

IsoRay, Inc.
Form POS AM
February 16, 2007

As filed with the Securities and Exchange Commission on February 16, 2007
Registration Statement No. 333-138024

SECURITIES AND EXCHANGE COMMISSION

**POST-EFFECTIVE
AMENDMENT NO. 1 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.)

**350 Hills Street, Suite 106
Richland, WA 99354
(509) 375-1202**
(Address and Telephone Number of Principal Executive Offices and Principal Place of Business)

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(602) 248-0088

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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	4,830,940	\$ 3.10 ⁽⁴⁾	\$ 14,975,914	\$ 1,602.42 ⁽³⁾
Common stock, \$0.001 par value, issuable upon exercise of warrants	4,233,950	\$ 3.10 ⁽²⁾	\$ 13,125,245	\$ 1,404.40 ⁽³⁾
Total	9,064,890		\$ 28,101,159	\$ 3,006.82⁽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 exercise of warrants 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 exercise of the warrants, 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 October 11, 2006.

⁽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 October 17, 2006.

ISORAY, INC.
9,064,890 Shares
Common Stock

This prospectus relates to the sale by the selling shareholders of up to 9,064,890 shares of our common stock, \$0.001 par value. The 9,064,890 shares being registered consist of the following: up to 4,830,940 shares of common stock and up to 4,233,950 shares of common stock underlying warrants to purchase common stock all currently held by the selling shareholders. The warrants are exercisable at prices ranging from \$3.00 to \$6.50 with expiration dates ranging from October 28, 2007 to August 17, 2011.

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	9,064,890 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};¹³¹Cs” 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 17,978,763 shares of common stock (including 4,233,950 shares issuable upon exercise of warrants registered hereunder and including not only shares registered through this prospectus but also the 4,637,100 shares registered through our Form SB-2 registration statement initially filed on November 10, 2005, 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 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.

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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 that they own. If all of the warrants owned by the selling shareholders are exercised in full, we would receive \$18,690,439 in proceeds. Any proceeds received upon exercise of the warrants will be used for working capital.

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.

Research and development. Research and development expenses for the three month period ended December 31, 2006 were \$216,254 which represents an increase of \$119,417 or 123% over the research and development expenses of \$96,837 for the corresponding period of 2005. The major components of the increase were wages, benefits and related taxes, patent legal expenses, consulting, and share-based compensation. Wages, benefits and related taxes were approximately \$79,000 and \$0 for the three months ended December 31, 2006 and 2005, respectively, as the Company hired research scientists. During the three months ended December 31, 2006, the Company incurred about \$19,000 of legal expenses related to patents and trademarks that were expensed. Consulting expenses increased about \$65,000 to approximately \$80,000 as the Company continues to increase the efficiency of production. Share-based compensation expense was approximately \$8,000 and \$0 for the three months ended December 31, 2006 and 2005, respectively, as the Company implemented SFAS No. 123R on July 1, 2006. Clinical study protocol expenses decreased about \$69,000 to approximately \$14,000 for the three months ended December 31, 2006 as the Company is near the end of its initial protocol study.

Sales and marketing expenses. Sales and marketing expenses were \$890,018 for the three months ended December 31, 2006. This represents an increase of \$549,486 or 161% compared to the three months ended December 31, 2005's expenditures of \$340,532 for sales and marketing. Wages, including payroll-related taxes, travel, office and other support expenses on behalf of our sales and marketing and customer service staff increased by approximately \$270,000 to approximately \$509,000 for the three months ended December 31, 2006 due to hiring additional sales and marketing personnel as the Company continues to expand market share. Conventions and tradeshow increased by approximately \$169,000 to approximately \$254,000 due to the Company's continued efforts to expand its market share. Consulting expenses increased by \$34,000 to approximately \$38,000 for consultants hired to increase brand and market awareness. Also included in sales and marketing expenses is share-based compensation expense of approximately \$52,000 due to the Company's implementation of SFAS No. 123R on July 1, 2006.

General and administrative expenses. General and administrative expenses for the three months ended December 31, 2006 were \$821,529 compared to general and administrative expenses of \$675,444 for the corresponding period of 2005. The increase of \$146,085 or 22% is primarily due to approximately \$36,000 of share-based compensation expense related to the implementation of SFAS No. 123R on July 1, 2006, approximately \$145,000 of increased payroll costs due to a higher headcount, and approximately \$64,000 relating to investor relations and other public company expenses. These increased expenses were partially offset by a reduction in consulting fees of approximately \$19,000 as the Company has hired more internal staff, a decrease in audit related fees of \$24,000 as the Company had more regulatory and other filings in 2005 following the merger, and a reduction in the bad debt expense of \$14,000 as the Company reduced its allowance for doubtful accounts during the three months ended December 31, 2006.

Operating loss. Due to our rapid structural growth, significant research and development expenditures, and additional responsibilities as a reporting company, we have not been profitable, and have generated operating losses since our inception. In the three months ended December 31, 2006, the Company had an operating loss of \$1,901,040 which is an increase of \$358,200 or 23% over the operating loss of \$1,542,840 for the three months ended December 31, 2005. Included in the operating loss for the three months ended December 31, 2006 is share-based compensation expense of \$116,444 due to the implementation of SFAS No. 123R on July 1, 2006.

Interest income. Interest income increased by \$46,811 or 1,466% to \$50,004 for the three months ended December 31, 2006. Interest income is mainly derived from excess funds held in certain near-liquid accounts.

Financing expense. Financing expense for the three months ended December 31, 2006 was \$67,413 or a decrease of \$128,067 or 66% from financing expense of \$195,480 for the corresponding period in 2005. Included in financing expense is interest expense of approximately \$46,000 and \$144,000 for the three months ended December 31, 2006 and 2005, respectively. The decrease in interest expense is due to the conversion of debentures to common stock during the fiscal year ended June 30, 2006 partially offset by interest expense related to the Hanford Area Economic Investment Fund Committee (HAEIFC) loan that was entered into in June 2006. The remaining balance of financing expense represents the amortization of deferred financing costs which decreased due to the write-off in fiscal year 2006 of the deferred financing costs relating to the debentures that were converted to common stock partially offset by the amortization of the HAEIFC deferred financing costs.

Debt conversion expense. Debt conversion expense for the three months ended December 31, 2005 relates to the one-time recognition of \$244,097 expense in short-term inducement to convert debentures.

Six months ended December 31, 2006 and 2005

Revenues. Sales for the six months ended December 31, 2006 were \$2,439,599 compared to sales of \$697,162 for the six months ended December 31, 2005. The increase of \$1,742,437 or 250% is due to increased sales volume of the Company's ¹³¹Cs seed. During the six months ended December 31, 2006 the Company sold its ¹³¹Cs seed to 35 different medical centers as compared to 15 centers during the corresponding period of 2005.

Cost of product sales. Cost of product sales was \$2,675,539 for the six months ended December 31, 2006 compared to cost of product sales of \$1,636,440 during the six months ended December 31, 2005. The increase of \$1,039,099 or 63% was due to the higher production levels during the six 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, share-based compensation, and rent and occupancy expenses. Wages, benefits, and related taxes increased about \$412,000 to approximately \$786,000 for the six months ended December 31, 2006 due to the hiring of additional production employees to support the higher production levels. Materials costs increased about \$263,000 to approximately \$879,000 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 six months ended December 31, 2006, the Company expensed payments of about \$135,000 to PNNL for these support functions. Depreciation and amortization expense increased about \$110,000 to approximately \$169,000 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 \$129,000 to approximately \$192,000 for the six months ended December 31, 2006 due to the higher volume of sales. Share-based compensation expense was approximately \$71,000 and \$0 for the six months ended December 31, 2006 and 2005, respectively, as the Company implemented SFAS No. 123R on July 1, 2006. Rent and occupancy expenses were approximately \$73,000 and \$40,000 for the six months ended December 31, 2006 and 2005, respectively, as the Company moved into its independent production facility during the second quarter of fiscal year 2005. These increases were offset by a decrease in small tools expense of \$172,000 to approximately \$48,000 as the prior year expense included start-up costs of the Company's production facility.

Gross margin / loss. Gross loss was \$235,940 for the six month period ended December 31, 2006. This represents an improvement of \$703,338 or 75% over the corresponding period of 2005's gross loss of \$939,278. The improvement in gross loss is due to higher revenues and greater production efficiency.

Research and development. Research and development expenses for the six months ended December 31, 2006 were \$461,852 which represents an increase of \$339,233 or 277% over the research and development expenses of \$122,619 for the corresponding period of 2005. The major components of the increase were wages, benefits and related taxes, consulting, and share-based compensation. Wages, benefits and related taxes were approximately \$143,000 and \$0 for the six months ended December 31, 2006 and 2005, respectively, as the Company hired research scientists. Consulting expenses increased about \$130,000 to approximately \$168,000 as the Company continues to increase the efficiency of production. Share-based compensation expense was approximately \$20,000 and \$0 for the six months ended December 31, 2006 and 2005, respectively, as the Company implemented SFAS No. 123R on July 1, 2006.

