

CENTURY PARK PICTURES CORP

Form 8-K

August 03, 2005

**United States Securities And Exchange Commission  
Washington, DC 20549**

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report: August 3, 2005

(Date of earliest event reported: July 28, 2005)

**ISORAY, INC.**

**(Exact name of registrant as specified in its charter)**

**Minnesota**

(State or other jurisdiction  
of incorporation)

**000-14247**

(Commission  
File Number)

**41-1458152**

(IRS Employer  
Identification No.)

**350 Hills Street, Suite 106, Richland, Washington 99354**

(Address of principal executive offices) (Zip Code)

**(509) 375-1202**

(Registrant's telephone number)

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## **ITEM 2.01 Completion of Acquisition or Disposition of Assets**

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, Century Park Transitory Subsidiary, Inc., IsoRay Medical, Inc. and certain shareholders (the "Merger Agreement"), was completed as of the filing of a Certificate of Merger with the Secretary of State of Delaware, merging Century Park Transitory Subsidiary, Inc. into IsoRay Medical, Inc.

As a result of the Merger and pursuant to the Merger Agreement, IsoRay Medical, Inc. has become a wholly-owned subsidiary of Century Park Pictures Corporation, Century Park Pictures Corporation has changed its name to "IsoRay, Inc." (hereinafter referred to as the "Registrant"), and the Registrant is issuing shares of its common stock and shares of its preferred stock to holders of common and preferred stock of IsoRay Medical, Inc. at a rate of 0.842362 share of the Registrant's stock for each share of IsoRay Medical, Inc. stock. Options and warrants to purchase common and preferred stock of IsoRay Medical, Inc. will also be converted at the same rate into options and warrants to purchase common and preferred stock of the Registrant. At the time of the Merger and following its recent 30:1 reverse stock split, the Registrant had approximately 2,498,000 shares of common stock outstanding.

Following the Merger, the Registrant will have 10,237,797 shares of common and preferred stock outstanding. The total amount of shares outstanding, on a fully-diluted basis, post merger will be 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. own 82% of the Registrant's outstanding securities, and the Registrant's shareholders own 18% of the Registrant's outstanding securities.

Among the conditions to the closing of the Merger, (i) all officers and directors of IsoRay Medical, Inc. have agreed to lock-up the shares of the Registrant they have received as part of the Merger for a period of one year from the closing; (ii) a major shareholder of the Registrant has agreed to lock-up 233,333 shares of the Registrant's common stock for a period of one year from the closing; (iii) IsoRay Medical, Inc. and the Registrant granted certain piggyback and demand registration rights to certain shareholders of the Registrant and holders of convertible debentures issued by IsoRay Medical, Inc. (for the shares of common stock into which the debentures are convertible); and (iv) Thomas Scallen, the Registrant's former Chief Executive Officer, and a major shareholder of the Registrant have each agreed to escrow 50,000 shares of the Registrant's common stock for a period of three years from the closing as collateral for these individuals' possible indemnification obligations pursuant to the Merger Agreement.

### **Business of the Registrant and Its Subsidiary**

#### ***Cautionary Note Regarding Forward-looking Statements and Risk Factors***

*The Company's Form 10-KSB, any Form 10-QSB or any Form 8-K of the Company or any other written or oral statements made by or on behalf of the Company may contain forward-looking statements which reflect the Company's current views with respect to future events and financial performance. The words "believe," "expect," "anticipate," "intends," "estimate," "forecast," "project," and similar expressions identify forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any statements of the plans, strategies and objectives of management for future operations; any statements concerning proposed new products, services, developments or industry rankings; any statements regarding future economic conditions or performance; any statements of belief; any statements regarding the validity of our intellectual property and patent protection; and any statements of assumptions underlying any of the foregoing. Such "forward-looking statements" are subject to risks and uncertainties set forth from time to time in the Company's SEC reports and include, among others, the Risk Factors beginning on page 20 below.*

*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.*

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***Explanatory Note***

Unless otherwise indicated or the context otherwise requires, all references below in this report on Form 8-K to "we," "us" and the "Company" are to IsoRay, Inc., a Minnesota corporation and its subsidiary, IsoRay Medical, Inc., a Delaware corporation. References to "IsoRay Medical" are to IsoRay Medical, Inc., a Delaware corporation.

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

Immediately prior to the completion of the Merger, the Registrant did not conduct any business operations and had minimal assets and liabilities.

***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, chemists and engineers, and management team to create a major therapeutic 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 Food and Drug Administration ("FDA") approved product, the IsoRay Cs<sup>131</sup> brachytherapy seed, in October 2004 for the treatment of prostate cancer. Management believes its technology will allow it to capture a leadership position in an expanded brachytherapy market. The more clinically beneficial characteristics of the Cesium-131 (Cs-131 or Cs<sup>131</sup>) 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 I-125 and Pd-103. Cs-131 offers a combination of patient benefits management believes are superior to currently available brachytherapy isotopes. Cs-131 could also enable meaningful penetration in other solid tumor applications such as breast cancer, expanding the total available market opportunity. The second radioisotope, Yttrium-90 (Y-90 or Y<sup>90</sup>), 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 Y<sup>90</sup> and IsoRay Medical believes production will not require clinical trials or an extensive FDA application process. Production is expected to begin in late 2005.

Management believes that the IsoRay Cs<sup>131</sup>seed represents the first major advancement in brachytherapy technology in over 17 years with attributes that management believes could make it the long term "seed of choice" for internal radiation procedures. The Cs<sup>131</sup>seed has FDA approval for treatment of malignant disease (e.g. cancers of the head and neck, brain, breast, prostate, etc.) and may be used in surface, interstitial, and intracavity applications for tumors with known radiosensitivity.

