POSITRON CORP
Form 10-K/A
September 15, 2011

U.S. SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K/A
Amendment No. 1

Ÿ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2010
Commissions file number: 0-24092

Positron Corporation
A Texas Corporation
7715 Loma Ct. Suite A, Fishers, IN. 46038 (317) 576-0183

IRS Employer Identification Number: 76-0083622

Securities registered under Section 12(b) of the Exchange Act: None.

Securities registered under Section 12(g) of the Exchange Act: Common Stock, $0.01 par value.

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

Indicate by a check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. o

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 o

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 o No o

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. o

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", or "smaller reporting company in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o	Smaller reporting Company x

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

Issuer's revenues for fiscal year ended December 31, 2010: $4,622,691.

Aggregate market value of common stock held by non-affiliates of the Registrant as of June 30, 2010: $66,598,674.As of March 31, 2011 there were 784,727,497 shares of the Registrant's common stock, $.01 par value outstanding.

Explanatory Note: The purpose of this Amendment on Form 10-K/A is to address certain comments received by the Securities and Exchange Commission regarding our disclosures concerning our beneficial ownership and to revise certain other items therein.

PART I

Forward-Looking Statements

This report contains various forward-looking statements regarding our business, financial condition, results of operations and future plans and projects. Forward-looking statements discuss matters that are not historical facts and can be identified by the use of words such as “believes,” “expects,” “anticipates,” “intends,” “estimates,” “projects,” “can,” “may,” “will,” “would” or similar expressions. In this report, for example, we make forward-looking statements regarding, among other things, our expectations about the rate of revenue growth in specific business segments and the reasons for that growth and our profitability, our expectations regarding an increase in sales, strategic traction and sales and marketing spending, uncertainties relating to our ability to compete, uncertainties relating to our ability to increase our market share, changes in coverage and reimbursement policies of third-party payors and the effect on our ability to sell our products and services, the existence and likelihood of strategic acquisitions and our ability to timely develop new products or services that will be accepted by the market.

Although these forward-looking statements reflect the good faith judgment of our management, such statements can only be based upon facts and factors currently known to us. Forward-looking statements are inherently subject to risks and uncertainties, many of which are beyond our control. As a result, our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under the caption “Risk Factors.” For these statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. You should not unduly rely on these forward-looking statements, which speak only as of the date on which they were made. They give our expectations regarding the future but are not guarantees. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

Corporate Information

Positron Corporation (the "Company" or “Positron”) was incorporated as a Texas corporation in 1983 with its main offices in Fishers, Indiana. Unless the context requires otherwise, in this report the terms “we,” “us” and “our” refer to Positron Corporation.

On June 5, 2008, the Company acquired all of the issued and outstanding stock of Dose Shield Corporation, an Indiana corporation (“Dose Shield”) for 80,000,000 shares of Common Stock), deliverable in two equal tranches, the first 40,000,000 shares at the closing, the second contingent upon verification by an independent third party that Dose Shield’s Cardio-Assist device is in commercially reasonable working order and is ready for resale not later than December 31, 2009; and (ii) cash in the amount of $600,000. In addition, the Company agreed to pay royalties equal to 1.5% of net revenues generated from all future sales of all Dose Shield equipment sold by Positron Pharmaceuticals following the Closing. The Nuclear Pharm-Assist™ system is designed to support the staff of nuclear medicine departments and nuclear pharmacies. The Nuclear Pharm -Assist™ compounds kits, fills vials and syringes, assays vials and syringes and dispenses vial and syringes in a shielded container. The unique design reduces worker radiation exposure and repetitive motion injuries. The shielding is integrated into the design and is considered standard.

On June 5, 2006, the Company, through a minority-owned subsidiary of the Company, Imaging PET Technologies, Inc. (“IPT”), and Quantum Molecular Pharmaceuticals Inc., a Canadian radiopharmaceutical corporation (“QMP”) acquired all of the operating assets of IS2 Medical Systems Inc., a developer and manufacturer of nuclear imaging devices based in Ottawa, Ontario, Canada (“IS2”). Initially, the Company and QMP held 49.9% and 50.1%, respectively, of the total outstanding capital stock of IPT. On January 26, 2007, the Company acquired the remaining 50.1% of the capital stock of IPT from Imagin Diagnostic Centers, Inc. In October 2008, the Company closed the IPT

facility in Canada. At December 31, 2010 and 2009, IPT continued to operate as a separate legal and accounting entity.

