

IsoRay, Inc.
Form POS AM
February 16, 2007

As filed with the Securities and Exchange Commission on February 16, 2006
Registration Statement No. 333-129646

SECURITIES AND EXCHANGE COMMISSION

**POST-EFFECTIVE
AMENDMENT NO. 5 TO
FORM SB-2
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

ISORAY, INC.
(Name of Small Business Issuer in its Charter)

Minnesota (State of Incorporation)	3841 (Primary Standard Industrial Classification Code Number)	41-1458152 (IRS Employer ID No.)
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**350 Hills Street, Suite 106
Richland, WA 99354
(509) 375-1202**
(Address and Telephone Number of Principal Executive Offices and Principal Place of Business)

**Roger Girard, CEO
350 Hills Street, Suite 106
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Edgar Filing: IsoRay, Inc. - Form POS AM

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Approximate date of commencement of proposed sale to the public: From time to time.

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

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act of 1933, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act of 1933, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act of 1933, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If delivery of the prospectus is expected to be made pursuant to Rule 434, check the following box. o

CALCULATION OF REGISTRATION FEE

Title Of Each Class Of Securities To Be Registered	Amount To Be Registered ⁽¹⁾	Proposed Maximum Offering Price Per Unit	Proposed Maximum Aggregate Offering Price	Amount Of Registration Fee
Common stock, \$0.001 par value, issuable upon conversion of preferred stock	43,219 \$	5.38 ⁽²⁾ \$	232,518 \$	24.88 ⁽³⁾
Common stock, \$0.001 par value, issuable upon exercise of stock options	218,454 \$	5.38 ⁽²⁾ \$	1,175,283 \$	125.76 ⁽³⁾
Common stock, \$0.001 par value	4,004,264 \$	5.45 ⁽⁴⁾ \$	21,823,238 \$	2334.87 ⁽³⁾
Common stock, \$0.001 par value, issuable upon exercise of warrants	371,163 \$	5.38 ⁽²⁾ \$	1,996,857 \$	213.66 ⁽³⁾
Total	4,637,100		\$ 25,227,896	\$ 2699.17⁽³⁾

⁽¹⁾Includes shares of our common stock, par value \$0.001 per share, which may be offered pursuant to this registration statement, a portion of which shares are issuable upon conversion of preferred stock and convertible debentures and exercise of warrants and stock options held by the selling shareholders. In addition to the shares set forth in the table, the amount to be registered includes an indeterminate number of shares, including those issuable upon conversion of the preferred stock and convertible debentures and exercise of the warrants and stock options, as such number may be adjusted as a result of stock splits, stock dividends and similar transactions in accordance with Rule 416.

⁽²⁾Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended, based upon the average of the bid and asked prices of the Registrant's common stock on November 7, 2005.

⁽³⁾ Previously paid.

⁽⁴⁾ Represents a combination of (2) and (5).

⁽⁵⁾Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended, based upon the average of the bid and asked prices of the Registrant's common stock on March 20, 2006.

ISORAY, INC.
4,637,100 Shares
Common Stock

This prospectus relates to the sale by the selling shareholders of up to 4,637,100 shares of our common stock, \$0.001 par value. The 4,637,100 shares being registered consist of the following: up to 4,004,264 shares of common stock, up to 43,219 shares of common stock underlying our convertible preferred stock (including up to 6,967 shares of common stock issuable upon conversion of preferred stock following the exercise of warrants to acquire our preferred stock), up to 371,163 shares of common stock underlying warrants to purchase common stock and up to 218,454 shares of common stock underlying options to purchase common stock, all currently held by the selling shareholders. The preferred stock is convertible into our common stock at one (1) share of common stock for each preferred share converted, the warrants are exercisable at prices ranging from \$0.70 to \$4.15 (excluding a warrant issued at an exercise price of \$10.00 for 12,500 shares of common stock) with expiration dates ranging from March 26, 2007 to May 10, 2008 and the options are exercisable at prices ranging from \$1.19 to \$2.00 per share with expiration in July of 2015.

The prices at which the selling shareholders may sell shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive any proceeds from the sale of our shares by the selling shareholders. The selling shareholders may be deemed underwriters of the shares of common stock which they are offering. We will pay the expenses of registering these shares.

Our common stock is listed on the OTC Bulletin Board under the symbol "ISRY.OB." On February 13, 2007, the closing price of our common stock was \$4.90 per share.

No underwriter or other person has been engaged to facilitate the sale of shares of common stock in this offering.

**INVESTING IN OUR SECURITIES INVOLVES RISKS. SEE "RISK FACTORS"
BEGINNING ON PAGE 4.**

**NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES
COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE
ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY
IS A CRIMINAL OFFENSE.**

The date of this prospectus is February 16, 2007.

**350 Hills Street, Suite 106
Richland, WA 99354
(509) 375-1202**

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ABOUT THIS PROSPECTUS

You should rely only on the information contained in this prospectus. We have not, and the selling shareholders have not, authorized anyone to provide you with information that is different from that contained in this prospectus. The selling shareholders are offering to sell shares of common stock and seeking offers to buy shares of common stock only in jurisdictions where offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our common stock.

Except as otherwise indicated, market data and industry statistics used throughout this prospectus are based on independent industry publications and other publicly available information. Although we believe that these data and statistics are reasonable and sound, they have been prepared on the basis of underlying data to which we do not have access, and which we cannot independently verify.

For definitions of many of the technical terms used throughout this prospectus, see page 2.

PROSPECTUS SUMMARY

The following summary highlights selected information contained in this prospectus. This summary does not contain all the information you should consider before investing in our common stock. Before making an investment decision, you should read the entire prospectus carefully, including the "RISK FACTORS" section, the financial statements and the notes to the financial statements. As used throughout this prospectus, the terms "IsoRay," the "Company," "we," "us" and "our" refer to IsoRay, Inc.

Our Business

We are a medical technology company focusing on innovative treatments for prostate cancer and other solid cancer tumors, with a goal of improved patient outcomes. Our wholly-owned subsidiary, IsoRay Medical, Inc., a Delaware corporation ("Medical"), began selling its initial product, the Food and Drug Administration approved IsoRay Cesium-131 brachytherapy seed (the "IsoRay ¹³¹Cs seed"), in October 2004 for the treatment of prostate cancer. Cesium-131 or ¹³¹Cs is an isotope of the element Cesium that gives off low energy, "soft" x-rays as it decays killing diseased tissue by irradiating it where it is placed. Brachytherapy seeds allow physicians to place ¹³¹Cs or another radioactive isotope within the body to kill cancerous tissue. Our management believes that the clinical benefits of Cesium-131 will enable us to capture market share within the existing brachytherapy market, which uses the radioactive isotopes Palladium-103 and Iodine-125.

