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

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

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

Commission File Number 001-36569

LANTHEUS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

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

(978) 671-8001

(Registrant s telephone number, including area code)

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

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

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

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

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

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

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

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

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PART I

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements contained in this annual report are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and section 21E of the Securities Exchange act of 1934. These forward-looking statements, including, in particular, statements about our plans, strategies, prospects and industry estimates are subject to risks and uncertainties. These statements identify prospective information and include words such as anticipates, intends, plans, seeks, believes, estimates, expects, should, could, predicts, h expressions. Examples of forward-looking statements include, but are not limited to, statements we make regarding: (i) our outlook and expectations including, without limitation, in connection with continued market expansion and penetration for our commercial products, particularly DEFINITY in the face of increased competition; (ii) our outlook and expectations in connection with future performance of Xenon in the face of potential increased competition; (iii) our outlook and expectations related to products manufactured at Jubilant HollisterStier, or JHS, and Pharmalucence and global isotope supply; (iv) our outlook and expectations related to our intention to seek to engage strategic partners to assist in developing and potentially commercializing development candidates; and (v) our liquidity, including our belief that our existing cash, cash equivalents, anticipated revenues and availability under our revolving credit facility, or Revolving Facility, are sufficient to fund our existing operating expenses, capital expenditures and liquidity requirements for at least the next twelve months. Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. The matters referred to in the forward-looking statements contained in this annual report may not in fact occur. We caution you therefore, against relying on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include regional, national or global political, economic, business, competitive, market and regulatory conditions and the following:

- our ability to continue to increase segment penetration for DEFINITY in suboptimal echocardiograms and the increased segment competition from other echocardiography contrast agents, including Optison from GE Healthcare and Lumason from Bracco Diagnostics Inc., or Bracco;

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

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

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

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

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

the instability of the global Molybdenum-99, or Moly, supply;

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

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

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

potential liability associated with our marketing and sales practices;

the occurrence of any side effects with our products;

our exposure to potential product liability claims and environmental liability;

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

- attract strategic partners to successfully complete the Phase 3 clinical program and possibly commercialize the agent;
- obtain Food and Drug Administration, or FDA, approval; and
- gain post-approval market acceptance and adequate reimbursement;

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

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

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

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

risks associated with prevailing economic conditions and financial, business and other factors beyond our control;

risks associated with our international operations;

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

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

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

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

risks related to the ownership of our common stock; and

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

Factors that could cause or contribute to such differences include, but are not limited to, those that are discussed in other documents we file with the Securities and Exchange Commission, or the SEC. Any forward-looking statement made by us in this annual report speaks only as of the date on which it is made. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law.

Trademarks

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

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Item 1. Business

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

Overview

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

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

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

Our Products

Our portfolio of 10 commercial products is diversified across a range of imaging modalities. Our products include contrast agents and medical radiopharmaceuticals (including technetium generators).

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

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

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

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

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

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

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

DEFINITY

DEFINITY is the leading ultrasound contrast imaging agent based on revenue and usage and, in the United States, is indicated for use in patients with suboptimal echocardiograms. Numerous patient conditions can decrease the quality of images of the left ventricle, the primary pumping chamber of the heart. Of the total number of echocardiograms performed each year in the United States over 31 million in 2015 a third party source estimates that approximately 20%, or approximately 6 million echocardiograms in 2015, produce suboptimal images. The use of DEFINITY during echocardiography allows physicians to significantly improve their assessment of the function of the left ventricle.

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

DEFINITY offers flexible dosing and administration through an IV bolus injection or continuous IV infusion. We believe DEFINITY s synthetic lipid-cased coating gives the compound a distinct competitive advantage, because it provides a strong ultrasound signal and is the only perflutren-based echo contrast agent made without albumin. As a result, we believe DEFINITY will be a key driver of the future growth of our business, both in the United States and in international markets as we continue to grow contrast penetration through sales and marketing efforts focused on the appropriate use of contrast and maintain our leading position.

Since its launch in 2001, DEFINITY has been used in imaging procedures in more than 6.7 million patients throughout the world. In 2015, DEFINITY was the leading ultrasound imaging agent based on revenue and usage, used by echocardiologists and sonographers. We estimate that DEFINITY had approximately 78% share of the market for contrast agents in echocardiography procedures in the United States as of December 2015. DEFINITY currently competes with Optison, a GE Healthcare product, Lumason, a recently-approved Bracco product (known as SonoVue outside the U.S.) as well as other non-echocardiography imaging modalities. DEFINITY, Optison and Lumason all carry an FDA-required boxed warning, which has been modified over time, to notify physicians and patients about potentially serious safety concerns or risks posed by the products. See Risk Factors Risks Relating to our Business and Industry Ultrasound contrast agents may cause side effects which could limit our ability to sell DEFINITY.