On November 18, 2008, Solaris Opportunity Fund, L.P. ("Solaris") became the Company's controlling shareholder, holding approximately 60% of the Company's voting capital stock at that time. Upon consummation of a Securities Exchange Agreement, Imagin Molecular Corporation, a publicly owned Delaware corporation ("Imagin") transferred and assigned all of its rights title and interest in two notes receivable due from the Company ("Note 1 and Note 2") and related pledged securities to Solaris in exchange for the return of the 20,000,000 shares of Imagin's common stock and 4,387,500 shares of Imagin's Series A Preferred Stock and the retirement and satisfaction of any obligations to the advances made in the amount of $200,000 to Imagin by Solaris. Simultaneously therewith, Solaris exchanged Note 1, Note 2 plus accrued interest and the Pledged Shares and the retirement and satisfaction of any obligations to the advances made to the Company in the aggregate amount of $1,155,000 for the issuance of 100,000 shares of the Company's Series S Preferred Stock (the "Exchange").

In early 2009, the Company moved all aspects its corporate administration, purchasing and logistics/shipping functions from its Houston, Texas facility to its Fishers, Indiana location. The Company continues to maintain its parts repair facility in the Houston area. Additionally, the Company also relocated Positron's PET Service Part Depot to its Niagara Falls, New York location. In second quarter 2010, the Company's accounting and corporate administration was moved to its Westmont, Illinois location.

Item 1. Business

General

Overview

Positron Corporation (the "Company" or "Positron") is a molecular imaging company that provides unique solutions for the Nuclear Medicine community through the production and distribution of molecular imaging devices and radiopharmaceutical products. Positron's proprietary product lines and services include; the Attrius®, a dedicated PET imaging system; PosiStar™, a world-class clinical, technical and service customer care plan; PosiRx™, a system that automates the elution, preparation and dispensing processes for radiopharmaceutical agents used in molecular imaging; and the Tech-Assist™, a PET infusion and shielding system.

Major developments and milestones achieved by Positron Corporation during 2010 include:

- Launch of the Attrius® – the only FDA approved standalone PET scanner optimized for cardiac imaging;
- Attrius® named "Most Innovative Device of 2010" by Frost & Sullivan;
- 15 Attrius® PET systems under sales contracts, 5 systems installed and revenue recognized;
- Signed co-development agreement with Covidien to develop technology for an innovative distribution model of radiopharmaceuticals based on a customized Positron device;
- Completed initial development of PosiRx™ formerly named Cardio-Assist™ – Positron's proprietary automated compounding and unit dose dispensing device;
- Acquired pharmaceutical manufacturing facility for development of radiopharmaceuticals and contract manufacturing;
- Received two U.S. patents for Positron's proprietary technologies – with several additional patents pending; and,
- Significantly improved the Company's balance sheet, ending the year effectively debt free.

Market Opportunity

Molecular Imaging Devices for Cardiology

Cardiovascular diseases (CVD) are the cause of death of approximately 17 million people worldwide each year; almost one-third of all deaths. By 2030, almost 23.6 million people will die annually from CVD (WHO, September 2009). Heart disease is the leading cause of death for both men and women in the USA – 34.2% of all deaths. Estimated 80 million adults within the United States, or approximately 1 in 3 of the total population, were affected with CVD (Heart Disease and Stroke Statistics – 2009 Update, www.americanheart.org). In 2010, heart disease cost the United States $316.4 billion, including the cost of health care services, medications, and lost productivity (Centers for Disease Control and Prevention).

Diagnostic imaging facilitates the early diagnosis of diseases and disorders, potentially minimizing the scope, cost and amount of care required, and potentially reducing the need for more invasive procedures. Nuclear imaging uses very low-level radioactive material, called radiopharmaceuticals, injected to a patient. The radiopharmaceuticals are specially formulated to concentrate temporarily in the specific part of the body to be studied. The radiation signals emitted by the materials are then converted into an image of the body part or organ. Nuclear imaging, in contrast to other diagnostic imaging modalities, shows not only the anatomy or structure of an organ or body part, but also its function—including blood flow, organ function, metabolic activity and biochemical activity. In cardiology, nuclear medicine provides the most accurate non-invasive tests for identifying narrowed coronary arteries, mild cholesterol build-up or diffuse coronary vascular disease that are responsible for most heart attacks. Management of coronary disease (CAD) currently utilizes noninvasive diagnostic testing as a ‘‘gatekeeper’’ and invasive coronary arteriography,

when results are abnormal, to provide a definitive diagnosis of CAD. There are two major modalities in nuclear medicine imaging, gamma cameras and Positron Emission Tomography (PET), both of which are used for cardiovascular procedures. The most widely used imaging acquisition technology utilizing gamma cameras is single photon emission computed tomography, or SPECT.

