

IsoRay, Inc.
Form SB-2/A
April 27, 2006

As filed with the Securities and Exchange Commission on April 27, 2006

Registration Statement No. 333-129646

SECURITIES AND EXCHANGE COMMISSION

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

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

Minnesota	3841	41-1458152
(State of Incorporation)	(Primary Standard Industrial Classification Code Number)	(IRS Employer ID No.)

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

**Roger Girard, CEO
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Approximate date of commencement of proposed sale to the public: From time to time after this registration statement becomes effective.

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. ☒

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. ☐

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. ☐

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. ☐

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

CALCULATION OF REGISTRATION FEE

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

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

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

- (3) Previously paid.
- (4) Represents a combination of (2) and (5).
- (5) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended, based upon the average of the bid and asked prices of the Registrant's common stock on March 20, 2006.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The selling shareholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Preliminary Prospectus, Subject to Completion, dated April 26, 2006

ISORAY, INC.

4,637,100 Shares

Common Stock

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

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

Our common stock is listed on the OTC Bulletin Board under the symbol "ISRY.OB." On April 21, 2006, the last reported bid price of our common stock was \$6.00 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 April 26, 2006.

**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 ("IsoRay 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. We are also in the process of developing a second product, Yttrium-90, which is a radioisotope that is already in use for the treatment of certain forms of metastasized, or "spread throughout the body," cancers.

Our Corporate History

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

IsoRay 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 in the near future to continue our operations. Management expects our independent auditors will continue to express doubt about our ability to continue as a going concern for the foreseeable future.

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

The Offering

Common Stock Offered	4,637,100 shares by selling shareholders
Offering Price	Market price or negotiated price
Common Stock Outstanding Before the Offering	14,717,686 shares as of April 25, 2006
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" or **"¹³¹Cs"** 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 Medical'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.

"Yttrium-90" or **"⁹⁰Y"** is a radioisotope that emits high energy beta particles with a half-life of 2.67 days.

"Zirconium-90" is a stable (non-radioactive) decay product of Yttrium-90.

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 Subsidiary's Independent Accountants Have Expressed Doubt About Its Ability To Continue As A Going Concern. IsoRay Medical 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 or obtaining loans and grants from various financial institutions where possible. The doubt expressed by our subsidiary's auditors about its ability to continue as a going concern increases the difficulty in meeting such goals. IsoRay Medical began generating revenue in October 2004, has generated revenue of approximately \$898,893 through December 31, 2005, and is in the early stages of marketing its IsoRay ¹³¹Cs seed. IsoRay Medical and the Company have limited historical, operating or financial information upon which to evaluate their 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 ("CMS") or third party payors; 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. Currently, 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 will require ever increasing market share to increase revenues.

We Have Limited Data On The Clinical Performance Of ¹³¹Cs. As of March 31, 2006 the IsoRay ¹³¹Cs seed had been implanted in approximately 227 patients. While this limited 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 findings support management's belief that the ^{131}Cs 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. Monthly operating cash requirements were approximately \$620,000, and monthly capital expenditures were approximately \$70,000, as of February 2006. 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. Budgets have been established with a goal of anticipating and supporting sales growth to meet increasing market demand. The IsoRay companies have raised over \$18 million from 1998 through February 2006, and we will need to raise additional cash to support market acceptance of our initial product and market readiness of any subsequent products. Consequently, we intend to seek to raise additional capital through not only public and private offerings of equity and debt securities, but also through collaborative arrangements, strategic alliances, or from other sources. IsoRay Medical has entered into a facility lease agreement and has relocated to a manufacturing and production facility located in Richland, Washington that its management believes will provide adequate space to manufacture the ^{131}Cs seed product for the prostate and other organ cancer markets until late 2007.

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, including the Pacific Northwest National Laboratory ("PNNL"), which is where our ^{131}Cs seed product has historically been manufactured. 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 December 2005 IsoRay transitioned production operations from PNNL to our new, leased facility outside of PNNL.

