IsoRay, Inc.
Form SB-2/A
May 26, 2006

**As filed with the Securities and Exchange Commission on May 26, 2006**
**Registration Statement No. 333-129646**

---

**SECURITIES AND EXCHANGE COMMISSION**

---

**AMENDMENT NO. 4 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.)** |

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

---

**Roger Girard, CEO**
**350 Hills Street, Suite 106**
**Richland, WA 99354**
**(509) 375-1202**
**(Name, Address and Telephone Number of Agent for Service)**

***Copies of communications to:***

**Stephen R. Boatwright, Esq.**
**Alicia M. Corbett, Esq.**
**Keller Rohrback, PLC**
**3101 North Central Avenue, Suite 900**
**Phoenix, Arizona 85012**
**(602) 248-0088**

**Facsimile Number: (602) 248-2822**

---

**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. x

---

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

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

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

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

**CALCULATION OF REGISTRATION FEE**

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

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

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

[3] Previously paid.

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

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

**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 May 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 May 24, 2006, the last reported bid price of our common stock was $4.20 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 May 26, 2006.

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

---

**TABLE OF CONTENTS**

## 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 $^{131}$Cs seed"), in October 2004 for the treatment of prostate cancer. Cesium-131 or $^{131}$Cs 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 $^{131}$Cs 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 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.

1

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 $^{131}Cs$ seed are insufficient to find 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 | 14,722,686 shares as of May 24, 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 **"$^{131}Cs$"** 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.

**"$^{131}$Cs 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 **"$^{90}$Y"** 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 were 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 $1,378,000 through March 31, 2006, and is in the early stages of marketing its IsoRay $^{131}$Cs 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 $^{131}$Cs 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 $^{131}$Cs 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 $^{131}$Cs seed is used exclusively for the treatment of prostate cancer. We believe the $^{131}$Cs seed will be used to treat cancers of other sites as well, as is currently the case with our competitors' $^{125}$I and $^{103}$Pd 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 $^{131}$Cs.* As of April 30, 2006 the IsoRay $^{131}$Cs seed had been implanted in approximately 230 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 $^{125}$I and $^{103}$Pd 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 $630,000, and monthly capital expenditures were approximately $50,000, as of May 17, 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 $^{131}$Cs seed, and on other third parties, including various radiopharmacies, to package our $^{131}$Cs 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 $^{131}$Cs 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 $^{131}$Cs seeds which are then shipped directly to customers for use in patient implants. IsoRay immediately began working to bring these functions in house. On March 28, 2006, following commencement of operations of the Company’s pre-load department, which performs third party assay, preloading and sterilization of the $^{131}$Cs seeds, CPCC resumed ordering from us. Initial shipments of $^{131}$Cs seeds, custom-loaded to this customer’s specifications, met the quality control guidelines established by CPCC. Although the temporary three month’s suspension of seed orders by CPCC had a negative impact on revenue in the quarter ended March 31, 2006, the Company’s management believes any long-term impact will be nominal.

*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 $^{131}$Cs 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 $^{131}$Cs 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 April 2006 totaled approximately $82,000. 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 $70,000 of additional 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.* 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 May 24, 2006, our average daily volume on the OTCBB was 2,400 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. We have applied for listing on the NASDAQ Capital Market but there is no assurance that our shares will ultimately be listed.

*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 Deemed To Be "Penny Stock."* Our common stock will be deemed to be "penny stock" as that term is defined in Rule 3a51-1 promulgated under the Securities Exchange Act of 1934, as amended, so long as it remains at a price of less than $5.00 per share. These requirements may reduce the potential market for our common stock by reducing the number of potential investors. This may make it more difficult for investors in our common stock to sell shares to third parties or to otherwise dispose of them. This could cause our stock price to decline. Penny stocks are stock:

- With a price of less than $5.00 per share;

- That are not traded on a "recognized" national exchange;

- Whose prices are not quoted on the NASDAQ automated quotation system (NASDAQ listed stock must still have a price of not less than $5.00 per share); or

- In issuers with net tangible assets less than $2 million (if the issuer has been in continuous operation for at least three years) or $5 million (if in continuous operation for less than three years), or with average revenues of less than $6 million for the last three years.

Broker/dealers dealing in penny stocks are required to provide potential investors with a document disclosing the risks of penny stocks. Moreover, broker/dealers are required to determine whether an investment in a penny stock is a suitable investment for a prospective investor.

*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 May 24, 2006, we had 14,722,686 outstanding shares of common stock, and the following additional shares were reserved for issuance: 2,952,699 shares upon exercise of outstanding options, 3,073,561 shares upon exercise of outstanding warrants, 181,249 shares upon conversion of preferred stock, 34,836 shares upon conversion of options to purchase 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 2,832,529 shares registered through our Form S-8 registration statement filed on August 19, 2005 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 38% of our shares of common stock on a fully diluted basis.

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 and warrants 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 "IsoRay $^{131}$Cs 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 $^{131}$Cs) 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 $^{90}$Y), 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 $^{90}$Y 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.

13

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 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 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 nine month periods ended March 31, 2006 and 2005

**Revenues.** During the three month period ended March 31, 2006, the Company generated $479,225 in sales of its $^{131}$Cs seed. This represents an increase of $428,660 over sales in the three months ended March 31, 2005 (the "Prior Quarter") of $50,565. Sales for the nine month period ended March 31, 2006 were $1,176,387. This represents an increase of $1,101,652 over sales in the nine month period ended March 31, 2005. IsoRay Medical began sales of its $^{131}$Cs seed on October 26, 2004 with one medical center customer. By March 31, 2006 the number of medical center customers who have ordered the $^{131}$Cs seed had grown to 21. Although sales in the three month period ended March 31, 2006 were largely unchanged from sales levels in the previous quarter, sales in the most recent quarter included no sales to Chicago Prostate Cancer Center ("CPCC"), whose orders comprised a significant portion of total sales in the three month period ended December 31, 2005. However, the expansion of our customer base during the most recent quarter provided additional new customers whose orders essentially maintained the sales levels of the previous quarter.

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 $^{131}$Cs 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 $^{131}$Cs seeds which are then shipped directly to customers for use in patient implants. IsoRay immediately began working to bring these functions in house. On March 28, 2006, following commencement of operations of the Company's pre-load department, which performs third party assay, preloading and sterilization of the $^{131}$Cs seeds, CPCC resumed ordering from us. Initial shipments of $^{131}$Cs seeds, custom-loaded to this customer's specifications, met the quality control guidelines established by CPCC. Although the temporary three month's suspension of seed orders by CPCC has had a negative impact on revenue in the past quarter, the Company's management believes any long-term impact will be nominal. With the resumption of orders by CPCC, added to the increasing customer base, management believes sales for the following quarters will increase.

**Gross loss.** Gross loss was $312,232 for the three month period ended March 31, 2006. This represents an improvement of $209,075, or 40% over the Prior Quarter's gross loss of $521,307. Gross loss was $1,251,510 for the nine month period ended March 31, 2006. This represents an increased loss of $367,322 over the gross loss of $884,188 for the nine month period ended March 31, 2005. Cost of products sold was $791,457 for the three month period ended March 31, 2006. Components of this cost include charges from Pacific Northwest National Laboratories of approximately $200,000 for ancillary manufacturing services, which terminated in January 2006, waste disposal, testing and sample analysis and assay and technical services; approximately $256,000 in wages, benefits and related taxes, approximately $208,000 in direct and indirect materials, and the balance of approximately $127,000 in overhead expenses. This was an increase in cost of products sold of $219,585 or 38% more than the Prior Quarter. Cost of products sold for the nine month period ended March 31, 2006 was $2,427,897. This was an increase in cost of products sold of $1,468,974 over the nine month period ended March 31, 2005. Increased costs in the three and nine month periods are generally attributable to the Company's increased selling activity during the nine month period ended March 31, 2006.

**Research and development.** Research and development expenses for the three month period ended March 31, 2006 were $86,194. This represents an increased expenditure of $56,164, or a 187% increase over the Prior Quarter's expense of $30,030. Research and development expenses for the nine month period ended March 31, 2006 were $208,813 or an increase of $150,752 over the nine month period ended March 31, 2005. Of this amount, $86,700 was paid in conjunction with an ongoing protocol study on the results of 100 patients who have recently been implanted, or will be implanted in the near future, with the Company's $^{131}$Cs brachytherapy seed.

**Sales and marketing expenses.** Sales and marketing expenses were $325,858 for the three-month period ended March 31, 2006. This represents an increase of $300,638 compared to the Prior Quarter's expenditure of $25,220 for sales and marketing. Of the $325,858, approximately $237,883 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. The balance was spent on advertising, market research, and trade shows and conferences. Sales and marketing expense for the nine month period ended March 31, 2006 was $981,429. This represents an increase of 560,667 or 133% compared to the nine month period ended March 31, 2005 expenditures of $420,762. These increases have occurred as the Company has hired more sales staff and incurred more marketing expenditures since October 2004 when we began selling our product.

**General and administrative expenses.** General and administrative expenses for the three month period ended March 31, 2006 amounted to $738,494. This represents an increase of $696,570 in comparison to the Prior Quarter's expense of $41,924. General and administrative expenses for the nine month period ended March 31, 2006 were $2,374,887. This is an increase of $1,568,845 over the nine month period ended March 31, 2005, during which general and administrative expense was $806,042. 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 nine month period ended March 31, 2006 were due to compliance with SEC regulations, which the consolidated companies first began to experience following the July 28, 2005 merger. Significant components of general and administrative expenses for the period ended March 31, 2006 included $296,093 in consulting expense, an increase from $161,609 in the comparative nine month period; payroll and related expenses of $448,449, an increase from $286,318 in the comparative nine month period; and professional fees, including accounting and legal fees and broker-dealer commissions of $347,598, an increase from $165,656 in the comparative nine month period.

**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 March 31, 2006, the Company had an operating loss of $1,462,778. This represents an increased loss of $844,297 or 137%, in comparison with the Prior Quarter's operating loss of $618,481. Operating loss for the nine month period ended March 31, 2006 was $4,816,639. Operating loss for the nine month period ended March 31, 2005 was $2,169,053.