Our Corporate History

We were incorporated under Minnesota law in 1983. Since 1998 and until our merger with Medical, we had no significant operations. On July 28, 2005, our subsidiary, Century Park Transitory Subsidiary, Inc. merged into IsoRay Medical, Inc., making Medical our wholly-owned subsidiary.

Medical was formed under Delaware law on June 15, 2004 and merged with IsoRay Products LLC and IsoRay, Inc., each formed under Washington law, on October 1, 2004. The first IsoRay company was originally organized in 1998 as a Washington limited liability company, IsoRay, LLC, to develop a medical device using the Cesium-131 seed technology and later transferred its operations to IsoRay, Inc. on May 1, 2002. IsoRay Products LLC was formed in September 2003 to raise capital to fund the operations of IsoRay, Inc. Both IsoRay, Inc. and IsoRay Products LLC merged with IsoRay Medical, Inc. on October 1, 2004.

Our independent auditors have expressed doubt about our ability to continue as a going concern due to ongoing operating losses, which our management expects to continue for the foreseeable future. Because our revenues from

sales of our ¹³¹Cs seed are insufficient to fund our operations at this time, we will need to obtain financing or grow our revenues in the near future to continue our operations. Management expects our independent auditors will continue to express doubt about our ability to continue as a going concern for the foreseeable future.

Our principal office is located at 350 Hills Street, Suite 106, Richland, Washington 99354. Our general office phone number is (509) 375-1202. Our website is www.isoray.com. Information on our website is not part of this prospectus.

The Offering

Common Stock Offered	4,637,100 shares by selling shareholders
Offering Price	Market price or negotiated price
Common Stock Outstanding Before the Offering	16,815,360 shares as of February 7, 2007
Use of Proceeds	We will not receive any proceeds from the resale of the shares offered hereby, all of which proceeds will be paid to the selling shareholders.
Risk Factors	The purchase of our common stock involves a high degree of risk. You should carefully review and consider the "RISK FACTORS" section beginning on page 4.
OTC Bulletin Board Symbol	ISRY.OB

Certain Defined Terms

The technical terms defined below are important to understand as they are used throughout this prospectus. When used in this prospectus, unless the context requires otherwise:

“Brachytherapy” refers to the process of placing therapeutic radiation sources in, or near, diseased tissue. Brachytherapy is derived from a Greek term meaning “short distance” therapy.

“Cesium-131^{131m}Cs” or **“Cs-131”** is an isotope of the element Cesium that gives off low energy, “soft” x-rays as it decays. Cesium-131 decays to 50% of its original activity every 9.7 days, becoming essentially inert after 100 days.

“EBRT” (external beam radiation therapy) is the external treatment of prostate cancer using an x-ray-like machine that targets a beam of radiation at the cancer site. The treatment damages genetic material within the cancer cells, which prevents the cells from growing and the affected cells eventually die. Treatments are generally performed at an outpatient center five days a week for seven or eight weeks.

“Half-life” means the time required for a radioisotope to decay to one-half of its previous activity. The amount of radiation emitted thus decreases to 25% of original activity in two half-lives, 12.5% in three half-lives, and so on.

“Isotope” refers to atoms of the same element that have different atomic masses. The word “isotope” means “same place,” referring to the fact that isotopes of a given element have the same atomic number and hence occupy the same place in the Periodic Table of the Elements. Thus, they are very similar in their chemical behavior.

¹³¹Cs seed” is the name by which IsoRay’s first product, the Cesium-131-based brachytherapy seed, is currently known.

“Pure-beta particle emitter” is a radioisotope whose only emissions during radioactive decay are beta particles (electrons). Beta particles can travel several millimeters in tissue.

“RP” (radical prostatectomy or prostatectomy) is the complete surgical removal of the prostate, under significant anesthesia. Two main types of surgery have evolved: nerve-sparing and non nerve-sparing. The nerve-sparing surgery is designed to minimize damage to the nerves that control penile erection.

“Radiobiologic” is characteristic of the effects of radiation on organisms or tissues, most commonly the effectiveness of therapeutic radiation in interrupting cell growth and replication.

“Radioisotope” is a natural or man-made isotope of an element that spontaneously decays while emitting ionizing radiation.

“Seed” is a common term for small radiation sources consisting of a radioisotope sealed within a biocompatible capsule such as gold or titanium, suitable for temporary or permanent brachytherapy implantation.

“Therapeutic radiation” refers to ionizing radiation with sufficient energy to disrupt basic biological processes of cells.

RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below and the other information in this prospectus and any other filings we may make with the United States Securities and Exchange Commission in the future before investing in our common stock. There may also be risks of which we are currently unaware, or that we currently regard as immaterial based on the information available to us that later prove to be material. If any of these risks occur, our business, operating results and financial condition could be seriously harmed, the trading price of our common stock could decline, and you could lose some or all of your investment.

Risks Related To Our Business

Our Independent Accountants Have Expressed Doubt About Our Ability To Continue As A Going Concern. IsoRay, Inc. (“IsoRay” or the “Company”) has generated material operating losses since inception. We expect to continue to experience net operating losses. Our ability to continue as a going concern is subject to our ability to obtain necessary funding from outside sources, including obtaining additional funding from the sale of our securities, the exercise of our warrants, or obtaining loans and grants from various financial institutions where possible. The substantial doubt expressed by our auditors about our ability to continue as a going concern increases the difficulty in meeting such goals. We have limited historical, operating or financial information upon which to evaluate our performance. There can be no assurance that the Company will attain profitability.

Our Revenues Depend Upon One Product. Until such time as we develop additional products, our revenues depend upon the successful production, marketing, and sales of the IsoRay ¹³¹Cs seed. The rate and level of market acceptance of this product may vary depending on the perception by physicians and other members of the healthcare community of its safety and efficacy as compared to that of competing products, if any; the clinical outcomes of the patients treated; the effectiveness of our sales and marketing efforts in the United States and Europe; any unfavorable publicity concerning our product or similar products; our product’s price relative to other products or competing treatments; any decrease in current reimbursement rates from the Centers for Medicare and Medicaid Services or third-party payers; regulatory developments related to the manufacture or continued use of the product; availability of sufficient supplies of enriched barium for ¹³¹Cs seed production; ability to produce sufficient quantities of this product; and the ability of physicians to properly utilize the device and avoid excessive levels of radiation to patients. Because of our reliance on this product as the sole source of our revenue, any material adverse developments with respect to the commercialization of this product may cause us to continue to incur losses rather than profits in the future.