The Cs<sup>131</sup> isotope has specific clinical advantages for treating cancer over Iodine (I-125 or I<sup>125</sup>) and Palladium (Pd-103 or Pd<sup>103</sup>), the other isotopes commonly used in brachytherapy procedures. IsoRay Medical believes that the short half life and high-energy characteristics of Cs<sup>131</sup> 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 (versus 17.5 days for Pd<sup>103</sup> and 60 days for I<sup>125</sup>) mitigates negative affects of long radiation periods on healthy tissue and is believed to reduce the duration of certain side effects. The high energy is believed to prove more effective on fast growing cancers by aggressively attacking cancer cells and disrupting cancer cell re-population cycles. The characteristics of Cs<sup>131</sup> may result in the use of 10-30% less seeds per procedure thereby reducing the total physical radiation dose to the patient and reducing the costs of the procedure for both third party payers and the patient.

Brachytherapy seeds are small devices used in an internal radiation 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 the cancer tumor (the word "brachytherapy" means close therapy). The seeds deliver therapeutic radiation by killing the immediate tumor cells

and cells located in the vicinity of the tumor while minimizing exposure to adjacent healthy cells. 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.

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 Y<sup>90</sup> are underway in the U.S. Also, Y<sup>90</sup> is used extensively at multiple treatment centers in Europe. Several members of the current IsoRay Medical team developed a process to produce high-purity Y<sup>90</sup> for medical applications during the mid-1990s. Currently over 90 percent of the Y<sup>90</sup> used in the U.S. is imported. IsoRay Medical's management believes there is an immediate market opportunity for a highly purified Y<sup>90</sup>.

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

- Development of treatment protocol by leading oncologist (January 2005);
  - Treated the first patient (October 2004);
  - Production of the Cs<sup>131</sup>seed commenced (August 2004);
- Five additional patent applications filed for Cs-131 and Y-90 processes (November 2003 - August 2004);
  - Radioactive Materials License received from Washington State Department of Health (July 2004);
  - Hired first two sales and marketing executives (July 2004);
- ISO-9000 Quality Management System and production operating procedures (under continuing development);
- Completed the Seed Integration Test object required by the Washington State Department of Health and the FDA (October 2004);
- Signed the 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 \$10.3 M in debt and equity funding (September 2003 - July 2005);
- Obtained favorable Medicare reimbursement codes for the Cs-131 brachytherapy seed (November 2003);
  - FDA approval to market the first product: the Cs-131 brachytherapy seed (March 2003);
- Initial seed production and 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
  - Patent obtained for Cs-131 isotope separation and purification (May 2000).

### Certain Defined Terms

The technical terms defined below are important to understand as they are used throughout this discussion of the business of IsoRay Medical. When used in this report, 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 **"Cs-131"** is an isotope of the element Cesium that gives off low energy, "soft" x-rays as it decays. Cs-131 decays to 50% of its original activity every 9.7 days, becoming essentially inert after 100 days.

**"Chelate"** and **"bifunctional chelate"** are molecules to which an element or radioisotope is chemically bound, typically having a biologically active portion that selectively binds to cancerous or diseased cells. Chelate also refers to the process of attaching an element or radioisotope to a molecule. A bifunctional chelate is a chelate with two functional groups able to form two chemical bonds per molecule.

**"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. Thus, they are very similar in their chemical behavior.

**"Cs<sup>131</sup>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 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 nerve that controls 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 having 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"** (Y-90) 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.

## Industry Information

### *Incidence of Prostate Cancer*



Excluding skin cancer, prostate cancer is the most common form of cancer, and the second leading cause of cancer deaths, in men. The American Cancer Society estimated there would be about 230,900 new cases of prostate cancer diagnosed and an estimated 29,900 deaths associated with the disease in the United States during 2004. Because of early detection techniques (e.g. PSA) approximately 70% (154,700) of these cases are potentially treatable with seed brachytherapy, when the cancers are still locally confined within the prostate.

The expanding population of men over age 55 and increased PSA screening leading to earlier diagnosis of prostate cancer in the U.S. may lead to growth in the number of prostate cancer cases treatable with brachytherapy. Also, positive changes in Medicare reimbursement for brachytherapy seeds together with a decrease in reimbursement rates for competing technologies have created a more favorable financial environment and stimulated market expansion.

#### *Treatment Options and Protocol*

In addition to brachytherapy, localized prostate cancer is most commonly treated with radical prostatectomy (RP) and external beam radiation therapy (EBRT). 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.

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

#### *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 U.K. Henschke. Don Lawrence later pioneered development of the titanium-encapsulated I-125 brachytherapy seed. His company, Lawrence Soft Ray Inc., provided the world's supply of seeds from 1967 to 1978 until the 3M Corporation purchased the technology. Eventually 3M sold the business to Amersham, which spun off this business to 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, a 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 or I-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 prostate tissue. Compounding this was the fact that often an unintended radiation dose was delivered to healthy surrounding tissues, particularly the urethra and rectum. Clinical results indicate that the brachytherapy insertion procedure, computer modeling, advanced imaging and other techniques used in brachytherapy today have significantly ameliorated these drawbacks.

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

Cs<sup>131</sup> represents the first major advancement in brachytherapy technology in over 17 years with attributes that management believes could make it the long term "seed of choice" for internal radiation procedures. The Cs<sup>131</sup> seed has specific clinical advantages for treating cancer over I-125 and Pd-103.



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. Brachytherapy has become the treatment of choice for early-stage prostate cancer and is now more common than surgery. 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 30 to 45 minute outpatient procedure.

### *Clinical Results*

Long term survival data is now available for brachytherapy with Pd-103 and I-125, which support the efficacy of brachytherapy. Clinical data indicates that brachytherapy offers success rates for early-stage prostate cancer treatment that are comparable 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.

*Improved patient outcomes.* A number of published studies on the use of brachytherapy in the treatment of early-stage prostate cancer have been very positive.

- A nine-year clinical study published in the March 2000 issue of *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).

The table below summarizes published results comparing survival rates 10 years after treatment for patients undergoing different types of treatment. Biochemical Disease-Free Survival is defined as the percentage of patients with normal prostate specific antigen or PSA after treatment and is the most rigorous definition of treatment success. Disease-Specific Survival is defined as the percentage of patients not dying from prostate cancer.