The U.S. Secretary of Energy is a party to litigation challenging the constitutionality of Initiative 297 in U.S. District Court. Due to this litigation, the State of Washington and the U.S. Justice Department have agreed to delay any implementation of Initiative 297 for an indefinite period of time. Thus, we have the ability to continue manufacturing seeds at PNNL for some period of time if needed as a back-up to our new IsoRay production facility, or to conduct further development activities there. If the State of Washington begins enforcement of the initiative, we may be unable to conduct any future activities at PNNL that would generate mixed radioactive and hazardous wastes.

Management believes that we will be able to continue our manufacturing operations in the State of Washington for the foreseeable future, whether at PNNL or at our new leased facility, which is now operational. 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 Medical and the Company have experience primarily in research and development of products and our experience in commercial-scale manufacturing is limited. IsoRay Medical began commercial production of the ^{131}Cs seed in the fourth quarter of 2004. IsoRay Medical recently demonstrated production of ^{90}Y using a process suitable for weekly production of commercial-scale quantities of this isotope. Although IsoRay Medical's management team has significant radiochemistry experience, there is a possibility that future production demands may result in challenges that may be too difficult or expensive to overcome. IsoRay Medical has developed and deployed semi-automated laser welding equipment that can produce seeds faster than a fully-automated lines of equipment the Company has reviewed that would cost several million dollars to design, fabricate and install. IsoRay Medical believes it 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. With its new facility, IsoRay's management believes that IsoRay will be able to meet future demand unless demand greatly exceeds management's current projections, which management does not believe will occur. IsoRay Medical has entered into a lease agreement and has relocated to a manufacturing and production facility located in Richland, Washington that its management believes will provide adequate space to manufacture the ^{131}Cs seed product for the prostate and other organ cancer markets until late 2007.

Sales And Marketing Experience. IsoRay Medical's sales and marketing team has extensive experience in successfully establishing and training domestic and international sales forces as well as successfully introducing new medical devices to the market, but we have less than three years of specific experience with commercial sales and marketing of the Cesium-131 radioisotope. IsoRay Medical has employed marketing professionals with extensive experience selling medical devices, including radioisotopes for large, international companies. Our initial marketing activities have been targeted to a select number of physicians and cancer treatment centers, and we will need to recruit additional sales representatives to assist in expanding our customer base. We have developed in-house customer service, order entry, shipping, billing, and sales support. In addition, the Company has engaged a nationally recognized reimbursement specialist Kathy Francisco, of The Pinnacle Health Group, with over 25 years of healthcare reimbursement experience, to assist with reimbursement questions and to provide reimbursement guidelines and appropriate insurance coding numbers needed to obtain reimbursement for seed costs and the implant procedure by our customers. This consulting project was completed by the spring of 2005 and cost IsoRay approximately \$7,500 plus travel-related expenses. Although this group and other consultants continue to be available to support the Company in its reimbursement and marketing programs, we cannot be certain that our products will be marketed and distributed in accordance with our expectations or that our market research will be accurate. We also cannot be certain that we will be able to develop our own sales and marketing capabilities to the extent anticipated by management. We may choose to add third-party distribution channels, but we may not be able to maintain satisfactory arrangements with the third parties upon whom we rely.

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, IsoRay Medical was notified by one of its primary customers, Chicago Prostate Cancer Center ("CPCC"), that it would no longer accept ¹³¹Cs products from the radiopharmacy exclusively used by IsoRay Medical 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. IsoRay immediately began negotiations with Advanced Care Medical, Inc. ("ACM"), an approved CPCC supplier, and executed a contract with ACM on March 1, 2006 for radiopharmacy services using our ¹³¹Cs seed. IsoRay anticipates CPCC will resume ordering and using our ¹³¹Cs seed product as soon as ACM receives an amendment to its radioactive materials license to process products containing the ¹³¹Cs isotope. Although this temporary suspension of seed orders by CPCC has had a negative impact on revenue in the near term, the Company's management believes any long-term impact will be non-material.