Sales and marketing expenses. Sales and marketing expenses were \$1,562,948 for the six months ended December 31, 2006. This represents an increase of \$907,377 or 138% compared to the six months ended December 31, 2005's expenditures of \$655,571 for sales and marketing. Wages, including payroll-related taxes, travel, office and other support expenses on behalf of our sales and marketing and customer service staff increased about \$268,000 to approximately \$353,000 due to the hiring of additional sales and marketing personnel as the Company continues to

expand market share. Conventions and tradeshow increased by about \$254,000 to approximately \$441,000 due to the Company's continued efforts to expand its market share. Consulting expenses increased by \$54,000 to approximately \$58,000 related to consultants hired to increase brand and market awareness. Also included in sales and marketing expenses is share-based compensation expense of about \$99,000 due to the implementation of SFAS No. 123R on July 1, 2006.

General and administrative expenses. General and administrative expenses for the six months ended December 31, 2006 were \$2,554,661 compared to general and administrative expenses of \$1,636,393 for the corresponding period of 2005. The increase of \$918,268 or 56% is primarily due to approximately \$708,000 of share-based compensation expense related to the implementation of SFAS No. 123R on July 1, 2006, a one-time severance accrual of \$288,000, approximately \$238,000 of increased payroll costs due to a higher headcount, and approximately \$97,000 relating to investor relations and other public company expenses. These increased expenses were partially offset by a reduction in consulting fees of approximately \$330,000 which represents merger consulting fees incurred in the three months ended September 30, 2005. Other consulting expenses also decreased approximately \$25,000 as the Company hired more internal resources. In addition, audit related fees decreased approximately \$24,000 as the Company had more regulatory and other filings in 2005 following the merger and bad debt expense was reduced by approximately \$36,000 as the Company reduced its allowance for doubtful accounts during the six months ended December 31, 2006.

Operating loss. Due to our rapid structural growth, product revenues not covering production costs, significant research and development expenditures, and additional responsibilities as a reporting company, we have not been profitable, and have generated operating losses since our inception. In the six months ended December 31, 2006, the Company had an operating loss of \$4,815,401 which is an increase of \$1,461,540 or 44% over the operating loss of \$3,353,861 for the six months ended December 31, 2005. Included in the operating loss for the six months ended December 31, 2006 is share-based compensation expense of \$897,887 due to the implementation of SFAS No. 123R during the period and a one-time severance accrual of \$288,000. Without these two expense items, our operating loss would have only increased by \$275,653 or 8%.

Interest income. Interest income increased by \$80,035 or 788% to \$90,187 for the six months ended December 31, 2006. Interest income is mainly derived from excess funds held in certain near-liquid accounts.

Financing expense. Financing expense for the six months ended December 31, 2006 was \$120,670 or a decrease of \$230,438 or 66% from financing expense of \$351,108 for the corresponding period in 2005. Included in financing expense is interest expense of approximately \$77,000 and \$248,000 for the six months ended December 31, 2006 and 2005, respectively. The decrease in interest expense is due to the conversion of debentures to common stock during the fiscal year ended June 30, 2006 partially offset by interest expense related to the Hanford Area Economic Investment Fund Committee (HAEIFC) loan that was entered into in June 2006. The remaining balance of financing expense represents the amortization of deferred financing costs which decreased due to the write-off in fiscal year 2006 of the deferred financing costs relating to the debentures that were converted to common stock partially offset by the amortization of the HAEIFC deferred financing costs.

Debt conversion expense. Debt conversion expense for the six months ended December 31, 2005 relates to the one-time recognition of \$244,097 expense in short-term inducement to convert debentures.

Liquidity and capital resources. At December 31, 2006, cash and cash equivalents amounted to \$3,700,108. During the six months ended December 31, 2006, the Company issued 2,063,000 shares of common stock at a price of \$2.50 per share and 2,269,300 common stock warrants (including broker warrant commissions) with an exercise price of \$3.00 per share pursuant to a round of institutional funding. This funding provided approximately \$4.7 million, net of offering costs. Additionally, the Company issued 755,829 shares of common stock pursuant to the exercise of common stock options and warrants and preferred stock warrants, which were exchanged for common stock immediately upon exercise. The Company received approximately \$1.2 million in cash pursuant to these exercises.

During January 2007, two warrant holders exercised warrants issued in connection with the August 2006 Stock Purchase Agreement. The Company received \$1,218,900 in cash and issued 406,300 common shares pursuant to these exercises. The Company had approximately \$3.7 million cash on hand as of February 2, 2007. As of that date management believes that the Company's monthly required cash operating expenditures were approximately \$630,000.

Management believes that assuming expenditures continue at approximately the same monthly rate and that it is able to fund a portion of its equipment purchases with the HAEIFC loan, that the Company's cash on hand will fund operating expenditures through the beginning of June 2007. This is based on the Company attaining its current revenue targets and the ability to continue to efficiently manufacture our product. If we should experience disruptions in our revenues then our monthly cash requirements would increase and necessitate that we obtain additional funding prior to May 2007.

Our growth plans for fiscal 2007 include expanding sales to new customers, growing sales volume with existing customers, and developing additional therapies. Additional production capability, including new equipment and additional employees, will be needed to meet our anticipated growth. The Company has also begun a review of its current facilities and future needs based on current forecasts. 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.

IsoRay has three loan facilities in place as of December 31, 2006. The first loan is from the Benton-Franklin Economic Development District ("BFEDD") in an original principal amount of \$230,000 and was funded in December 2004. It bears interest at eight percent and has a sixty month term with a final balloon payment. As of December 31, 2006, the principal balance owed was \$193,720. This loan is secured by certain equipment, materials and inventory of IsoRay, and also required personal guarantees, for which the guarantors were issued approximately 70,455 shares of common stock. The second loan is a line of credit from Columbia River Bank, which provides credit in the amount of \$375,000. It bears interest at a floating prime plus two percent rate, and is secured by certain accounts receivable and inventory and personal guarantees, for which the guarantors were issued approximately 107,401 shares of common stock. As of December 31, 2006, no balance was outstanding on the line of credit. The line of credit expires on March 1, 2007. Management believes the line of credit will be renewed. The third loan is from the Hanford Area Economic Investment Fund Committee and was originated in June 2006. The loan has a total facility of \$1,400,000 and bears interest at nine percent. As of December 31, 2006, the Company has taken only a partial draw of \$418,670 on the facility and the remaining facility of \$981,330 is available to use to purchase equipment. The principal balance owed on the loan as of December 31, 2006 was \$405,443. This loan is secured by receivables, equipment, materials and inventory of IsoRay, and certain life insurance policies.

The Company has certain capital leases for production and office equipment that expire at various times from March 2008 to April 2009. These leases currently call for total monthly payments of \$19,361. The total of all capital lease obligations at December 31, 2006 was \$315,485.

At December 31, 2006, the Company had outstanding \$455,000 of convertible debentures. These debentures could be converted into 109,639 shares of common stock at a conversion rate of \$4.15 per share. Each debenture bears interest at an annual rate of eight percent (not compounded) with accrued interest paid quarterly. The debentures mature at various times from February 2007 to June 2007.

In February 2006, the Company signed a license agreement with International Brachytherapy s.a. ("IBt") covering North America and providing the Company with access to IBt's Ink Jet production process and its proprietary polymer seed technology for use in brachytherapy procedures using Cesium-131. The Company paid license fees of \$275,000 during 2006 and another payment of \$225,000 was to be made in August 2006 pursuant to the license agreement. Royalty payments based on net sales revenue are also required, with minimum quarterly royalties ranging from \$100,000 to \$200,000 and minimum annual royalties ranging from \$400,000 to \$800,000 over the term of the agreement. Management is engaged in further negotiations with IBt and may ultimately terminate this agreement,

although management has not yet decided on a course of action.

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As of the date of this report, the payment due in August 2006 has not been made as the Company has been in continued negotiations with IBt concerning the amount and timing of future royalty payments due to the low market acceptance of the polymer seed technology.

In September 2006, the Company entered into a settlement agreement with a former executive. As part of the settlement the Company agreed to pay the former executive \$100,000 in September 2006 and \$215,000 in January 2007.

The Company finalized the settlement agreement with its former Chief Financial Officer in December 2006. An initial payment of \$50,000 and the cashless exercise of 50,000 options at \$1.00 per share in lieu of another cash payment of \$50,000 were recorded in December 2006. A final payment of \$93,000 and a cashless exercise of 95,000 options at \$1.00 per share in lieu of an additional cash payment of \$95,000 were recorded in January 2007.

The industry that the Company operates in is subject to product liability litigation. Through its production and quality assurance procedures, the Company works to mitigate the risk of any lawsuits concerning its product. The Company also carries product liability insurance to help protect it from this risk.

The Company expects to finance its future cash needs through the sale of equity securities, solicitation to warrant holders to exercise their warrants, and possibly strategic collaborations or debt financing or through other sources that may be dilutive to existing shareholders. If the Company needs to raise additional money to fund its operations, funding may not be available to it on acceptable terms, or at all. If the Company is unable to raise additional funds when needed, it may not be able to market its products as planned or continue development and regulatory approval of its future products. If the Company raises additional funds through equity sales, these sales may be dilutive to existing investors.

The Company has no off-balance sheet arrangements.

Going Concern Issues

Our financial statements have been prepared assuming we will continue as a going concern. We had net losses of \$8,218,130 and \$4,269,188 for the years ended June 30, 2006 and 2005 and an accumulated deficit of \$13,546,261 at June 30, 2006. Our accumulated deficit at December 31, 2006 was \$18,392,145. These factors, among others, raise substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustment that might result from the outcome of this uncertainty. Management plans to obtain the necessary financing and to continue to grow revenues in order to achieve profitability but no assurances can be given that management will be able to obtain additional financing or grow revenues to a profitable level.

