

Lantheus Holdings, Inc.  
Form S-1/A  
November 07, 2014  
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As filed with the Securities and Exchange Commission on November 7, 2014

Registration No. 333-196998

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

Amendment No. 5 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**

Prior to the 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 NOVEMBER 7, 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 18.**

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.

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

(1) We refer you to Underwriting (Conflicts of Interest) beginning on page 175 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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Image of Heart Without Using Contrast Agent

Image of Heart Using DEFINITY®

SPECT Image Showing Probable Coronary Artery Disease (CAD) in Patient Without CAD

Flurpiridaz F 18 Image Confirming No CAD in Same Patient Without CAD

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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®, Cardiolite®, 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 (including the related 1-for- reverse stock split) 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 six months ended June 30, 2014, we recorded revenues, net income (loss) and Adjusted EBITDA of \$148.9 million, \$(2.9) million and \$32.3 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 six months ended June 30, 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 (3) 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 Agent 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 over 30 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 June 2014, the average contrast penetration rate increased to 3.6%. 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 76% share of these procedures in the United States in June 2014.

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

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agents. Technetium results from the radioactive decay of Molybdenum-99, or Moly, itself a radioisotope with a 66-hour half-life produced in nuclear research reactors around the world from enriched uranium. 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.

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**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.

**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, 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.





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### **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 (such as Cardiolite and Neurolite) designed to localize in specific organs and tissues. 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

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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. Many of our imaging agents and products are used in connection with diagnostic imaging for heart disease.

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### **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 echocardiography 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 76% share of these procedures in the United States in June 2014. 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 Pharmedica Inc., or Pharmedica, an additional manufacturing partner for DEFINITY, and we currently believe that Pharmedica will obtain FDA approval to manufacture DEFINITY in 2015.

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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, UPPI and GE Healthcare, who together distributed over an estimated 80% 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.

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### **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;

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

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

reduced disclosure about executive compensation arrangements.

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

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**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 18 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;

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;

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.

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### **Corporate Reorganization**

After the effectiveness of the registration statement of which this prospectus forms a part and 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 (other than shares held in treasury) will be converted into the right to receive \_\_\_\_\_ shares of our newly issued common stock, with any fractional shares rounded down (which equates to a 1-for-\_\_\_\_\_ reverse stock split), and shares held in treasury will be cancelled and retired. 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, and certain unvested performance-vesting stock options will be amended (see Executive and Director Compensation Outstanding Incentive Awards and Anticipated Awards in Connection with this Offering ). 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 \$300.0 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.

### **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.



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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 Use of Proceeds for a more complete description of our intended use of the net proceeds from this offering.
<b>Conflicts of Interest</b>	The net proceeds from this offering will be used to repay borrowings under our revolving credit facility. Because an affiliate of Wells Fargo Securities, LLC is a lender under our revolving credit facility and will receive 5% or more of the net proceeds of this offering, Wells Fargo Securities, LLC is deemed to have a conflict of interest under Rule 5121 of the Financial Industry Regulatory Authority, Inc., or FINRA. As a result, this offering will be conducted in accordance with FINRA Rule 5121. Pursuant to that rule, the appointment of a qualified independent underwriter is not required in connection with this offering as the members primarily responsible for managing the public offering do not have a conflict of interest, are not affiliates of any member that has a conflict of interest and meet the requirements of paragraph (f)(12)(E) of FINRA Rule 5121. See Use of Proceeds and Underwriting (Conflicts of Interest).
<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 Dividend Policy.
<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 Risk Factors and the historical consolidated financial statements, and the related notes thereto, included elsewhere in this prospectus, before investing in our common stock.

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Unless otherwise indicated, the number of shares of common stock to be outstanding after this offering is based on \_\_\_\_\_ shares outstanding as of June 30, 2014 and excludes:

\_\_\_\_\_ shares of our common stock issuable upon exercise of outstanding stock options as of June 30, 2014, with a weighted average exercise price of \$ \_\_\_\_\_ per share; and

\_\_\_\_\_ 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 (excluding our consolidated financial statements and related notes included elsewhere in this prospectus):

\_\_\_\_\_ gives effect to our corporate reorganization, including the related 1-for-\_\_\_\_\_ reverse stock split (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;

\_\_\_\_\_ 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 June 30, 2014 and statements of operations data for the six months ended June 30, 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.