Although Approved To Treat Any Malignant Tissue, Our Sole Product Is Currently Used To Treat One Type Of Cancer. As of the date of this Prospectus, the IsoRay ¹³¹Cs seed is used exclusively for the treatment of prostate cancer. We believe the ¹³¹Cs seed will be used to treat cancers of other sites as well, as is currently the case with our competitors’ ¹²⁵I and ¹⁰³Pd seeds. However, we believe that clinical data gathered by select groups of physicians under treatment protocols specific to other organs will be needed prior to widespread acceptance of our product for treating other cancer sites. If our current and future products do not become accepted in treating cancers of other sites, our sales will depend solely on treatment of prostate cancer and we will require ever increasing market share to increase revenues.

The Lease On Our Production Facility Ends In October 2007. The Company’s current production facility lease ends in October 2007. While the landlord has agreed to work with the Company to minimize production disruptions, the landlord has indicated that it does not intend to enter into a long-term leasing agreement with the Company. Management is in the final stages of negotiation to lease space for a new production facility. Once the new lease is signed, the Company will begin to obtain the necessary permits and licenses and to make the necessary leasehold improvements. Management believes that the Company will be able to obtain the necessary permits for the new

facility in a timely manner that will not cause delays in the leasehold improvements construction schedule. This new facility is expected to be operational at the end of calendar year 2007. Management believes that the new production facility lease currently being negotiated will be able to accommodate the Company's anticipated future growth for several years. The Company continues to use PNNL to provide third-party assay of its products, but has otherwise vacated PNNL facilities. Management believes that if the Company is unable to obtain the new lease, the necessary permits, or finish the leasehold improvements before having to vacate the present manufacturing facility, that a temporary manufacturing facility is available and could be used although production capacity and scheduling flexibility would be limited.

We Have Limited Data On The Clinical Performance Of ¹³¹Cs. As of February 15, 2007, the IsoRay ¹³¹Cs seed had been implanted in over 900 patients. While this number of patients may prevent us from drawing statistically significant conclusions, the side effects experienced by these patients were less severe than side effects observed in seed brachytherapy with ¹²⁵I and ¹⁰³Pd and in other forms of treatment such as radical prostatectomy. These early results indicate that the onset of side effects generally occurs between one and three weeks post-implant, and the side effects are resolved between five and eight weeks post-implant, indicating that, at least for these initial patients, side effects resolved more quickly than the side effects that occur with competing seeds or with other forms of treatment. These limited findings support management's belief that the ¹³¹Cs seed will result in less severe side effects than competing treatments, but we may have to gather data on outcomes from additional patients before we can establish statistically valid conclusions regarding the incidence of side effects from our seeds.

We Will Need To Raise Additional Capital. The hiring of upper level executives and increasing production requirements significantly increased IsoRay's monthly cash requirements since August 2005. Monthly operating cash requirements as of February 1, 2007 were approximately \$700,000, excluding capitalized items. Capital expenditures typically include the purchase or capital lease of equipment, with a life-expectancy of more than 12 months, costing in excess of \$2,500, which would include among other things: analytical systems, improved packaging for final products and, new production systems which increase manufacturing throughput. Ongoing requirements to meet greater payroll obligations coupled with legal and accounting fees associated with our public reporting status have resulted in greater amounts of short-term cash demands. We will need to continue to raise capital.

We will also need substantial funds to complete the development, manufacturing, and marketing of our current and future products. Consequently, we will seek to raise additional capital through not only warrant solicitation, public and private offerings of equity and debt securities, but also collaborative arrangements, strategic alliances, or from other sources. Management is now in discussions to raise up to \$20 million of equity financing through a Form S-3 Registration Statement declared effective on February 15, 2007 but there is no assurance that this funding will be closed and if closed, at prices which do not dilute existing investors.

We may be unable to raise additional capital on commercially acceptable terms, if at all, and if we raise capital through additional equity financing, existing shareholders may have their ownership interests diluted. Our failure to be able to generate adequate funds from operations or from additional sources would harm our business.

The Passage Of Initiative 297 In Washington May Result In The Relocation Of Our Manufacturing Operations. Washington voters approved Initiative 297 in late 2004, which may impose restrictions on sites at which mixed radioactive and hazardous wastes are generated and stored. IsoRay has been assured by the Attorney General's office of the State of Washington that medical isotopes are not included in Initiative 297 and that manufacturing in IsoRay's new production facility would not be interrupted, but there is no assurance that this interpretation of Initiative 297 by the Attorney General's Office will continue to exclude medical isotopes. In June 2006, a U.S. District Court judge ruled that Initiative 297 was unconstitutional in its entirety. However, the State of Washington has indicated that it may appeal the decision. If this decision is overturned and Initiative 297 is enforced it could impact our ability to manufacture our seeds in the State of Washington.

Management believes that we will be able to continue our manufacturing operations in the State of Washington for the foreseeable future. In the event Initiative 297 is enforced against us, management may consider establishing an alternate manufacturing facility outside of Washington, and we may consider moving all or part of our operations to another state even if Initiative 297 is not enforced against us.

We Have Limited Manufacturing Experience And May Not Be Able To Meet Demand. The existing management team and staff of IsoRay have experience primarily in research and development of products and our experience in commercial-scale manufacturing is limited. We began commercial production of the ¹³¹Cs seed in the fourth quarter of 2004. Although our management team has significant radiochemistry experience, there is a possibility that

production demands may result in challenges that may be too difficult or expensive to overcome. We have developed and deployed semi-automated laser welding equipment that can produce seeds faster than fully-automated equipment the Company has reviewed that would cost several million dollars to design and fabricate. We believe we will continually find more efficient means of welding the titanium seeds; however, there is a possibility that future demand will outstrip our ability to produce seeds using the semi-automated process. Management believes that the new production facility lease currently being negotiated will be able to accommodate the Company's anticipated future growth for several years. The Company continues to use PNNL to provide third-party assay of its products, but has otherwise vacated PNNL facilities.