## Comparative Survival and Disease-Free States

Treatment	Seed Implants	External Radiation	Prostatectomy
Disease-Free Survival	64% - 85%	59% - 78%	65%
Disease-Specific Survival	98% - 100%	75% - 97%	84% - 85%
Source: Kaiser Brachytherapy Department, Roseville, CA			

*Reduced Incidence of Side Effects.* Because the IsoRay Cs<sup>131</sup> 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 fewer incidents of side effects and complications than may be incurred with other conventional therapies, and if side effects do occur, they should be lower in intensity and resolve more rapidly than those experienced with competing I-125 and Pd-103 isotopes.

Sexual potency and urinary incontinence are two major concerns men face when choosing among various forms of treatment for prostate cancer. Kaiser patient education information lists the following data from clinical studies that monitored rates of impotence and incontinence.

## Comparative Rates of Potency and Incontinence

Treatment	Seed implants	External Radiation	Prostatectomy (nerve sparing)	Prostatectomy (non nerve-sparing)
Rate of Impotence	10% - 50%	40% - 60%	14% - 56%	65% - 90%
Urinary Incontinence	1%	1%	NR	7% - 8%
Source: Kaiser Brachytherapy Department, Roseville, CA				

*Favorable Market Factors*

*Lower Treatment Cost.* The total one-time cost of brachytherapy ranges from \$13,000 to \$17,000 per procedure. This is approximately two-thirds the cost of a radical prostatectomy or RP, which ranges from \$19,000 to \$25,000, excluding treatment for side effects and post-operative complications that can be quite costly. Brachytherapy cost is comparable to the cost of EBRT (external beam radiation), which ranges from \$13,000 up to \$40,000 for a seven to nine week course of treatment.

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

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

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

## Our Strategy

The key elements of IsoRay Medical's strategy include:

- *Introduce the IsoRay Cs<sup>131</sup>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 plans to construct a state-of-the-art manufacturing facility in Richland, Washington, or if I-297 presents a strategic roadblock to the Company, in another state, implementing our proprietary manufacturing process designed to improve profit margins, provide adequate manufacturing capacity to support future growth and ensure quality control. Working with leading scientists, IsoRay Medical is in the process of designing a proprietary separation process for the manufacturing of enriched barium, a key source material for Cs<sup>131</sup>, to ensure adequate supply and greater manufacturing efficiencies. Also planned is a value-added repackaging service to supply pre-loaded needles, stranded seeds and pre-loaded cartridges used in the implant procedure. IsoRay Medical plans to enter into a long-term program with a leading brachytherapy seed automation design and engineering company to design and build a highly automated manufacturing process to help ensure constant quality and improve profitability.
- *Introduce Cs<sup>131</sup> 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, neck, and brain cancer. IsoRay Medical's management believes that the first major opportunity may be for the use of Cesium 131 for adjunct therapy for the treatment of breast cancer.
- *Introduce other isotope products to the U.S. market.* IsoRay Medical plans to introduce its Yttrium-90 radioisotope in late 2005. Currently, FDA approved Y<sup>90</sup> 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 plans to identify and prioritize 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 will 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 is now available for brachytherapy. Brachytherapy has become the treatment of choice for early-stage prostate cancer and is now more common than surgery. 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 50,000 procedures were forecasted to occur in the U.S. in 2004. This represents a \$150 million seed market that is forecast to grow to \$242 million 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 Cs<sup>131</sup>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 Cs-131, and the anticipated reduction of side effects.





## Products

IsoRay Medical markets the Cs<sup>131</sup>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 Cs<sup>131</sup>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 (impotence and incontinence are reduced when seeds are used to treat prostate cancer); short, convenient outpatient procedure (typically 30 - 45 minutes); faster recovery time (days vs. weeks); lower cost than other treatment modalities; higher cure rates for solid tumors; and less pain.

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 Cs<sup>131</sup>seed*

### *Competitive Advantages of Cs-131*

Cs<sup>131</sup> 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 Cs<sup>131</sup> will increase industry growth and facilitate meaningful penetration into the treatment of other forms of cancer tumors such as breast cancer.

**Brachytherapy Isotope Comparison**

	<b>Cesium-131</b>	<b>Palladium-103</b>	<b>Iodine-125</b>
<b>Half Life</b>	9.7 Days	17.5 days	60 days
<b>Energy</b>	29 KeV	22 KeV	28 KeV
<b>Dose Delivery</b>	90% in 33 days	90% in 58 days	90% in 204 days
<b>Total Dose</b>	110 Gy	125 Gy	145 Gy
<b>Anisotropy Factor*</b>	.969	.877 (TheraSeed 2000)	.930 (Oncura 6711)

\*degree of symmetry of therapeutic dose, a factor of 1 indicates symmetry.

*Shorter Half life.* The Company believes that Cesium-131's shorter half life of 9.7 days will prove to have greater biological effectiveness by mitigating the negative effects of long radiation periods on healthy tissue and reducing 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 to 34 KeV (versus 22 KeV for P-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) and therefore more Pd-103 seeds are required to attain the same therapeutic 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 higher energy from Cs<sup>131</sup> seeds is more effective on fast growing cancers than other isotopes by aggressively attacking cancer cells and disrupting cancer cell re-population cycles, resulting in reduced side effects.

*Reduced side effects.* Because the IsoRay Cs<sup>131</sup> 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. This should result in fewer and less severe side effects and complications than may be incurred with other conventional therapies.

*Shape of radiation field.* The shape of the radiation field generated by a Cs<sup>131</sup> 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. Data from these tests were compiled in IsoRay Medical's 510(k) submission to the FDA. The results of these tests showed superior dose characteristics relative to the leading I-125 and Pd-103 seeds.

Figure 2. Cs131 seed Autoradiograph

*Reduced Costs.* The characteristics of Cs<sup>131</sup> seeds described above may result in the use of 10%-30% less seeds per procedure, compared to other isotopes, thereby reducing the total physical radiation dose to the patient and reducing

the costs of the procedure for the third party payers and the patient.

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*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, by the end of 2005. When used in combination with molecular targets, 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 is currently developing a proprietary separation process that will produce Y-90 that management believes should 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 by 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 will 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 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 is further purified and converted to pharmaceutical grade material in a shielded environmentally-controlled glove box. After completing the separation process every two weeks (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 policies and procedures for the Y-90 isotope that will 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, Inc., Perkin-Elmer Life Sciences, Inc., Amersham PLC and Iso-Tex Diagnostics, Inc.