**Non-operating income (expense).** Total non-operating income (expense) was $(197,091) for the three month period ended March 31, 2006. This represents an increase in net expense of $91,258 or 86% over the Prior Quarter's non-operating income (expense) of $(105,833). This decrease in non-operating income (expense) was largely due to a debt conversion expense of $141,414 (see Note 6) The Company earned $25,472 of interest income on funds held in certain near-liquid accounts. This was $25,238 more than the Prior Quarter's interest income of $234. During this period, financing expense was $81,149, or an increased expense of $43,653 or 116% over the Prior Quarter's financing expense of $37,496. Of this amount, $29,376 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 non-operating income (expense) for the nine month period ended March 31, 2006 was $(782,144) which represents an increase of $603,498 or 338% over the nine month period ended March 31, 2005. This increase is mainly due to the one-time recognition of expense associated with a short-term inducement to convert debentures (see Note 6) and an increase in financing expenses as noted above.

**Liquidity and capital resources**. At March 31, 2006, cash and cash equivalents amounted to $2,472,218. During the three months ended March 31, 2006, the Company issued 1,123,384 shares of common stock and granted an equal number of warrants to purchase shares of common stock pursuant to the October 17, 2005 and February 1, 2006 Offerings. This issuance of common stock provided the Company approximately $4,200,000, in cash, net of legal costs and commissions paid pursuant to the Offerings. Additionally, the Company issued 32,000 shares of common stock pursuant to the exercise of options to purchase common stock. This exercise of options provided the Company with $37,130.

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 March 31, 2006.

The Company had approximately $1.2 million cash on hand as of May 17, 2006**.** As of that date the Company's monthly required cash operating expenditures were approximately $630,000, and capital expenditures were approximately $50,000. As of May 17, 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 end of the fiscal year, June 30, 2006.

Our growth plan for 2006 includes expanding sales to existing customers, continuing a trend that has improved starting in the second quarter of FY 2006; continuing to reduce the level of services provided by Pacific Northwest National Laboratory as equivalent company resources become available, 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 9, 2006, IsoRay signed a definitive license agreement with International Brachytherapy s.a. (“IBt”) covering North America and providing IsoRay with access to IBt’s fluid jet production process and its proprietary polymer seed technology for use in brachytherapy procedures using Cesium-131. IsoRay intends to apply for FDA approval for the use of IBt’s proprietary technology in tandem with IsoRay’s Cesium-131 proprietary technology following completion of initial milestones designed to determine whether the two technologies are compatible. This agreement required a cash outlay of approximately $225,000 in March 2006, which was paid. A second payment of $225,000 will be due in August 2006.

At March 31, 2006 IsoRay Medical had four outstanding loans. The first, from Tri-City Industrial Development Council, with an original principal amount of $40,000, was funded in 2001 and requires a final principal only payment of $10,000 in August 2006. It is non-interest bearing and unsecured. The second loan is from the Benton-Franklin Economic Development District 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 March 31, 2006, the principal balance owed was $208,511. This loan is secured by certain equipment, materials and inventory of IsoRay Medical, and also required personal guarantees, for which the guarantors were issued approximately 70,455 shares of our common stock. The third loan is a revolving 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 our common stock. As of March 31, 2006, there were no advances outstanding under the line of credit. The fourth loan is with Columbia River Bank in the amount of $150,000, of which $50,000 was funded as of October 31, 2005. This loan is to be used for equipment purchases only and is secured by the equipment purchased with the borrowed funds. It bears interest at seven percent for thirty-six months. As of March 31, 2006, the principal balance owed was approximately $30,813. This loan was retired subsequent to March 31, 2006. On April 26, 2006, the Company received a commitment letter from the Hanford Area Economic Investment Fund Committee, or HAEIFC, for a $1.4 million loan for equipment purchases, to be funded at a future date. There can be no assurance that the HAEIFC loan will ever be funded.

The BFEDD has granted IsoRay Medical a waiver from enforcing violations of paying officers in excess of $100,000 per year and maintaining a certain current asset ratio. The waiver, effective from March 31, 2005 through June 30, 2006, also excuses non-compliance with covenants prohibiting fixed asset or lease obligations in excess of $24,000 per year, covenants prohibiting mergers, and covenants requiring maintenance of a certain long-term debt to equity ratio. However, IsoRay Medical is currently in default of a covenant requiring that it pay no greater than forty-five thousand dollars ($45,000) annually for lease payments during the life of the loan. Management believes that if the BFEDD accelerates repayment that is has sufficient cash resources to satisfy this obligation.

IsoRay Medical also had $455,000 in principal amount of convertible debentures outstanding as of March 31, 2006, which were issued between February and July 2005. These debentures could be converted into 127,711 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), and has a twenty-four month term with accrued interest paid quarterly.

IsoRay Medical also had $71,001 in principal amount of notes payable outstanding as of March 31, 2006, which were issued in a private placement to a predecessor IsoRay company between October 2003 and September 2004. Each note bears interest at an annual rate of ten percent (not compounded), and has a thirty-six month term with accrued interest paid quarterly. Subsequent to March 31, 20065 the Company retired these note payable obligations with part of the proceeds received from the New Offering of February 1, 2006 (See Note 9).

On April 4, 2005 a capital lease agreement was executed by IsoRay Medical with Nationwide Funding LLC, whereby the lessor funded the $75,000 acquisition of a glove box built to the Company's specifications by Premier Technology, Inc. of Pocatello, ID. This is a 48 month agreement with minimum monthly lease payments of $2,475.

On May 16, 2005 a capital lease agreement was executed by IsoRay Medical with Vencore Solutions LLC. This is a capital lease for a hot cell with a lease line in the amount of $430,000. This is a 36 month lease, with a purchase option at fair market value, defined in the lease agreement as not more than 15% of the initial fair value purchase price. Based on this amount, for the first five months, the minimum monthly lease payment will be $8,349. The minimum monthly lease payment increases to $17,500 for the remaining 31 months, based on the entire value of the $430,000 lease line. In connection with the lease agreement, IsoRay granted warrants to purchase 5,692 shares of its common stock at $4.15/share.

We expect to finance our 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 we need to raise additional money to fund our operations, funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may not be able to market our products as planned or continue development and regulatory approval of our future products. If we raise additional funds through equity sales, these sales may be dilutive to existing investors, and we may decide to lower the exercise price of previously issued warrants.

We have no material commitments for capital expenditures and no off-balance sheet arrangements.

## MARKET FOR COMMON 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, 2003 through December 31, 2005, 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.

| Period | High | Low |
|---|---|---|
| October 1, 2003 - December 31, 2004 | N/A | N/A |
| January 2, 2005 - March 31, 2005 | * | * |
| April 1, 2005 - June 30, 2005[1] | N/A | N/A |
| July 1, 2005 - September 30, 2005 | $5.95 | $1.00 |
| October 1, 2005 - December 31, 2005 | $8.25 | $4.50 |
| January 2, 2006 - March 31, 2006 | $7.00 | $6.50 |

* 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.

On May 24, 2006, the last reported bid price of our common stock as reported on the OTC Bulletin Board was $4.20 per share. As of May 24, 2006, we had approximately 850 shareholders of record of our common stock and 14,722,686 outstanding shares of our common stock. Certain of the shares of common stock are held in "street" name and may be held by numerous beneficial owners.

*Dividends*. The Company's Board of Directors, in its sole discretion, may declare and pay dividends on the common stock, payable in cash or other consideration, out of funds legally available, if all dividends due on the preferred stock have been declared and paid. The Company has not paid any cash dividends on its common stock and does not plan to pay any cash dividends on its common stock for the foreseeable future.

***Equity Compensation Plans***

On July 28, 2005, the Company adopted the Amended and Restated 2005 Stock Option Plan (the "Option Plan") and the Amended and Restated 2005 Employee Stock Option Plan (the "Employee 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. As of March 31, 2006, options to purchase 1,630,472 shares had been granted under the Option Plan and options to purchase 1,420,511 shares had been granted under the Employee Plan. Of these options, 66,291 had been exercised under the Employee Plan, and 26,993 had been exercised under the

Option Plan, as of March 31, 2006.

| ***Plan Category*** | *Number of securities to be issued upon exercise of outstanding options, warrants and rights (#)* | *Weighted-average exercise price of outstanding options, warrants and rights ($)* | *Number of securities remaining available for future issuance under equity compensation plans* |
|---|---|---|---|
| *Equity compensation plans approved by shareholders* | N/A | N/A | N/A |
| *Equity compensation plans not approved by shareholders* | 3,050,983 | $1.90 | 749,017 |
| *Total* | 3,050,983 | $1.90 | 749,017 |

## DESCRIPTION OF BUSINESS

***The Merger***

On July 28, 2005, the merger (the "Merger") contemplated by the Merger Agreement dated as of May 27, 2005 by and among Century Park Pictures Corporation (the former name of the Company), Century Park Transitory Subsidiary, Inc., IsoRay Medical, Inc. and certain shareholders (the "Merger Agreement"), was completed.

As a result of the Merger and pursuant to the Merger Agreement, IsoRay Medical, Inc. became a wholly-owned subsidiary of Century Park Pictures Corporation, Century Park Pictures Corporation changed its name to "IsoRay, Inc.", and the Company issued shares of its common and preferred stock, and options and warrants to purchase shares of its common and preferred stock, to holders of securities in IsoRay Medical, Inc.

Immediately after the Merger, the Company had 10,237,797 shares of common and preferred stock outstanding. The total amount of shares outstanding post merger was 13,880,822, which includes not only shares of common stock, but also shares of preferred stock, warrants, options and convertible debentures that could be exercised or converted into shares of common stock. Following the Merger, on a fully diluted basis, the shareholders of IsoRay Medical, Inc. owned approximately 82% of the Company's outstanding securities, and the Company's shareholders owned approximately 18% of the Company's outstanding securities.

***Business of IsoRay, Inc.***

The Company was incorporated in Minnesota in 1983. Until 1998, the Company was engaged in the development, production and marketing of various entertainment intellectual properties and other assets in the motion picture, television and theatrical stage markets. Since 1998 and until the completion of the Merger, the Company did not conduct any business operations and had minimal assets and liabilities. The Company is now a holding company for its wholly-owned subsidiary, IsoRay Medical, Inc.