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 approval, 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 Heavily Rely 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. 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 control and our suppliers' control.

Future Production Increases Will Depend on Our Ability to Acquire Larger Quantities of ^{131}Cs and Hire More Employees. IsoRay currently obtains ^{131}Cs through reactor irradiation of natural barium and subsequent separation of cesium from the irradiated barium targets. The amount of ^{131}Cs 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 ^{130}Ba . 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 an exclusive agreement with the Institute of Nuclear Materials in the former Soviet Union to provide irradiated barium and ^{131}Cs in quantities sufficient to supply a significant percentage of future demand for ^{131}Cs . Delivery of the isotopes from the Institute of Nuclear Materials began in January 2006. IsoRay believes this supplier may also provide access to sufficient quantities of enriched barium that may be recycled for use in other reactors to increase the production of ^{131}Cs . Although the agreement provides for supplying ^{131}Cs 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.

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 payors, 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 payors 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 payors, and we can provide no assurance that our products will continue to qualify for reimbursement from all third-party payors 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, IsoRay applied to CMS and received reimbursement codes for use of our ^{131}Cs seed (HCPCS code C2633 and APC code 2633). However, since January 1, 2004 hospitals and clinics ordering brachytherapy seeds have been reimbursed for the cost of the seeds plus a fixed mark-up at a rate prescribed by CMS. Reimbursement amounts are reviewed and revised periodically, and on an ad hoc basis. Although the Company is not currently aware of any changes to CMS reimbursement rates that would have a material effect on our ability to maintain our pricing structure, 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 ^{131}Cs 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. 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, and the deadline to file for patent protection in certain countries is approaching. If management determines that the cost of filing in certain countries is not justified, our products may not have adequate protection in those countries.

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 ^{131}Cs 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 IsoRay 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 Food and Drug Administration ("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.

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 coverage in amounts our management believes are customary for similarly situated businesses, 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. We currently dispose of radioactive waste generated at PNNL under a one year renewable agreement that also covers our use of PNNL's facilities and personnel for our activities there. Waste disposal costs for production runs through December 2005 totaled approximately \$70,000. At our new, leased facility we intend to use a commercial disposal contractor, although we have not yet entered into any agreements for these services. We may incur substantial costs related to the disposal of these materials depending on final waste classification. Waste disposal costs for 2006 are projected by management to be similar to disposal costs for 2005. In addition to ongoing waste disposal costs, we anticipate paying approximately \$75,000 of cleanup costs in 2006 as a result of our withdrawal from PNNL. 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. We have an employment agreement with Roger Girard, our Chief Executive Officer, and our 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 ^{90}Y 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 contract with the Institute of Nuclear Materials.

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. 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 additional provisions of the Sarbanes Oxley Act of 2002 are implemented. These reporting obligations will 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 And No Existing Market For Our Warrants. Currently only a limited trading market exists for our common stock. Our common stock trades on the OTC Bulletin Board, a market with limited liquidity, under the symbol "ISRY.OB" and on the Pink Sheets, also a market with limited liquidity, under the symbol "ISRY.PK." During the fifty days preceding April 25, 2006, our average daily volume on the OTCBB was 3,300 shares. 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, and quotations are limited and sporadic. 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 for 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. If the market price of our shares declines below \$5.00 per share, our shares would be subject to the provisions of Section 15(g) and Rule 15g-9 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), 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 registrant's net tangible assets; or exempted from the definition by the SEC. If our shares were deemed to be "penny stocks", trading in the shares would be subject to additional sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors.

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 April 25, 2006, we had 14,717,686 outstanding shares of common stock, and the following additional shares were reserved for issuance: 2,992,535 shares upon exercise of outstanding options, 3,073,560 shares upon exercise of outstanding warrants, 181,248 shares upon conversion of preferred stock, and 109,639 shares upon conversion of convertible debentures. On the effective date of this prospectus, a total of 7,654,272 shares of common stock (including 632,836 shares issuable upon conversion or exercise of preferred stock and derivative securities and including not only shares registered through this prospectus but also the 2,389,595 shares registered through our Form S-8 registration statement filed on August 19, 2005 and 627,577 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 38% of our shares

of common stock on a fully diluted basis.