Though PET tests are much more accurate and has been shown to reduce long-term costs, the nuclear cardiology imaging has been dominated by SPECT. This imbalance is a result of lower prices of SPECT cameras and decades long preferable reimbursement rates for cardiac SPECT procedures. The Company believes that recent market dynamic changes, including the dramatic increase of reimbursement rates for cardiac PET procedures, SPECT reimbursement cuts and the world shortage of the molybdenum-99 isotope used in cardiac SPECT, will significantly improve the economics of cardiac PET imaging and make PET technology much more competitive and appealing to cardiologists.

1

Our Products

Since 1983, the Company has been designing, manufacturing, marketing and servicing advanced molecular imaging devices / software for cardiology utilizing PET technology products such as Auricle™, HZ™, HZL™, mPOWER™ and th new Attrius® and since 2006, SPECT technology under the trade name Pulse CDC™. Positron's PET and SPECT and cardiac molecular imaging devices are installed in more than 175 hospitals and physician offices around the world.

Positron Corporation is the only company in the world that offers a dedicated PET scanner. Positron's Attrius® PET scanner can be used for all imaging modalities and has proprietary software that is optimized for cardiac studies. Positron manufactures the Attrius® through its joint venture, Neusoft Positron Medical Systems, based in Shenyang, China.

Positron has upgraded its PET scanner to accommodate the growing need for an inexpensive, high quality molecular imaging device in today's challenging economy. Positron's technology for PET imaging provides superior image quality comparable to PET/CT manufacturers with a fraction of their price. In addition, Positron offers a software patient management solution to improve patient care. The Attrius® Cardiac PET system received FDA approval in 2009 and has been marketed in the U.S. since March 2010. The Attrius® has attracted significant interest from cardiologists, and Positron sold 15 scanners and installed 5 in 2010.

For the Attrius® PET, Positron was recognized with the 2010 Frost & Sullivan Award for New Product Innovation in the cardiac molecular imaging devices market. Each year, Frost & Sullivan presents this award to the company that has demonstrated superior performance against key competitors based on the following benchmarking criteria: innovative element of the product; leverage of leading edge technologies; value added features/benefits; increased customer value; and customer acquisition/penetration potential. Frost & Sullivan acknowledge that Attrius® is the ideal solution for cardiologists and hospitals looking to add high accuracy, cost effective imaging technology.

Radiopharmaceutical Devices

The U.S. market for SPECT and PET radiopharmaceuticals is large and potentially fast growing: sales reached $1.16 billion in 2009 and are expected to rise to $4.76 billion by 2017 (Bio-Tech Systems, Report 310). In 2009, SPECT pharmaceuticals sales were $817 million and by 2017 are expected to reach $1,737 million.

Tc-99m accounts for 82 percent of all diagnostic radiopharmaceutical injections each year (Arlington Medical Resources, Inc., The Imaging Market Guides – United States Edition, 2008). A current distribution model of Tc-99m is based on centralized radio pharmacies which provides scheduled deliveries of unit doses of radiopharmaceuticals to their clients located in a 70-75 miles range.

Positron has completed initial development of a proprietary automated radiopharmaceutical system and has completed testing validation at the University of New Mexico in March 2011. The PosiRx™, formerly named Cardio-Assist provides on-site preparation and dispensing of cardiovascular radiopharmaceutical agents used in SPECT imaging and eliminates the need in centralized radiopharmacies. The device automates procedures that currently are performed manually: elutes generator, compounds kits, fills syringe, assays and dispenses the unit dose into a syringe shield. A nuclear cardiology facility equipped with the PosiRx™ has 24/7 unit dose accessibility and reliability of an on-site supply. A self-contained device, the PosiRx™ assists in the compliant with all regulations that involve compounding and dispensing sterile injectables and meets or exceeds guidelines set forth by the United States Pharmacopeia (USP-797). The Company has begun marketing the device in the first quarter of 2011.