If we are unable to generate profits and unable to obtain additional financing to meet our working capital requirements, we may have to curtail our business or cease operations. Our continuation as a going concern is dependent upon our ability to generate sufficient cash flow to meet our obligations on a timely basis, to obtain additional financing, and, ultimately, to attain profitability. Should any of these events not occur, the accompanying financial statements will be adversely effected and we may have to cease operations.

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 Company believes the following critical accounting policies affect its more significant judgments and estimates used in the preparation of its consolidated financial statements.

Accounts Receivable

Accounts receivable are stated at the amount that management of the Company expects to collect from outstanding balances. Management provides for probable uncollectible amounts through an allowance for doubtful accounts. Additions to the allowance for doubtful accounts are based on management's judgment, considering historical write-offs, collections and current credit conditions. Balances which remain outstanding after management has used reasonable collection efforts are written off through a charge to the allowance for doubtful accounts and a credit to the applicable accounts receivable. Payments received subsequent to the time that an account is written off are considered bad debt recoveries.

Inventory

Inventory is reported at the lower of cost, determined using the weighted average method, or net realizable value.

Asset Retirement Obligation

SFAS No. 143, *Asset Retirement Obligations*, establishes standards for the recognition, measurement and disclosure of legal obligations associated with the costs to retire long-lived assets. Accordingly, under SFAS No. 143, the fair value of the future retirement costs of the Company's leased assets are recorded as a liability on a discounted basis when it is incurred and an equivalent amount is capitalized to property and equipment. The initial recorded obligation, which has been discounted using the Company's credit-adjusted risk free-rate, will be reviewed periodically to reflect the passage of time and changes in the estimated future costs underlying the obligation. The Company amortizes the initial amount capitalized to property and equipment and recognizes accretion expense in connection with the discounted liability over the estimated remaining useful life of the leased assets.

Revenue Recognition

The Company applies the provisions of SEC Staff Accounting Bulletin ("SAB") No. 104, *Revenue Recognition*. SAB No. 104, which supersedes SAB No. 101, *Revenue Recognition in Financial Statements*, provides guidance on the recognition, presentation and disclosure of revenue in financial statements. SAB No. 104 outlines the basic criteria that must be met to recognize revenue and provides guidance for the disclosure of revenue recognition policies. The Company recognizes revenue related to product sales when (i) persuasive evidence of an arrangement exists, (ii) shipment has occurred, (iii) the fee is fixed or determinable, and (iv) collectibility is reasonably assured.

Revenue for the fiscal years ended June 30, 2006 and 2005 was derived solely from sales of the ¹³¹Cs brachytherapy seed, which is used in the treatment of cancer. The Company recognizes revenue once an order has been received and shipped to the customer. Prepayments, if any, received from customers prior to the time that products are shipped are recorded as deferred revenue. In these cases, when the related products are shipped, the amount recorded as deferred revenue is recognized as revenue. The Company accrues for sales returns and other allowances at the time of shipment.

Legal Contingencies

In the ordinary course of business, the Company is involved in legal proceedings involving contractual and employment relationships, product liability claims, patent rights, and a variety of other matters. The Company records contingent liabilities resulting from asserted and unasserted claims against it, when it is probable that a liability has been incurred and the amount of the loss is reasonably estimable. The Company discloses contingent liabilities when

there is a reasonable possibility that the ultimate loss will exceed the recorded liability. Estimating probable losses requires analysis of multiple factors, in some cases including judgments about the potential actions of third-party claimants and courts. Therefore, actual losses in any future period are inherently uncertain. Currently, the Company does not believe any of its pending legal proceedings or claims will have a material impact on its financial position or results of operations. However, if actual or estimated probable future losses exceed the Company's recorded liability for such claims, it would record additional charges as other expense during the period in which the actual loss or change in estimate occurred.

Results of Operations

Financial Presentation

Statement of Financial Accounting Standards (SFAS) No. 141, *Business Combinations*, requires that following a merger the accounting acquirer's financial statements should be used for historical comparisons. Although the legal acquirer was Century Park Pictures Corporation ("Century"), for accounting purposes Medical was the acquirer and as such Medical's historical financial statements are shown for comparative purposes. Also for accounting purposes, the merger was accounted for as though it happened on July 1, 2005.

The following sets forth a discussion and analysis of the Company's financial condition and results of operations for the two years ended June 30, 2006. This discussion and analysis should be read in conjunction with our consolidated financial statements appearing elsewhere in this Prospectus. The following discussion contains forward-looking statements. Our actual results may differ significantly from the results discussed in such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in "Risk Factors" of this Prospectus.

Year ended June 30, 2006 compared to year ended June 30, 2005

Product sales. Revenues for the year ended June 30, 2006 were \$1,994,306, an increase of \$1,792,575 over sales for the year ended June 30, 2005 of \$201,731. All of the Company's revenues were generated through sales of its ¹³¹Cs seeds. IsoRay began sales of its ¹³¹Cs seed on October 26, 2004 with one medical center customer. By June 30, 2006 the number of medical center customers who had ordered the ¹³¹Cs seed had grown to 26.

Gross loss. Gross loss was \$1,820,816 for the year ended June 30, 2006 or an increase of \$548,296 as compared to a gross loss of \$1,272,520 for the year ended June 30, 2005. Cost of products sold was \$3,815,122 for the year ended June 30, 2006 or an increase of \$2,340,871 over the \$1,474,251 incurred for the year ended June 30, 2005. During the year ended June 30, 2006, the Company paid \$868,650 to Pacific Northwest National Laboratory (PNNL) under our contract with them for use of their facilities and personnel to support production. During the fourth quarter of fiscal year 2006, we paid approximately \$110,000 for quality assurance support and as a deposit to extend our contract through December 31, 2007. The Company is currently using PNNL for certain research and development and quality assurance activities. Also during fiscal 2006, the Company paid approximately \$1 million in wages, benefits, and related taxes for production personnel and approximately \$1.6 million in direct and indirect material costs. These costs increased due to a larger staff and material and supply costs related to an increase in sales during fiscal year 2006.

Also included in cost of products sold during 2006 were over \$109,000 for production and small tools, none of which individually exceeded the \$2,500 threshold we use in determining whether to capitalize production equipment. These materials and small tools were needed to commence production in our independent production facility, the PEcoS-IsoRay Radioisotope Laboratory ("PIRL"). Most are long-lived items and will not need replacing in the next fiscal year. The Company has moved essentially all of its Cs-131 production operations to PIRL.

Research and development. Research and development expenses for the year ended June 30, 2006 were \$450,425, an increase of \$312,893 over research and development expenses of \$137,532 for the year ended June 30, 2005. During 2006, \$116,200 was spent on protocol studies of patients that have been implanted with the Company's ¹³¹Cs brachytherapy seeds. Also during 2006, \$144,588 was spent on research to improve Cs-131 production.

Sales and marketing expenses. Sales and marketing expenses were \$1,420,500 for the year ended June 30, 2006. This represents an increase of \$718,678 over the expense of \$701,822 for the year ended June 30, 2005. During fiscal 2006, approximately \$994,000 was spent on wages, travel, office, and other support expenses on behalf of the sales and marketing and customer service staff. The balance was spent on advertising, market research and trade shows and

conferences. The increases are due to increased marketing of the Company's ^{13}C s seed since introduction of our product to the market in October 2004.

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General and administrative expenses. General and administrative expenses were \$3,503,522 for the year ended June 30, 2006 or an increase of \$1,632,197 as compared to \$1,871,325 for the year ended June 30, 2005. Included in general and administrative expenses in 2006 is \$330,000 relating to consulting fees for the reverse acquisition that was paid with the issuance of common stock (see "Description of Business"). The increases over the prior periods are due to supporting the Company's increased manufacturing and sales activities. These activities have increased as the Company has only been manufacturing and selling its product since October 2004. Additionally, increased expenses in the 2006 fiscal year were due to compliance with SEC regulations following the July 28, 2005 merger. Significant components of general and administrative expenses include \$838,797 in consulting expense, payroll and related expenses of \$866,863 and professional fees, including accounting and legal fees of \$522,318. Consulting services increased in connection with the establishment of the independent PIRL production facilities, which commenced production in the late Fall of 2005, and associated equipment installation, customization and validation; review and advice on business and capital strategies, and the addition of a medical director who serves as a consultant. Professional fees increased due to the Company's July 28, 2005 merger, SEC compliance activities including the Company's registration statement on Form SB-2 filed that was effective in June 2006, and other general business activities.

Operating loss. Due to the Company's significant research and develop expenditures, additional responsibilities as a reporting company, rapid structural growth, and nominal product revenues, the Company has not been profitable, and has generated operating losses since inception. For the year ended June 30, 2006, the Company had an operating loss of \$7,195,263. This represents an increased loss of \$3,212,064 in comparison with the year ended June 30, 2005 operating loss of \$3,983,199.

Interest income. Interest income increased by \$49,350 to \$51,744 for the year ended June 30, 2006. Interest income is mainly derived from excess funds held in certain near-liquid accounts.