	Six Months ended		Year ended December 31,		
	June 30,		2013	2012	2011
	2014	2013	2013	2012	2011
	(dollars in thousands except share and per share data)				
Revenues	\$ 148,949	\$ 141,619	\$ 283,672	\$ 288,105	\$ 356,292
Cost of goods sold	87,829	97,860	206,311	211,049	255,466
Loss on firm purchase commitment				1,859	5,610
Total cost of goods sold	87,829	97,860	206,311	212,908	261,076
Gross profit	61,120	43,759	77,361	75,197	95,216
Operating expenses					
Sales and marketing expenses	18,900	18,790	35,227	37,437	38,689
General and administrative expenses	17,842	18,423	33,036	32,520	32,862
Research and development expenses	5,909	19,535	30,459	40,604	40,945
Proceeds from manufacturer			(8,876)	(34,614)	
Impairment on land			6,406		
Total operating expenses	42,651	56,748	96,252	75,947	112,496
Operating income (loss)	18,469	(12,989)	(18,891)	(750)	(17,280)
Interest expense	(21,132)	(21,358)	(42,915)	(42,014)	(37,658)
Interest income	13	70	104	252	333
Other income (expense), net	(589)	634	1,161	(44)	1,429

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Loss before income taxes	(3,239)	(33,643)	(60,541)	(42,556)	(53,176)
Provision (benefit) for income taxes	(318)	546	1,014	(555)	84,082

Net income (loss)	\$ (2,921)	\$ (34,189)	\$ (61,555)	\$ (42,001)	\$ (137,258)
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Net income (loss) per common share:

Basic and diluted, historical	\$ (0.06)	\$ (0.68)	\$ (1.21)	\$ (0.84)	\$ (2.73)
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Basic and diluted, pro forma(1) (unaudited)	\$	\$	\$	\$	\$
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Common shares:

Basic and diluted, historical	50,805,504	50,534,526	50,670,274	50,250,957	50,237,490
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Basic and diluted, pro forma(1) (unaudited)					
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Pro forma as adjusted net income (loss) per common share(2) (unaudited):

Basic	\$	\$	\$		
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Diluted	\$	\$	\$		
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Pro forma as adjusted common shares(2) (unaudited):

Basic					
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Diluted					
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	Six Months ended June 30, 2014	2013	2013 (dollars in thousands)	Year ended December 31, 2012	2011
			(unaudited)		
<b>Other Financial Data:</b>					
Adjusted EBITDA(3)	\$ 32,335	\$ 11,418	\$ 47,359	\$ 56,212	\$ 79,978
				As of June 30, 2014	
			Actual	Pro forma(1)	Pro forma as adjusted(4)
				(dollars in thousands)	
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents			\$ 16,022	\$	\$
Total assets			255,237		
Total liabilities			492,795		
Revolving credit facility			13,500		
Current portion of long-term debt					
Total long-term debt, net			399,159		
Total stockholders' deficit			(237,558)		

- (1) Pro forma information gives effect to our corporate reorganization, which will have no impact on our historical net income (loss) or balance sheet data, however, it will reduce the number of common shares and net income (loss) per common share due to the impact of a 1-for- reverse stock split as described in Corporate Reorganization.
- (2) Pro forma as adjusted net income (loss) assumes \$ million of the net offering proceeds are used to redeem a portion of our Notes and pay down the outstanding amount of our revolving credit facility 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 of approximately \$ million, \$ million and \$ million for the six months ended June 30, 2014 and June 30, 2013 and the year ended December 31, 2013, respectively, related to such redemption and pay down, assuming that the offering, redemption, and the related application of net proceeds was completed on January 1, 2013. We also expect to pay a \$ million premium upon the redemption of the Notes. The redemption premium expense has not been included in pro forma as adjusted net income (loss) per share due to the expense being a nonrecurring charge. Pro forma as adjusted net income (loss) per common share and number of common shares gives effect to our corporate reorganization (including the related 1-for- reverse stock split) 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) 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.