Positron has signed a co-development agreement with Covidien to develop technology for an innovative distribution model of radiopharmaceuticals based on a customized Positron device. Positron will develop, prototype, custom manufacture, validate and test this new nuclear pharmacy automated equipment. Positron will produce the equipment customized to fit, manipulate and function with Covidien radiopharmaceutical products.

Positron also offers a PET infusion system under the name Tech-Assist™, for dispensing F-18 radiopharmaceuticals. This device has been proven to significantly reduce radiation exposure to personnel and allows for patient specific dosing. The Tech-Assist does not require any special syringes or tubing sets as part of its daily use, keeping operational costs low.

Radiopharmaceuticals

In August 2010, Positron opened a cGMP (current Good Manufacturing Practices) ready facility in Indiana for manufacturing of both radioactive and non-radioactive pharmaceutical products and devices.

While the Company intends to focus on small batch, radioactive PET products, the facility is also planned to be utilized to support current and future Positron equipment and expand into new markets. The approximately 10,000 square foot facility, with room for expansion, contains ample clean room space and laboratory equipment for production of pharmaceuticals and support products for both industrial and medical use.

3

Competitive Strengths

We believe that our Company has the following competitive strengths:

- Well-Known Name Among Cardiologists. The high count-rate capability and sensitivity of Positron's PET systems result in good diagnostic accuracy, faster imaging and ability to use short half-life radiopharmaceuticals, which made Positron's PET systems a system of choice for certain cardiac applications.

- The Only Cardiac PET System on the Market. All major PET manufacturers have discontinued manufacturing of stand-alone PET systems, offering very expensive PET combined with Computerized Tomography (PET/CT) instead. In cardiac applications, the Positron's Attrius® provides image quality comparable to PET/CT at significantly lower price. It also significantly reduces radiation exposure compared to PET/CT and even SPECT. A small footprint and affordable price makes it ideal for imaging clinics.

- Cardiac Specific Software. The Attrius® provides a robust, cardiac specific imaging software package designed to ensure effortless interpretation for today's most challenging clinical cases for nuclear cardiologists. Heart disease specific software includes the ability to monitor therapy, coronary artery overlay display, and open architecture for new protocol development and customization and motion correction software.

- Unique Automated Radiopharmaceutical System. Positron's "virtual pharmacy" solution PosiRx™, enables the automation of all critical steps in the prepraationand dispensing of radiopharmaceuticals in the pharmacy and/or practice setting. The PosiRx™ system provides unprecedented "unit dose" flexibility to imaging providers at the touch of a button, 24/7. The device automates basic radiopharmaceutical compounding procedures and meets the requirements of the United States Pharmacopeia Chapter 797 compounding regulations as a compounding aseptic containment isolator (CACI) and provides the ISO Class 5 environment necessary for USP-797 compliance..

- Value-Added Offering of Complimentary Products to Customers. Addition of complementary products, such as maintenance service, radiopharmaceutical dispensing devices and, potentially, radiopharmaceuticals, enhance the value of the offering to Positron's customers.

Business Strategy

We intend to increase our revenues by:

- Launch of the Attrius® – the only FDA approved standalone PET scanner optimized for cardiac imaging;
- Attrius® named "Most Innovative Device of 2010" by Frost & Sullivan;
- 15 Attrius® PET systems contracts`, 5 systems installed and revenue recognized;
- Signed co-development agreement with Covidien to develop technology for an innovative distribution model of radiopharmaceuticals based on a customized Positron device;
- Completed initial development of PosiRx™ formerly named Cardio-Assist™ – Positron's proprietary automated compounding and unit dose dispensing device;
- Acquired pharmaceutical manufacturing facility for development of radiopharmaceuticals and contract manufacturing;
- Received two U.S. patents for Positron's proprietary technologies – with several additional patents pending; and,

- Significantly improved the Company's balance sheet, ending the year effectively debt free.

Sales and Marketing

To market its equipment and services, Positron employs an internal sales and marketing team dedicated to promote, educate and sell Positron products. Positron is also able to rely on referrals from users of its existing base of installed scanners and cameras, trade show exhibits, trade journal advertisements, clinical presentations at professional and industry conferences, and published articles in trade journals. The Company's sales personnel vary in geographic location and/or market expertise.