Financing expense. Financing expense for the year ended June 30, 2006 includes \$332,493 of interest expense incurred on long-term debt and convertible debentures outstanding. The interest expense increased over the prior year due to interest payments on the convertible debentures that were sold as part of the January 1, 2005 PPM, computed interest expense on the capital leases entered into during fiscal 2006, and interest expense on other loans that were initiated in January 2005. The remaining balance of financing expense represents amortization of deferred financing costs primarily related to the January 2005 issuance of common stock to guarantors of certain loans made to the Company, commissions and legal costs paid in conjunction with the issuance of convertible debentures, issuance of warrants as an inducement for a note payable, and costs associated with the initiation of the Hanford Area Economic Investment Fund Committee (HAEIFC) note payable. During 2006, \$89,516 of deferred financing costs were expensed relating to debentures that were converted to common stock.

Debt conversion expense. This amount of approximately \$385,000 relates to the one-time, non-cash expense resulting from the short-term inducement offered to debenture holders to their convert debentures to common stock (see Note 11). This expense was recognized in accordance with Statement of Financial Accounting Standard No. 84, *Induced Conversions of Convertible Debt*.

Year ended June 30, 2005 compared to year ended June 30, 2004

Product sales. Revenues for the year ended June 30, 2005 were \$201,731. The Company did not have any revenues for the year ended June 30, 2004. IsoRay began sales of its ¹³¹Cs seed on October 26, 2004 with one medical center customer. All of the Company's sales in 2005 were generated through sales of its ¹³¹Cs seeds.

Gross loss. Gross loss was \$1,272,520 and cost of products sold was \$1,474,251 for the year ended June 30, 2005. The Company did not have any gross loss or cost of products sold for the year ended June 30, 2004. During the year ended June 30, 2005, the Company paid \$574,225 to Pacific Northwest National Laboratory (PNNL) under our

contract with them for use of their facilities and personnel to support production. The Company was using PNNL for production of its seeds and other activities.

Research and development. Research and development expenses for the year ended June 30, 2005 were \$137,532 an increase of \$95,206 over research and development expenses of \$42,326 for the year ended June 30, 2004. The change is due to research to improve production of Cs-131 and other isotopes.

Sales and marketing expenses. Sales and marketing expenses were \$701,822 for the year ended June 30, 2005. This represents an increase of \$620,336 over the expense of \$81,486 for the year ended June 30, 2004. Most of the 2005 expenses were spent on wages, travel, office, and other support expenses on behalf of the sales and marketing and customer service staff. The increases are due to hiring sales personnel during 2005 to market the Company's¹³¹Cs seed which was only introduced to the market in October 2004.

General and administrative expenses. General and administrative expenses were \$1,871,325 for the year ended June 30, 2005 as compared to \$650,161 for the year ended June 30, 2004. The increase is due to increased salaries for officers who were foregoing salaries or were paid under market and the hiring of additional staff as the Company began manufacturing and selling its product. Approximately \$870,000 was spent on payroll, benefits, and related employment costs during fiscal year 2005. Other significant components of general and administrative expenses included about \$178,000 in consulting services and \$269,000 of professional fees. Consulting expenses increased as the Company hired advisors for operations, business and capital strategies. Professional fees increased due to the merger of the two predecessor companies into IsoRay Medical, Inc. as well as the Company's private placements and other general business matters.

Operating loss. Due to the Company's significant research and development expenditures, large general and administrative expenses and payroll related to properly staffing the Company for anticipated further growth coupled with nominal product revenues, the Company generated operating losses. For the year ended June 30, 2005, the Company had an operating loss of \$3,983,199. This represents an increased loss of \$3,209,226 in comparison with the year ended June 30, 2004 operating loss of \$773,973.

Interest income. Interest income was \$2,394 for the year ended June 30, 2005 which was an increase of \$496 over interest income of \$1,898 for the year ended June 30, 2004.

Financing expense. Financing expense for the year ended June 30, 2005 includes amortization of deferred financing costs and interest expense incurred on long-term debt and convertible debentures outstanding. The deferred financing costs relate primarily to the January 2005 issuance of common stock to guarantors of certain loans made to the Company and commissions and legal costs paid in conjunction with the issuance of convertible debentures. Amortization of these costs amounted to \$76,746 during 2005. The remaining balance relates to interest expense which increased due to the issuance of the convertible debentures in 2005.

Loss on disposal of fixed assets. This loss in 2005 relates to the write-off of certain rudimentary production equipment that was replaced by complex production equipment that improves the manufacturing process.

MARKET FOR COMMON STOCK

The Company's Articles of Incorporation provide that the Company has the authority to issue 200,000,000 shares of capital stock, which are currently divided into two classes as follows: 194,000,000 shares of common stock, par value of \$0.001 per share; and 6,000,000 shares of preferred stock, par value of \$0.001 per share. As of February 7, 2007, we had 16,815,360 outstanding shares of Common Stock and 59,065 outstanding shares of Preferred Stock.

Our common stock is quoted on the OTC Bulletin Board under the symbol "ISRY.OB" and on the Pink Sheets under the symbol "ISRY.PK." There is limited trading activity in our securities, and there can be no assurance a regular trading market for our common stock will be sustained. We resumed trading on the Pink Sheets on August 18, 2005, after a period of no trading activity from February 18, 2005 until August 18, 2005. We also had a period of no trading activity from July 2003 until February 7, 2005. On November 2, 2005, we began trading on the OTC Bulletin Board.

The following table sets forth, for the calendar periods indicated, the range of the high and low last reported bid prices of our common stock from October 1, 2004 through December 31, 2006, as reported by the Pink Sheets and the OTC Bulletin Board. The quotations represent inter-dealer prices without retail mark-ups, mark-downs or commissions, and may not necessarily represent actual transactions. The quotations may be rounded for presentation. There is an absence of an established trading market for the Company's common stock, as the market is limited, sporadic and highly volatile, which may affect the prices listed below.

The following table sets forth, for the fiscal quarters indicated, the high and low sales prices for our common stock as reported on the OTC Bulletin Board and the Pink Sheets.

<u>Year ended June 30, 2007</u>		High		Low
First quarter	\$	3.50	\$	2.50
Second quarter	\$	6.00	\$	3.00
<u>Year ended June 30, 2006</u>		High		Low
First quarter	\$	5.95	\$	1.00
Second quarter		8.25		4.50
Third quarter		7.25		6.20
Fourth quarter		6.40		3.25
<u>Year ended June 30, 2005</u>		High		Low
First quarter	\$	N/A	\$	N/A
Second quarter		*		*
Third quarter ⁽¹⁾		N/A		N/A

* Less than \$0.01.

⁽¹⁾ Due to our change of fiscal year end from September 30 to June 30, our 2005 fiscal year was only nine months long.

The Company has never paid any cash dividends on its Common Stock and does not plan to pay any cash dividends in the foreseeable future.

As of February 13, 2007, we had approximately 902 shareholders of record, exclusive of shares held in street name.

Equity Compensation Plans

On May 27, 2005, the Company adopted the 2005 Stock Option Plan, as subsequently amended and restated (the "Option Plan"), and the 2005 Employee Stock Option Plan, as subsequently amended and restated (the "Employee Plan"), pursuant to which it may grant equity awards to eligible persons. On August 15, 2006, the Company adopted the 2006 Director Stock Option Plan, as subsequently amended and restated (the "Director Plan"), pursuant to which it may grant equity awards to eligible persons. The Option Plan allows the Board of Directors to grant options to purchase up to 1,800,000 shares of common stock to directors, officers, key employees and service providers of the Company, and the Employee Plan allows the Board of Directors to grant options to purchase up to 2,000,000 shares of common stock to officers and key employees of the Company. The Director Plan allows the Board of Directors to grant options to purchase up to 1,000,000 shares of common stock to directors of the Company. Options granted under all of the Plans have a ten year maximum term, an exercise price equal to at least the fair market value of the Company's common stock (based on the trading price on the OTC Bulletin Board) on the date of the grant, and with varying vesting periods as determined by the Board.

As of June 30, 2006, the following options had been granted under the option plans.

Plan Category	Number of securities to be issued on exercise of outstanding options, warrants	Weighted-average exercise price of outstanding options, warrants, and	Number of securities remaining available for future issuance
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	and rights #	rights \$	under equity compensation plans
Equity compensation plans approved by shareholders	N/A	N/A	N/A
Equity compensation plans not approved by shareholders	3,257,592	\$ 2.11	333,982
Total	3,257,592	\$ 2.11	333,982

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DESCRIPTION OF BUSINESS

General

Century was organized under Minnesota law in 1983. Century had no operations since its fiscal year ended September 30, 1999 through June 30, 2005.

On July 28, 2005, IsoRay Medical, Inc. became a wholly-owned subsidiary of Century pursuant to a merger. Century changed its name to IsoRay, Inc. In the merger, the Medical stockholders received approximately 82% of the then outstanding securities of the Company.

Medical, a Delaware corporation, was incorporated effective June 15, 2004 to develop, manufacture and sell isotope-based medical products and devices for the treatment of cancer and other diseases. Medical is headquartered in Richland, Washington.

Medical was formed for the purpose of combining the operations of IsoRay, Inc. (a former Washington corporation) (“IsoRay (WA)”) and its subsidiary, IsoRay Products LLC, two companies that shared common ownership and management with Medical. Medical’s management initiated a merger transaction effective October 1, 2004, to combine operations.