DEFINITY is currently patent protected in the United States until 2021 and in numerous foreign jurisdictions with patent or regulatory protection until 2019, and we have an active life cycle management program for this agent. DEFINITY generated revenues of $111.9 million, $95.8 million and $78.1 million for the years ended December 31, 2015, 2014 and 2013, respectively. DEFINITY represented approximately 38%, 32% and 28% of our revenues in 2015, 2014 and 2013, respectively.

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Our leading commercial radiopharmaceutical products are:

TechneLite

TechneLite is a self-contained system or generator of Technetium (Tc99m), a radioactive isotope with a six hour half-life, used by radiopharmacies to prepare various nuclear imaging agents. Technetium results from the radioactive decay of molybdenum-99, or Moly, itself a radioisotope with a 66-hour half-life produced in nuclear research reactors around the world from enriched uranium. The TechneLite generator is a little larger than a coffee can in size, and the self-contained system houses a vertical glass column at its core that contains Moly. During our manufacturing process, Moly is added to the column within the generator where it is adsorbed onto alumina powder. The column is sterilized, enclosed in a lead shield and further sealed in a cylindrical plastic container, which is then immediately shipped to our radiopharmacy customers. Because of the short half-lives of Moly and technetium, radiopharmacies typically purchase TechneLite generators on a weekly basis pursuant to standing orders.

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

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

The Moly used in our TechneLite generators can be produced using targets made of either highly-enriched uranium, or HEU, or low-enriched uranium, or LEU. LEU consists of uranium that contains less than 20% of the uranium-235 isotope. HEU is often considered weapons grade material, with 20% or more of uranium-235. On January 2, 2013, President Obama signed into law the American Medical Isotopes Production Act of 2012, or AMIPA, as part of the 2013 National Defense Authorization Act. AMIPA encourages the domestic production of LEU Moly and provides for the eventual prohibition of the export of HEU from the United States. Although Medicare generally does not provide separate payment to hospitals for the use of diagnostic radiopharmaceuticals administered in an outpatient setting, since January 1, 2013, the Centers for Medicare and Medicaid Services, or CMS, the federal agency responsible for administering the Medicare program, has provided an add-on payment under the hospital outpatient

prospective payment system for every technetium diagnostic dose produced from non-HEU sourced Moly, to cover the marginal cost for radioisotopes produced from non-HEU sources. Our LEU TechneLite generator satisfies the reimbursement requirements under the applicable CMS rules.

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TechneLite has patent protection in the United States and various foreign countries on certain component technology currently expiring in 2029. In addition, given the significant know-how and trade secrets associated with the methods of manufacturing and assembling the TechneLite generator, we believe we have a substantial amount of valuable and defensible proprietary intellectual property associated with the product. We believe that our substantial capital investments in our highly automated TechneLite production line and our extensive experience in complying with the stringent regulatory requirements for the handling of nuclear materials create significant and sustainable competitive advantages for us in generator manufacturing and distribution. TechneLite generated revenues of $72.6 million, $93.6 million and $92.2 million for the years ended December 31, 2015, 2014 and 2013, respectively. TechneLite represented approximately 25%, 31% and 33% of our revenues in 2015, 2014 and 2013, respectively.

Xenon Xe 133 Gas

Xenon is a radiopharmaceutical gas that is inhaled and used to assess pulmonary function and also to image cerebral blood flow. Our Xenon is manufactured by a third party as part of the Moly production process and packaged by us. We are currently the leading provider of Xenon in the United States. In 2015, 2014 and 2013, Xenon Xe 133 Gas represented approximately 17%, 12% and 11%, respectively, of our revenues.

Other Commercial Products

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

Cardiolite, also known by its generic name sestamibi, is an injectable, technetium-labeled imaging agent used in MPI procedures to assess blood flow to the muscle of the heart using SPECT. Cardiolite was approved by the FDA in 1990 and its market exclusivity expired in July 2008. Included in Cardiolite revenues are branded Cardiolite and generic sestamibi revenues, some of which we produce and some of which we procure from third parties from time to time.