The Company has signed on as a Corporate Partner with MedAxiom, a comprehensive subscription-based service provider and information resource exclusively for cardiology practices. MedAxiom's network is compiled of over 300 practices representing 5,400 physicians covering 45 states across the U.S. Aligning with MedAxiom provides Positron direct access to most cardiology practices in the country, many of them are in the immediate market for Positron's products.

Positron sells and/or distributes its products and services directly to end-users. We have certain experience with one-level distribution channels (our SPECT cameras were previously sold to end-users and to dealers). Selling to dealers helped to increase the number of cameras sold. However, such sales negatively impacted profit margin and left Positron with less recurring revenue from the service contracts.

There is no assurance that the Company's marketing and distribution strategy is sufficient

Customer Care, Service and Warranty

Positron has implemented PosiStar™, a complete customer care plan that offers full clinical support from Positron's experienced clinical and technical staff and industry luminaries that consult for the Company or are affiliated though Positron's customer network. PosiStar™ Customer Care provides; physician interpretation training, nurse training, billing and prior-authorization training, physician over reads, post install, 24/7 clinical and service support, priority response with after hours maintenance/service available, uptime guarantees and software upgrades, remote access diagnostic/maintenance capabilities.

The Company has field service engineers who have primary responsibility for supporting and maintaining the Company's installed equipment base. In addition, the Company has field engineers involved in site planning, customer training, sales of hardware upgrades, sales and administration of service contracts, telephone technical support and customer service.

The Company services domestic customers of our systems remotely through Internet access that facilitates system diagnosis several times without the need for field service or repair. When physical repair is required, our modular part replacement capability allows our field service engineers to perform field repairs that minimize customer downtime.

The Company typically provides a one-year warranty to purchasers of our equipment. Following the warranty period, the Company offers purchasers a comprehensive service contract under which the Company provides all parts and labor, system software upgrades and unlimited service calls. At December 31, 2010, the Company had twenty-eight (28) full service agreements under contract, and three (3) parts and labor contracts.

The Company's service goal is to maintain maximum system uptime. Success of a clinical site is largely dependent on patient volume during normal working hours and, therefore, equipment uptime and reliability are key factors in this success. Records compiled by the Company show an average uptime of more than 95% for all installed PET scanners; a study of 50 SPECT cameras yielded an average uptime of all units of 99.94 % and less than one service related incoming call per month.

As we have expanded our business model from primary manufacturing and selling equipment to primary service of our products, when a major share of revenue is expected from services to the clients, customer service will play a more important role in the Company. Due to the Company's expertise and access to parts we expect to service all new PET scanners sold.

Competition

The Company faces no direct competition from other manufacturers of PET scanners as it offers the only commercial standalone PET scanner, Attrius®. However, the Company has experienced , competition from used PET/CT scanners although the remaining supply of used PET/CT systems is believed to be extremely low. The Company does not believe that MRI and CT scan imaging represent significant competing technologies, but potentially complementary technologies to PET, since PET, MRI and CT scans each provide information not available from the other modalities. Computed tomography angiography ("CTA") was once seen by some cardiologists to be competitive with PET myocardial perfusion imaging; however, there is an increasing public concern about a high radiation exposure of CT and no substantial movement into this modality.

In 2001-2002, GE, Siemens and Philips introduced PET/CT systems that combine CT scanning and PET in one unit. Since then production of standalone PET scanners have been discontinued and replaced by high priced PET/CT systems with costs much greater than Positron's Attrius® PET system. PET/CT integrates functional (PET) and structural (CT) information into a single scanning session, allowing fusion of the PET and CT images and thus improving lesion localization and interpretation accuracy. The CTscan is also used for attenuation correction, ultimately leading to high patient throughput. These combined advantages have rendered PET/CT a preferred imaging modality over standalone PET except in the imaging of cardiac studies. All major PET manufacturers, except Positron, pursue the similar strategies of developing more and more sophisticated and expensive whole-body PET/CT scanners. A hospital or medical imaging clinic with a whole-body PET/CT device has flexibility of using the scanner for oncology, cardiology or neurology purposes. However, the redundancy of functions, as well as the high price and large size, has negative impact on usage of PET scanners by specialty physicians (cardiologists, neurologists, urologists, etc.).