***Business of IsoRay Medical, Inc.***

IsoRay Medical, Inc. was formed on June 15, 2004 as a corporation in the State of Delaware, and in October 2004 it merged with two predecessor companies to combine all of the IsoRay operations into one company.

IsoRay Medical intends to utilize 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 cancer tumors. IsoRay Medical began production and sales of its initial FDA approved product, the IsoRay $^{131}$Cs 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 physical characteristics of the Cesium-131 (Cs-131 or $^{131}$Cs) 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 $^{90}$Y), is currently being used in the treatment of non-Hodgkin's lymphoma and is in clinical trials for other applications. Other manufacturers have received FDA approval for $^{90}$Y 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 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 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.

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 Medical 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 tumors such as breast cancer. The shorter half-life of 9.7 days for $^{131}$Cs (versus 17.5 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 thereby reducing the total physical radiation dose to the patient and reducing the costs of the procedure for both third party payors and the patient.

IsoRay Medical's second product, Yttrium-90, is also a short-lived (half-life of 64 hrs) radioisotope that is already used in the treatment of non-Hodgkin's lymphoma, leukemia, ovarian cancer, prostate cancer, osteosarcomas, and tumors of the breast, lung, kidney, colon and brain. These applications apply primarily to metastasized, or spread through the body, cancers. Currently more than 20 clinical trials using $^{90}$Y are underway in the U.S. Yttrium-90 is also used at multiple treatment centers in Europe. Several members of the current IsoRay Medical team developed a process to produce high-purity $^{90}$Y for medical applications during the mid-1990s. Currently over 90 percent of the $^{90}$Y used in the U.S. is imported. IsoRay Medical's management believes there is an immediate market opportunity for a highly purified $^{90}$Y.

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

· Began offering seeds loaded in sterile strands and needles from IsoRay’s custom preloading service (March 2006);

· Began radioactive operations in our new manufacturing facility in Richland, Washington (November 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 $^{131}Cs$ and $^{90}Y$ processes (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 Medical, allowing initial production of seeds through 2006 at PNNL (April 2004);

· Raised over $17.5 M in debt and equity funding (September 2003 - February 2006)

· Obtained favorable Medicare reimbursement codes for the Cs-131 brachytherapy seed (November 2003);

· Obtained FDA 510(k) approval 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 that about 232,090 new cases of prostate cancer were diagnosed and an estimated 30,350 deaths were associated with the disease in the United States during 2005. Because of early detection techniques (e.g., screening for prostate specific antigen, or PSA) approximately 70% (162,400) of these cases are potentially treatable with seed brachytherapy, when the cancers are still locally confined within the prostate.

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, although only one man in thirty-three will die of this disease.

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, but this theory has not been confirmed. 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 (which, until protocols are developed, does not include the Cesium-131 seed).

*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 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 development of breasts, and common side effects of chemotherapy are nausea, hair loss and fatigue.

"Watchful waiting," 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 more 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 series of 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 $^{125}I$ 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 Medical.

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 are borne out 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, $^{103}$Pd 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 $^{131}$Cs seed has specific clinical advantages for treating cancer over $^{125}$I and $^{103}$Pd.

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 would be 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 $^{103}$Pd and $^{125}$I, 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 $^{103}$Pd and $^{125}$I brachytherapy in the treatment of early-stage prostate cancer have been very positive. We have not obtained consent to cite the studies listed below.

- A twelve-year clinical study published in the 2004 Supplement of the *International Journal of Radiation Oncology, Biology and Physics*, reported that the relative survival rate is 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 the Pd-103 device 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 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 $^{131}$Cs 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.

25

**Our Strategy**

The key elements of IsoRay Medical's strategy include:

- *Continue to introduce the IsoRay $^{131}$Cs seed into the U.S. brachytherapy market*. Utilizing a direct sales organization and selected channel partners, IsoRay Medical 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 Medical has constructed a state-of-the-art manufacturing facility in Richland, Washington in its newly 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, IsoRay plans to construct a permanent manufacturing facility in another state. Working with leading scientists, IsoRay Medical intends to design and create a proprietary separation process to manufacture enriched barium, a key source material for $^{131}$Cs, to ensure adequate supply and greater manufacturing efficiencies.

- *Introduce Cesium-131 therapies for other solid cancer tumors*. IsoRay Medical intends to partner with other companies to develop the appropriate delivery technology and therapeutic delivery systems for treatment of other solid cancer tumors such as breast, lung, liver, pancreas, neck, and brain cancer. IsoRay Medical'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.

- *Introduce other isotope products to the U.S. market*. IsoRay Medical plans to introduce its Yttrium-90 radioisotope in 2006. Currently, FDA approved $^{90}$Y manufactured by other suppliers is used in the treatment of non-Hodgkin's lymphoma and is in clinical trials for other applications. Other products may be added in the future as they are developed. IsoRay Medical has the ability to make several different isotopes for multiple medical and industrial applications. During 2005 the Company identified and prioritized additional market opportunities for these isotopes.

- *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 Medical 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 Medical's core radioisotope technology.

Management believes there is a large and growing addressable market for IsoRay Medical'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 a 45-minute outpatient procedure. Over 60,000 procedures were forecasted to occur in the U.S. in 2005. At the April 30, 2006 seed price for $^{131}$Cs of $55, this represents a potential $330 million seed market 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 Medical's management believes that the $^{131}$Cs 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 $^{131}$Cs, and the

anticipated reduction of side effects.

**Products**

IsoRay Medical markets the Cesium-131 seed and intends to market Yttrium-90 and 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 Medical's $^{131}$Cs 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 case. 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 $^{131}$Cs seed*

*Competitive Advantages of Cs-131*

Management believes that $^{131}$Cs 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 $^{131}$Cs 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 |
| **Energy** | 29 KeV$^{+}$ | 22 KeV$^{+}$ | 28 KeV$^{+}$ |
| **Dose Delivery** | 90% in 33 days | 90% in 58 days | 90% in 204 days |
| **Total Dose** | 100 Gy | 125 Gy | 145 Gy |
| **Anisotropy Factor**$^{*}$ | .969 | .877 (TheraSeed® 2000) | .930 (OncoSeed® 6711) |

$^{+}$KeV = kiloelectron volt, a standard unit of measurement for electrical energy.
$^{*}$Degree of symmetry of therapeutic dose, a factor of 1.00 indicates symmetry.

27

*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).

*High energy*. The Cs-131 isotope decay energy of 29 KeV (versus 22 KeV for Pd-103 and 28 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 $^{103}$Pd 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.

*Reduced side effects*. Because the IsoRay $^{131}$Cs 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 $^{131}$Cs seed is uniform, and this uniformity may result in better radiation dose coverage and improved therapeutic effectiveness. The adjacent picture is 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 Medical 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 Medical'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 payors and the patient.

*Yttrium-90*

Y-90 and Cs-131 are short-lived isotopes that are well suited to treatment of tumors by cell-directed therapy. The Company plans to introduce its second product, Yttrium-90, in 2006. Y-90 is already available from other companies. When used in combination with molecular targeting agents, Y-90 is proving to be an ideal isotope to provide localized radiation therapy for various types of cancer, such as non-Hodgkin's lymphoma, leukemia, ovarian and prostate cancers, osteosarcomas, and tumors of the breast, lung, kidney, colon, and brain. Y-90's properties of short half-life, high specific activity, high energy and pure beta-emissions can be chemically attached to targeting agents that are

highly selective for specific tumors. These targeting agents may include monoclonal antibodies, molecules derived from antibodies, peptides, or other tumor-specific molecules. Most Y-90 currently used in the U.S. is imported with varying degrees of quality. IsoRay Medical has developed a proprietary separation process that produces Y-90 that management believes will meet or exceed the purity and quality required for clinical trials and medical applications.

Y-90 is a significant component of several commercially available products. These products use radiopharmaceutical grade Y-90 derived using manufacturing methods and techniques that conform to current cGMP (current Good Manufacturing Practices), allowing them to be used invasively in commercially available healthcare products.

We intend to initially target the clinical trial market. Currently there are several clinical trials and medical applications involving Y-90 underway around the world that represent a potential market for Y-90. These customers hold significant growth potential, as products undergoing successful trials become approved for general use. Our strategy will be to attempt to develop exclusive sales arrangements with companies that are close to FDA approval or foreign companies authorized to commercially sell their products in various overseas markets.

Y-90 is a pure-beta particle emitter with a physical half-life of 64.1 hours (2.7 days) that decays to stable Zirconium-90. The average energy of the beta emissions from Y-90 is 2.37 MeV, with an effective path-length in tissue of 5.3 mm. This means that 90% of the energy is absorbed within a 5.3-mm radius.

Y-90 is manufactured by chemical separation from a long-lived Strontium-90 (Sr-90) generator stock. We intend to purchase or lease the Sr-90 feedstock from the U.S. DOE and international suppliers. Due to the radiological characteristics of Sr-90, initial processing will occur under stringent radiological controls in a highly shielded isolator or "hot cell" using remote manipulators. Following preliminary separation, the Y-90 may be further purified and converted to pharmaceutical grade material in a shielded environmentally-controlled glove box. After completing the separation process (e.g., collecting or "milking" the therapeutic Y-90), the residual Sr-90 generator is recycled for subsequent separations. In theory, the Sr-90 generator can continue to generate Y-90 for decades. However, the process periodically requires infusion of new Sr-90. In addition to acquiring Sr-90, we will need to acquire equipment and develop manufacturing procedures for the Y-90 isotope that meet cGMP criteria. While we initially plan to produce solely radiochemical purity Y-90, which does not need to meet the more stringent manufacturing standards required for radiopharmaceutical purity Y-90, we intend to develop our manufacturing methods to this higher level and produce radiopharmaceutical purity Y-90 in the future.

IsoRay Medical has identified four principal suppliers of Y-90: MDS Nordion (a division of MDS, Inc.), Perkin-Elmer, Inc., Amersham (part of General Electric Company) and Iso-Tex Diagnostics, Inc. If we begin marketing Y-90, these companies will be our principal competitors within this market.