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

	Six Months ended June 30,		Year ended December 31,		
	2014	2013	2013 (dollars in thousands) (unaudited)	2012	2011
Net income (loss)	\$ (2,921)	\$ (34,189)	\$ (61,555)	\$ (42,001)	\$ (137,258)
Interest expense, net	21,119	21,288	42,811	41,762	37,325
Provision for income taxes(a)	(121)	274	(127)	(901)	82,702
Depreciation and amortization	8,924	13,098	25,783	27,955	33,258
<b>EBITDA</b>	<b>27,001</b>	<b>471</b>	<b>6,912</b>	<b>26,815</b>	<b>16,027</b>
Non-cash stock-based compensation	535	563	578	1,240	(969)
Legal fees(b)	465	387	660	1,455	2,017
Loss on firm purchase commitment(c)				1,859	5,610
Asset write-off(d)	511	2,058	28,349	13,095	52,973
Severance and recruiting costs(e)	301	4,491	5,239	1,761	1,995
Sponsor fee and other(f)	509	938	1,457	1,042	1,719
New manufacturer costs(g)	3,013	2,510	4,164	8,945	606
<b>Adjusted EBITDA(h)</b>	<b>\$ 32,335</b>	<b>\$ 11,418</b>	<b>\$ 47,359</b>	<b>\$ 56,212</b>	<b>\$ 79,978</b>

- (a) 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.
- (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 June 30, 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 \$10.6 million, which were realized for the years



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ended December 31, 2013 and 2012 and the six months ended June 30, 2013, respectively, primarily relating to our strategic shift from in-house R&D to an external partnering model of R&D.

- (4) Pro forma as adjusted information gives effect to our corporate reorganization, including the related 1-for- reverse stock split (see Corporate Reorganization ), the termination of our Advisory Services and Monitoring Agreement, dated as of January 8, 2008, which we will terminate prior to the consummation of this offering and pay a \$ million termination fee in connection therewith (see Certain Relationships and Related Person Transactions Advisory and Monitoring Services Agreement ), the receipt of net proceeds of \$ million from 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 \$ million of the net proceeds from this offering to reduce our indebtedness, including a \$ million redemption premium, 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

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international business, results of operations, financial condition and cash flows will continue to be adversely affected.

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

In addition to the products described above, for reasons of quality assurance or cost-effectiveness, we purchase certain components and raw materials from sole suppliers (including, for example, the lead casing for our TechneLite generators 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. As with all manufacturing facilities, equipment and infrastructure age and become subject to increasing maintenance and repair. If we or one of our manufacturing partners experiences an event, including a labor dispute, natural disaster, fire, power outage, machinery breakdown, security problem, failure to meet regulatory requirements, product quality issue, technology transfer issue or other issue, we may be unable to manufacture the relevant products at previous levels or on the forecasted schedule, if at all. Due to the stringent regulations and requirements of the governing regulatory authorities regarding the manufacture of our products, we may not be able to quickly restart manufacturing at a third party or our own facility or establish additional or replacement sources for certain products, components or materials.

In addition to our existing manufacturing relationships, we are also pursuing new manufacturing relationships to establish and secure additional or alternative suppliers for our commercial products. For example, on November 12, 2013, we entered into a Manufacturing and Supply Agreement with Pharmeducence 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



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

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

A critical ingredient of TechnoLite, historically our largest product by annual revenues, is Moly. We currently purchase finished Moly from four of the five main processing sites in the world, namely 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 TechnoLite 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 TechnoLite 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 TechnoLite 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

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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.

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 TechnoLite 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 TechnoLite generators, which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

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

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

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

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

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

The growth of our business is substantially dependent on increased market penetration for the appropriate use of DEFINITY in suboptimal echocardiograms. Of the over 30 million echocardiograms performed each year in the United States, a third party source estimates that 20%, or approximately six million echocardiograms, produce suboptimal images. We estimate that DEFINITY had approximately 76% share of the market for contrast agents in the United States in June 2014. 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 six months ended June 30, 2014 and 2013 and the year ended December 31, 2013, Xenon represented approximately 12%, 11% 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.



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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

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challenges or price increase would have a negative effect on our business, results of operations, financial condition and cash flows.