Though PET/CT has been commercially accepted, the clinical benefits and the need for this technology in cardiology imaging remain controversial and are debated. Leading cardiologists believe that combined PET/CT is not important in imaging myocardial perfusion. The heart does not require that fine level of resolution to diagnose coronary disease due to the thickness of the heart. Significant limitations of cardiac PET/CT are also respiratory motion and metallic artifacts, which can result in artifactual PET defects in up to 40% of patients, and these defects are moderate to severe in 23%. An interest in PET by cardiologists has increased significantly since 2009 boosted by preferable reimbursement rates and shortage of Tc-99m, a major cardiac SPECT radiopharmaceutical. Positron Corporation has been exploiting this raise of the demand by cardiologists and lack of the supply of affordable PET systems on the market by offering its cardiac specific, standalone Attrius® PET.

The Radiopharmaceutical Delivery is dominated today by Cardinal Health (160 nuclear pharmacies and 26 cyclotron-based PET radiopharmaceutical manufacturing facilities), PETnet Solutions, a fully owned subsidiary of Siemens Medical Solutions USA (52 radiopharmacies and distribution centers), Triad Isotopes (63 radiopharmacies after acquiring a Covidien's network and 6 cyclotrons), and GE healthcare (31 radiopharmacies). There are also about 73 independent radiopharmacies and 70 institutional radiopharmacies (affiliated with major medical schools).

Radiopharmaceuticals for cardiac applications are prepared in radiopharmaceutical generators, Tc-99m generators for SPECT (manufactured by Covidien and Lantheus) and Rb-82 generators for PET (Bracco Diagnostics). Rb-82 has a half-life of only 75 seconds, and Rb-82 generators are delivered by Bracco directly to end users 13 times per year.

Tc-99m has a half-life of 6 hours, and centralized radiopharmacies use Tc-99m generators to deliver unit doses of Tc-99m based radiopharmaceuticals to customers. Centralized radiopharmacies incur very high fixed costs (around $1.0 million per year) and freight costs (two-three times-a-day deliveries to each client) and are affected by geographical factors: clients have to be in a 70-75 miles proximity to the pharmacy due to a short half-life of Tc-99m. The Positron Corporation's Cardio-Assist does not have these limitations, as the radiopharmaceutical unit dose

drawing devices can be placed directly into physicians' offices with once-a-week deliveries. Positron has signed a co-development agreement with Covidien to develop technology for an innovative distribution model of radiopharmaceuticals based on a customized Positron's device.

Until lately, cardiac radiopharmaceuticals have been protected by patents combined with exclusive distribution relationships. Since the end of 2008, Rb-82 (Cardiogen®) and Tc-99m Sestamibi (Cardiolite®) are available generically. This is a landmark event that opened the billion dollar nuclear cardiology radiopharmaceutical market.

Many of our competitors enjoy significant competitive advantages over us, including: greater name recognition; greater financial, technical and service resources; established relationships with healthcare professionals; established distribution networks; additional lines of products and the ability to offer rebates or bundle products to offer discounts or incentives; and greater resources for product development and sales and marketing. See “Item 1. Description of Business—Risk Associated with Business Activities—Substantial Competition and Effects of Technological Change”.

Third-Party Reimbursement

Our customers typically rely on the Medicare and Medicaid programs and private payors for reimbursement. As a result, demand for our products is dependent in part on the coverage and reimbursement policies of these payors. Third party coverage and reimbursement is subject to extensive federal, state, local, and foreign regulation, and private payor rules and policies. In many instances, the applicable regulations, policies and rules have not been definitively interpreted by the regulatory authorities or the courts, and are open to a variety of interpretations and are subject to change without notice.

The scopes of coverage and payment policies vary among third-party private payors. For example, some payors will not reimburse a provider unless the provider has a contract with the payor, and in many instances such payors will not enter into such contracts. Other payors prohibit reimbursement unless physicians own or lease our scanners and cameras on a full-time basis, or meet certain accreditation or privileging standards. Such requirements and limitations can significantly restrict the types of business models we can successfully utilize.

Medicare reimbursement rules impose many standards and policies on the payment of services that our customers provide. For instance, the Medicare prohibition on the “mark-up” of diagnostic tests can restrict what a physician may charge Medicare for diagnostic tests. Medicare also imposes medical necessity and other standards on physician and facilities that bill Medicare for services.

Any limitation of Medicare, Medicaid or private payer coverage for PET or SPECT procedures using will likely have a material adverse effect on the Company’s business, financial condition, results of operations and cash flows.

