research and Development**

For the three months ended March 31, 2014 and 2013, we invested \$3.2 million and \$12.0 million, respectively, and for the years ended December 31, 2013, 2012 and 2011, we invested \$30.5 million, \$40.6 million and \$40.9 million, respectively, in R&D. Our R&D team includes our medical affairs and medical information functions, which educate physicians on the scientific aspects of our commercial products and the approved indications, labeling and the receipt of reports relating to product quality or adverse events. We have developed a pipeline of three potential cardiovascular imaging agents which were discovered and developed in-house and which are protected by patents and patent applications we own in the United States and numerous foreign jurisdictions.





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

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

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

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

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

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

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

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

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

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

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The Phase 2 trial results showed the following:

a significantly higher percentage of images were rated as either excellent or good quality with PET imaging, compared to SPECT imaging for stress images (98.8% vs. 84.9%,  $p < 0.01$ ) and rest images (95.3% vs. 69.8%,  $p < 0.01$ );

diagnostic certainty of interpretation, the percentage of cases with definitely abnormal or definitely normal interpretation, was significantly higher for flurpiridaz F 18 compared to SPECT (90.7% vs. 75.6%,  $p < 0.01$ );

the area under the ROC curve (the relative operating characteristic curve comparing the true positive rate to the false positive rate for coronary artery disease diagnosis) was significantly higher for flurpiridaz F 18 than SPECT ( $0.82 \pm 0.05$  vs.  $0.70 \pm 0.05$ ,  $p < 0.05$ ), indicating higher diagnostic performance;

superiority for sensitivity (that is, the ability to identify disease) with flurpiridaz F 18 imaging was significantly higher than SPECT (78.8% vs. 61.5%,  $p = 0.02$ );

a trend toward higher specificity (that is, the ability to rule out disease) was noted, although the advantage was not statistically significant in the study; and

no drug-related serious adverse events were observed, demonstrating a positive safety profile for PET MPI imaging with flurpiridaz F 18.

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

Our Phase 3 program for flurpiridaz F 18 includes a 301 trial and a 302 trial, each of which is an open-label, multicenter trial to assess the diagnostic efficacy of flurpiridaz F 18 PET MPI, as compared with SPECT MPI, in the detection of significant coronary artery disease. Coronary angiography is the truth standard for all subjects. The clinical development program includes hypotheses for superiority for sensitivity (identifying disease) and non-inferiority for specificity (ruling out disease) with an adequate sample size to demonstrate superior specificity if present.

In March 2011, we obtained agreement from the FDA on an SPA for our 301 trial and, in April 2012, we received an SPA for our 302 trial. See [Business Regulatory Matters Food and Drug Laws](#).

During the third quarter of 2013, we completed patient enrollment in the 301 trial. In the fourth quarter of 2013, we announced preliminary results from the 301 trial. Flurpiridaz F 18 appeared to be well-tolerated from a safety perspective and outperformed SPECT in a highly statistically significant manner ( $p < .001$ ) in the co-primary endpoint of sensitivity. In addition, flurpiridaz F 18 showed statistically significant improvements ( $p < .001$ ) in the secondary endpoints of image quality and diagnostic certainty in comparison to SPECT. However, flurpiridaz F 18 did not meet its other co-primary endpoint of non-inferiority for identifying subjects without disease.

Because of our failure to meet the specificity endpoint, we are having discussions in connection with the development process with the FDA. At the same time, we are seeking strategic partners to further develop and, if approved, commercialize flurpiridaz F 18.

*18F LMI 1195 Cardiac Neuronal Activity Imaging Agent*

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

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Heart failure is a major public health problem in North America, associated with high morbidity and mortality, frequent hospitalizations and a major cost burden on the community. In the United States alone, there are over five million patients living with congestive heart failure, and over a half million new diagnoses each year. Mortality for this condition is around 50% within five years of diagnosis. Expensive therapies for heart failure are often utilize