**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 many potential facilities in the United States. Due to the short half life of both the Ba-131 and Cs-131 isotopes, the isotope generation cycle must occur over several weeks as dictated by the physics of isotope formation and decay and the facilities must be capable of removing irradiated materials from the reactor core on a routine (daily or weekly) basis. Reactor personnel will ship the irradiated barium on a mutually agreed schedule to our facilities for subsequent separation, purification and seed assembly. The Company has identified five reactors in the U.S. and Europe 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, which can be accomplished in three to five days, following customer orders. To ensure Cesium supply reliability, we intend to seek agreements with multiple facilities to produce Cs-131. As of the date of this report, IsoRay Medical has an agreement in place with its supplier for irradiated Ba-131. The Company is engaged in the development of a barium enrichment device that, if successful, would reduce the cost of Cs-131 while maintaining the purity and consistency needed for expeditious manufacture of Cs-131 isotope products.

- *Isotope Separation and Purification.* Following the harvesting of Ba-131, the isotope decays, becomes Cs-131, and is moved through a number of proprietary processes until it reaches seed form. After receiving the irradiated barium feedstock from the nuclear reactor facility, the rest of the manufacturing process will occur at our facilities. This includes the isotope purification required prior to insertion in the seed. Due to the high-energy decay of Ba-131, initial processing will occur under stringent radiological controls in a highly shielded isolator or "hot cell" using remote manipulators. After removal of the energetic Ba-131, subsequent seed processing will be completed in locally shielded fume hoods or glove boxes. Isotope purification involves chemically separating the Cs-131 isotope from the irradiated material. Upon completion of the separation process (e.g., collecting or "milking" the therapeutic Cs-131), the residual enriched barium will be recycled back to the reactor facility for subsequent irradiation. This material will be recycled as many times as economically feasible, which should make the process more cost effective.
- *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 will include 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 will be capable of identifying and classifying these variations for quality control ensuring a minimal amount of material is wasted. Finally, the rapid placement and removal of components from the welding zone will affect overall product throughput.
- *Quality Control.* We expect to establish 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 to completion of product manufacture can be reduced to three to five 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.

#### *Automated Manufacturing Process*

IsoRay Medical has begun discussions with a leading designer and manufacturer of automated seed manufacturing equipment that developed an automated line in the US for manufacturing Iodine-125 that was sold to a competitor in early 2003. In addition, IsoRay Medical is engaged in preliminary discussions with another seed manufacturer regarding obtaining an existing automated production line. An automated production line would require less labor, reduce costs, and help ensure consistent manufacturing quality.

#### *Manufacturing Facility*

The initial production of the IsoRay Cs-131 brachytherapy seed commenced at PNNL in 2004. IsoRay Medical has signed a lease agreement for a new interim production facility that management anticipates will be ready by September of 2005. The Company is also considering Idaho 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 in Idaho.

#### *Repackaging 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 - seed manufacturers usually load and sterilize Mick cartridges in their own manufacturing facilities)

No single package configuration dominates the market at this point. Market share estimates for each of the four packaging types are: loose seeds (20% - 30%) Mick cartridges (25% - 35%), pre-loaded needles (40% - 55%) and strands (10% - 20%). Market trends indicate some movement to the recently introduced stranded configuration, as there is some clinical data suggesting less 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 to the customer is through independent radiopharmacies such as Advanced Care Pharmacy and Custom Care Pharmacy. Manufacturers send loose seeds along with the physician's prescription to the radiopharmacy who, in turn, loads needles and/or strands the seeds according to the doctor's prescription. These pharmacies then assay and certify the final packaging prior to shipping the product directly to the end user.





IsoRay Medical has held discussions with the major independent radiopharmacies and determined the shortest achievable turnaround time from delivery of loose seeds to the radiopharmacy to delivery of the final assayed and packaged seeds to the end user is 3 - 4 days. Because of the short half life of Cs-131, management believes adding 3 - 4 days to the product delivery schedule is prohibitive on a long-term basis although to boost immediate sales we intend to use these services on an interim basis until our value-added repackaging service is operational.

Because the short half life of the Cs-131 isotope requires fast delivery to the end user, the Company intends to establish its own value-added repackaging service to provide these services. The Company intends to market its seeds to the end user in all four of the commonly used packaging configurations, and the Company has retained an experienced consultant to assist in the development of the value-added repackaging service.

Prior to the establishment of a value-added repackaging service, IsoRay Medical is offering loose seeds which will require the implant center to load the seeds into their preferred implant configuration. Management has contacted the maker of Mick cartridges and believes it will be able to load Mick cartridges on site for those implant centers using the Mick applicator as their method of injecting the seeds into the prostate. The Company currently offers non-sterile, pre-loaded Mick cartridges. As soon as the Company acquires the proper sterilization equipment, loose seeds and pre-loaded Mick cartridges will be offered in a sterile package. When the value-added repackaging service is operational, the Company will add pre-loaded needles and strands in a sterile and non-sterile package. Management believes the value-added repackaging service will be operational by the end of 2005.

Independent radiopharmacies usually provide the final packaging of the product delivered to the end user. This negates an opportunity for reinforcing the "branding" of the 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 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 a value-added repackaging service in its new, leased facility to be \$100,000 to \$150,000 and adequate space has already been identified in that facility. One or more technicians will be added to the staff to handle the seed loading, stranding and assaying operations. 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 found sources of enriched barium 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 based on its clinical advantages over Iodine and Palladium. Management believes there is no apparent clinical reason to use Palladium-103 or Iodine-125 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 intend to target these competing isotopes as our principal competition rather than the various manufacturers and distributors of these products. 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 will focus 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 unique and important role in the ultimate choice of prostate cancer treatment and the specific isotope chosen for seed brachytherapy treatment. The Company will tailor 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 will coordinate the creation and distribution of all advertising material and work with the print and visual media.