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In addition, we are granting registration rights that may not be exercised prior to October 2006 to purchasers of units pursuant to the October 17, 2005 private placement memorandum, as amended, which closed in January 2006 (the "October 17, 2005 Offering"), pursuant to the February 1, 2006 private placement memorandum, which closed on February 28, 2006, and to debenture holders that elected to remove the shares into which their debentures are convertible from this Prospectus and convert their debentures instead into units, consisting of 5,000 shares of common stock to purchase 5,000 shares of common stock per unit at a price of \$20,000 per unit. 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 were converted or exercised into shares of common stock, there would be an additional 594,651 shares of common stock outstanding as a result. The issuance of these shares will have the effect of further diluting the proportionate equity interest and voting power of holders of our common stock, including investors in this offering.

We Do Not Expect To Pay Any Dividends For The Foreseeable Future. We do not anticipate paying any dividends to our shareholders for the foreseeable future. The terms of certain of our and IsoRay 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.

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" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and subject to the safe harbor created by the Private Securities Litigation Reform Act of 1995, which reflect the Company's current views with respect to future events and financial performance. The words "believe," "expect," "anticipate," "intends," "estimate," "forecast," "project," and similar expressions identify forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any statements of the plans, strategies and objectives of management for future operations; any statements concerning proposed new products, services, developments or industry rankings; any statements regarding future economic conditions or performance; any statements of belief; any statements regarding the validity of our intellectual property and patent protection; and any statements of assumptions underlying any of the foregoing. Such "forward-looking statements" are subject to risks and uncertainties set forth from time to time in the Company's SEC reports and include, among others, the Risk Factors set forth above.

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

USE OF PROCEEDS

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

MANAGEMENT'S DISCUSSION AND ANALYSIS

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

IsoRay, Inc. (formerly known as Century Park Pictures Corporation) is 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, began selling its initial product, the Food and Drug Administration approved IsoRay Cesium-131 brachytherapy seed (the "IsoRay¹³¹Cs seed"), in October 2004 for the treatment of prostate cancer. Our management believes that the clinical benefits of using Cesium-131 will enable us to capture market share within the existing brachytherapy market, which uses Palladium-103 and Iodine-125. We are also in the process of developing a second product, Yttrium-90, which is a radioisotope that is already in use for the treatment of certain forms of metastasized, or "spread throughout the body," cancers.

The physical 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. The second radioisotope, Yttrium-90 (Y-90 or ⁹⁰Y), is currently being used in the treatment of non-Hodgkin's lymphoma and is in clinical trials for other applications, including brachytherapy. Other manufacturers have received FDA approval for ⁹⁰Y and IsoRay Medical believes production will not require clinical trials or an extensive FDA application process. Production is expected to begin in 2006.

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 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 ¹³¹Cs 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

¹³¹Cs seed has FDA approval 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.

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

Results of Operations.

Nine months ended June 30, 2005 compared to the year ended September 30, 2004

Century Park Pictures Corporation (now IsoRay, Inc.) had no revenue for the nine months ended June 30, 2005 or for either of the years ended September 30, 2004 and 2003.

On July 28, 2005, the Company entered into a reverse merger transaction with IsoRay Medical, Inc. whereby IsoRay Medical, Inc. became a wholly-owned subsidiary of the Company.

The acquisition of IsoRay Medical on July 28, 2005 by the Company was accounted for as a "reverse acquisition" whereby IsoRay is the accounting acquirer for financial statement purposes. Accordingly, for all periods subsequent to July 28, 2005, the financial statements of the Company reflect the historical financial statements of IsoRay from the inception of each respective entity composing IsoRay Medical, Inc. at the July 28, 2005 change in control transaction and the operations of the Company subsequent to the July 28, 2005 transaction.