We Are Subject To The Risk That Certain Third Parties May Mishandle Our Product. We rely on third parties, such as Federal Express, to deliver our ¹³¹Cs seed, and on other third parties, including various radiopharmacies, to package our ¹³¹Cs seed in certain specialized packaging forms that, as of the date of this Prospectus, we do not provide at our own facilities. We are subject to the risk that these third parties may mishandle our product, which could result in adverse effects, particularly given the radioactive nature of our product. As an example, on January 5, 2006, we were notified by one of our primary customers, Chicago Prostate Cancer Center (“CPCC”), that it would no longer accept ¹³¹Cs products from the radiopharmacy exclusively used by us at that time due to quality control concerns. The role of the radiopharmacy is to provide third-party assay, preloading, and sterilization of the ¹³¹Cs seeds which are then shipped directly to customers for use in patient implants. We immediately began working to bring these functions in house. On March 28, 2006, CPCC resumed ordering from us.

Our Operating Results Will Be Subject To Significant Fluctuations. Our quarterly revenues, expenses, and operating results are likely to fluctuate significantly in the future. Fluctuation may result from a variety of factors, which are discussed in detail throughout this “RISK FACTORS” section, including:

- § our achievement of product development objectives and milestones;
- § demand and pricing for the Company’s products;
- § effects of aggressive competitors;
- § hospital, clinic and physician buying decisions;
- § research and development and manufacturing expenses;
- § patient outcomes from our therapy;
- § physician acceptance of our products;
- § government or private healthcare reimbursement policies;
- § our manufacturing performance and capacity;
- § incidents, if any, that could cause temporary shutdown of our manufacturing facilities;
- § the amount and timing of sales orders;
- § rate and success of future product approvals;
- § timing of FDA clearance, if any, of competitive products and the rate of market penetration of competing products;
- § seasonality of purchasing behavior in our market;
- § overall economic conditions; and
- § the successful introduction or market penetration of alternative therapies.

We Rely Heavily On A Limited Number Of Suppliers. Some materials used in our products are currently available only from a limited number of suppliers. For example, virtually all titanium tubing used in brachytherapy seed manufacture comes from a single source, Accellent Corporation. We currently obtain a key component of our seed core from a single supplier. We do not have formal written agreements with either this key supplier or with Accellent Corporation. Any interruption or delay in the supply of materials required to produce our products could harm our business if we were unable to obtain an alternative supplier or substitute equivalent materials in a cost-effective and timely manner. Over sixty percent (60%) of our cesium is now supplied through the Institute of Nuclear Materials (“INM”) located in the former Soviet Union. This percentage will continue to increase as demand for our products increases. Management expects that we will be able to supplement our supply of cesium with deliveries under our recent contract with the Russian Research Institute of Atomic Reactors (“RIAR”), although deliveries have not yet begun under this contract and are now not expected until October 2007. Failure to obtain deliveries of cesium from these sources would have a material adverse effect on seed production and there may be a delay before we could locate alternative suppliers. Additional factors that could cause interruptions or delays in our source of materials include limitations on the availability of raw materials or manufacturing performance experienced by our suppliers and a breakdown in our commercial relations with one or more suppliers. Some of these factors may be completely out of our and our suppliers’ control.

Future Production Increases Will Depend on Our Ability to Acquire Larger Quantities of ¹³¹Cs and Hire More Employees. IsoRay currently obtains ¹³¹Cs through its contract with INM and through reactor irradiation of natural barium and subsequent separation of cesium from the irradiated barium targets. The amount of ¹³¹Cs that can be produced from a given reactor source is limited by the power level and volume available within the reactor for irradiating targets. This limitation can be overcome by utilizing barium feedstock that is enriched in the stable isotope ¹³⁰Ba. However, the number of suppliers of enriched barium is limited and they may be unable to produce this material in sufficient quantities at a reasonable price.

IsoRay has entered into exclusive agreements with the Institute of Nuclear Materials and the Russian Research Institute of Atomic Reactors in Russia to provide ¹³¹Cs in quantities sufficient to supply a significant percentage of future demand for this isotope. Delivery of the isotope from the Institute of Nuclear Materials began in January 2006 and delivery of initial quantities of the isotope from RIAR are expected to begin during October 2007. IsoRay believes these suppliers may also provide access to sufficient quantities of enriched barium that may be recycled for use in other reactors to increase the production of ¹³¹Cs. Although the agreements provide for supplying ¹³¹Cs in significant quantities, there is no assurance that this will result in IsoRay gaining access to a sufficient supply of enriched barium feedstock and if sufficient supplies are attained we will need to increase our manufacturing staff. If we were unable to obtain supplies of isotopes from Russia in the future, our overall supply of cesium and barium would be reduced significantly.

We Are Subject To Uncertainties Regarding Reimbursement For Use Of Our Products. Hospitals and freestanding clinics may be less likely to purchase our products if they cannot be assured of receiving favorable reimbursement for treatments using our products from third-party payers, such as Medicare, Medicaid and private health insurance plans. Currently, Medicare reimburses hospitals, clinics and physicians for the cost of seeds used in brachytherapy procedures on a per seed basis. Historically, private insurers have followed Medicare guidelines in establishing reimbursement rates. However, third-party payers are increasingly challenging the pricing of certain medical services or devices, and we cannot be sure that they will reimburse our customers at levels sufficient for us to maintain favorable sales and price levels for our products. There is no uniform policy on reimbursement among third-party payers, and we can provide no assurance that our products will continue to qualify for reimbursement from all third-party payers or that reimbursement rates will not be reduced. A reduction in or elimination of third-party reimbursement for treatments using our products would likely have a material adverse effect on our revenues.

In 2003, we applied to the Centers for Medicare and Medicaid Services (CMS) and received reimbursement codes for use of our ¹³¹Cs seed (HCPCS code C2633 and APC code 2633). Reimbursement amounts are reviewed and revised periodically on an ad hoc basis. Adjustments could be made to these reimbursement amounts or policies, which could result in reduced reimbursement for brachytherapy services, which could negatively affect market demand for our products.

Furthermore, any federal and state efforts to reform government and private healthcare insurance programs could significantly affect the purchase of healthcare services and products in general and demand for our products in particular. We are unable to predict whether potential healthcare reforms will be enacted, whether other healthcare legislation or regulations affecting the business may be proposed or enacted in the future or what effect any such legislation or regulations would have on our business, financial condition or results of operations.

It Is Possible That Other Treatments May Be Deemed Superior To Brachytherapy. Our ¹³¹Cs seed faces competition not only from companies that sell other radiation therapy products, but also from companies that are developing alternative therapies for the treatment of cancers. It is possible that advances in the pharmaceutical, biomedical, or gene therapy fields could render some or all radiation therapies, whether conventional or brachytherapy, obsolete. If alternative therapies are proven or even perceived to offer treatment options that are superior to brachytherapy, physician adoption of our product could be negatively affected and our revenues from our product could decline.