The clinical advantages of Cs-131's unique combination of high energy and short half life will be heavily promoted within the clinical market. Because there is no apparent clinical reason to choose Palladium over Cesium, we have and will continue to target those high volume users of Palladium as our first implant sites. We will 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 will use a combination of marketing messages to appear in print and visual media. Planned marketing activities include: exhibiting 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 will also promote its 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 will emphasize 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](http://www.isoray.com), advertising in magazines read by prostate cancer patients and their care givers, and through patient advocacy efforts.

Another key element of our strategy will be 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 the seeds of our competitors. During the remainder of 2005, 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 will 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 already 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 of 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. The Company has begun its implant program by supplying the Cs<sup>131</sup>seed to 9 well-known implant centers strategically located throughout the U.S. Implant centers are currently located in the states of Arizona, California, Illinois, Pennsylvania, Tennessee, Texas and Washington, which have implanted our seed into 49 patients as of July 28, 2005. As production increases, additional centers will be added. Clinical results from the patients implanted through July 28, 2005, while not a large enough group to draw any statistically significant conclusions, have been consistent with the reduced side effects expected from the shorter half life of Cs-131.

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 will eliminate 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 significantly reduces 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 payers including Medicare/Medicaid and private insurance groups. These payers 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 (Centers for Medicare and Medicaid Services) approved a HCPCS/CPT code for Cs-131 brachytherapy seeds of \$44.67 per seed. 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. payer for prostate brachytherapy services, and is the payer in close to 70% of all U.S. prostate brachytherapy cases.

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 marginally during the next few years.

Management believes the Cs<sup>131</sup>seed will command a premium because of its unique characteristics and its clinical advantages over Palladium and Iodine. 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**

#### *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, 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 by the U.S. Patent and Trademark Office (USPTO) under Patent Number 6,660,302. The process was developed by Lane Bray, a shareholder of the Company, and has been assigned exclusively to IsoRay Medical. IsoRay'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 patent applications were 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.

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. Additionally, when IsoRay Medical attains a 15% domestic market share, it will pay to the Lawrence Family Trust, a major shareholder of the Company, 1% of the "Factory Price" with a minimum annual royalty of \$4,000, pursuant to an agreement with Don Lawrence.

#### *Research And Development*

From inception (December 17, 2001) through December 31, 2004, IsoRay Medical and its predecessor companies incurred more than \$1.6 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 Cs<sup>131</sup>seed for the treatment of localized solid tumors. A new 510(k) clearance would be required for any modifications in the device or its labeling that could significantly affect the safety or effectiveness of the original product.

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. 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 aware of a decrease in orders for the Cs<sup>131</sup>seed during the month of December. This decrease in orders is related to a decrease in the number of brachytherapy procedures performed during the month of December, as many physicians are on vacation. The Company is not aware of any other 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*

Currently IsoRay, Inc. has no employees, but certain executives of IsoRay Medical will likely be employed by IsoRay, Inc. prior to September 30, 2005. IsoRay Medical employs twenty-one full-time individuals, two temporary individuals and three 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 15 additional employees by the end of 2005.

#### *Plan of Operations*

The Company has \$1,191,545 cash on hand as of July 28, 2005. At the Company's current operational burn rate of approximately \$500,000 per month, cash on hand and additional financing currently available would fund the Company's operations until November 2005, not including capital expenses. Management believes that an additional \$9.4 million will need to be raised by the end of 2005 to fund planned growth and operations through 2006.

IsoRay Medical has four outstanding loans. The first, from TRIDEC, with a principal amount of \$40,000, was funded in 2001 and requires annual principal only payments of \$10,000. It is non-interest bearing and unsecured. The second loan is with the Benton-Franklin Economic Development District in the 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. This loan is secured by certain equipment, materials and inventory of IsoRay Medical, and also required personal guarantees, for which the guarantors were issued 83,640 shares of common stock in IsoRay Medical. The third loan is a line of credit, from Columbia River Bank in the amount of \$395,000. 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 127,500 shares of common stock of IsoRay Medical. The fourth loan is with Columbia River Bank in the amount of \$150,000, of which \$50,000 was funded as of July 28, 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. IsoRay Medical is in negotiations with the Hanford Area Economic Investment Fund Committee (HAEIFC) for a \$1,400,000 loan. There can be no assurance that this loan will be funded.

On April 4, 2005 a capital lease agreement was executed by IsoRay Medical with Nationwide Funding LLC, whereby the lessor will fund the \$75,000 acquisition of a glove box being built to the Company's specifications by Premier

Technology, Inc. of Pocatello, ID. This is a 48 month agreement with a minimum monthly lease payment of \$2,475.38.

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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, a provision of which is that IsoRay Medical can purchase the hot cell for fair market price, 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 \$7,589.50. The minimum monthly lease payment increases to \$15,910 for the remaining 31 months, based on the entire value of the \$430,000 lease line. In connection with the lease agreement, IsoRay Medical granted warrants to purchase 6,757 shares of its common stock at \$3.50/share. These warrants expire after four years from the date of issuance, and were converted at the ratio listed above as part of the merger.

#### *Property*

The Company's executive offices are located at 350 Hills Street, Suite 106, Richland, WA 99354, (509) 375-1202, where it currently leases approximately 3,100 square feet of office and laboratory space for \$4,196 per month. The lease expires December 31, 2005. Additional office space will be needed as employees are hired, and is currently available at this location. The Company believes that the current administrative facilities will be adequate until the end of 2005, but it will need additional facilities at that time. In the future, due to business growth, the Company may elect to combine administrative services and production in one building which the Company 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<sup>131</sup> seeds in PNNL for up to 18 months subsequent to commencement of production in PNNL. The PNNL facility has limited capacity and if demand for Cs<sup>131</sup> seeds exceeds this capacity the Company may need to shift production to its new leased facility before the end of the 18 month period. We have entered into a lease, to commence as of regulatory licensing approval, for an approximately 4300 square foot facility located in Richland, Washington that our management believes will provide adequate space to manufacture the Cs-131 product for the prostate cancer markets until late 2007. The lease is for a term of twelve months following regulatory licensing approval, which management believes will be obtained during the third quarter of 2005, and payment for the lease term is the issuance of 25,800 shares of IsoRay Medical (pre-merger) common stock. The lease may be extended on a month-to-month basis by mutual agreement of the parties.