The Company originally had a September 30 year end. As a result of the July 28, 2005 reverse acquisition transaction, the Company's Board of Directors changed IsoRay, Inc.'s (formerly Century Park Pictures Corporation) year-end to June 30 to correspond to the year end of its newly acquired subsidiary, IsoRay Medical, Inc.

General and administrative expenses for the nine months ended June 30, 2005 were approximately \$30,128 as compared to approximately \$9,095 for the year ended September 30, 2004. The increase was directly related to various professional fees incurred in the consummation of the July 2005 business combination transaction with IsoRay Medical, Inc.

In conjunction with a May 2005 sale of equity securities for approximately \$85,000, the Company, the Company's then-CEO and the purchasing shareholders negotiated a settlement whereby all outstanding debt owed to the then-CEO in the form of accrued compensation and working capital advances was settled in full for approximately \$50,000. As a result of these negotiations, the Company's then-CEO forgave approximately \$304,500 in accrued salary for prior periods and this forgiveness was credited as "additional paid-in capital".

Year ended September 30, 2004 compared to year ended September 30, 2003

General and administrative expenses for the years ended September 30, 2004 and 2003 were approximately \$9,095 and \$19,022, respectively. The principal component of these expenditures was the accrual of interest on outstanding notes payable and operating expenses related to maintaining the Company's compliance with the Securities Exchange Act of 1934. Interest expense for the years ended September 30, 2004 and 2003 was approximately \$2,100 in each

respective year. Included in interest expense for Fiscal 2004 and 2003 is approximately \$2,100 and \$41,000 in imputed interest calculated as a result of the respective noteholders agreeing to discontinue their rights to interest subsequent to July 31, 2002.

The Company's expenditures prior to the merger consisted solely of items necessary to comply with the Company's periodic reporting obligations under the Securities Exchange Act of 1934 and were not necessarily reflective of what may be expected in future periods subsequent to the merger.

Three and six month periods ended December 31, 2005 and 2004

Revenues. During the three month period ended December 31, 2005, the Company generated \$486,247 in sales of its ¹³¹Cs seed. This represents an increase of \$275,332 or 131% over sales in the three months ended September 30, 2005 (the "Prior Quarter") of \$210,915. Sales for the six month period ended December 31, 2005 were \$697,162. No revenue was recorded by the Company in the three month and six month periods ended December 31, 2004 as the Company had no operations then. IsoRay Medical began sales of its ¹³¹Cs seed on October 26, 2004, prior to its merger with the Company, with one medical center customer. By December 31, 2005 the number of medical center customers who have ordered the ¹³¹Cs seed had grown to seventeen.

On January 5, 2006, IsoRay Medical was notified by one of its primary customers, Chicago Prostate Cancer Center ("CPCC"), that it would no longer accept ¹³¹Cs products from the radiopharmacy exclusively used by IsoRay Medical 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. IsoRay immediately began negotiations with Advanced Care Medical, Inc. ("ACM"), an approved CPCC supplier, and executed a contract with ACM for radiopharmacy services using our ¹³¹Cs seed on March 1, 2006. IsoRay anticipates CPCC will resume ordering and using our ¹³¹Cs seed product as soon as ACM receives an amendment to its radioactive materials license to process products containing the ¹³¹Cs isotope. Although this temporary suspension of seed orders by CPCC has had a negative impact on revenue in the near term, the Company's management believes any long-term impact will be non-material.

Gross loss. Gross loss was \$(430,027) for the three month period ended December 31, 2005. This represents an improvement of \$79,224, or 16% over the Prior Quarter's gross loss of \$(509,251). Gross loss was \$(939,278) for the six month period ended December 31, 2005. Cost of products sold was \$916,274 for the three month period ended December 31, 2005. Of this, approximately \$356,000 was paid to Pacific Northwest National Laboratory (PNNL) under our contract with them for use of their facilities and personnel to support production. This was an increase in cost of products sold of \$196,108 or 27% more than the Prior Quarter. In the three month period ended December 31, 2005, we spent in excess of \$109,000 for production materials 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 current fiscal year. According to plan, by the end of the quarter ended December 31, 2005 we had moved essentially all Cs-131 production operations to PIRL. We will continue to use the PNNL facility only for certain research and development and quality assurance activities. In the next quarter, we expect to substantially reduce the PNNL expense. Cost of products sold for the six month period was \$1,636,440. As the Company had no operations for several years prior to its merger with IsoRay Medical, no cost of sales was reported for the three and six month periods ended December 31, 2004.