Our Industry Is Intensely Competitive. The medical products industry is intensely competitive. We compete with both public and private medical device, biotechnology and pharmaceutical companies that have been established longer than we have, have a greater number of products on the market, have greater financial and other resources, and have other technological or competitive advantages. In addition, centers that wish to offer the ^{131}Cs seed must comply with licensing requirements specific to the state in which they do business and these licensing requirements may take a considerable amount of time to comply with. Certain centers may choose to not offer our ^{131}Cs seed due to the time required to obtain necessary license amendments. We also compete with academic institutions, government agencies, and private research organizations in the development of technologies and processes and in acquiring key personnel. Although we have patents granted and patents applied for to protect our isotope separation processes and ^{131}Cs seed manufacturing technology, we cannot be certain that one or more of our competitors will not attempt to obtain patent protection that blocks or adversely affects our product development efforts. To minimize this potential, we have entered into exclusive agreements with key suppliers of isotopes and isotope precursors.

We May Be Unable To Adequately Protect Or Enforce Our Intellectual Property Rights Or Secure Rights To Third-Party Patents. Our ability and the abilities of our partners to obtain and maintain patent and other protection for our products will affect our success. We are assigned, have rights to, or have exclusive licenses to patents and patents pending in the U.S. and numerous foreign countries. The patent positions of medical device companies can be highly uncertain and involve complex legal and factual questions. Our patent rights may not be upheld in a court of law if challenged. Our patent rights may not provide competitive advantages for our products and may be challenged, infringed upon or circumvented by our competitors. We cannot patent our products in all countries or afford to litigate every potential violation worldwide.

Because of the large number of patent filings in the medical device and biotechnology field, our competitors may have filed applications or been issued patents and may obtain additional patents and proprietary rights relating to products or processes competitive with or similar to ours. We cannot be certain that U.S. or foreign patents do not exist or will not be issued that would harm our ability to commercialize our products and product candidates.

One Of Our Licensed Patents May Be Terminated Under Certain Conditions. Our ¹³¹Cs separation patent is essential for the production of Cesium-131. The owner of the patent, Lane Bray, a shareholder of the Company and Chief Chemist of Medical, has the right to terminate the license agreement that allows the Company to use this patent if we discontinue production for any consecutive 18 month period. The Company has no plans to discontinue production, and management considers it highly unlikely that production will be discontinued for any significant period at any time in the future.

Failure To Comply With Government Regulations Could Harm Our Business. As a medical device and medical isotope manufacturer, we are subject to extensive, complex, costly, and evolving governmental rules, regulations and restrictions administered by the FDA, by other federal and state agencies, and by governmental authorities in other countries. Compliance with these laws and regulations is expensive and time-consuming, and changes to or failure to comply with these laws and regulations, or adoption of new laws and regulations, could adversely affect our business.

In the United States, as a manufacturer of medical devices and devices utilizing radioactive by-product material, we are subject to extensive regulation by federal, state, and local governmental authorities, such as the FDA and the Washington State Department of Health, to ensure such devices are safe and effective. Regulations promulgated by the FDA under the U.S. Food, Drug and Cosmetic Act, or the FDC Act, govern the design, development, testing, manufacturing, packaging, labeling, distribution, marketing and sale, post-market surveillance, repairs, replacements, and recalls of medical devices. In Washington State, the Department of Health, by agreement with the federal Nuclear Regulatory Commission ("NRC"), regulates the possession, use, and disposal of radioactive byproduct material as well as the manufacture of radioactive sealed sources to ensure compliance with state and federal laws and regulations. Our ¹³¹Cs brachytherapy seeds constitute both medical devices and radioactive sealed sources and are subject to these regulations.

Under the FDC Act, medical devices are classified into three different categories, over which the FDA applies increasing levels of regulation: Class I, Class II, and Class III. Our ¹³¹Cs seed has been classified as a Class II device and has received clearance from the FDA through the 510(k) pre-market notification process. Although not anticipated, any modifications to the device that would significantly affect safety or effectiveness, or constitute a major change in intended use, would require a new 510(k) submission. As with any submittal to the FDA, there is no assurance that a 510(k) clearance would be granted to the Company.

In addition to FDA-required market clearances and approvals for our products, our manufacturing operations are required to comply with the FDA's Quality System Regulation, or QSR, which addresses requirements for a company's quality program such as management responsibility, good manufacturing practices, product and process design controls, and quality controls used in manufacturing. Compliance with applicable regulatory requirements is monitored through periodic inspections by the FDA Office of Regulatory Affairs ("ORA"). We anticipate both announced and unannounced inspections by the FDA. Such inspections could result in non-compliance reports (Form 483) which, if not adequately responded to, could lead to enforcement actions. The FDA can institute a wide variety of enforcement actions, ranging from public warning letters to more severe sanctions such as fines, injunctions, civil penalties, recall of our products, operating restrictions, suspension of production, non-approval or withdrawal of pre-market clearances for new products or existing products, and criminal prosecution. There can be no assurance that we will not incur significant costs to comply with these regulations in the future or that the regulations will not have a material adverse effect on our business, financial condition and results of operations.

The marketing of our products in foreign countries will, in general, be regulated by foreign governmental agencies similar to the FDA. Foreign regulatory requirements vary from country to country. The time and cost required to obtain regulatory approvals could be longer than that required for FDA clearance in the United States and the requirements for licensing a product in another country may differ significantly from FDA requirements. We will rely, in part, on foreign distributors to assist us in complying with foreign regulatory requirements. We may not be able to obtain these approvals without incurring significant expenses or at all, and the failure to obtain these approvals would prevent us from selling our products in the applicable countries. This could limit our sales and growth.

Our Business Exposes Us To Product Liability Claims. Our design, testing, development, manufacture, and marketing of products involve an inherent risk of exposure to product liability claims and related adverse publicity. Insurance coverage is expensive and difficult to obtain, and, although we currently have a five million dollar policy, in the future we may be unable to obtain or renew coverage on acceptable terms, if at all. If we are unable to obtain or renew sufficient insurance at an acceptable cost or if a successful product liability claim is made against us, whether fully covered by insurance or not, our business could be harmed.

Our Business Involves Environmental Risks. Our business involves the controlled use of hazardous materials, chemicals, biologics, and radioactive compounds. Manufacturing is extremely susceptible to product loss due to radioactive, microbial, or viral contamination; material or equipment failure; vendor or operator error; or due to the very nature of the product's short half-life. Although we believe that our safety procedures for handling and disposing of such materials comply with state and federal standards there will always be the risk of accidental contamination or injury. In addition, radioactive, microbial, or viral contamination may cause the closure of the respective manufacturing facility for an extended period of time. By law, radioactive materials may only be disposed of at state-approved facilities. At our leased facility we use commercial disposal contractors. We may incur substantial costs related to the disposal of these materials. If we were to become liable for an accident, or if we were to suffer an extended facility shutdown, we could incur significant costs, damages, and penalties that could harm our business.