Business Operations

Overview

IsoRay is utilizing its patented radioisotope technology, experienced chemists and engineers, and management team to create a major therapeutic medical isotope and medical device company with a goal of providing improved patient outcomes in the treatment of prostate cancer and other solid tumor cancers. IsoRay began production and sales of its Food and Drug Administration (“FDA”) cleared product, the IsoRay¹³¹Cs brachytherapy seed, in October 2004 for the treatment of prostate cancer. Management believes its technology will allow it to capture a leadership position in an expanded brachytherapy market. The more clinically beneficial characteristics of the Cesium-131 (Cs-131 or ¹³¹Cs) isotope are expected to decrease radiation exposure to the patient and reduce the severity and duration of side effects, while treating cancer cells as effectively, if not more so than other isotopes used in seed brachytherapy. Cesium-131 could also enable meaningful penetration in other solid tumor applications such as breast, lung, liver, brain and pancreatic cancer, expanding the total available market opportunity.

Brachytherapy seeds are small devices used in an internal radiation therapy procedure. In recent years the procedure has become one of the primary treatments for prostate cancer and is now used more often than surgical removal of the prostate. The brachytherapy procedure places radioactive seeds as close as possible to (in or near) the cancer tumor (the word “brachytherapy” means close therapy). The seeds deliver therapeutic radiation by killing the tumor cells and cells located in the immediate vicinity of the tumor while minimizing exposure to adjacent healthy tissue. This allows doctors to administer a higher dose of radiation at one time than is possible with external beam radiation. Each seed contains a radioisotope sealed within a welded titanium capsule. Approximately 85 to 135 seeds are permanently implanted in the prostate in a 45-minute outpatient procedure. The isotope decays over time and the seeds become inert. The seeds may be used as a primary treatment or, in conjunction with other treatment modalities such as external beam radiation therapy, chemotherapy, or as treatment for residual disease after excision of primary tumors.

Management believes that the IsoRay ^{131}Cs seed represents the first major advancement in brachytherapy technology in over 18 years with attributes that could make it the long term “seed of choice” for internal radiation procedures. The ^{131}Cs seed has FDA clearance for treatment of malignant disease (e.g. cancers of the head and neck, brain, liver, lung, breast, prostate, etc.) and may be used in surface, interstitial, and intracavity applications for tumors with known radiosensitivity.

The ^{131}Cs isotope appears to have specific advantages for treating cancer over Iodine-125 (I-125 or ^{125}I) and Palladium-103 (Pd-103 or ^{103}Pd), the other isotopes commonly used in brachytherapy procedures. IsoRay believes that the short half-life and higher dose rate characteristics of ^{131}Cs will expand industry applications and facilitate meaningful penetration into the treatment of other forms of cancer such as breast cancer. The shorter half-life of 9.7 days for ^{131}Cs (versus 17 days for ^{103}Pd and 60 days for ^{125}I) mitigates negative effects of long radiation periods on healthy tissue and is believed to reduce the duration of certain side effects. The higher initial dose rate is believed to be more effective on fast growing cancers by aggressively attacking cancer cells and disrupting cancer cell re-population cycles. The characteristics of ^{131}Cs may result in the use of 10-30% fewer seeds per procedure compared to Pd-103, thereby reducing the total physical radiation dose to the patient and reducing the costs of the procedure for both third-party payers and the patient.

IsoRay and its predecessor companies have accomplished the following key milestones:

- Treated 900th patient (February 2007);
- Raised over \$25.0 M in debt and equity funding (September 2003 - January 2007)
- Opened a new manufacturing and production facility (October 2005);
- Deployed a direct sales force to the market (July 2004 - July 2005);
- Developed a treatment protocol for prostate cancer with a leading oncologist (January 2005);
- Treated the first patient (October 2004);
- Commenced production of the ^{131}Cs seed (August 2004);
- Filed five additional patent applications for the ^{131}Cs process (November 2003 - August 2004);
- Obtained a Nuclear Regulatory Commission Sealed Source and Device Registration required by the Washington State Department of Health and the FDA (September 2004);
- Received a Radioactive Materials License from the Washington State Department of Health (July 2004);
- Implemented an ISO-9000 Quality Management System and production operating procedures (under continuing development);
- Signed a Commercial Work for Others Agreement between Battelle (manager of the Pacific Northwest National Laboratory or PNNL) and IsoRay, allowing initial production of seeds through 2006 at PNNL (April 2004);
- Obtained favorable Medicare reimbursement codes for the Cs-131 brachytherapy seed (November 2003);
- Obtained FDA 510(k) clearance to market the first product: the ^{131}Cs brachytherapy seed (March 2003);

- Completed initial radioactive seed production, design verification, computer modeling of the radiation profile, and actual dosimetric data compiled by the National Institute of Standards and Technology and PNNL (October 2002); and

- Obtained initial patent for ^{131}Cs isotope separation and purification (May 2000).

Industry Information

Incidence of Prostate Cancer

Excluding skin cancer, prostate cancer is the most common form of cancer, and the second leading cause of cancer deaths in men. The American Cancer Society estimated there would be about 234,460 new cases of prostate cancer diagnosed and an estimated 27,350 deaths associated with the disease in the United States during 2006. Because of early detection techniques (e.g., screening for prostate specific antigen, or PSA) approximately 70% (164,100) of these cases are potentially treatable with monotherapy seed brachytherapy, when the cancers are still locally confined within the prostate. A substantial majority of these cases are potentially treatable with dual therapy using seed brachytherapy in combination with different variations of external beam radiation.

The prostate is a walnut-sized gland surrounding the male urethra, located below the bladder and adjacent to the rectum. The two most prevalent prostate diseases are benign prostatic hyperplasia (BPH) and prostate cancer. BPH is a non-cancerous enlargement of the innermost part of the prostate. Prostate cancer is a malignant tumor that begins most often in the periphery of the gland and, like other forms of cancer, may spread beyond the prostate to other parts of the body.

Prostate cancer incidence and mortality increase with age. Prostate cancer is found most often in men who are over the age of 50. More than seven out of ten men diagnosed with prostate cancer are over the age of 65. According to the American Cancer Society, approximately one man in six will be diagnosed with prostate cancer during his lifetime.

In addition to age, other risk factors are linked to prostate cancer, such as genetics. Men who have relatives that have been affected, especially if the relatives were young at the time of diagnosis, have an even higher risk of contracting the disease. Researchers have discovered that changes in certain genes, influenced by DNA mutations inherited from a parent, may cause some men to be more inclined to develop prostate cancer. It has also been suggested that environmental factors such as exposure to cancer-causing chemicals or radiation may cause DNA mutations in many organs. Another factor that may contribute to prostate cancer is diet, with diets high in fat and high in calcium possibly increasing the risk of prostate cancer.

The American Cancer Society recommends that men without symptoms, risk factors and who have a life expectancy of at least ten years, should begin regular annual medical exams at the age of 50, and believes that health care providers should offer as part of the exam the prostate-specific antigen (PSA) blood test and a digital rectal examination. The PSA blood test determines the amount of prostate specific antigen present in the blood. PSA is found in a protein secreted by the prostate, and elevated levels of PSA can be associated with either prostatitis (a noncancerous inflammatory condition) or a proliferation of cancer cells in the prostate. Transrectal ultrasound tests and biopsies are typically performed on patients with elevated PSA readings to confirm the existence of cancer.

A tumor found by a prostate biopsy is usually assigned a grade by a pathologist. The most common prostate cancer grading system is called the Gleason grading system. A Gleason score, which ranges from 2 to 10, usually is used to estimate the tumor's growth rate. Typically, the lower the score, the slower the cancer grows. Most localized cancers of the prostate gland are associated with an intermediate score ranging from Gleason scores 4 through 6.

Staging is the process of determining how far the cancer has spread. The treatment and recovery outlook depend on the stage of the cancer. The TNM system is the staging process used most often. The TNM system describes the extent of the primary tumor (T stage), whether the cancer has spread to nearby lymph nodes (N stage), and the absence or presence of distant metastasis (M stage). The TNM descriptions can be grouped together with stages labeled 0 through IV (0-4). The higher the number, the further the cancer has spread. The following table summarizes the various stages of prostate cancer.

Stages	Characteristics of Prostate Cancer
T1 or T2	Localized in the prostate
T3 or T4	Locally advanced
N+ or M+	Spread to pelvic lymph nodes (N+) or distant organs (M+)

Treatment Options and Protocol

In addition to brachytherapy, localized prostate cancer is commonly treated with radical prostatectomy (RP) and external beam radiation therapy (EBRT). Recently, intensity modulated radiation therapy (IMRT) has seen increased application, particularly in combination with brachytherapy for cancers that have begun to spread beyond the prostate. Other treatments include cryosurgery, hormone therapy, watchful waiting, and finasteride, a drug commonly prescribed to treat benign enlargement of the prostate and male baldness. Some of these therapies may be combined in special cases to address a specific cancer stage or patient need. When the cancerous tissue is not completely eliminated, the cancer typically returns to the primary site, often with metastases to other areas.

Radical Prostatectomy. Historically the most common treatment option for prostate cancer, radical prostatectomy is an invasive surgical procedure in which the entire prostate gland is removed. RP is performed under general anesthesia and typically involves a hospital stay of several days for patient observation and recovery. This procedure

is often associated with relatively high rates of impotence and incontinence. For instance, a study published in the *Journal of the American Medical Association* in January 2000 reported that approximately 60% of men who had received RP reported erectile dysfunction as a result of surgery. The same report found that approximately 40% of the patients studied reported at least occasional incontinence. New bilateral nerve-sparing techniques are currently being used more frequently in order to address these side effects, but these techniques require a high degree of surgical skill. RP is typically more expensive than other common treatment modalities.