**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 of Cs-131. The 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). IsoRay Medical has evaluated several international nuclear reactors and a few potential facilities in the United States. Due to the short half-life of both the Ba-131 and Cs-131 isotopes, these facilities must be capable of removing irradiated materials from the reactor core on a routine basis. Reactor personnel will ship the irradiated barium on a pre-determined schedule to our facilities for subsequent separation, purification and seed assembly. The Company has identified more than five reactors in the U.S., Europe and the former Soviet Union that are capable of meeting these requirements. This routine isotope generation cycle at supplier reactors will allow significant quantities of Ba-131 to be on hand at our facilities for the completion of the rest of the manufacturing process. To ensure reliability of supply, we intend to seek agreements with multiple facilities to produce Ba-131. As of the date of this Prospectus, IsoRay Medical has agreements in place with two suppliers of irradiated Ba-131. The Company’s agreement with Russia’s Institute of Nuclear Materials for irradiated

Ba-131 has a seven year term (ending August 25, 2012) and 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 irradiated Ba-131 projected to be delivered in the first year. Through March 31, 2006, the Company had paid approximately $30,000 to the Institute of Nuclear Materials. In addition, the Company continues to engage 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 will be incorporated into an internal assembly that contains a binder, spacer and 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, a seed is hermetically sealed 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 ensuring less material is wasted. Finally, the rapid placement and removal of components from the welding zone will affect 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.

The Company intends to implement a just-in-time production capability that is keenly responsive to customer input and orders to ensure that individual customers receive a higher level of customer service from us than from existing seed suppliers who have the luxury of longer lead times due to longer half-life products. Time from order confirmation to completion of product manufacture can be reduced to several working days, including receipt of irradiated barium (from a supplier's reactor), separation of Cs-131 (at our facilities), isotope labeling of the core, and loading of cores into pre-welded titanium "cans" for final welding, testing, quality assurance and shipping.

It is up to each physician to determine the dosage necessary for implants and acceptable dosages vary among physicians. Many of the physicians who order our seeds order more seeds than necessary but wish to assure themselves that they have a sufficient amount. Upon receipt of an order, the Company either delivers the seeds from its facility directly to the physician using Federal Express or sends the order to an independent third party with expertise in seed delivery who delivers the seeds prior to implant. If the implant is postponed or rescheduled, the short half-life of the seeds makes them unsuitable for use and therefore they must be re-ordered. The Company's historical profit margin on seeds has been sufficient to justify unusable inventory and management has monitored the amount of unused inventory carefully to review its calculations of wastage in its business plans.

*Automated Manufacturing Process*

IsoRay Medical has held discussions with a leading designer and manufacturer of automated seed manufacturing equipment that has manufactured, installed and deployed automated production lines in Europe and the United States. In addition, IsoRay Medical engaged in preliminary discussions with another seed manufacturer regarding obtaining an existing automated seed production line. Based on technical evaluations and on-site reviews of both lines, IsoRay elected to automate its current manufacturing process in phases. Current production rates with IsoRay's semi-automated seed welding equipment exceed those attainable with the fully automated lines. Phased implementation of automation is expected to be less costly than fully automated production lines and will benefit IsoRay by reducing labor costs and helping to ensure consistent manufacturing quality.

*Manufacturing Facility*

The initial production of the IsoRay Cs-131 brachytherapy seed commenced at PNNL in 2004. IsoRay Medical began operations in its new interim leased production facility in Richland, Washington on November 30, 2005. The Company is also considering another state as a location for a future facility, either as the Company's sole manufacturing facility or as a secondary facility. No agreements have been reached for any possible facilities outside of Washington.

*Isotope Testing in Idaho*

On December 14, 2005, IsoRay and Idaho's Advanced Test Reactor entered into a collaboration and partnership agreement for the design, analysis and fabrication of a capsule containing barium carbonate, which will be irradiated at the Advanced Test Reactor and then shipped to IsoRay for processing and analysis of the $^{131}$Cs product. If testing of this production method is successful, it would further enhance IsoRay's production capabilities. The testing has commenced and is expected to be completed by August 2006. As an adjunct to the testing, IsoRay and the Pocatello Development Authority entered into an Economic Development Agreement, dated December 14, 2005, under which the Pocatello Development Authority provided IsoRay with $200,000 (subject to repayment under certain conditions) to use toward the costs of the testing at the Advanced Test Reactor.

*Repackaging/Preloading Services*

Most brachytherapy manufacturers offer their seed product to the end user packaged in four principal packing configurations provided in a sterile or non-sterile package depending on the customer's preference. These include:

- *Loose seeds*

- *Pre-loaded needles* (loaded with 3 to 5 seeds and spacers)

- *Strands of seeds* (consists of seeds and spacers in a biocompatible "shrink wrap")

· *Pre-loaded Mick cartridges* (fits the Mick applicator)

No single package configuration dominates the market at this point. Market share estimates, based on internal management studies of the market, for each of the four packaging types are: loose seeds (negligible amount) Mick cartridges (30%), pre-loaded needles (20%) and strands (50%). Market trends indicate significant movement toward the stranded configuration, as there are some clinical data suggesting less potential for post-implant seed migration when a stranded configuration is used.

The role of the repackaging service is to package, assay and certify the contents of the final product configuration shipped to the customer. A commonly used method of providing this service is through independent radiopharmacies such as Anazao Healthcare and Advanced Care Medical Inc.. Manufacturers send loose seeds along with the physician's instructions to the radiopharmacy who, in turn, loads needles and/or strands the seeds according to the doctor's instructions. These pharmacies then sterilize the product and certify the final packaging prior to shipping directly to the end user.

IsoRay Medical has held discussions with the major independent radiopharmacies and determined the additional time required for delivery of loose seeds to an off-site radiopharmacy for subsequent assay, preloading and sterilization creates additional loss of our isotope due to decay and is prohibitive on a long-term basis. However, to increase sales in the near-term we are using these services until our own custom preloading operation comes fully on-line in 2006. On March 1, 2006, the Company entered into a Service Agreement with Advanced Care Medical, Inc. for radiopharmacy services. The term of the Service Agreement is one year, with automatic one year extensions unless terminated, and prices vary from $6-15 per seed depending on how the seeds are packaged. In late March, 2006, the Company’s stranding service became operational and our first stranded order was shipped from the facility on April 5, 2006.

We currently load Mick cartridges in our own facility which in recent months accounted for more than 50% of total seed orders. The Company has retained an experienced consultant to assist with implementation of the custom preloading service and is now marketing its seeds to the end user in all four of the commonly used packaging configurations. We will continue to utilize the independent radiopharmacies in the future both as a backup to our own preloading operation and to handle periodic increases in demand.

Independent radiopharmacies usually provide the final packaging of the product delivered to the end user. This negates an opportunity for reinforcing the "branding" of our seed product. By providing its own repackaging service, the Company preserves the product branding opportunity and eliminates any concerns related to the handling of its product by a third party prior to delivery to the end user.

Providing different packaging configurations adds significant value to the product while providing an additional revenue stream and incremental margins to the Company through the pricing premiums that can be charged. The end users of these packaging options are willing to pay a premium because of the savings realized by eliminating the need for loose seed handling and loading capabilities on site, eliminating the need for additional staffing to load and sterilize seeds and needles, and eliminating the expense of additional assaying of the seeds.

Management estimates the cost of establishing the custom preloading service in its new, leased facility to be approximately $250,000, most of which has already been spent on capital equipment. The custom preloading area has been created in the facility the necessary equipment has been delivered and installed. Operating procedures are in place, staff have been trained, and process validation activities have been completed. Technicians have been added to the staff to handle the seed loading and stranding operations. PNNL will continue to provide independent third party assay of the seeds for the foreseeable future. Our customer service staff will provide assistance with shipping, documentation and tracking of all orders from the repackaging service to the end user.

*Barium Enrichment Device*

Barium-130 is the original source material for Cs-131. When Ba-130 is put into a nuclear reactor it becomes Ba-131, the radioactive material that is the parent of Cs-131. Barium metal found in nature contains only 0.1% of Ba-130 with six other isotopes making up the other 99.9%. As part of its manufacturing process the Company intends to develop a barium enrichment device that should create "enriched barium" with a higher concentration of the Ba-130 isotope than is found in naturally occurring barium. In addition to creating a higher purity Ba-130, which translates into higher purity Cs-131, a barium enrichment device will result in higher yields of Cs-131. The Company has identified sources

of enriched barium, including in the former Soviet Union, that we believe we can use until the barium enrichment device is developed.

**Marketing and Sales**

*Marketing Strategy*

The Company intends to position Cs-131 as the isotope of choice for prostate brachytherapy. Based on preliminary clinical studies, management believes there is no apparent clinical reason to use other isotopes when Cesium-131 is available. The advantages associated with a high energy and short half-life isotope are generally accepted within the clinical community and the Company intends to help educate potential patients about the clinical benefits a patient would experience from the use of Cs-131 for his brachytherapy seed treatment. The potential negative effects of the prolonged radiation times associated with the long half-life of Iodine-125 make this isotope less attractive than Cesium-131.

We target competing isotopes as our principal competition rather than the various manufacturers and distributors of these isotopes. In this way, the choice of brachytherapy isotopes will be less dependent on the name and distribution strengths of the various iodine and palladium manufacturers and distributors and more dependent on the therapeutic benefits of Cs-131. The Company focuses the purchasing decision on the advantages and functionality of the Cs-131 isotope while seeking to educate the prostate cancer patient about these clinical benefits.

The professional and patient market segments each play a role in the ultimate choice of prostate cancer treatment and the specific isotope chosen for seed brachytherapy treatment. The Company is tailoring its marketing message to each audience. IsoRay Medical has retained an advertising agency in the Seattle area to assist with its marketing communication program. The agency is coordinating the creation and distribution of all advertising material and work with the print and visual media.

The advantages of Cs-131's unique combination of high energy and short half-life are heavily promoted within the clinical market. Because we believe there is no apparent clinical reason to choose other isotopes over cesium, we have and will continue to target those high volume users of other isotopes as our first implant sites. We also emphasize the prolonged radiation times and the high doses of radiation given to the patient by the iodine isotope and the possible negative effects of this prolonged radiation to the adjacent healthy tissues. We believe that this is an important marketing message because clinicians generally agree the radiation given by Iodine has little or no clinical benefit after 120 to 150 days.