We Rely Upon Key Personnel. Our success will depend, to a great extent, upon the experience, abilities and continued services of our executive officers and key scientific personnel. IsoRay has an employment agreement with Roger Girard, its Chief Executive Officer, and Lori Woods, its Vice President, and its subsidiary has employment agreements with most of its executive officers and key scientific personnel. If we lose the services of several of these officers or key scientific personnel, our business could be harmed. Our success also will depend upon our ability to attract and retain other highly qualified scientific, managerial, sales, and manufacturing personnel and their ability to develop and maintain relationships with key individuals in the industry. Competition for these personnel and relationships is intense and we compete with numerous pharmaceutical and biotechnology companies as well as with universities and non-profit research organizations. We may not be able to continue to attract and retain qualified personnel.

The Value Of Our Granted Patent, and Our Patents Pending, Is Uncertain. Although our management strongly believes that our patent on the process for producing ^{131}Cs , our patent pending on the manufacture of the brachytherapy seed, our patent applications on additional methods for producing ^{131}Cs and other isotopes which have been filed, and anticipated future patent applications, which have not yet been filed, have significant value, we cannot be certain that other like-kind processes may not exist or be discovered, that any of these patents is enforceable, or that any of our patent applications will result in issued patents.

Our Ability To Expand Into Foreign Markets Is Uncertain. Our future growth will depend in part on our ability to establish, grow and maintain product sales in foreign markets, particularly in Europe and Asia. However, we have limited experience in marketing and distributing products in other countries. Any foreign operations would subject us to additional risks and uncertainties, including our customers' ability to obtain reimbursement for procedures using our products in foreign markets; the burden of complying with complex and changing foreign regulatory requirements; language barriers and other difficulties in providing long-range customer service; potentially longer accounts receivable collection times; significant currency fluctuations, which could cause third-party distributors to reduce the number of products they purchase from us because the cost of our products to them could fluctuate relative to the price they can charge their customers; reduced protection of intellectual property rights in some foreign countries; and the possibility that contractual provisions governed by foreign laws would be interpreted differently than intended in the event of a contract dispute. Any future foreign sales of our products could also be adversely affected by export license requirements, the imposition of governmental controls, political and economic instability, trade restrictions, changes in tariffs and difficulties in staffing and managing foreign operations. Many of these factors may also affect our ability to import enriched barium from Russia under our contracts with the INM and RIAR.

Our Ability To Initiate Operations And Manage Growth Is Uncertain. Our efforts to commercialize our medical products will result in new and increased responsibilities for management personnel and will place a strain upon the entire company. To compete effectively and to accommodate growth, if any, we may be required to continue to implement and to improve our management, manufacturing, sales and marketing, operating and financial systems, procedures and controls on a timely basis and to expand, train, motivate and manage our employees. There can be no assurance that our personnel, systems, procedures, and controls will be adequate to support our future operations. If the IsoRay ¹³¹Cs seed were to rapidly become the "seed of choice," it is unlikely that we could meet demand. We could experience significant cash flow difficulties and may have difficulty obtaining the working capital required to manufacture our products and meet demand. This would cause customer discontent and invite competition.

Our Reporting Obligations As A Public Company Are Costly. Operating a public company involves substantial costs to comply with reporting obligations under federal securities laws that are continuing to increase as provisions of the Sarbanes Oxley Act of 2002 are implemented. These reporting obligations increase our operating costs. We may not reach sufficient business volume to justify our public reporting status.

Risks Related To This Offering

There Is A Limited Market For Our Common Stock. Currently only a limited trading market exists for our common stock. Our common stock currently trades on the Over-The-Counter Bulletin Board, a market with limited liquidity and minimal listing standards, under the symbol "ISRY.OB." While management has applied for listing on the American Stock Exchange, the Company is uncertain as to when its application will be approved assuming it continues to meet the applicable listing requirements. Any broker/dealer that makes a market in our stock or other person that buys or sells our stock could have a significant influence over its price at any given time. Shareholders may experience more difficulty in attempting to sell their shares than if the shares were listed on a national stock exchange or quoted on the NASDAQ Stock Market. We cannot assure our shareholders that a market of our stock will be sustained. There is no assurance that our shares will have any greater liquidity than shares that do not trade on a public market.

Our Stock Price Is Likely To Be Volatile. There is generally significant volatility in the market prices and limited liquidity of securities of early stage companies, and particularly of early stage medical product companies. Contributing to this volatility are various events that can affect our stock price in a positive or negative manner. These events include, but are not limited to: governmental approvals, refusals to approve, regulations or actions; market acceptance and sales growth of our products; litigation involving the Company or our industry; developments or disputes concerning our patents or other proprietary rights; changes in the structure of healthcare payment systems; departure of key personnel; future sales of our securities; fluctuations in our financial results or those of companies

that are perceived to be similar to us; investors' general perception of us; and general economic, industry and market conditions. If any of these events occur, it could cause our stock price to fall.

Our Common Stock May be Subject To Penny Stock Regulation. So long as our shares' market price is below \$5.00 per share, our shares are subject to the provisions of Section 15(g) and Rule 15g-9 of the Securities Exchange Act of 1934, as amended, commonly referred to as the "penny stock" rule. Section 15(g) sets forth certain requirements for transactions in penny stocks and Rule 15g-9(d)(1) incorporates the definition of penny stock as that used in Rule 3a51-1 of the Exchange Act. The SEC generally defines penny stock to be any equity security that has a market price less than \$5.00 per share, subject to certain exceptions. Rule 3a51-1 provides that any equity security is considered to be penny stock unless that security is: registered and traded on a national securities exchange meeting specified criteria set by the SEC; authorized for quotation on The NASDAQ Stock Market; issued by a registered investment company; excluded from the definition on the basis of price (at least \$5.00 per share) or the Company's net tangible assets; or exempted from the definition by the SEC. As our shares may be deemed to be "penny stocks", trading in the shares may be subject to additional sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. This classification also could make our shares ineligible for market coverage by many established brokerage firms.