External Beam Radiation Therapy. EBRT allows patients to receive treatment on an outpatient basis and at a lower cost than RP. EBRT involves directing a beam of radiation from outside the body at the prostate gland in order to destroy cancerous tissue. The course of treatment usually takes seven to eight weeks to deliver the total dose of radiation prescribed to kill the tumor. Studies have shown, however, that the ten-year disease free survival rates with treatment through EBRT are less than the disease free survival rates after RP or brachytherapy treatment. In addition, because the radiation beam travels through the body to reach the prostate, normal tissue lying in the path of the radiation beam is also damaged. Other side effects are associated with EBRT. For instance, rectal wall damage caused by the radiation beam is a noted negative side effect. Data suggests that between 30% and 40% of the patients who undergo EBRT suffer problems with erectile dysfunction after treatment.

Intensity Modulated Radiation Therapy. IMRT is a newer, more advanced form of EBRT in which sophisticated computer control is used to aim the beam at the target volume from multiple different angles and to vary the intensity of the beam. Thus, damage to normal tissue and critical structures is minimized by distributing the unwanted radiation over a larger geometric area. The course of treatment is similar to EBRT and requires daily doses over a period of seven to eight weeks to deliver the total dose of radiation prescribed to kill the tumor. IMRT is relatively new and thus not widely available for use as a treatment modality. As a result fewer clinical data regarding treatment effectiveness and the incidence of side effects are available. One advantage of IMRT, and to some extent EBRT, is the ability to treat cancers that have begun to spread from the tumor site. An increasingly popular therapy for patients with more advanced prostate cancer is a combination of IMRT with seed implant brachytherapy.

Cryosurgery. Cryosurgery, a procedure in which tissue is frozen to destroy tumors, is another treatment option for prostate cancer. Currently, this procedure is less widely used, although promising treatment outcomes have been reported. Cryosurgery typically requires a one to two day hospital stay and is associated with higher rates of impotence and other side effects than seed implant brachytherapy.

Other Treatments. Other treatments include hormone therapy and chemotherapy, which may be used to reduce the size of cancerous tumors. However, these treatments are not intended to ultimately cure a patient of prostate cancer. Instead, such treatment choices are made by physicians in an attempt to extend patients' lives if the cancer has reached an advanced stage or as ancillary treatment methods used in conjunction with other treatment modalities. Common side effects of hormone therapy are impotence, decreased libido and breast enlargement. Common side effects of chemotherapy are nausea, hair loss and fatigue.

“Watchful waiting” or “active surveillance”, while not a treatment, is recommended by some physicians in extreme circumstances based on the severity and growth rate of the disease, as well as the age and life expectancy of the patient. Physicians and patients who choose watchful waiting are frequently seeking to avoid the negative side effects associated with RP or other treatment modalities. Through careful monitoring of PSA levels and close examination for advancing symptoms of prostate cancer, physicians may choose active treatments at a later date.

Treatment Protocol. Prostate cancer patients electing seed therapy first undergo an ultrasound test or CT scan, which generates a two-dimensional image of the prostate. With the assistance of a computer program, a three-dimensional treatment plan is created that calculates the number and placement of the seeds required for the best possible distribution of radiation to the prostate. Once the implant model has been constructed, the procedure is scheduled and the seeds are ordered. The number of seeds implanted normally ranges from 85 to 135, with the number of seeds varying with the size of the prostate. The procedure is usually performed under local anesthesia in an outpatient setting. The seeds are implanted using needles inserted into the prostate. When all seeds have been inserted, seed placement is verified through an ultrasound image, CT scan, fluoroscope or MRI. An experienced practitioner typically performs the procedure in approximately 45 minutes, with the patient normally returning home the same day. Most patients are able to return to their normal activities within one or two days following the procedure.

Origin of Brachytherapy seeds

One of the first reports in the medical literature regarding brachytherapy seeds that deliver “soft x-ray” radiation directly to tumors by permanent implantation appeared in 1965, authored by Donald C. Lawrence and Dr. Ulrich K. Henschke. Don Lawrence later developed and patented the titanium-encapsulated I-125 brachytherapy seed. His company, Lawrence Soft Ray Inc., provided the world’s supply of seeds from 1967 to 1978 until the 3M Corporation purchased the technology. Eventually 3M sold the business to Amersham PLC, which spun off this business to its division ONCURA, today the market leader in Iodine-125 seeds. All commercially available seeds trace their origin to Mr. Lawrence’s invention. Don Lawrence was a founder of IsoRay, LLC, the first predecessor company to IsoRay.

Brachytherapy has been used as a treatment for prostate cancer for more than 30 years. Formerly, seeds containing the radioactive isotope Iodine-125 were implanted in prostate tumors through open surgery. However, this technique fell into disfavor because the seeds were often haphazardly arranged resulting in radiation not reaching all of the targeted cancerous tissue. Compounding this was the fact that often an unintended radiation dose was delivered to healthy surrounding tissues, particularly the urethra and rectum. Originally, brachytherapy earned an unfavorable reputation because the early adopters did not have the imaging technologies needed for accurate placement of the seeds. This resulted in poor tumor control and greater damage to surrounding healthy tissue. Since the introduction of the ultrasound-guided, transperineal implantation technique in the late 1980s, brachytherapy has become a treatment that not only provides excellent therapeutic value but is very convenient and economical for the patient. The benefits of the advancements in imaging, computer dose planning, and the actual implant procedure have been validated by the improved clinical results achieved using modern brachytherapy techniques.

The introduction of Palladium-103 in the mid-1980s represented a major technology advancement in brachytherapy and played a significant role in the dramatic increase in the number of brachytherapy procedures performed. Within a relatively short period of time, ¹⁰³Pd captured 40% of the growing brachytherapy market.

Cesium-131 represents the first major advancement in brachytherapy technology in over 18 years with attributes that management believes could make it the long term “seed of choice” for internal radiation procedures. Management believes that the ¹³¹Cs seed has specific clinical advantages for treating cancer over ¹²⁵I and ¹⁰³Pd.

There is a large and growing potential market for the Company’s products. Several significant clinical and market factors are contributing to the increasing popularity of the brachytherapy procedure. In Europe brachytherapy is growing in excess of 25% per year and it is expected that market growth in the U.S. will also increase dramatically. In 1996 only 4% of prostate cancer cases were treated with brachytherapy, or about 8,000 procedures. In 2005, it was estimated that over 60,000 brachytherapy procedures were performed for prostate cancer. Brachytherapy as a treatment is now more common than radical prostatectomy and has become the treatment of choice for early-stage prostate cancer. Considerable attention is now being given to high risk and faster growing prostate cancers as well. Brachytherapy has significant advantages over competing treatments including lower cost, better survival data, fewer side effects, a faster recovery time and the convenience of a single outpatient procedure that generally lasts 45 minutes (Merrick, et al., *Techniques in Urology*, Vol. 7, 2001; Potters, et al., *Journal of Urology*, May 2005; Sharkey, et al., *Current Urology Reports*, 2002).

Clinical Results

Long term survival data are now available for brachytherapy with ¹⁰³Pd and ¹²⁵I, which support the efficacy of brachytherapy. Clinical data indicate that brachytherapy offers success rates for early-stage prostate cancer treatment that are equal to or better than those of RP or EBRT. While clinical studies of brachytherapy to date have focused on results from brachytherapy with Pd-103 and I-125, management believes that this data will be relevant for brachytherapy with Cs-131, and Cs-131 may offer improved clinical outcomes over Pd-103 and I-125, given its shorter half-life and higher energy.

Improved patient outcomes. A number of published studies on the use of ¹⁰³Pd and ¹²⁵I brachytherapy in the treatment of early-stage prostate cancer have been very positive (we have not obtained consent to cite the studies listed below).