To promote our products to the clinical and professional audience, we use a combination of marketing messages to appear in print and visual media. Past and planned marketing activities include: attendance at the major brachytherapy-related clinical conferences to exhibit our products and provide marketing information for annual meetings, conferences and other forums of the various professional societies; print advertising in brachytherapy clinical journals; and promoting clinical presentations by experts in the field at major conferences.

In today's U.S. health care market patients are more informed and involved in the management of their health and any treatments required. Many physicians relate incidents of their patients coming for consultations armed with articles researched on the Internet and other sources describing new treatments and medications. In many cases, these patients are demanding a certain therapy or drug and the physicians are complying when medically appropriate.

Because of this market factor, we also promote our products directly to the general population. The audience targeted will be the prostate cancer patient, his spouse, family and care givers. The marketing message to this segment of the market emphasizes the specific advantages of Cs-131, including fewer side effects, less total radiation, and shorter period of radiation. The Company plans to reach this market through its website, located at www.isoray.com, advertising in magazines read by prostate cancer patients and their caregivers, and through patient advocacy efforts.

Another key element of our strategy is to validate and support all product claims with well-designed and executed clinical studies that support the efficacy and positive patient outcomes of our Cs-131 seed. We intend to sponsor physician-directed studies that will compare the performance of our seeds to Pd-103 and I-125 seeds. During 2006, IsoRay Medical plans to continue its collaboration with leading physicians to develop clinical data on the efficacy of Cs-131 seeds. Noted contributors from the medical physics community will be consulted regarding the benefits of brachytherapy using shorter half-life, improved dosimetry, and higher decay energy seeds. Articles will be submitted to professional journals such as *Medical Physics* and the *International Journal of Radiation Oncology, Biology, and Physics*.

*Sales and Distribution*

According to a recent industry survey, approximately 2,000 hospitals and free standing clinics are currently offering radiation oncology services in the United States. Not all of these facilities offer seed brachytherapy services. These institutions are staffed with radiation oncologists and medical physicists who provide expertise in radiation therapy treatments and serve as consultants for urologists and prostate cancer patients. We target the radiation oncologists and the medical physicists as well as urologists as key clinical decision makers in the type of radiation therapy offered to prostate cancer patients.

IsoRay Medical has started to build a direct sales organization to introduce Cs-131 to radiation oncologists and medical physicists. In August 2004 IsoRay Medical hired two highly successful sales professionals from the brachytherapy industry that bring well established relationships with key radiation oncologists and medical physicists, and in 2005, IsoRay Medical expanded its sales force to four experienced individuals. By hiring experienced and successful brachytherapy sales people, the Company reduces the risk of delay in penetrating the market due to a lack of knowledge of the industry or unfamiliarity with the key members of the brachytherapy community.

The initial response to our new isotope from prominent radiation oncologists, medical physicists and urologists in the US has been very positive. As of May 24, 2006, forty cancer therapy centers located across the United States have received licenses from state and federal authorities to provide Cesium-131 seed implants for their prostate cancer patients. States where cancer treatment centers were offering Cesium-131 seed implants as of May 24, 2006 include Washington, California, Arizona, Texas, Illinois, Wisconsin, Michigan, Pennsylvania, Tennessee, New York, Massachusetts, Maryland, Florida, Arkansas and North Carolina. Additional centers will be added as the Company's manufacturing capacity increases. Preliminary reported clinical outcomes for patients receiving Cesium-131 indicate a normal level of toxicity related to radiation but a much faster resolution of side effects associated with seed brachytherapy. These results are not statistically significant nor are they large enough to make any definitive conclusions, however, they are consistent with what clinicians might expect from a high-energy, short half-life isotope.

The Company will expand its U.S. sales force as it increases production capacity and expands the customer base. If the Company expands outside the U.S. market, it plans to use established distributors in the key markets in these other countries. This strategy should reduce the time and expense required to identify, train and penetrate the key implant centers and establish relationships with the key opinion leaders in these markets. Using established distributors also should reduce the time spent acquiring the proper radiation handling licenses and other regulatory requirements of these markets.

*Pricing*

Payment for IsoRay Medical products comes from third-party payors including Medicare/Medicaid and private insurance groups. These payors reimburse the hospitals and clinics via well-established payment procedures. On October 31, 2003, as a result of IsoRay Medical's predecessor's filing for an Additional Device Category, CMS approved a HCPCS/CPT code for Cs-131 brachytherapy seeds of $44.67 per seed. We have never sold a seed at this

price. This is the same price as awarded to Pd-103 seeds, and compares favorably to the $37.34 price granted to I-125 seeds. Medicare is the most significant U.S. payor for prostate brachytherapy services, and is the payor in close to 70% of all U.S. prostate brachytherapy cases. CMS reviews and adjusts outpatient reimbursement on a periodic and ad hoc basis, but no changes are expected for 2006. As of April 30, 2006, the price for our loose seeds was $55 per seed.

Prostate brachytherapy is typically performed in the outpatient setting, and as such, is covered by the CMS Outpatient Prospective Payment System. In January 2004, brachytherapy procedure prices were unbundled by CMS, allowing itemized invoicing for seeds with no limit on the number of seeds used per procedure, and CMS currently reimburses hospitals and clinics for their seed purchases on a cost basis. Other insurance companies have followed these CMS changes. With the new reimbursement structure and industry consolidation, prices of brachytherapy seeds are expected to stabilize and increase over the next few years.

Pricing premiums for pre-loaded needles, strands and pre-loaded Mick cartridges will be added as these packaging alternatives are offered to our customers. When charges for the seeds are correctly submitted in the appropriate format to CMS, 100% of the total cost of the seeds is reimbursed to the hospital or clinic by CMS.

**Other Information**

*Customers*

Customers representing ten percent or more of total Company sales for the three months ended March 31, 2006 include:

| | | |
|---|---|---|
| Eisenhower Medical Center | Rancho Mirage, CA | 25% of revenue |
| Mills Peninsula Health Services | San Mateo, CA | 19% of revenue |
| Community Hospital of Los Gatos | Los Gatos, CA | 18% of revenue |

The loss of either of these significant customers would have a temporary adverse effect on the Company’s revenues, which would continue until the Company located new customers to replace them.

*Proprietary Rights*

The Company relies on a combination of patent, copyright and trademark laws, trade secrets, software security measures, license agreements and nondisclosure agreements to protect its proprietary rights. Some of the Company's proprietary information may not be patentable.

The Company intends to vigorously defend its proprietary technologies, trademarks, and trade secrets. Members of management, employees, and certain equity holders have previously signed non-disclosure, non-compete agreements, and future employees, consultants, and advisors, with whom the Company engages, and who are privy to this information, will be required to do the same. A patent for the Cesium separation and purification process has been granted on May 23, 2000 by the U.S. Patent and Trademark Office (USPTO) under Patent Number 6,066,302, with an expiration date of May 23, 2020. The process was developed by Lane Bray, a shareholder of the Company, and has been assigned exclusively to IsoRay Medical. IsoRay Medical's predecessor also filed for patent protection in four European countries under the Patent Cooperation Treaty. Those patents have been assigned to IsoRay Medical.

Our management believes that certain aspects of the IsoRay seed design and construction techniques are patentable innovations. These innovations have been documented in IsoRay laboratory records, and a patent application was filed with the USPTO on November 12, 2003. Certain methodologies regarding isotope production, separation, and seed manufacture are retained as trade secrets and are embodied in IsoRay Medical's procedures and documentation. In June and July of 2004, three patent applications were filed relating to methods of deriving Cs-131 and Y-90 developed by IsoRay Medical employees. The Company is currently working on developing and patenting additional methods of deriving Cs-131 and Y-90, and other isotopes.

35

There are specific conditions attached to the assignment of the Cs-131 patent from Lane Bray. In particular, the associated Royalty Agreement provides for 1% of gross profit payment from seed sales (gross seed sales price minus direct production cost) to Lane Bray and 1% of gross profit from any use of the Cs-131 process patent for non-seed products. If IsoRay Medical reassigns the Royalty Agreement to another company, these royalties increase to 2%. The Royalty Agreement has an anti-shelving clause which requires IsoRay Medical to return the patent if IsoRay Medical permanently abandons sales of products using the invention.

Effective August 1, 1998, Pacific Management Associates Corporation (PMAC) transferred its entire right, title and interest in an exclusive license agreement with Donald Lawrence to IsoRay, LLC in exchange for a membership interest. The license agreement was transferred to IsoRay, Inc. (WA domiciled) effective May 1, 2002 in connection with the tax-free reorganization.

The terms of the license agreement require the payment of a royalty based on the Net Factory Sales Price, as defined in the agreement, of licensed product sales. Because the licensor’s patent application was ultimately abandoned, only a 1% “know-how” royalty based on Net Factory Sales Price, as defined, remains applicable. To date, there have been no product sales incorporating the licensed technology and there is no royalty due pursuant to the terms of the agreement. Management believes that because this technology is not presently being used and believes it will not be used in the future that no royalties will be paid under this agreement.

*Research And Development*

From inception (December 17, 2001) through March 31, 2006, IsoRay Medical and its predecessor companies incurred approximately $2 million in costs related to research and development activities. The Company expects to continue to have employees working on activities that will be classified as research or development for the foreseeable future.

*Government Regulation*

The Company's present and future intended activities in the development, manufacture and sale of cancer therapy products are subject to extensive laws, regulations, regulatory approvals and guidelines. Within the United States, the Company's therapeutic radiological devices must comply with the U.S. Federal Food, Drug and Cosmetic Act, which is enforced by the FDA. The Company is also required to adhere to applicable FDA regulations for Good Manufacturing Practices, including extensive record keeping and periodic inspections of manufacturing facilities. IsoRay Medical's predecessor obtained FDA 510(k) clearance in March 2003 to market the IsoRay $^{131}$Cs seed for the treatment of localized solid tumors. The Company has not applied for clearance from the FDA to market its second product (currently in development), Yttrium-90, but management believes that it will not be difficult to obtain clearance for Y-90, since other manufacturers of this product have already obtained clearance for it.