#### *Legal Proceedings*

There are no legal actions pending against the Company.

#### *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 devices. RP currently represents 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 currently claims nearly 50% of the market with the original I-125 seed. Theragenics, 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.

Because the exterior seed dimensions of all seeds are substantially the same, the threshold to physician acceptance of the IsoRay seed is not significant. Treatment planning systems and seed implantation equipment used worldwide all rely on seeds of the same length and diameter. Technical costs for users to switch from I-125 and Pd-103 to the IsoRay Cs-131 seed should be minimal.

Several companies have obtained regulatory approval to produce and distribute Palladium-103 and Iodine-125 seeds, which compete directly with our seed. Ten of those companies represent nearly 100% of annual brachytherapy seed sales worldwide: ONCURA, Theragenics Corp., North American Scientific, Inc., Mentor Corp., Implant Sciences Corp., International Brachytherapy S.A., Cardinal Health, Inc., SourceTech Medical LLC, DRAXIMAGE (a division of DRAXIS Health, 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 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 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<sup>131</sup> 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, and liver cancer, and the Company believes that a major opportunity exists as an adjunct therapy for the treatment of breast 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.

### **Risk Factors**

*IsoRay Medical Has Begun Generating Revenue But Is Not Yet Profitable.* IsoRay Medical began generating revenue in October 2004, generated revenue of approximately \$262,836 through July 28, 2005, and is in the early stages of marketing its IsoRay Cs<sup>131</sup> seed. IsoRay Medical and the Company have minimal historical, operating or financial information upon which to evaluate its performance. There can be no assurance that the Company will obtain profitability.

*Our Revenues Depend Primarily Upon One Product.* Our revenues depend upon the successful production, marketing, and sales of the IsoRay Cs<sup>131</sup> seed. A number of factors may affect the rate and level of market acceptance of this product including:



- “ 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;
  - “ any unfavorable publicity concerning our product or similar products;
    - “ its price relative to other products or competing treatments;
  - “ any decrease in current reimbursement rates from Medicare and/or third party payers;
  - “ regulatory developments related to the manufacture or continued use of the product;
    - “ 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 incur losses rather than profits in the future.

*We Have Limited Data On The Clinical Performance Of Cs-131.* As of July 28, 2005, the IsoRay Medical Cs<sup>131</sup> seed has been implanted in forty-nine patients. While this limited number of patients prevents us from drawing statistically significant conclusions, we can report that the side effects experienced by these patients were consistent with the types of side effects seen in seed brachytherapy with Iodine and Palladium. 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 weeks six and eight post-implant, indicating that, at least for these initial patients, side effects resolved more quickly than the side effects that occur with competing seeds. These limited findings support management's belief that the Cs<sup>131</sup> seed will result in less severe side effects than competing treatments, but we will have to wait for outcomes from additional patients before we can definitively establish the incidence of side effects from our seeds.

*Our Subsidiary's Independent Accountants Have Expressed Doubt About Its Ability To Continue As A Going Concern.* IsoRay Medical's ability to continue as a going concern is an issue raised as a result of the material operating losses incurred since inception, and its stockholders' deficit. 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 going concern increases the difficulty in meeting such goals.

*We Will Need To Raise Additional Capital.* The hiring of upper level sales executives, entry into capital lease agreements for a glove box and a hot cell, and entry into executive contracts requiring payments upon reaching certain milestones significantly increased IsoRay Medical's monthly cash "burn rate" since August 2004. Ongoing obligations to meet greater payroll obligations coupled with legal and accounting fees related to completing the recent merger with Century Park Pictures Corp. have resulted in greater amounts of short term cash demands than ever before in the history of IsoRay Medical. We have been actively raising capital and will need to continue to do so in greater amounts than we have raised in the past.

We will also need substantial funds to complete the development, manufacturing, and marketing of our potential future products. Consequently, we will seek to raise further capital through not only public and private offerings of equity and debt securities, but also collaborative arrangements, strategic alliances, and equity and debt financings or

from other sources. We will need to raise at least \$9.4 million of additional funding by the end of 2005 to fund working capital through 2006 and to acquire additional equipment for the interim production facility currently under construction. IsoRay Medical has entered into a lease, to commence as of regulatory licensing approval, for an approximately 4300 square foot facility located in Richland, Washington that its management believes will provide adequate space to manufacture the Cs-131 product for the prostate 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.

In the event of our insolvency, bankruptcy, liquidation, reorganization, or dissolution or upon our default in payment with respect to any indebtedness or an event of default with respect to such indebtedness resulting in the acceleration thereof, our assets are not expected to be sufficient to result in any payment to holders of the Company's preferred or common stock.

*The Recent Passage Of Initiative 297 In Washington May Result In The Relocation To Idaho Of Our Manufacturing Operations.* 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. The U.S. Secretary of Energy is a party to litigation challenging the constitutionality of this initiative 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 manufacture seeds at PNNL for some period of time. If the State of Washington begins enforcement of the initiative and the protective legislation described above has not been enacted, we may be unable to continue to produce seeds at PNNL under our Commercial Work For Others contract with the Department of Energy, and if we cannot continue to produce seeds at PNNL, we would have to move our manufacturing operations to an alternate facility that may be outside the State of Washington.

Management believes that we will be able to continue our manufacturing operations in the State of Washington for the foreseeable future, whether at PNNL or at our leased interim facility in the State of Washington. In the event Initiative 297 is enforced against us, management has been engaged in discussions with officials in Idaho regarding an alternate manufacturing facility in Idaho. Because Idaho has a business friendly environment and the state has offered an attractive incentive package, we would expect to be able to build our own manufacturing facility at a cost below that anticipated for a similar facility in the State of Washington. We may consider moving all or part of our operations to Idaho even if Initiative 297 is not enforced against us.