Neurolite is an injectable, technetium-labeled imaging agent used with SPECT technology to identify the area within the brain where blood flow has been blocked or reduced due to stroke. We launched Neurolite in 1995.

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

Gallium Ga 67 is an injectable radiopharmaceutical imaging agent used to detect certain infections and cancerous tumors, especially lymphoma. We manufacture Gallium using cyclotron technology.

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

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

Ablavar is an injectable, gadolinium-based contrast agent used with magnetic resonance angiography, or MRA, a type of MRI scan, to image the iliac arteries that start at the aorta and go through the pelvis into the legs, in order to diagnose narrowing or blockage of these arteries in known or suspected peripheral vascular disease. We launched Ablavar in January 2010.

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For revenue and other financial information for our U.S. and International segments, see Note 20, Segment Information to our consolidated financial statements.

Distribution, Marketing and Sales

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

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

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

In the United States and Canada, we sell DEFINITY through our sales team of approximately 80 employees that call on healthcare providers in the echocardiography space, as well as group purchasing organizations and integrated delivery networks. In 2013, we transitioned the sales and marketing efforts for Ablavar from our sales team to our customer service team in order to allow our sales team to focus exclusively on driving our DEFINITY sales growth. For the year ended December 31, 2015, DEFINITY sales represented approximately 38% of our revenues.

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

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

UPPI is a cooperative purchasing group (roughly analogous to a group purchasing organization) of approximately 77 independently owned or smaller chain radiopharmacies located in the United States. UPPI s radiopharmacies are typically broadly dispersed geographically, with some urban presence and a substantial number of radiopharmacies located in suburban and rural areas of the country. We estimate that these independent radiopharmacies, together with an additional 36 unaffiliated, independent radiopharmacies, distributed more than 28% of the aggregate U.S. SPECT doses sold in the first half of 2015. We currently have an agreement with UPPI for the distribution of TechneLite, Xenon and certain other products to radiopharmacies or families of radiopharmacies within the UPPI cooperative purchasing group. The agreement contains specified pricing levels based upon specified purchase amounts for UPPI. We are entitled to terminate the UPPI agreement upon 60 days written notice. The UPPI agreement expires on December 31, 2016.

GE Healthcare maintains 31 radiopharmacies in the United States that purchase our TechneLite generators. These radiopharmacies primarily distribute GE Healthcare s Myoview, a technetium-labeled MPI agent. We estimate that GE Healthcare distributed approximately 8% of the aggregate U.S. SPECT doses sold in the first half of 2015. We currently have an agreement with GE Healthcare for the distribution of TechneLite, Xenon and other products. The agreement provides that GE Healthcare will purchase a minimum percentage of TechneLite generators as well as certain other products in the United States or Canada from us. Our agreement, which expires on December 31, 2017, may be terminated by either party on (i) two years written notice relating to TechneLite and (ii) six months written notice relating to the other products. Our agreement also allows for termination upon the occurrence of specified events including a material breach by either party, bankruptcy by either party and force majeure events.

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

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

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

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clinics that maintain in-house radiopharmaceutical capabilities and operations. In the latter case, this represents a small percentage of overall sales because the majority of hospitals and clinics do not maintain these in-house capabilities.

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

First, submission of a Clinical Trial Application which seeks Import Drug License approval. Double-Crane submitted the Clinical Trial Application to the Chinese Food and Drug Administration, or CFDA, in June 2013. The CFDA accepted the Clinical Trial Application for review in July 2013.

Second, approval of the Clinical Trial Application, at which point Double-Crane can commence two small confirmatory clinical trials one for abdominal (liver and kidney) and one for cardiac. The CFDA approved the Clinical Trial Application in February 2016.

Third, approval of the Import Drug License. If the regulatory process, including the clinical trials, is successful, we currently estimate the timing for approval of DEFINITY in China could be as soon as 2017.

We believe that international markets, particularly China, represent significant growth opportunities for our products. The Mallinckrodt and Double-Crane distribution agreements did not have a significant impact on our revenue during 2015.