Future Sales By Shareholders, Or The Perception That Such Sales May Occur, May Depress The Price Of Our Common Stock. The sale or availability for sale of substantial amounts of our shares in the public market, including shares covered by this prospectus and shares issuable upon exercise or conversion of outstanding preferred stock and derivative securities, or the perception that such sales could occur, could adversely affect the market price of our common stock and also could impair our ability to raise capital through future offerings of our shares. As of February 7, 2007, we had 16,815,360 outstanding shares of common stock, and the following additional shares were reserved for issuance: 3,089,639 shares upon exercise of outstanding options, 4,300,831 shares upon exercise of outstanding warrants, 59,065 shares upon conversion of preferred stock, 28,614 shares upon conversion of warrants to purchase preferred stock, and 109,639 shares upon conversion of convertible debentures. On the effective date of this prospectus, a total of 8,910,367 shares of common stock (including 632,836 shares issuable upon conversion or exercise of preferred stock and derivative securities and including not only shares registered through this prospectus but also the 3,418,498 shares registered through our Form S-8 registration statement filed on August 19, 2005, the 250,000 shares registered through our Form S-8 registration statement filed on August 18, 2006 and 604,769 shares eligible for resale under Rule 144(k)) to be offered and sold by selling shareholders will be eligible for sale in the public market, collectively constituting approximately 37% of our shares of common stock on a fully diluted basis.

In addition, we granted registration rights to purchasers of units pursuant to the October 17, 2005 private placement memorandum, as amended, which closed in January 2006 (the "October 17, 2005 Offering"), pursuant to the February 1, 2006 private placement memorandum, which closed on February 28, 2006, and to debenture holders that elected to remove the shares into which their debentures are convertible from this Prospectus and convert their debentures instead into units, consisting of 5,000 shares of common stock and warrants to purchase 5,000 shares of common stock per unit at a price of \$20,000 per unit. We have also granted registration rights to purchasers of shares of common stock and warrants pursuant to our August 17, 2006 private offering. The Company filed a registration statement covering the shares described in this paragraph on October 16, 2006, and this registration statement was declared effective on December 5, 2006. As a result, there are an additional 9,064,890 shares of common stock held by shareholders eligible for sale in the public market, which together with the shares eligible for sale in the public market described in the prior paragraph would collectively constitute approximately 74% of our shares of common stock on a fully diluted basis.

In addition to the shares available for resale by selling shareholders, the Company has filed a Form S-3 registration statement on January 26, 2007 (declared effective on February 15, 2007) providing for the shelf registration of a primary offering of up to \$20,000,000 of common stock, warrants to purchase common stock, or a combination of the two. The terms of this future primary offering have not been determined and will be provided in supplements to the prospectus.

As additional shares of our common stock become available for resale in the public market, the price of our common stock may decrease due to the additional shares in the market. Any decline in the price of our common stock may encourage short sales, which could place further downward pressure on the price of our common stock and may impair our ability to raise additional capital through the sale of equity securities.

The Issuance Of Shares Upon Conversion Or Exercise Of The Preferred Stock And Derivative Securities May Cause Immediate And Substantial Dilution To Our Existing Shareholders. The issuance of shares upon conversion of the preferred stock and convertible debentures and the exercise of warrants and options may result in substantial dilution to the interests of other shareholders since the selling shareholders may ultimately convert or exercise and sell all or a portion of the full amount issuable upon conversion or exercise. If all derivative securities being registered through this prospectus and through our other currently effective registration statements were converted or exercised into shares of common stock, there would be an additional 8,335,284 shares of common stock outstanding as a result. The issuance of these shares will have the effect of further diluting the proportionate equity interest and voting power of holders of our common stock, including investors in this offering.

We Do Not Expect To Pay Any Dividends For The Foreseeable Future. We do not anticipate paying any dividends to our shareholders for the foreseeable future. The terms of certain of our and Medical's outstanding indebtedness substantially restrict the ability of either company to pay dividends. Accordingly, investors must be prepared to rely on sales of their common stock after price appreciation to earn an investment return, which may never occur. Investors seeking cash dividends should not purchase our common stock. Any determination to pay dividends in the future will be made at the discretion of our Board of Directors and will depend on our results of operations, financial conditions, contractual restrictions, restrictions imposed by applicable law and other factors our Board deems relevant.

Certain Provisions Of Minnesota Law And Our Charter Documents Have An Anti-Takeover Effect. There exist certain mechanisms under Minnesota law and our charter documents that may delay, defer or prevent a change of control. Anti-takeover provisions of our articles of incorporation, bylaws and Minnesota law could diminish the opportunity for shareholders to participate in acquisition proposals at a price above the then-current market price of our common stock. For example, while we have no present plans to issue any preferred stock, our Board of Directors, without further shareholder approval, may issue shares of undesignated preferred stock and fix the powers, preferences, rights and limitations of such class or series, which could adversely affect the voting power of your shares. In addition, our bylaws provide for an advance notice procedure for nomination of candidates to our Board of Directors that could have the effect of delaying, deterring or preventing a change in control. Further, as a Minnesota corporation, we are subject to provisions of the Minnesota Business Corporation Act, or MBCA, regarding "business combinations," which can deter attempted takeovers in certain situations. Pursuant to the terms of a shareholder rights plan adopted in February 2007, each outstanding share of common stock has one attached right. The rights will cause substantial dilution of the ownership of a person or group that attempts to acquire the Company on terms not approved by the Board of Directors and may have the effect of deterring hostile takeover attempts. The effect of these anti-takeover provisions may be to deter business combination transactions not approved by our Board of Directors, including acquisitions that may offer a premium over the market price to some or all stockholders. We may, in the future, consider adopting additional anti-takeover measures. The authority of our Board to issue undesignated preferred or other capital stock and the anti-takeover provisions of the MBCA, as well as other current and any future anti-takeover measures adopted by us, may, in certain circumstances, delay, deter or prevent takeover attempts and other changes in control of the company not approved by our Board of Directors.

Cautionary Note Regarding Forward-looking Statements and Risk Factors

This prospectus, the Company's Form 10-KSB, any Form 10-QSB or any Form 8-K of the Company or any other written or oral statements made by or on behalf of the Company may contain "forward-looking statements", which reflect the Company's current views with respect to future events and financial performance. The words "believe," "expect," "anticipate," "intends," "estimate," "forecast," "project," and similar expressions identify forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any statements of the plans, strategies and objectives of management for future operations; any statements concerning proposed new products, services, developments or industry rankings; any statements regarding future economic conditions or performance; any statements of belief; any statements regarding the validity of our intellectual property and patent protection; and any statements of assumptions underlying any of

the foregoing. Such "forward-looking statements" are subject to risks and uncertainties set forth from time to time in the Company's SEC reports and include, among others, the Risk Factors set forth above.