*We Have Limited Manufacturing Experience And May Not Be Able To Meet Demand.* Our manufacturing experience is limited and existing management team and staff of IsoRay Medical and the Company have experience primarily in research and development of products and not in manufacturing products. IsoRay Medical began commercial production of the Cs<sup>131</sup> seed in the fourth quarter of 2004. IsoRay Medical has not tested commercial production of Yttrium-90, although certain members of its management team previously produced weekly batches of Y-90 for the research market when they were affiliated with another company. Although IsoRay Medical's management team has significant radiochemistry experience, there is a possibility that commercial-scale production may result in challenges that may be too expensive or difficult to overcome. IsoRay Medical has procured equipment for a semi-automated process of laser welding, but its ability to produce the Cs<sup>131</sup> seed in very large quantities may be limited by the current lack of a completely automated process for welding. IsoRay Medical believes it will find a more efficient means of welding the titanium seeds, however, there can be no assurance that seeds will not be welded individually by the semi-automated process for the foreseeable future. Consequently, we cannot ensure that either IsoRay Medical's manufacturing process or its ability to sustain ongoing production of its products will be able to meet demand.

*We Have Limited Sales And Marketing Experience.* Some members of IsoRay Medical's team have 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 limited specific experience with the commercial sales and marketing of the Cesium-131 radioisotope. IsoRay Medical has marketing professionals with extensive experience selling medical devices, including radioisotopes for large, international companies. Its initial marketing activities have begun, and we will need to recruit additional employees to assist with these functions. 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 ever be able to develop our own sales and marketing capabilities to the extent anticipated by management. We may need to rely on third-party efforts and distribution channels and may

not be able to maintain satisfactory arrangements with the third parties on whom we rely. We are currently developing in-house customer service, order entry, shipping, billing, customer reimbursement assistance and sales support. We cannot be certain that we will successfully develop and coordinate these departments and may need to find outside contractors to carry out part or all of these functions. Even if needed, we cannot be certain that we can successfully contract with outside contractors or that they will be available at projected prices.



*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, including:

- “ our achievement of product development objectives and milestones;
  - “ demand and pricing for the Company's products;
    - “ effects of aggressive competitors;
    - “ hospital and clinic 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;
    - “ the amount and timing of sales orders;
    - “ rate and success of product approvals;
- “ timing of FDA approval, if any, of competitive products and the rate of market penetration of competing products;
  - “ foreign currency exchange rates;
  - “ seasonality of purchasing behavior in our market;
    - “ overall economic conditions; and
- “ the successful introduction or market penetration of alternative therapies.

*We Rely Heavily On A Limited Number Of Suppliers.* Some materials used in our products are currently available only from a limited number of suppliers. 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 for these 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.

*We Are Subject To Uncertainties Regarding Healthcare Reimbursement And Reform.* In 2003, IsoRay Medical's predecessor applied for, and CMS (Centers for Medicare and Medicaid Services) created a classification for reimbursement for our Cs<sup>131</sup>seed (HCPCS code C2633 and APC code 2633) The initial reimbursement under these codes was \$44.67 per seed. However, since January 1, 2004 hospitals and clinics ordering our seeds are to be paid on a cost basis instead. On an ongoing basis, our ability to commercialize products depends in part on the extent to which healthcare services and products are paid by governmental agencies, private health insurers and other organizations,

such as health maintenance organizations, for the cost of such products and related treatments. Our business could be harmed if healthcare payers and providers implement cost-containment measures and governmental agencies implement healthcare reform measures that reduce payment to our customers for their use of our products.

*Our Industry Is Intensely Competitive.* The medical device 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 in the development of technologies and processes and in acquiring personnel and technology from academic institutions, government agencies, and other private and public research organizations. We cannot be certain that one or more of our competitors will not receive patent protection that dominates, blocks or adversely affects our product development or business; will benefit from significantly greater sales and marketing capabilities or will not develop products that are accepted more widely than ours.

*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 in the U.S. and four foreign countries. The patent positions of medical device companies can be highly uncertain and involve complex legal and factual questions. Our patent rights may not be upheld in a court of law if challenged. Our patent rights may not provide competitive advantages for our products and may be challenged, infringed upon or circumvented by our competitors. We cannot patent our products in all countries or afford to litigate every potential violation worldwide.

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

Our Cs-131 separation patent is essential for 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 at 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, as well as our contract manufacturers and suppliers are subject to extensive, complex, costly, and evolving governmental rules, regulations and restrictions administered by the FDA, by other federal and state agencies, and by governmental authorities in other countries. In the United States, our products cannot be marketed until they are approved for market by the FDA. IsoRay Medical has received FDA approval for the marketing of the Cs<sup>131</sup>seed and our competitors have received FDA approval for marketing Yttrium-90. Accordingly, we believe our application for FDA approval of our Y-90 will be limited, and require no patient trials.

Obtaining FDA market approval involves the submission, among other information, of the results of preclinical and clinical studies on the product, and requires substantial time, effort and financial resources. The FDA, Washington State Department of Health, and other federal and state agencies, as well as equivalent agencies of other countries with whom we will export our products, will also perform pre-licensing inspections of our facility and our contract manufacturers' and suppliers' facilities. Our failure or the failure of our partners, contract manufacturers, or suppliers to meet FDA or other agencies' requirements would delay or preclude our ability to sell our products potentially having an adverse material effect on our business.

Even with FDA market approval, we, as well as our partners, contract manufacturers and suppliers, are subject to numerous FDA requirements covering, among other things, testing, manufacturing, quality control, labeling and continuing review of medical products, and to permit government inspection at all times. Failure to meet or comply with any rules, regulations, or restrictions of the FDA or other agencies could result in fines, unanticipated expenditures, product delays, non-approval or recall, interruption of production, and criminal prosecution.



Although we have implemented internal compliance programs and will continue to address any compliance issues raised from time to time by the FDA and the other agencies, we may not be able to meet regulatory agency standards, and any lack of compliance may harm our business.

*Our Business Exposes Us To Product Liability Claims.* Our design, testing, development, manufacture, and marketing of products involve an inherent risk of exposure to product liability claims and related adverse publicity. Insurance coverage is expensive and difficult to obtain, and, although we currently have a five million dollar policy, in the future we may be unable to obtain coverage on acceptable terms, if at all. If we are unable to obtain 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 equipment failure; or 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 our radioactive waste through the Battelle managed PNNL site under a one year renewable agreement. We intend to open our own facility and intend to use commercial disposal contractors. We may incur substantial costs related to the disposal of these materials. If we were to become liable for an accident, or if we were to suffer an extended facility shutdown, we could incur significant costs, damages, and penalties that could harm our business.