Specifically, in the United States, the FDA regulates, among other things, new product clearances and approvals to establish the safety and efficacy of these products. We are also subject to other federal and state laws and regulations, including the Occupational Safety and Health Act and the Environmental Protection Act.

The Federal Food, Drug, and Cosmetic Act and other federal statutes and regulations govern or influence the research, testing, manufacture, safety, labeling, storage, record keeping, approval, distribution, use, reporting, advertising and promotion of such products. Noncompliance with applicable requirements can result in civil penalties, recall, injunction or seizure of products, refusal of the government to approve or clear product approval applications, disqualification from sponsoring, or conducting clinical investigations, prevent us from entering into government supply contracts, withdrawal of previously approved applications and criminal prosecution.

Approval of new medical devices is a lengthy procedure and can take a number of years and the expenditure of significant resources. There is a shorter FDA review and clearance process, the premarket notification process, or the 510(k) process, whereby a company can market certain medical devices that can be shown to be substantially equivalent to other legally marketed devices. We have been able to achieve market clearance for our $^{131}$Cs seed using the 510(k) process.

In the United States, medical devices are classified into three different categories over which FDA applies increasing levels of regulation: Class I, Class II and Class III. Most Class I devices are exempt from premarket notification (510(k)); most Class II devices require premarket notification (510(k)) and most Class III devices require premarket approval. Our $^{131}$Cs seed is a Class II device and has received 510(k) clearance.

As a registered medical device manufacturer with the FDA, we are subject to inspection to ensure compliance with their current Good Manufacturing Practices, or cGMP. These regulations require that we and any of our contract manufacturers design, manufacture and service products and maintain documents in a prescribed manner with respect to manufacturing, testing, distribution, storage, design control and service activities. Modifications or enhancements that could significantly affect the safety or effectiveness of a device or that constitute a major change to the intended use of the device require a new 510(k) notice for any product modification. Management has no current intent to modify the $^{131}$Cs seed such that a new 510(k) notice would be required, but if management in the future determines that it would be beneficial to substantially modify the $^{131}$Cs seed or use a delivery device not previously approved by the FDA, we would be prohibited from marketing the modified product until the 510(k) notice is cleared by the FDA.

The Medical Device Reporting regulation requires that we provide information to the FDA on deaths or serious injuries alleged to be associated with the use of our devices, as well as product malfunctions that are likely to cause or contribute to death or serious injury if the malfunction were to recur. Labeling and promotional activities are regulated by the FDA and, in some circumstances, by the Federal Trade Commission.

As a medical device manufacturer, we are also subject to laws and regulations administered by governmental entities at the federal, state and local levels. For example, our facility is licensed as a medical product manufacturing facility in the State of Washington and is subject to periodic state regulatory inspections. Our customers are also subject to a wide variety of laws and regulations that could affect the nature and scope of their relationships with us.

In the United States, as a manufacturer of medical devices and devices utilizing radioactive by product material, we are subject to extensive regulation by not only federal governmental authorities, such as the FDA, but also by state and local governmental authorities, such as the Washington State Department of Health, to ensure such devices are safe and effective. 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 $^{131}$Cs brachytherapy seeds constitute both medical devices and radioactive sealed sources and are subject to these regulations.

Moreover, our use, management and disposal of certain radioactive substances and wastes are subject to regulation by several federal and state agencies depending on the nature of the substance or waste material. We believe that we are in compliance with all federal and state regulations for this purpose.

Washington voters approved Initiative 297 in late 2004, which may impose additional restrictions on sites at which mixed radioactive and hazardous wastes are generated and stored, including PNNL, as it prohibits additional mixed radioactive and hazardous waste from being brought to sites, such as PNNL, until the existing on-site waste conforms to all state and federal environment laws. The constitutionality of this initiative has been challenged, but if it were enforced it could impact our ability to manufacture our seeds, whether at PNNL or elsewhere in the State of Washington.

*Seasonality*

The Company is not aware of any significant seasonal influences on its business. The composition of certain products and services changes modestly with shifts in weather with no material impact on total revenues.

*Employees*

IsoRay, Inc. has one full-time employee**.** As of March 31, 2006, IsoRay Medical employed thirty-three full-time individuals, one occasional individual and two part-time individuals. The Company's future success will depend, in part, on its ability to attract, retain, and motivate highly qualified technical and management personnel. From time to time, the Company may employ independent consultants or contractors to support its research and development, marketing, sales and support and administrative organizations. Neither the Company's nor IsoRay Medical's employees are represented by any collective bargaining unit. IsoRay Medical estimates that successful implementation of its growth plan would result in up to 37 additional employees by the end of 2006.

*Competition*

The Company competes in a market characterized by technological innovation, extensive research efforts and significant competition. In general, the IsoRay seed competes with conventional methods of treating localized cancer, including, but not limited to, radical prostatectomy and external beam radiation therapy which includes intensity modulated radiation therapy, as well as competing permanent brachytherapy devices. RP has historically represented the most common medical treatment for early-stage, localized prostate cancer. EBRT is also a well-established method of treatment and is widely accepted for patients who represent a poor surgical risk or whose prostate cancer has advanced beyond the stage for which surgical treatment is indicated. Management believes that if general conversion from these treatment options (or other established or conventional procedures) to the IsoRay seed does occur, such conversion will likely be the result of a combination of equivalent or better efficacy, reduced incidence of side effects and complications, lower cost, quality of life issues and pressure by health care providers and patients.

History has shown the advantage of being the first to market a new brachytherapy product. For example, ONCURA, now part of General Electric Company, currently claims nearly 50% of the market with the original I-125 seed. Theragenics Corp., which introduced the original Pd-103 seed, is second with a nearly 30% market share. The Company believes it will obtain a similar and significant advantage by being the first to introduce a Cs-131 seed.

The Company's patented Cs-131 separation process is likely to provide us a sustainable competitive advantage in this area. Production of Cs-131 also requires specialized facilities (hot cells) that represent high cost and long lead time if not readily available. In addition, a competitor would need to develop a method for isotope attachment and seed assembly, would need to conduct testing to meet NRC and FDA requirements, and would need to obtain regulatory approvals before marketing a competing device.

Several companies have obtained regulatory approval to produce and distribute Palladium-103 and Iodine-125 seeds, which compete directly with our seed. Nine of those companies represent nearly 100% of annual brachytherapy seed sales worldwide: Oncura (part of General Electric Company), Theragenics Corp., North American Scientific, Inc., Mentor Corp., Implant Sciences Corp., International Brachytherapy S.A., Cardinal Health, Inc., C.R. Bard, Inc., and Best Medical International, Inc. The top three - ONCURA, Theragenics, and North American Scientific - currently garner nearly 90% of annual sales.

It is possible that three or four of the current I-125 or Pd-103 seed manufacturers (i.e., ONCURA, Theragenics, North American Scientific, etc.) are capable of producing and marketing a Cs-131 seed, but none have reported efforts to do so. Best Medical obtained a seed core patent in 1992 that named 10 different isotopes, including Cs-131, for use in their seeds. Best Medical received FDA 510(k) approval to market a Cs-131 seed on June 6, 1993 but has failed to

produce any products for sale.

*Additional Growth Opportunities*

The Cs-131 isotope has the performance characteristics to be a technological platform for sustained long-term growth. The most immediate opportunities are introducing Cs-131 to Canada, Europe and other international markets, introducing Cs-131-based therapies for other forms of solid tumors focusing first on breast tumors, and through the marketing of other radioactive isotopes. These growth initiatives are in the early stages of planning and appear to be significant incremental opportunities.

The Company plans to introduce Cs-131 initially into Europe and later into other international markets through partnerships and strategic alliances with channel partners for manufacturing and distribution. Another advantage of the Cs-131 isotope is its potential applicability to other cancers and other diseases. Cs-131 has FDA approval to be used for treatments for a broad spectrum of cancers including breast, brain, lung, and liver cancer, and the Company believes that a major opportunity exists as an adjunct therapy for the treatment of breast cancer. Preliminary discussions have begun with prominent physicians regarding the use of Cs-131-based therapies for the treatment of lung, pancreatic and brain cancer. In addition to Y-90, there is the opportunity to develop and market other radioactive isotopes to the US market, and to market the Cs-131 isotope itself, separate from its use in our seeds. The Company is also in the preliminary stages of exploring alternate methods of delivering our isotopes to various organs of the body, as it may be advantageous to use delivery methods other than a titanium-encapsulated seed to deliver radiation to certain organs.

## DESCRIPTION OF PROPERTY

The Company's executive offices are located at 350 Hills Street, Suite 106, Richland, WA 99354, (509) 375-1202, where IsoRay Medical currently leases approximately 3,100 square feet of office and laboratory space for $4,282 per month from Energy Northwest. The lease expires December 31, 2006. The Company is not affiliated with its lessor. Additional office space will be needed as employees are hired, and is currently available at this location. The Company recently added approximately 650 square feet of space to this lease at $1.138 per square foot per month. The Company believes that its current facilities will be adequate until late Summer 2006, at which time we will need to add administrative facilities. In the future, due to business growth, the Company may elect to combine administrative services and production in one building which we may lease or build depending on market conditions.

In April 2004, IsoRay Medical's predecessor signed a contract with PNNL, permitting IsoRay Medical to subcontract certain of its manufacturing needs to PNNL, use PNNL facilities to produce the Cs-131 brachytherapy seeds, and ship them to customers from the PNNL facilities. Using PNNL's facilities has reduced the immediate need for IsoRay Medical to purchase specialized capital-intensive equipment. The contract allows it to manufacture Cs-131 seeds in PNNL until it expires in December 2006. Management believes that IsoRay will have sufficient time prior to this contract's expiration to shift production to IsoRay's new facility, described below.

We have entered into a lease, which commenced as of regulatory licensing approval on October 6, 2005, for a facility located in Richland, Washington that management believes will provide adequate space to manufacture the Cs-131 product for the prostate cancer markets until late 2007, with a maximum manufacturing capacity of approximately 60,000 seeds per month and total square footage of 4,400 feet. The lease is for a term of twelve months following regulatory licensing approval, with a twelve-month extension option. Payment for the lease term is the issuance of 24,007 shares of IsoRay, Inc. common stock annually. The lease may be extended on a month-to-month basis by mutual agreement of the parties. The lessor is Pacific EcoSolutions Incorporated (PEcoS), and the Company is not affiliated with this lessor. Equipment installed at this 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. If additional production space is needed it is available at the PEcoS facility.