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

In the United States, we 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 six months ended June 30, 2014, we incurred net loss of \$2.9 million and total stockholders' deficit of \$237.6 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

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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

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products that are comparable to our own, development or introduction of new products that are more cost-effective or have superior performance than our current products, the introduction of generic versions when our proprietary products lose their patent protection or the new entry into a generic market in which we are already a participant. 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.

In October 2014, Bracco received FDA approval in the United States for its echocardiography agent, Lumason (known as SonoVue outside of the U.S.), which is already approved for sale in Europe and certain Asian markets, including China, Japan and Korea. Bracco now has one of three FDA-approved echocardiography contrast agents in the United States, together with GE Healthcare's Optison and our DEFINITY. If Bracco successfully commercializes Lumason in the United States without otherwise increasing the overall usage of ultrasound contrast agents, our current and future sales volume could suffer, which would have a material adverse effect on our business, results of operations, financial condition and cash flows.

***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 11% of our revenues in the three months ended June 30, 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.



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and can deny coverage for treatments that include the use of our products or revise payment policies such that payments do not adequately cover the cost of our products. Even if third party payors make coverage and reimbursement available, that reimbursement may not be adequate or these payors' reimbursement policies may have an adverse effect on our business, results of operations, financial condition and cash flows.

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

limiting payments for imaging services in physician offices and free-standing imaging facility settings based upon rates paid to hospital outpatient departments;

reducing payments for certain imaging procedures when performed together with other imaging procedures in the same family of procedures on the same patient on the same day in the physician office and free-standing imaging facility setting;

making significant revisions to the methodology for determining the practice expense component of the Medicare payment applicable to the physician office and free-standing imaging facility setting which results in a reduction in payment; and

revising payment policies and reducing payment amounts for imaging procedures performed in the hospital outpatient setting.

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 TechnoLite generators are manufactured using non-HEU, not all of our TechnoLite generators meet CMS' definition of non-HEU, and therefore this payment will not be available for the latter category of TechnoLite 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



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that these types of changes have the effect of reducing the aggregate number of diagnostic medical imaging procedures performed in the United States, our business, results of operations, financial condition and cash flows would be adversely affected. See Business Regulatory Matters.

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

A significant portion of our patient volume is derived from U.S. government healthcare programs, principally Medicare, which are highly regulated and subject to frequent and substantial changes. For example, in March 2010, the President signed one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the 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



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Healthcare Reform Act also extended coverage to approximately 25 million previously uninsured people (based on April 2014 estimates from the

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Congressional Budget Office), which may result in an increase in the demand for our services, but we cannot be assured of a proportional, or any, increase in the use of our products.

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

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

Both before and after the approval of our products and agents in development, we, our products, development agents, operations, facilities, suppliers, distributors, contract manufacturers, contract research organizations and contract testing laboratories are subject to extensive and, in certain circumstances, expanding regulation by federal, state and local government agencies in the United States as well as non-U.S. and transnational laws and regulations, with regulations differing from country to country. In the United States, the FDA regulates, among other things, the pre-clinical testing, clinical trials, manufacturing, safety, efficacy, potency, labeling, storage, record keeping, quality systems, advertising, promotion, sale, distribution, and import and export of drug products. We are required to register our business for permits and/or licenses with, and comply with the stringent requirements of the FDA, the 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 or 2015, 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,



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

Business Regulatory Matters Healthcare Fraud and Abuse Laws.

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.

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

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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 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. Bracco's newly approved ultrasound contrast agent, Lumason, has substantially similar safety labeling as DEFINITY and Optison. If additional safety issues arise, this may result in further changes in

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labeling or result in restrictions on the approval of our product, including removal of the product from the market. Lingering safety concerns about DEFINITY among some healthcare providers or future unanticipated side effects or safety concerns associated with DEFINITY could limit expanded use of DEFINITY and have a material adverse effect on the unit sales of this product and our financial condition and results of operations.

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

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

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

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

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

the timing of our market entry;

our ability to market and distribute our products effectively;

market acceptance of our products; and

our ability to obtain adequate reimbursement.

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

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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 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



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our products, which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

*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.