Research and development. Research and development expenses for the three month period ended December 31, 2005 were \$96,837. This represents an increased expenditure of \$71,055, or a 276% increase over the Prior Quarter's expense of \$25,782. Of total research and development expenses, \$82,500 was paid in conjunction with the ongoing protocol study on the results of 100 patients who have recently been implanted with the Company's ¹³¹Cs brachytherapy seed. Research and development expenses for the six month period ended December 31, 2005 were \$122,619. The Company had no research and development activities for several years prior to its merger with IsoRay Medical, accordingly no research and development cost was recorded for the three and six month periods ended December 31, 2004.

Sales and marketing expenses. Sales and marketing expenses were \$340,532 for the three-month period ended December 31, 2005. This represents an increase of \$25,493 or 8% compared to the Prior Quarter's expenditure of \$315,039 for sales and marketing. Of total sales and marketing expenses, approximately \$236,000 was paid for wages, including payroll-related taxes, travel, office and other support expenses on behalf of our sales and marketing and

customer service staff. This represents a \$4,600, or 2% increase of expenditure over the prior quarter. The balance was spent on advertising, market research, and trade shows and conferences. Sales and marketing expense for the six month period ended December 31, 2005 was \$655,571. As the Company had no sales for several years prior to its merger with IsoRay Medical, no sales and marketing expenses were recorded for the three or six month periods ended December 31, 2004.

General and administrative expenses. General and administrative expenses for the three month period ended December 31, 2005 amounted to \$675,444. This represents an expense reduction of \$285,505 or 30% in comparison to the Prior Quarter's expense of \$960,949. The reduction is mostly due to the Prior Quarter's recognition of a one-time compensation expense of \$330,000, representing the value of 168,472 shares of IsoRay common stock issued to an individual as a finder's fee in conjunction with the merger of the Company and IsoRay Medical, Inc.

Approximately \$199,040 was paid in wages and related benefits and taxes during the period. This represented a decrease of approximately \$29,750, or 13% compared to the Prior Quarter. Legal expenses were \$104,110 for the period, representing a reduction of \$57,220 or a 35% reduction in legal expense as compared to the Prior Quarter's expense of \$161,330. This reduction was almost entirely due to approximately \$56,000 spent in the Prior Quarter in conjunction with a successful out-of-court settlement of an employment dispute. General and administrative expenses for the six month period ended December 31, 2005 amounted to \$1,628,661. General and administrative expenses for the three and six month period ended December 31, 2004 were \$3,574 and \$7,743, respectively.

Operating (loss). Due to our significant research and development expenditures, additional responsibilities as a reporting company, rapid structural growth, and nominal product revenues, we have not been profitable, and have generated operating losses since our inception. In the three month period ended December 31, 2005, the Company had an operating loss of \$(1,542,840). This represents a reduced loss of \$268,181 or 15%, in comparison with the Prior Quarter's operating loss of \$(1,811,021). Operating loss for the six month period ended December 31, 2005 was \$(3,346,130). Operating loss for the three and six month periods ended December 31, 2004 was \$(3,574) and \$(7,743), respectively.