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

Customers

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

Competition

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

The market for diagnostic medical imaging agents is highly competitive and continually evolving. Our principal competitors in existing diagnostic modalities include large, global companies that are more diversified than we are and that have substantial financial, manufacturing, sales and marketing, distribution and other resources. These competitors include Mallinckrodt, GE Healthcare, Bayer, Bracco and DRAXIS Specialty

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Pharmaceuticals Inc. (an affiliate of JHS), or Draxis, as well as other competitors. We cannot anticipate their competitive actions in the same or competing diagnostic modalities, such as significant price reductions on products that are comparable to our own, development of new products that are more cost-effective or have superior performance than our current products or the introduction of generic versions after our proprietary products lose their current patent protection. In addition, distributors of our products could attempt to shift end-users to competing diagnostic modalities and products. Our current or future products could be rendered obsolete or uneconomical as a result of these activities.

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

Raw Materials and Supply Relationships

We rely on certain raw materials and supplies to produce our products. Due to the specialized nature of our products and the limited, and sometimes intermittent, supply of raw materials available in the market, we have established relationships with several key suppliers. Our most important and widely used raw material is Moly. For the year ended December 31, 2015, our largest supplier of raw materials and supplies was Nordion, accounting for approximately 13% of our total purchases.

Molybdenum-99

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

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

Historically, our largest supplier of Moly has been Nordion, which relies on the NRU reactor for its supply of Moly. Our agreement with Nordion contains minimum percentage purchase requirements for Moly. The agreement allows for termination upon the occurrence of certain events. Nordion can terminate if we fail to purchase a minimum percentage of Moly or if Nordion incurs certain cost increases. Either party may terminate if the other party fails to comply with material obligations, is bankrupt or experiences a force majeure event subject to a waiting period. The current agreement expires on October 31, 2016, and the NRU reactor has announced a transition in 2016 from providing regular supply of medical isotopes to providing only emergency back-up supply of HEU based medical isotopes from November 1, 2016 through March 2018.

Our agreement with NTP includes their consortium partner, ANSTO. ANSTO has under construction, in cooperation with NTP, a new Moly processing facility that ANSTO believes will expand its production capacity by approximately 2.5 times, with expanded commercial production planned to start in the latter part of 2016. In addition, IRE recently received approval from its regulator to expand its production capability by up to 50% of its former capacity. This new

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

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

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

To further augment and diversify our current supply, we are pursuing additional sources of Moly from potential new producers around the world that seek to produce Moly with existing or new reactors or technologies. For example, in November 2014, we announced entering into a new strategic agreement with SHINE Medical Technologies, Inc., a Wisconsin-based company, or SHINE, for the future supply of Moly. Under the terms of the supply agreement, SHINE will provide Moly produced using its proprietary LEU-solution technology for use in our TechneLite generators once SHINE s facility becomes operational and receives all necessary regulatory approvals, which SHINE currently estimates will occur in 2019. See Item 1A Risk Factors The global supply of Moly is fragile and not stable. Our dependence on a limited number of third party suppliers for Moly could prevent us from delivering some of our products to our customers in the required quantities, with the required timeframe, or at all, which could result in order cancellations and decreased revenues.

Xenon

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

Other Materials

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

Manufacturing

We maintain manufacturing operations at our North Billerica, Massachusetts facility. We manufacture TechneLite on a highly automated production line and also manufacture Thallium and Gallium at this site using our cyclotron technology and Xenon using our hot cell infrastructure. We manufacture, finish and distribute our

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

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

BVL, JHS and Pharmalucence

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

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

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

On November 12, 2013, we entered into a Manufacturing and Supply Agreement with Pharmalucence to manufacture and supply DEFINITY and we are currently in the technology transfer process with Pharmalucence in order to diversify our supply. We currently anticipate that we will file for FDA approval in 2016 to manufacture DEFINITY at Pharmalucence. There are no minimum purchase requirements under this agreement, which has an initial term of five years from the effective date and is renewable at our option for an additional five years. The Manufacturing Agreement allows for termination upon the occurrence of certain events, including material breach or bankruptcy by either party. During the optional five year term, either party may terminate upon thirty months advance notice. Based on our current projections, we believe that we will have sufficient supply of DEFINITY from JHS to meet expected demand.

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

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anticipate that we will file for FDA approval in 2016 to manufacture Cardiolite at JHS. Under the agreement, JHS has agreed to manufacture product for an initial term of five years. We have the right to extend the agreement for an additional five-year period, with automatic renewals for additional one year periods thereafter. The agreement allows for termination upon the occurrence of specified events, including material breach or bankruptcy by either party. The agreement requires us to place orders for a minimum percentage of our requirements for Cardiolite with JHS during such term. Based on our current projections, we believe that we will have sufficient Cardiolite product supply from our current supplier and JHS for when the technology transfer process is completed and we have obtained regulatory approval for this manufacturing site to meet expected demand.