Readers are cautioned not to place undue reliance on such forward-looking statements as they speak only of the Company's views as of the date the statement was made. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by selling shareholders. We will receive no proceeds from the sale of shares of common stock in this offering. Certain of the selling shareholders will receive shares of our common stock upon conversion of outstanding warrants and options that they own. If all of the warrants and options owned by the selling shareholders are exercised in full, we would receive \$1,512,180 in proceeds. Any proceeds received upon exercise of the warrants and options will be used for working capital. We will receive no proceeds from the conversion of the preferred stock owned by the selling shareholders.

MANAGEMENT'S DISCUSSION AND ANALYSIS

You should read the following discussion in conjunction with our financial statements, including the notes thereto, at the end of this prospectus. Some of the information contained in this discussion, or set forth elsewhere in this prospectus contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of a variety of certain factors, including those set forth under "Risk Factors" and elsewhere in this prospectus.

Critical Accounting Policies and Estimates

The discussion and analysis of the Company's financial condition and results of operations are based upon its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent liabilities. On an on-going basis, management evaluates past judgments and estimates, including those related to bad debts, inventories, accrued liabilities, and contingencies. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The accounting policies and related risks described in the Company's annual report on Form 10-KSB as filed with the Securities and Exchange Commission on September 28, 2006 are those that depend most heavily on these judgments and estimates. As of December 31, 2006, there have been no material changes to any of the critical accounting policies contained therein except for the adoption of SFAS No. 123R as noted below.

Share-Based Compensation

As part of our adoption of SFAS No. 123R as of July 1, 2006, we were required to recognize the fair value of share-based compensation awards as an expense. We apply the Black-Scholes option-pricing model in order to determine the fair value of stock options on the date of grant, and we apply judgment in estimating key assumptions that are important elements in the model such as the expected stock-price volatility, expected stock option life and expected forfeiture ratios. Our estimates of these important assumptions are based on historical data and judgment regarding market trends and factors. If actual results are not consistent with our assumptions and judgments used in estimating these factors, we may be required to record additional share-based compensation expense, which could be material to our results of operations.

Adoption of SFAS No. 123R

During December 2004, the Financial Accounting Standards Board (“FASB”) issued SFAS No. 123R, which requires companies to measure and recognize compensation expense for all share-based payments at fair value. Share-based payments include stock option and nonvested share grants. We grant options to purchase common stock to some of our employees and directors under various plans at prices equal to the market value of the stock on the dates the options were granted. We historically have accounted for stock options using the method prescribed in APB 25 whereby if stock options are granted at market price then no compensation cost is recognized, and disclosed the pro forma effect on net earnings assuming compensation cost had been recognized in accordance with SFAS No. 123. SFAS No. 123R, which was effective for us beginning on July 1, 2006, eliminates the ability to account for share-based compensation transactions using APB 25, and generally requires that such transactions be accounted for using prescribed fair-value-based methods. SFAS No. 123R permits public companies to adopt its requirements using one of two methods: (a) a “modified prospective” method in which compensation costs are recognized beginning with the effective date based on the requirements of SFAS No. 123R for all share-based payments granted or modified after the effective date, and based on the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date or (b) a “modified retrospective” method which includes the requirements of the modified prospective method described above, but also permits companies to restate based on the amounts previously recognized under SFAS No. 123 for purposes of pro forma disclosures either for all periods presented or for prior interim periods of the year of adoption. We have decided to adopt SFAS No. 123R using the modified prospective method.

The following table presents the share-based compensation expense recognized in accordance with SFAS No. 123R during the three and six months ended December 31, 2006 and in accordance with APB 25 during the three and six months ended December 31, 2005:

	Three months ended December 31,		Six months ended December 31,	
	2006	2005	2006	2005
Cost of product sales	\$ 20,492	\$ --	\$ 71,325	\$ --
Research and development	7,879	--	19,714	--
Sales and marketing	52,456	--	99,237	--
General and administrative	35,617	--	707,611	--
Total share-based compensation	\$ 116,444	\$ --	\$ 897,887	\$ --

As of December 31, 2006, total unrecognized compensation cost related to stock-based options and awards was \$1,041,962 and the related weighted-average period over which it is expected to be recognized is approximately 1.16 years.

Results of Operations**Three months ended December 31, 2006 and 2005**

Revenues. The Company generated sales of \$1,414,155 during the three months ended December 31, 2006, compared to sales of \$486,247 during the three months ended December 31, 2005. The increase of \$927,908 or 191% is due to increased sales volume of the Company’s ¹³¹Cs seed. During the three months ended December 31, 2006, the Company sold its ¹³¹Cs seed to 33 different medical centers as compared to 15 centers during the corresponding period of 2005.

Cost of product sales. Cost of product sales was \$1,387,394 for the three months ended December 31, 2006 compared to cost of product sales of \$916,274 during the three months ended December 31, 2005. The increase of \$471,120 or 51% was due to the higher production levels during the three months ended December 31, 2006 which were related to the increase in sales volume over the corresponding period from 2005. The major components of the increase were wages, benefits and related taxes, materials, depreciation, preload expenses, and share-based compensation. Wages, benefits, and related taxes increased about \$211,000 to approximately \$412,000 for the three months ended December 31, 2006 due to the hiring of additional production employees to support the higher production levels. Materials costs increased about \$137,000 to approximately \$478,000 in 2006, due to increased sales volumes. Material costs in 2005 included payments to Pacific Northwest National Laboratory (“PNNL”) for facilities and personnel to manufacture the seeds. The Company no longer uses PNNL to produce the seeds but continues to use PNNL for certain analytical support functions. During the three months ended December 31, 2006, the Company expensed payments of about \$55,000 to PNNL for these support functions. Depreciation expense increased about \$69,000 to approximately \$87,000 in 2006 due to the addition of equipment that was placed in service during the second half of the fiscal year ended June 30, 2006. Preload expenses also increased by about \$52,000 to approximately \$98,000 for the three months ended December 31, 2006 due to the higher volume of sales. Share-based compensation expense was approximately \$20,000 and \$0 for the three months ended December 31, 2006 and 2005, respectively, as the Company implemented SFAS No. 123R on July 1, 2006. These increases were offset by a decrease in small tools expense of about \$90,000 to approximately \$16,000 as the prior year expense included start-up costs of the Company’s production facility.

Gross margin / loss. Gross margin was \$26,761 for the three month period ended December 31, 2006. This represents an improvement of \$456,788 or 106% over the corresponding period of 2005's gross loss of \$430,027. The improvement in gross margin is due to higher revenues and greater production efficiency.