- In September 2006 a 5 year prospective study to assess the impact of interstitial brachytherapy on the quality of life of patients with localized prostate cancer was published. The results of the present study confirm that the impact of interstitial brachytherapy on the patients' quality of life is low despite its transient negative effects on some function, and extend existing knowledge concerning quality of life after interstitial brachytherapy. *International Journal of Radiation Oncology; Volume 66; 1;31-37.*
- A twelve-year clinical study published in the 2004 Supplement of the *International Journal of Radiation Oncology, Biology and Physics*, reported relative survival rate of 84% for low risk cancer patients, 78% for intermediate risk cancer patients and 68% for high risk cancer patients. The study was conducted by Dr. Lou Potters, et al. of the New York Prostate Institute and included 1,504 patients treated with brachytherapy between 1992 and 2000.
- A study published in the January 2004 issue of the *International Journal of Radiation Oncology, Biology and Physics*, reported that brachytherapy, radical prostatectomy, high-dose external beam radiation therapy and combined therapies produced similar cure rates. The study was conducted by Dr. Patrick Kupelian, Dr. Louis Potters, et al. and included 2,991 patients with Stage T1 or T2 prostate cancer. Of these patients, 35% of patients underwent surgery, 16% received low-dose EBRT, 10% received high-dose EBRT, 7% received combination therapy and 32% received brachytherapy. After five years, the biochemical relapse-free survival rate was 83% for brachytherapy, 81% for radical prostatectomy, 81% for high-dose EBRT, 77% for combination therapy and 51% for low-dose EBRT.
- A nine-year clinical study published in the March 2000 issue of the *International Journal of Radiation Oncology, Biology and Physics*, reported that 83.5% of patients treated with Pd-103 seeds were cancer-free at nine years. The study was conducted by Dr. John Blasko of the Seattle Prostate Institute and included 230 patients with clinical stage T1 and T2 prostate cancer. Only 3% experienced cancer recurrence in the prostate.
- Results from a 10-year study conducted by Dr. Datolli and Dr. Wallner published in the *International Journal of Radiation Oncology, Biology and Physics* in September 2002, were presented at the October 2002 American Society for Therapeutic Radiology and Oncology (ASTRO) conference confirming the effectiveness of the Pd-103 seed in patients with aggressive cancer who previously were considered poor candidates for brachytherapy. The 10-year study was comprised of 175 patients with Stage T2-T3 prostate cancer treated from 1991 through 1995. Of these patients, 79 percent remained completely free of cancer without the use of hormonal therapy or chemotherapy.
- A study by the Northwest Prostate Institute in Seattle, Washington reported 79% disease-free survival at 12 years for brachytherapy in combination with external beam radiation (Ragde, *et al.*, *Cancer*, July 2000). The chance of cure from brachytherapy is nearly 50% higher than for other therapies for men with large cancers (PSA 10-20) and over twice as high as other therapies for men with the largest cancers (PSA 20+) (K. Wallner, *Prostate Cancer: A Non-Surgical Perspective*, Smart Medicine Press, 2000).

Reduced Incidence of Side Effects. Sexual potency and urinary incontinence are two major concerns men face when choosing among various forms of treatment for prostate cancer. Because the IsoRay ¹³¹Cs seed delivers a highly concentrated and confined dose of radiation directly to the prostate, healthy surrounding tissues and organs typically experience less radiation exposure. Management believes, and initial results appear to support, that this should result in lower incidence of side effects and complications than may be incurred with other conventional therapies, and when side effects do occur, they should resolve more rapidly than those experienced with I-125 and Pd-103 isotopes.

Favorable Market Factors

Lower Treatment Cost. The total one-time cost of brachytherapy ranges from \$10,000 to \$17,000 per procedure. This is less than the cost of a radical prostatectomy or RP, which ranges from \$17,000 to \$20,000, excluding treatment for side effects and post-operative complications. Brachytherapy cost is comparable to the cost of EBRT (external beam radiation), which is approximately \$14,000 to \$35,000 for a seven to nine week course of treatment.

Favorable Demographics. Prostate cancer incidence and mortality increase with age. Prostate cancer is found most often in men who are over the age of 50. The National Cancer Institute has reported that the incidence of prostate cancer increases dramatically in men over the age of 55. Currently, one out of every six men is at lifetime risk of developing prostate cancer. More than seven out of ten men diagnosed with prostate cancer are over the age of 65. At the age of 70, the chance of having prostate cancer is 12 times greater than at age 50. According to the American Cancer Society, prostate cancer incidence rates increased between 1988 and 1992 due to earlier diagnosis in men who otherwise had no sign of symptoms. Early screening has fostered a decline in the prostate cancer death rate since 1990.

The number of prostate cancer cases in the U.S. is expected to increase due to the expanding population of men over the age of 55. The U.S. Census Bureau estimates this segment of the population will increase from 25.9 million men in 2000 to 32 million men by 2008 - a 24% increase. Extrapolating that data, management believes that the U.S. will provide over 180,000 candidates annually for prostate brachytherapy by 2008.

Increased PSA Screening. Early PSA screening and testing leads to early diagnosis. The American Cancer Society recommends that men without symptoms or risk factors and who have a life expectancy of at least ten years, should begin regular annual medical exams at the age of 50, and believes that health care providers should offer as part of the exam the prostate-specific antigen blood test. The PSA blood test determines the amount of prostate specific antigen present in the blood. PSA is found in a protein secreted by the prostate, and elevated levels of PSA can be associated with either prostatitis (a noncancerous inflammatory condition) or a proliferation of cancer cells in the prostate. Industry studies have shown that the PSA test can detect prostate cancer up to five years earlier than the digital rectal exam. Ultrasound tests and biopsies are typically performed on patients with elevated PSA readings to confirm the existence of cancer.

Our Strategy

The key elements of IsoRay's strategy include:

- *Continue to introduce the IsoRay ¹³¹Cs seed into the U.S. brachytherapy market.* Utilizing a direct sales organization and selected channel partners, IsoRay intends to capture a leadership position by expanding overall use of the brachytherapy procedure for prostate cancer, capturing much of the incremental market growth and taking market share from existing competitors.
- *Create a state-of-the-art manufacturing process.* IsoRay has constructed a state-of-the-art manufacturing facility in Richland, Washington in its leased facility, to implement our proprietary manufacturing process which is designed to improve profit margins and provide adequate manufacturing capacity to support future growth and ensure quality control. If Initiative 297 presents a strategic roadblock to the Company, or if attractive financing alternatives are available in another state, IsoRay will construct a permanent manufacturing facility in another state. Working with leading scientists, IsoRay intends to design and create a proprietary separation process to manufacture enriched barium, a key source material for ¹³¹Cs, to ensure adequate supply and greater manufacturing efficiencies.
- *Introduce Cesium-131 therapies for other cancers.* IsoRay intends to partner with other companies to develop the appropriate delivery technology and therapeutic delivery systems for treatment of other solid tumors such as breast, lung, liver, pancreas, neck, and brain cancer. IsoRay's management believes that the first major opportunities may be for the use of Cesium-131 in adjunct therapy for the treatment of residual lung and breast cancers.
- *Support clinical research and sustained product development.* The Company plans to structure and support clinical studies on the therapeutic benefits of Cs-131 for the treatment of solid tumors and other patient benefits. We are and will continue to support clinical studies with several leading radiation oncologists to clinically document patient outcomes, provide support for our product claims and compare the performance of our seeds to competing seeds. IsoRay plans to sustain long-term growth by implementing research and development programs with leading medical institutions in the U.S. to identify and develop other applications for IsoRay's core radioisotope technology.

Management believes there is a large and growing addressable market for IsoRay's products. Several factors appear to contribute to the increasing popularity of the brachytherapy procedure. Long-term survival data are now available for brachytherapy (other than with respect to treatment from Cs-131 seeds). Brachytherapy has become the treatment of choice for not only early-stage prostate cancer but is now being considered for treatment of fast growing, aggressive tumors. For the treatment of prostate cancer, seed brachytherapy is now more common than surgery (radical prostatectomy). Seed brachytherapy has significant advantages over competing treatments including lower cost, better

survival data, fewer side effects, a faster recovery time and the convenience of an outpatient procedure that generally lasts 45 minutes. Over 60,000 procedures were forecasted to occur in the U.S. in 2005. At the February 1, 2007 Cs-131 seed price of \$59, this represents a potential \$350 million market for seeds that is forecast to grow substantially by 2009 according to a recent market survey performed by Frost & Sullivan, a nationally recognized market research firm. IsoRay's management believes that the ¹³¹Cs seed will add incremental growth to the existing brachytherapy seed market as physicians who are currently reluctant to recommend brachytherapy for their prostate patients due, in part, to side effects caused by longer-lived isotopes, become comfortable with the shorter half-life of ¹³¹Cs, and the anticipated reduction of side effects.

Products

IsoRay markets the Cesium-131 seed and intends to market other radioactive isotopes in the future. Additionally, it will attempt to create a market, primarily in clinical trials, for the liquid Cs-131 isotope, which is created in the production of IsoRay's ¹³¹Cs seed.

Cs-131 Seed Product Description and Use in Cancer Treatment

Brachytherapy seeds are small devices that deliver therapeutic radiation directly to tumors. Each seed contains a radioisotope sealed within a welded titanium capsule. In prostate cancer procedures, approximately 85 to 135 seeds are permanently implanted in a 45-minute outpatient procedure. The isotope decays over time, and the seeds become inert. The seeds may be used as a primary treatment or in conjunction with other treatment modalities such as external beam radiation therapy, chemotherapy, or as treatment for residual disease after excision of primary tumors.

Significant advantages of brachytherapy over competing treatments include: fewer side effects (the likelihood of impotence and incontinence is reduced when seeds are used to treat prostate cancer); short, convenient outpatient procedure (typically 45 minutes); faster recovery time (days vs. weeks); lower cost than other treatment modalities; higher cure rates for solid tumors; less pain; and overall considerably better quality of life. The primary disadvantage of brachytherapy is subjecting the human body to radiation and the side effects of radiation. Physician errors in seed placement and the number of seeds implanted may also result in the failure to eradicate the cancer or in negative side effects from over-radiation of certain tissues in the body.

A diagram of the IsoRay seed appears in Figure 1. The seed contains an x-ray opaque marker surrounded by a ceramic substrate to which the isotope is chemically attached. The seed core is placed in a titanium tube and precision laser welded to form a hermetically sealed source of therapeutic radiation suitable for permanent implantation. The x-ray marker allows the physician to accurately determine seed placement within the tumor.