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

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

Although we are pursuing new manufacturing relationships to establish and secure additional long-term or alternative suppliers as described above, we are uncertain of the timing as to when these arrangements could provide meaningful quantities of product. See Item 1A Risk Factors Risks Relating to Our Business and Industry The global supply of Moly is fragile and not stable. Our dependence on a limited number of third party suppliers for Moly could prevent us from delivering some of our products to our customers in the required quantities, within the required timeframes, or at all, which could result in order cancellations and decreased revenues, Item 1A Risk Factors Challenges with product quality or product performance, including defects, caused by us or our suppliers could result in a decrease in customers and sales, unexpected expenses and loss of market share and Item 1A Risk Factors Our business and industry are subject to complex and costly regulations. If government regulations are interpreted or enforced in a manner adverse to us or our business, we may be subject to enforcement actions, penalties, exclusion and other material limitations on our operations.

PET Manufacturing Facilities

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

agent distributors that operate radiopharmacies. See Research and Development Flurpiridaz F 18 Phase 3 Program.

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Research and Development

For the years ended December 31, 2015, 2014 and 2013, we invested $14.4 million, $13.7 million, and $30.5 million, respectively, in research and development, or R&D. Our R&D team includes our medical affairs and medical information functions, which educate physicians on the scientific aspects of our commercial products and the approved indications, labeling and the receipt of reports relating to product quality or adverse events. We have developed a pipeline of three potential cardiovascular imaging agents which were discovered and developed in-house and which are protected by patents and patent applications we own in the United States and numerous foreign jurisdictions.

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

Flurpiridaz F 18 PET Perfusion Agent Myocardial Perfusion

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

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

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

Flurpiridaz F 18 Clinical Overview

We submitted an Investigational New Drug Application, or IND, for flurpiridaz F 18 to the FDA in August 2006. Our clinical program to date has consisted of three Phase 1 studies, a Phase 2 clinical trial, conducted from 2007 to 2010, involving 176 subjects who received PET MPI performed with flurpiridaz F 18 and completed the trial, and a Phase 3 clinical trial conducted from 2011 to 2013 involving 755 subjects who received PET MPI procedures with flurpiridaz F 18, completed the trial and were included in the efficacy analysis.

Flurpiridaz F 18 Phase 2 Trial

We evaluated flurpiridaz F 18 in a Phase 2 trial consisting of 176 subjects who completed the trial from 21 centers. These subjects underwent both SPECT and PET MPI with flurpiridaz at rest and at stress and were evaluated for safety. Of these subjects, 86 underwent coronary angiography, the current standard clinical method

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for diagnosing coronary artery disease. Coronary angiography is an invasive procedure using fluoroscopy performed in a cardiac catheterization lab while the subject is under mild sedation. These 86 subjects formed the population for evaluating diagnostic performance.

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

The Phase 2 trial results showed the following:

- a significantly higher percentage of images were rated as either excellent or good quality with PET imaging, compared to SPECT imaging for stress images (98.8% vs. 84.9%, p<0.01) and rest images (95.3% vs. 69.8%, p<0.01);

- diagnostic certainty of interpretation, the percentage of cases with definitely abnormal or definitely normal interpretation, was significantly higher for flurpiridaz F 18 compared to SPECT (90.7% vs. 75.6%, p<0.01);

- the area under the ROC curve (the relative operating characteristic curve comparing the true positive rate to the false positive rate for coronary artery disease diagnosis) was significantly higher for flurpiridaz F 18 than SPECT (0.82±0.05 vs. 0.70±0.05, p<0.05), indicating higher diagnostic performance;

- superiority for sensitivity (that is, the ability to identify disease) with flurpiridaz F 18 imaging was significantly higher than SPECT (78.8% vs. 61.5%, p=0.02);

- a trend toward higher specificity (that is, the ability to rule out disease) was noted, although the advantage was not statistically significant in the study; and

- no drug-related serious adverse events were observed, demonstrating a positive safety profile for PET MPI imaging with flurpiridaz F 18.

FlurpH="100%">*To be filed, if necessary, subsequent to the effectiveness of this Registration Statement by an amendment to this Registration Statement or incorporated by reference to a Current Report on Form 8-K in connection with an offering of securities.