Net non-operating expense. Total net non-operating expense was \$(436,384) for the three month period ended December 31, 2005. This represents an increase in net expense of \$(287,715) or 194% over the Prior Quarter's net non-operating expense of \$(148,669). This increase in non-operating income (expense) was largely due to the one-time recognition of \$244,097 expense in short-term inducement to convert debentures (see Note 7). The Company earned \$3,193 interest income on funds held in certain near-liquid accounts. This was \$3,766, or 54% less, than the Prior Quarter's interest income of \$6,959. During this period, financing expense was \$195,480, or an increased expense of \$39,852 or 26% over the Prior Quarter's financing expense of \$155,628. Of this amount, \$143,706 was paid as interest on loans, notes and convertible debentures outstanding. The balance of the financing expense was amortization of pre-paid financing expense, primarily 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. Total net non-operating expense for the six month period ended December 31, 2005 was \$(585,053). No net non-operating expense was recorded by the Company for the three and six month periods ended December 31, 2004.

Liquidity and capital resources. At December 31, 2005, cash and cash equivalents amounted to \$648,684. During the three months ended December 31, 2005, the Company issued 645,500 shares of common stock and granted warrants to purchase 645,500 shares of common stock pursuant to the October 17, 2005 Offering. This issuance of common stock provided the Company \$2,324,168, in cash, net of legal costs and commissions paid pursuant to the October 17, 2005 Offering. Additionally, the Company issued 5,488 shares of common stock pursuant to the exercise of options to purchase common stock, and options to purchase preferred stock, which were exchanged for common stock immediately upon exercise. This exercise of options provided the Company with \$5,009. Also during the three months ended December 31, 2005, the Company issued 10,000 shares of common stock in exchange for \$40,000 of production equipment repair and maintenance, certain capital production equipment, and consulting, and 24,007 shares of common stock in exchange for one year's lease of the PIRL facility.

On January 30, 2006, IsoRay closed a round of private financing under its October 17, 2005 private placement memorandum, as amended, which was fully sold at \$6 million. In February, IsoRay commenced a new round of private financing under its February 1, 2006 private placement memorandum, and had raised approximately \$1.2 million under that offering as of February 28, 2006, the date on which this offering was closed.

The Company had approximately \$2.5 million cash on hand as of March 31, 2006. As of that date the Company's monthly required cash operating expenditures were approximately \$620,000, and monthly capital expenditures were approximately \$70,000. Equipment installed at our facility includes a hot cell, a glove box, three fume-hoods, laser welders and laser welding tooling, which complete the laser sealing of the seeds; sophisticated testing equipment that allows us to test materials used at several stages of the production process and assay the completed seeds prior to shipment; and sterilizing and packaging systems that allow the seeds to be pre-loaded into delivery systems according to customer specifications. We believe we will need to add to the capital production equipment installed at this facility within the next six to twelve months to meet increasing demand for our product, and have adequate room at the facility to install equipment that would approximately double the production capacity up to 60,000 seeds per month; approximately 600 patient treatments. As of February 10, 2006, management believes that assuming expenditures continue at approximately the same monthly rate that the Company's cash on hand would fund operating expenditures through the beginning of August 2006.

On December 7, 2005, the Company entered into a SICAV ONE Securities Purchase Agreement and a SICAV TWO Securities Purchase Agreement (collectively, the "Purchase Agreements") with Mercatus & Partners, Limited, a United Kingdom private limited company ("Mercatus"). Pursuant to the Purchase Agreement, Mercatus agreed, subject to receipt of sufficient funding, to purchase 1,778,146 shares of the Company's common stock at a purchase price of \$3.502 per share, or an aggregate payment of \$6,227,067.29. In the event Mercatus does not purchase the shares, the share certificates will be returned to the Company and each party will have no further obligations under the Purchase Agreements. To date no funding has been received by the Company and the Company intends to request the return of the share certificates shortly.

Our growth plan for 2006 includes expanding sales to existing customers, continuing a trend that has improved in the second quarter of FY 2006; discontinuing production efforts at Pacific Northwest National Laboratory, which should decrease operating costs; enhancing efforts to reduce internal production costs; and expanding the base of suppliers of direct materials and value added services to direct materials.

On February 2, 2006, IsoRay signed a definitive license agreement with International Brachytherapy s.a. ("IBt") covering North America and providing IsoRay with access to IBt's Ink Jet produ