On October 30, 2010, Centers for Medicare & Medicaid Services (CMS) released their 2011 Medicare Physician Fee schedule which outlines the payment rates for medical services paid to private physicians in the outpatient office setting. This fee schedule stated that Myocardial PET perfusion imaging was decreased 22.53% to $1,107.36 per study. The Schedule also states that Cardiovascular SPECT reimbursement for outpatient cardiology practices billing under CPT codes has been reduced by 1.72%.

Manufacturing

Our manufacturing strategy combines our internal design expertise and proprietary process technology with strategic outsourcing to achieve cost efficiencies. All of the Company’s PET scanners are manufactured through its joint venture, Neusoft Positron Medical Systems, at its development and manufacturing facility in Shenyang, China. The manufacturing of the PosiRx™ line takes place in Fishers, Indiana. Production of radiopharmaceuticals and the development and manufacturing of radiopharmaceutical products and devices will take place in Crowne Point, Indiana.

The Company expects to continue outsourcing additional components and processes to gain efficiencies and cost savings. The Company expects to perform subassembly and final system performance tests, packaging and labeling at our facility. The Company provides connectivity solutions which include consulting and configured computers. The Company also sells accessories which are outsourced and include printers, equipment for handling and measuring radioactive materials, and software for the cameras and systems.

The Company and its third-party manufacturers are subject to the FDA's Quality System Regulation, state regulations, and regulations promulgated by the European Union.

Joint Venture with Neusoft Medical Systems Co., Ltd.

On June 30, 2005 the Company entered into a Joint Venture Contract with Neusoft Medical Systems Co., Inc. of Shenyang, in the People's Republic of China ("Neusoft"). Pursuant to the Joint Venture Contract the parties formed a jointly-owned company, Neusoft Positron Medical Systems Co., Ltd. , to engage in the manufacturing of PET and CT/PET medical imaging equipment. The JV Company received its business license and was organized in September 2005.

The parties to the joint venture contributed an aggregate of US $2,000,000 in capital contributions. Neusoft's aggregate contribution to the capital of the JV Company was 67.5% of the total registered capital of the Company, or US$ 1,350,000, and was made in cash. The Company's aggregate contribution to the capital of the JV Company was 32.5% of the total registered capital of the JV Company, or US$ 650,000, of which US$ 250,000 was made in cash, and US$ 400,000 was made in the form of a technology license. Positron has transferred to the JV Company certain of its PET technology. During 2008-2009, as a result of additional capital contributions by Neusoft, the Company’s share in JV Company decreased to 1%.The parties share the profits, losses and risks of the JV Company in proportion to and, in the event of losses, to the extent of their respective contributions to the registered capital of the JV Company.

Under its Joint Venture Contract with Neusoft, the Company has the exclusive right to sell PET system products developed by the JV Company in Canada, the U.S. and Mexico under its registered trademarks . Neusoft has the exclusive right to sell products developed by the JV Company in China under its registered trademarks. Each of Neusoft and the Company has the right to sell products developed by the JV Company in the countries and regions worldwide with the exception of China, Canada, the U.S. and Mexico where select exclusive rights apply.

The joint venture obtained the FDA 510k regulatory approval of Attrius® Cardiac PET in April 2009.

While the parties believe that the joint venture will meet their objectives, there can be no assurance that the joint venture will meet such objectives, including production and timely delivery of PET systems.

Research and Development

The Company’s research and development expenses were approximately $1,275,893 and $178,000 for the years 2010 and 2009, respectively. The research and development activities have been focused on development of radiopharmaceutical delivery systems. We continue to improve and/or customize our radiopharmaceutical equipment to fit it to new products and meet sometimes unique user requirements. In addition, there have been significant resources allocated in the initial start up, preparation and regulatory compliance of the Company’s radiopharmaceutical manufacturing facility. We are also developing additional software and hardware for our PET scanner for additional functions that enhance performance and diagnostic efficacy and also in preparation for new cardiac radiopharmaceuticals that are in a pipeline of a major radiopharmaceutical manufacturer. These research and development activities are costly and critical to the Company’s ability to maintain, develop and improve its “state of the art” products. The Company’s inability to conduct such activities in the future may have a material adverse affect on the Company’s business as a whole.

Patent, Trademarks and Royalty Arrangements