On December 14, 2005, IsoRay and Idaho's Advanced Test Reactor entered into a collaboration and partnership agreement for the design, analysis and fabrication of a capsule containing barium carbonate, which will be irradiated at the Advanced Test Reactor and then shipped to IsoRay for final analysis. This agreement is part of management's plan to possibly expand the Company's manufacturing capabilities in the future through the construction of an additional facility in Idaho. If a facility is constructed in the future, it could provide additional capacity to meet increased demand for our products.

The Company's management believes that all facilities occupied by the Company are adequate for present requirements, and that the Company's current equipment is in good condition and is suitable for the operations involved.

## LEGAL PROCEEDINGS

We are not a party to any pending legal proceeding. Management is not aware of any threatened litigation, claims or assessments.

## DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS

Set forth below is certain information regarding our directors and executive officers, each of whom took office in July 2004, except for Mr. Babcock and Mr. Smith, who took office on March 31, 2006. Our Board of Directors is comprised of five directors. There are no family relationships between any of our directors or executive officers. Each of our directors is elected to serve until our next annual meeting of our shareholders and until his successor is elected and qualified or until such director's earlier death, removal or termination. Our Board of Directors appoints our officers, and their terms of office are at the discretion of the Board of Directors, except to the extent governed by an employment contract.

| Name | Age | Position |
|---|---|---|
| Roger E. Girard | 62 | CEO, President, Chairman |
| Michael K. Dunlop | 54 | CFO, Treasurer |
| David J. Swanberg | 49 | Exec. VP- Operations, Secretary, Director |
| Robert R. Kauffman | 65 | Director |
| Thomas C. Lavoy | 46 | Director |
| Stephen R. Boatwright | 42 | Director |
| Dwight Babcock | 58 | Director |
| Albert Smith | 62 | Director |

**Roger E. Girard**: In addition to serving as President, Chairman and CEO for the Company, Mr. Girard is also the CEO, President and Chairman of the Board of IsoRay Medical, Inc., and has served in these positions since the formation of IsoRay Medical, Inc. Mr. Girard was CEO and Chairman of IsoRay Medical's predecessor company from August of 2003 until October 1, 2004. Mr. Girard has been actively involved in the management and the development of the management team at IsoRay Medical, and his experienced leadership has helped drive IsoRay's development to date. From June 1998 until August of 2003, Mr. Girard served as President of Strategic Financial Services, a business consulting company based in Seattle, Washington designed to help wealthy individuals and companies with strategic planning and financial strategy. Strategic Financial Services had annual revenues under $500,000 and previously provided its services to a medical device company. Mr. Girard served as its sole employee. Mr. Girard also served as the managing partner for the Northwest office of Capital Consortium, another business consulting company based in Seattle, during this time. Capital Consortium employed four people and analyzed business market potential for start-ups and early stage companies. Mr. Girard has knowledge, experience and connections to private, institutional and public sources of capital and is experienced in managing and designing capital structures for business

organizations as well as organizing and managing the manufacturing process, distribution, sales, and marketing, based on his 35 years of experience.

**Michael K. Dunlop:** Mr. Dunlop has been responsible for IsoRay Medical and its predecessor companies' financial and accounting operations and administrative services in his position as CFO since April 2001. Mr. Dunlop has over 18 years of financial and administrative experience in the healthcare industry. As Director of Contracting and Marketing for Community Choice, Physician Hospital Community Organization, an organized healthcare delivery system, from October 1997 to December 2003, he assisted in developing the strategic direction and business plan of the PHCO, negotiated and maintained contractual relations with state-wide major health insurance plans, increased compensation for 80+ independent providers and 6 area hospitals, and enhanced PHCO provider membership through development of programs that lowered clinic and hospital operating costs. He was granted the Pentad Industry Council, Chelan-Douglas Counties' Employer of the Year award in 1996, while administrator of Lake Chelan Clinic. Mr. Dunlop holds an M.B.A. from California State University and B.M. Education from Walla Walla College.

**David J. Swanberg:** Mr. Swanberg has more than 22 years experience in engineering and materials science, nuclear waste and chemical processing, aerospace materials and processes, and environmental technology development and environmental compliance. Beginning in November 1995 and until January 2004, Mr. Swanberg was employed full time as Sr. Chemical/Environmental Engineer for Science Applications International Corporation working on a variety of projects including nuclear waste research and development. Mr. Swanberg joined IsoRay Medical's predecessor company in March of 1999 on a part-time basis and has held management positions in the IsoRay companies since 2000. Mr. Swanberg began full-time employment with IsoRay Medical in February 2004. He has been instrumental in development of IsoRay Medical's initial product, the Cs-131 brachytherapy seed, including interfaces with technical, regulatory, and quality assurance requirements. With IsoRay Medical and its predecessor companies, he has managed the development and production of radioactive seeds to support testing to meet NRC and FDA requirements, provided technical guidance for characterization of the IsoRay seed to meet AAPM Task Group 43 protocols, and coordinated production and testing of non-radioactive seeds to conform to ISO standards for brachytherapy devices. He is President of the Nuclear Medicine Research Council. He holds an MS in Chemical Engineering, is a licensed Chemical Engineer, and a certified Level II Radiation Worker.

**Robert R. Kauffman:** Mr. Kauffman has served as Chief Executive Officer and Chairman of the Board of Alanco Technologies, Inc. (NASDAQ: ALAN), an Arizona-based information technology company, since July 1, 1998. Mr. Kauffman was formerly President and Chief Executive Officer of NASDAQ-listed Photocomm, Inc., from 1988 until 1997 (since renamed Kyocera Solar, Inc.). Photocomm was the nation's largest publicly owned manufacturer and marketer of wireless solar electric power systems with annual revenues in excess of $35 million. Prior to Photocomm, Mr. Kauffman was a senior executive of the Atlantic Richfield Company (ARCO) whose varied responsibilities included Senior Vice President of ARCO Solar, Inc., President of ARCO Plastics Company and Vice President of ARCO Chemical Company. Mr. Kauffman earned an M.B.A. in Finance at the Wharton School of the University of Pennsylvania, and holds a B.S. in Chemical Engineering from Lafayette College, Easton, Pennsylvania.

**Thomas C. Lavoy:** Mr. Lavoy has served as Chief Financial Officer of SuperShuttle International, Inc., since July 1997 and as Secretary since March 1998. SuperShuttle is one of the largest providers of shuttle services in major cities throughout the West and Southwest regions of the United States. He has also served as a director of Alanco Technologies, Inc. (NASDAQ: ALAN) since 1998. From September 1987 to February 1997, Mr. Lavoy served as Chief Financial Officer of NASDAQ-listed Photocomm, Inc. Mr. Lavoy was a Certified Public Accountant with the firm of KPMG Peat Marwick from 1980 to 1983. Mr. Lavoy has a Bachelor of Science degree in Accounting from St. Cloud University, Minnesota, and is a Certified Public Accountant.

**Stephen R. Boatwright:** Mr. Boatwright has been a member of Keller Rohrback, PLC in Phoenix, Arizona since January 2005. From 1997 through January 2005 Mr. Boatwright was a partner at Gammage & Burnham, PLC, also in Phoenix, Arizona. Throughout his career, he has provided legal counsel to both private and public companies in many diverse industries. In recent years, Mr. Boatwright's legal practice has focused on representing technology, biotechnology, life science and medical device companies for their securities, corporate and intellectual property licensing needs. Mr. Boatwright earned both a J.D. and an M.B.A. from the University of Texas at Austin, and holds a

B.A. in Philosophy from Wheaton College.

**Dwight W. Babcock:** Mr. Babcock has served as Chairman and Chief Executive Officer of Apex Data Systems, Inc. an information technology company, since 1975. Apex Data Systems automates the administration and claims adjudication needs of insurance companies both nationally and internationally. Mr. Babcock was formerly President and CEO of Babcock Insurance Corporation (BIC) from 1974 until 1985. BIC was a nationally recognized Third Party Administrator operating within 35 states. Mr. Babcock has knowledge and experience in the equity arena and has participated in various activities within the venture capital, private and institutional capital markets. Mr. Babcock studied marketing and economics at the University of Arizona where he currently serves on the University of Arizona Astronomy Board.

**Albert Smith:** Mr. Smith was the co-founder of and served as Vice Chairman of CSI Leasing, Inc., a private computer leasing company from 1972 until March 2005. He founded Extreme Video, LLC a private video conferencing company in Scottsdale, Arizona in December 2005 where he presently serves as CEO and President. Mr. Smith presently serves as a director for Center for Arizona Policy (Scottsdale) and Doulos Ministries (Denver). Mr. Smith has extensive experience in marketing and sales having managed a national sales force of over fifty people while at CSI Leasing, Inc. Mr. Smith has a BS in Business Administration from Ferris State College.

***Significant Employees***

Certain significant employees of our subsidiary, IsoRay Medical, Inc., and their respective ages as of the date of this report are set forth in the table below. Also provided is a brief description of the experience of each significant employee during the past five years.

| Name | Age | Position with IsoRay Medical, Inc. |
|---|---|---|
| Lane Bray | 77 | Chief Chemist |
| Garrett Brown | 43 | Chief Technology Officer |
| Oleg Egorov | 36 | Director of Radiochemical Development |
| Lisa Mayfield | 37 | Director of Operations |
| Keith Welsch | 59 | Chief Quality Officer |

**Lane Bray**: Mr. Bray is known nationally and internationally as a technical expert in separations, recovery, and purification of isotopes and is a noted authority in the use of cesium and strontium ion exchange for Department of Energy's West Valley and Hanford nuclear waste cleanup efforts. In 2000, Mr. Bray received the 'Radiation Science and Technology' award from the American Nuclear Society. Mr. Bray has authored or co-authored over 110 research publications, 12 articles for 9 technical books, and holds 24 U.S. and foreign patents. Mr. Bray patented the USDOE/PNNL process for purifying medical grade Yttrium-90 that was successfully commercialized in 1999. Mr. Bray also recently invented and patented the proprietary isotope separation and purification process that is assigned to IsoRay. Mr. Bray was elected 'Tri-Citian of the Year' in 1988, nominated for 'Engineer of the Year' by the American Nuclear Society in 1995, and was elected 'Chemist of the Year for 1997' by the American Chemical Society, Eastern Washington Section. Mr. Bray retired from the Pacific Northwest National Laboratory in 1998. Since retiring in 1998, Mr. Bray worked part time for PNNL on special projects until devoting all of his efforts to IsoRay in 2004. Mr. Bray has been a Washington State Legislator, a Richland City Councilman, and a Mayor of Richland. Mr. Bray has a B.A. in Chemistry from Lake Forest College.