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Regulatory authorities may require us or our partners to conduct additional clinical testing, in which case we would have to expend additional time and resources. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in regulatory policy that occur prior to or during regulatory review. The failure to provide clinical and preclinical data that are adequate to demonstrate to the satisfaction of the regulatory authorities that our agents in development are safe and effective for their proposed use will delay or preclude approval and will prevent us from marketing those products.

In our flurpiridaz F 18 Phase 3 program, in the fourth quarter of 2013 we announced preliminary results from the 301 trial, which is subject to 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



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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 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, Cardiolite, 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 six months ended June 30, 2014 and 2013, 23% and 25%, 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 in the future. Accordingly, our business is subject to risks associated with doing business internationally, including:

less stable political and economic environments and changes in a specific country's or region's political or economic conditions;

entering into or renewing commercial agreements with international governments or provincial authorities or entities directly or indirectly controlled by such governments or authorities, such as our Chinese partner Double-Crane;

international customers which are agencies or institutions of foreign governments,

local business practices which may be in conflict with the FCPA and Bribery Act;

currency fluctuations;

potential negative consequences from changes in tax laws affecting our ability to repatriate profits;

unfavorable labor regulations;

greater difficulties in relying on non-U.S. courts to enforce either local or U.S. laws, particularly with respect to intellectual property;

greater potential for intellectual property piracy;

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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 six months ended June 30, 2014 and 2013, the net impact of foreign currency changes on transactions was a loss of \$0.4 million and \$6,000, 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 June 30, 2014, we had approximately \$413.5 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 \$13.5 million. In addition to the \$13.5 million outstanding under our revolving credit facility, there is an \$8.8 million unfunded Standby Letter of Credit as of June 30, 2014. As of June 30, 2014, our revolving credit facility had \$22.2 million of remaining availability. In June 2014, we amended our revolving credit facility to increase the size from \$42.5 million to \$50.0 million. During periods of volatility and disruption in the U.S., European, or global credit markets, obtaining additional or replacement financing may be more difficult and the cost of issuing new debt or replacing our revolving credit facility could be higher than under our current revolving credit facility. Higher cost of new debt may limit our ability to have cash on hand for working capital, capital expenditures and acquisitions on terms that are acceptable to us. Additionally, our revolving credit facility has a variable interest rate. By its nature, a variable interest rate will move up or down based on changes in the economy and other factors, all of which are beyond our control. If interest rates increase, our interest expense could increase, affecting earnings and reducing cash flows available for working capital, capital expenditures and acquisitions.

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

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

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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 equipment and infrastructure age and become subject to increasing maintenance and repair and our systems generally are vulnerable to potential damage or interruptions from fires, natural disasters, power outages, blackouts, machinery breakdown, telecommunications failures and other unexpected events, as well as to break-ins, sabotage, increasingly sophisticated intentional acts of vandalism or cyber threats. As these threats continue to evolve, we may be required to expend additional resources to enhance our information security measures or to investigate and remediate any information security vulnerabilities. Given the extensive reliance of our business on technology, any substantial disruption or resulting loss of data that is not avoided or corrected by our backup measures could harm our business, operations and financial condition.

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

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

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

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

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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 June 30, 2014, we had approximately \$413.5 million of total principal indebtedness consisting of \$400.0 million of the Notes, which mature on May 15, 2017, and \$13.5 million outstanding under our revolving credit facility. As of June 30, 2014, in addition to the \$13.5 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 June 30, 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 (Conflicts of Interest), (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 (which gives effect to the corporate reorganization, including the related 1-for- reverse stock split) 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 June 30, 2014, if you purchase our common stock in this offering, you will suffer immediate dilution in pro forma 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 in the face of increased competition; (iii) our outlook and expectations related to our intention to seek to engage strategic partners to assist in developing and potentially commercializing development candidates; (iv) our preliminary estimated results for the three months ended June 30, 2014; and (v) 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 and the increased segment competition from other echocardiography contrast agents, including Optison from GE Healthcare and the newly approved Lumason (known as SonoVue outside of the U.S.) from Bracco Diagnostics, Inc., or Bracco;

risks associated with supply and demand for Xenon;

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

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;

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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