Figure 1: Cross section of ¹³¹Cs seed

Competitive Advantages of Cs-131

Management believes that ¹³¹Cs has specific clinical advantages for treating cancer over I-125 and Pd-103, the other isotopes currently used in brachytherapy seeds. The table below highlights the key differences of the three seeds. The Company believes that the short half-life, high-energy characteristics of ¹³¹Cs will increase industry growth and facilitate meaningful penetration into the treatment of other forms of cancer such as breast cancer.

Brachytherapy Isotope Comparison

	Cesium-131	Palladium-103	Iodine-125
Half Life	9.7 Days	17.5 days	60 days
Avg. Energy	30.4 KeV+	21 KeV+	28.5 KeV+
Dose Delivery	90% in 33 days	90% in 58 days	90% in 204 days
Total Dose	115 Gy	125 Gy	145 Gy
Anisotropy Factor*	.969	.877 (TheraSeed® 2000)	.930 (OncoSeed® 6711)

* Degree of symmetry of therapeutic dose, a factor of 1.00 indicates symmetry.

+ KeV = kiloelectron volt, a standard unit of measurement for electrical energy.

Shorter half-life. The Company believes that Cesium-131's shorter half-life of 9.7 days will prove to have greater biological effectiveness, will mitigate the negative effects of long radiation periods on healthy tissue and will reduce the duration of any side effects. A shorter half-life produces more intense therapeutic radiation over a shorter period of time and may reduce the potential for cancer cell survival and tumor recurrence. Radiobiological studies indicate that shorter-lived isotopes are more effective against faster growing tumors (Dicker, et. al., *Semin. Urol. Onc.* 18:2, May 2000). Other researchers conclude that "half-lives in the approximate range 4-17 days are likely to be significantly better for a wide range of tumor types for which the radiobiologic characteristics may not be precisely known in advance." (Armpilia CI, et. al., *Int. J. Rad. Oncol. Biol. Phys.* 55:2, February 2003).

Higher energy. The Cs-131 isotope average decay energy of 30.4 KeV (versus 21 KeV for Pd-103 and 28.5 KeV for I-125) generates a therapeutic radiation field that extends beyond the current dosimetry reference point of 1 cm. Pd-103 seeds emit radiation that does not penetrate as far in tissue (up to 40% lower than Cs-131). To compensate for this more Pd-103 seeds are required to attain the equivalent dose as if Cs-131 seeds were used. This increase in the number of seeds implanted increases the time and cost required to perform Pd-103-based procedures. The lower energy from ¹⁰³Pd seeds may also result in greater non-uniformity of the implant dose as dose rates near the surface of each seed must be higher to compensate for lower doses at greater distances from each seed. The high energy of Cs-131 can result in radiation toxicity if the dosage is not properly calculated by the implanting physician and staff but the higher energy of Cs-131 does make the isotope more "forgiving" for treatment planning purposes.

Reduced side effects. Because the IsoRay ¹³¹Cs seed device delivers a highly concentrated and confined dose of radiation directly to the prostate, healthy surrounding tissues and organs are exposed to less radiation than with other treatments. Management believes this should result in fewer and less severe side effects and complications than may be incurred with other conventional therapies.

Figure 2: Cs-131 seed Autoradiograph

Shape of radiation field. The shape of the radiation field generated by a ¹³¹Cs seed is more uniform than most brachytherapy seed designs, and this uniformity may result in better radiation dose coverage and improved therapeutic effectiveness. Figure 2 shows an autoradiograph (film exposed by radiation from the seed itself) of an IsoRay seed, which shows this uniformity of the radiation field that is expected to result in better radiation dose coverage. IsoRay has conducted extensive computer modeling and testing of the seed design. The IsoRay seed has passed all Nuclear Regulatory Commission ("NRC") requirements for sealed radioactive sources. Dose uniformity was tested and the results compared well to those predicted by industry standard computer modeling techniques. In the third quarter of 2002, seeds were sent to the National Institute for Standards and Technology for calibration, and have undergone dosimetry testing according to American Association of Physicists in Medicine ("AAPM") protocols. The results of these tests were compiled in IsoRay's 510(k) submission to the FDA and were subsequently published in the June 2004 issue of *Medical Physics*. The results of these tests showed superior dose characteristics relative to the leading I-125 and Pd-103 seeds.

Reduced costs. The characteristics of ^{131}Cs seeds described above may result in the use of 10%-30% less seeds per procedure, compared to other isotopes, thereby reducing the total physical radiation dose to the patient and reducing the costs of the procedure for the third-party payers and the patient.

Cs-131 Manufacturing Process

Cs-131 is a radioactive isotope that can be produced by the neutron bombardment of Barium-130. When Ba-130 is put into a nuclear reactor it becomes Ba-131, the radioactive material that is the parent isotope of Cs-131. The overall process includes the following:

Isotope Generation. The radioactive isotope Cs-131 is normally produced by placing a quantity of stable non-radioactive barium (ideally pure Ba-130) into the neutron flux of a nuclear reactor. The irradiation process converts a small fraction of this material into a radioactive form of barium (Ba-131). The Ba-131 decays by electron capture to the radioactive isotope of interest (Cs-131). Due to the short half-life of both the Ba-131 and Cs-131 isotopes, potential suppliers must be capable of removing irradiated materials from the reactor core on a routine basis for subsequent processing to produce ultra-pure Cs-131. The Company has identified more than five reactors facilities in the U.S., Europe and the former Soviet Union that are capable of meeting these requirements. As of November 10, 2006, IsoRay had agreements in place with three suppliers of irradiated Ba-131 or Cs-131. The Company's agreement with Russia's Institute of Nuclear Materials (which commenced as of August 25, 2005 and ends August 25, 2012) allows the Company to purchase irradiated Ba-131 for \$300.00 per Curie of the isotope. The projected value of the agreement over its term is \$30,000,000 with \$300,000 worth of isotope projected to be delivered in the first full year of production, although neither of these amounts are obligations to purchase any given quantity of the isotopes in a particular time period. Through September 30, 2006, the Company had paid approximately \$202,000 to the Institute of Nuclear Materials. On October 6, 2006, Medical entered into a Contract with FSUE "SSE - Research Institute of Atomic Reactors ("RIAR") in Russia. The Contract provides for delivery to Medical of purified Cs-131 isotope, which is used by Medical to produce its proprietary Cs-131 brachytherapy seed used in the treatment of prostate cancer. The total value of the Contract over its term, which expires on May 1, 2014, is \$6,300,000. Delivery of the isotope is scheduled to commence in October 2007 and continue through December 2013, upon submission of written orders by Medical forty-five days in advance of the planned date of delivery. Medical also entered into an Agreement for Exclusive Rights to Buy on October 6, 2006 with RIAR. This Agreement gives Medical the exclusive right to purchase the Cs-131 isotope produced by RIAR for a period of seven years, or through October 6, 2013. In addition, the Company is engaged in the development of a barium enrichment device that, if successful, should reduce the cost of producing Cs-131 while maintaining the purity and consistency required in the end product.

Isotope Separation and Purification. Upon irradiation of the barium feedstock, the Ba-131 begins decaying to Cs-131. At pre-determined intervals the Cs-131 produced is separated from the barium feedstock and purified using a proprietary radiochemical separations process (patent applied for). Due to the high-energy decay of Ba-131, this process is performed under stringent radiological controls in a highly shielded isolator or "hot cell" using remote manipulators. After separating Cs-131 from the energetic Ba-131, subsequent seed processing may be performed in locally shielded fume hoods or glove boxes. If enriched barium feedstock is used, the residual barium remaining after subsequent Cs-131 separation cycles ("milkings") will be recycled back to the reactor facility for re-irradiation. This material will be recycled as many times as economically feasible, which should make the process more cost effective. As an alternative to performing the Cs-131 separation in our own facilities, IsoRay may enter into agreements with other entities to supply "raw" Cs-131 by performing the initial barium/cesium separation at their facilities, followed by final purification at IsoRay's facility.

§ Internal Seed Core Technology. The purified Cs-131 isotope is incorporated into an internal assembly that contains a binder, spacer and a gold X-ray marker. This internal core assembly is subsequently inserted into a titanium case. The dimensional tolerance for each material is extremely important. Several carrier materials and placement

methods have been evaluated, and through a process of elimination, we have developed favored materials and methods during our laboratory testing. The equipment necessary to produce the internal core includes accurate cutting and gauging devices, isotope incorporation vessels, reaction condition stabilization and monitoring systems, and tools for placing the core into the titanium tubing prior to seed welding.

·*Seed Welding.* Following production of the internal core and placement into the titanium capsule, each seed is laser welded to produce a sealed radioactive source and biocompatible medical device. This manufacturing technology requires: accurate placement of seed components with respect to the welding head, accurate control of welding parameters to ensure uniform temperature and depth control of the weld, quality control assessment of the weld integrity, and removal of the finished product for downstream processing or rejection of unacceptable materials to waste. Inspection systems are capable of identifying and classifying these variations for quality control and to ensure low scrap rates. Finally, the rapid placement and removal of components from the welding zone affects overall product throughput.

·*Quality Control.* We have established procedures and controls to meet all FDA and ISO 9001:2000 Quality Standards. Product quality and reliability will be secured by utilizing multiple sources of irradiation services, feedstock material, and other seed manufacturing components. An intensive production line preventive maintenance and spare parts program will be implemented. Also, an ongoing training program will be established for customer service to ensure that all regulatory requirements for the FDA, DOT and applicable nuclear radiation and health authorities are fulfilled.