**Garrett Brown**: Dr. Brown was Manager of Radiochemistry - Hot Cell Operations for International Isotopes, Inc., a major radiopharmaceutical and medical device startup company, from January 1998 until May 1999 and was instrumental in bringing a new brachytherapy seed implant device to commercialization. Dr. Brown's responsibilities included hands-on radiological work in fume hoods, glove boxes and remote manipulator hot cells, process definition, research, development, installation, optimization, waste minimization, procedure documentation, facility design and training. Dr. Brown also served as the technical interface to executive management for business development, shipping/receiving, QA/QC, facilities and marketing/sales. Prior to that, Dr. Brown, as a Senior Research Scientist at

the Pacific Northwest National Laboratory, was responsible for the weekly production of multi-Curie quantities of medical grade Y-90, and research programs to develop high tech sorbents for separation of Cs-137, Sr-90 and Tc-99 from high-level radioactive wastes stored at the Hanford Nuclear Reservation. From May 1999 to the present, Dr. Brown has been a technical consultant with GNB Technical Consultants. Dr. Brown has co-authored numerous technical publications in the field. Dr. Brown has a Ph.D. in Analytical Chemistry and BS in Chemistry, cum laude. He has served as IsoRay Medical's Chief Technical Officer since May of 2000. In March 2004, Dr. Brown was certified as a Radiological Safety Officer.

**Oleg Egorov:** Dr. Egorov is recognized nationally and internationally for his work in radiochemistry, radioanalytical chemistry, analytical chemistry and instrumentation. Prior to joining IsoRay in December of 2005 as Director of Radiochemical Development, Dr. Egorov worked from May 1998 as a Senior Research Scientist at the Pacific Northwest National Laboratory (PNNL). Prior to that time, he served the Environmental Molecular Sciences Laboratory at PNNL as a Graduate Research Fellow, from August 1994 to May 1998, and as a Graduate Research Assistant to the University of Washington's Center for Process Analytical Chemistry from September 1992 to August 1993. Former positions included a tenure as a Research Engineer at the Department of Radiochemistry at the Moscow State University, Moscow, Russia between September 1998 to August 1992, and Field Chemist at the Institute of Volcanology, at the Russian Academy of Science at Petropavlovsk-Kamchatsky, Russia, during the summers of 1989 and 1990 concurrent to studies that lead to his acquisition of Master of Science in Radiochemistry from the Moscow State University. During his tenure at PNNL, Dr. Egorov had led world-class basic and applied R&D programs directed at new chemistries and instrumentation for automated production of short-lived medical isotopes for the treatment of cancer, automated process monitoring, radionuclide sensors for groundwater monitoring, and laboratory automation. Dr. Egorov pioneered the application of flow-based techniques for automating radiochemical analyses of nuclear wastes, renewable surface sensing and separations, and equilibration-based radionuclide sensing. He has authored/co-authored numerous peer-reviewed publications in these areas, including several book chapters. Dr. Egorov holds four U.S./international patents, three of which have been licensed to industry. Dr. Egorov was a recipient of numerous outstanding performance and key contributor awards. In 2003, Dr. Egorov was nominated for the American Chemical Society Arthur F. Findeis Award for Achievements by a Young Analytical Scientist. In 2004, Dr. Egorov was a recipient of a Federal Laboratory Consortium Award for Excellence in Technology Transfer for "Alpha Particle Immunotherapy for Treating Leukemia and Solid-Tumor Metastases". Dr. Egorov holds a M.S. in Radiochemistry from Moscow State University, Moscow, Russia; a M.S. in Environmental and Analytical Chemistry and a Ph.D. in Analytical Chemistry from the University of Washington.

**Lisa Mayfield:** Lisa Mayfield comes to IsoRay with over ten years of commercial healthcare sales, marketing and business development experience. Between December 1993 and August 2004, Ms. Mayfield has held senior management positions in the pharmaceutical and medical device and diagnostics sectors of Johnson & Johnson as well as at J&J Corporate. During her time at J&J and prior to joining IsoRay in December 2005, Ms. Mayfield was responsible for implementing positive business results in over 11 different therapeutic markets. After leaving J&J and prior to joining IsoRay, Ms. Mayfield worked as a consultant to various healthcare companies in the radioisotope and oncology markets. As a result of her exposures, Ms. Mayfield has built a wealth of knowledge about the healthcare marketplace as a whole and complements this knowledge with a comprehensive understanding of internal operations. Ms. Mayfield has been responsible for best practices for product development, branding, forecasting, regulatory compliance, reimbursement and strategic planning. During her time at IsoRay, Ms. Mayfield has been able to successfully implement new policies and procedures that facilitate growth as well as provide top level guidance over strategic business operations. Currently Ms. Mayfield is acting Director of Operations at IsoRay. Ms. Mayfield holds a Bachelors of Science in Economics from the University of Washington.

**Keith Welsch**: Mr. Welsch is a quality control professional with experience in a wide range of organizations and disciplines including the nuclear, aerospace, environmental restoration, construction, tubing, steel and aluminum industries. Mr. Welsch managed the registration of a plant to ISO 9002:1994 and subsequently transitioned the facility to ISO 9001:2000 and conducted continuous improvement actions. These included statistical process control, six sigma, lean manufacturing, and total preventive maintenance programs. Mr. Welsch's other significant achievements include facilitation of quality improvement and stand down teams, innovative education training manager, management of records review for two nuclear sites, management of audit programs and corrective-action systems, and teaching safety, technical, and quality courses. He has earned the Certified Quality Auditor, Certified Quality Technician and Certified Quality Improvement Associate certifications from the American Society for Quality. Prior to joining IsoRay in 2004, Mr. Welsch served as Quality Assurance Manager for Kaiser Aluminum Products of Richland, Washington since 1997. Mr. Welsch received a BA in Business Administration from Washington State University.

43

***Executive Compensation***

The following summary compensation table sets forth information concerning compensation for services rendered in all capacities during our past three fiscal years awarded to, earned by or paid to each of the following executive officers (the "Executive Officers"). None of the Company's executive officers, other than those listed below, received compensation in fiscal year 2004 in excess of $100,000.

| | | Annual Compensation | Long-Term Compensation Awards | | |
|---|---|---|---|---|---|
| **Name and Principal Position** | **Fiscal Year[1]** | Salary | **Restricted Stock Awards** | **Securities Underlying Options** | **All Other Compensation** |
| Roger Girard, Chief Executive Officer[2] | 2005 | $ 113,958 | -- | -- | -- |
| | 2004 | $ 71,031 | $ 9,900 | 513,840 | -- |
| | 2003 | $ 4,000 | $ 49,900 | -- | -- |
| Thomas Scallen, Former Chief Executive Officer[3] | 2005 | -- | -- | -- | $ 50,000 [4] |
| | 2004 | -- | $ 7,871 | -- | -- |
| | 2003 | -- | -- | -- | -- |

[1] Fiscal year 2005 consisted of the period from October 1, 2004 through June 30, 2005; fiscal year 2004 consisted of the year ended September 20, 3004; and fiscal year 2003 consisted of the year ended September 30, 2003.
[2] Mr. Girard did not begin serving as our CEO until July 28, 2005, but he has served as CEO of our subsidiary and its predecessor company since August 2003. The compensation listed was paid to Mr. Girard by IsoRay Medical or its predecessor company.
[3] Mr. Scallen served as our CEO during the listed fiscal years and until his resignation effective July 28, 2005.
[4] Represents a $50,000 cash payment in June 2005 to Mr. Scallen in settlement of all accrued but unpaid compensation.

***Aggregated Option Exercises in Last Fiscal Year and Fiscal Year End Option Values***

The following table sets forth the number of shares covered by unexercised stock options held by the Executive Officers as of June 30, 2005, and the value of "in-the-money" stock options, which represents the positive spread between the exercise price of a stock option or warrant and the market price of the shares subject to such option or warrant as of June 30, 2005**.**

| | | | Number of Securities Underlying Unexercised Options at Fiscal Year-End(#) | | Value of Unexercised In-the-Money Options at Fiscal Year-End($) | |
|---|---|---|---|---|---|---|
| Name | Number of Shares Acquired on Exercise (#) | Value Realized ($) | Exercisable | Unexercisable | Exercisable | Unexercisable |
| Roger Girard[1] | 0 | 0 | 513,841 | 0 | $ 39,650 | n/a |
| Thomas Scallen | 0 | 0 | 0 | 0 | n/a | n/a |

(1) Mr. Girard held options to acquire 513,841 IsoRay Medical, Inc. shares at June 30, 2005. He held no options in the Registrant at June 30, 2005.

***Employment Agreements***

The Company entered into an employment agreement with Roger Girard, its Chief Executive Officer, effective October 6, 2005 (the "Girard Agreement"). The term of the Girard Agreement is through October 6, 2009, and will automatically extend for an additional one year term on each anniversary date unless the term is modified or terminated in accordance with the terms of the Girard Agreement at least ninety days prior to a given anniversary date. The Girard Agreement provides for a base salary of $180,000, an automatic increase to $220,000 effective January 1, 2006, and an increase to $300,000 effective July 1, 2006 at the discretion of the Board of Directors. Mr. Girard is also entitled to participate in any benefit plans provided to key executives of the Company, and to a bonus at the discretion of the Board of Directors.

***Equity Compensation Plans***