*We Rely Upon Key Personnel.* Our success will depend, to a great extent, upon the experience, abilities and continued services of our executive officers and key scientific personnel. If we lose the services of any 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 our 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 Cesium-131, our patent pending on the manufacture of the brachytherapy seed, our patent applications on additional methods for producing Cesium-131 and Yttrium-90 which have been filed, and anticipated future patent applications, which have not yet been filed, have significant value, we cannot be confident that other like-kind processes may not exist or be discovered, or that any of these patents is enforceable.

*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 our management, operating software, financial systems, and resources. To compete effectively and to accommodate growth, if any, we may be required to continue to implement and to improve our management, operating and financial systems, procedures and controls on a timely basis and to expand, train, motivate and manage our employees. There can be no assurance that our personnel, systems, procedures, and controls will be adequate to support our future operations. If Cesium-131 were to become the "seed of choice," explosive sales growth could occur, making it unlikely that we could meet demand. This would cause customer discontent and invite competition.

*Our Reporting Obligations As A Public Company Will Be Costly.* Operating a public company involves substantial costs to comply with reporting obligations under federal securities laws that are continuing to increase as provisions of the Sarbanes Oxley Act of 2002 are implemented. These reporting obligations will increase our operating costs. We

may not reach sufficient size to justify our public reporting status.

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*There Is A Limited Market For Our Common Stock.* Currently only a limited trading market exists for our common stock. Our common stock trades solely on the Pink Sheets, a market with very limited liquidity and minimal listing standards under the symbol "CPPC.PK." This symbol will change as a result of the Merger. 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. We intend to seek a listing on the Over-the Counter Bulletin Board, but there can be no assurance that such a listing will be obtained. We cannot assure our shareholders that a market for our stock will be sustained. There is no assurance that our shares will have any greater liquidity than shares that do not trade on a public market.

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

### **ITEM 3.02 Unregistered Sales of Equity Securities**

Pursuant to the Merger, the Registrant will issue 6,401,081 shares of its common stock, 1,338,167 shares of its Series B preferred stock, options to purchase 2,069,337 shares of its common stock, warrants to purchase 344,792 shares of its common stock, and warrants to purchase 233,014 shares of its preferred stock. These securities will be issued by the Registrant in reliance upon an exemption from registration under Section 4(2) and Regulation D of the Securities Act of 1933, as amended.

### **Market for Common Equity and Related Stockholder Matters; Description Of Securities**

#### ***Overview***

The Company's Articles of Incorporation provide that the Company has the authority to issue 200 million shares of capital stock, which are currently divided into two classes as follows: 194 million shares of common stock, par value of \$0.001 per share; and 6 million shares of preferred stock, also with a par value of \$0.001 per share. Immediately prior to the Merger, and following its recent 30:1 reverse stock split, the Company had approximately 2,498,000 shares of common stock outstanding, and no shares of preferred stock outstanding. As of July 28, 2005, the Company had 8,899,630 shares of common stock and 1,338,137 shares of Series B preferred stock outstanding.

Since October 1, 2002 and until their delisting earlier this year, the Company's common shares have traded on the Pink Sheets under the symbol "CPPC.PK." There have been only very limited or sporadic quotations, none exceeded \$0.10 per share, and there has been no trading activity in our stock since February 17, 2005. As of July 28, 2005, there were approximately 676 beneficial holders of record of the Company's common stock, exclusive of shares held in street name.

#### ***The Common Stock***

*Voting.* Holders of the common stock are entitled to one vote per share on all matters to be voted on by the Company's shareholders. The Company's bylaws provide that a majority of the outstanding shares of the corporation entitled to

vote constitute a quorum at a meeting of the shareholders.

*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.



*Liquidation, Subdivision, or Combination.* In the event of any liquidation, dissolution or winding up of the Company or upon the distribution of its assets, all assets and funds remaining after payment in full of the Company's debts and liabilities, and after the payment to holders of any then outstanding preferred stock of the full preferential amounts to which they were entitled, would be divided and distributed among holders of the common stock.

### ***The Preferred Stock***

The Company's preferred stock is divided into two series - Series A and Series B - designated as follows:

- 1,000,000 shares of Series A are authorized and 5,000,000 shares of Series B are authorized. There are no shares of Series A issued and outstanding; there are 1,338,167 Series B preferred shares issued and outstanding. The Company has no plans to issue any Series A shares for the foreseeable future.
- The Series A shares are entitled to a 10% dividend annually on the stated value per share (\$1.20) of the Series A, while the Series B shares are entitled to a cumulative 15% dividend annually on the stated value per share (\$1.20) of the Series B. Such dividends will be declared and paid at the discretion of the Board to the extent funds are legally available for the payment of dividends.
- Both series of preferred shares vote equally with the common stock, with each share of preferred having the number of votes equal to the voting power of one share of common stock, except that the vote or written consent of a majority of the outstanding preferred shares is required for any changes to the Company's Articles of Incorporation, Bylaws or Certificate of Designation or for any bankruptcy, insolvency, dissolution or liquidation of the company.
- Upon the liquidation of the company, the company's assets would be distributed ratably to the holders of Series A preferred stock first, then to the holders of Series B preferred stock and then to the holders of common stock.
- Shares of either series of preferred stock may be converted at the option of the holder into shares of common stock at a rate of one share of common stock for each share of preferred stock being converted, subject to adjustment for certain corporate events.
- Both series of preferred stock are subject to automatic conversion into common stock upon the closing of a firmly underwritten public offering pursuant to an effective registration statement under the Act, covering the offer and sale of common stock in which the gross proceeds to the Company are at least \$4 million.

### ***Equity Compensation Plans***

On May 27, 2005, the Company adopted the 2005 Stock Option Plan (the "Option Plan") and the 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 1,500,000 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 1,500,000 shares of common stock to officers and key employees of the Company. As of July 28, 2005, options to purchase 1,180,472 shares had been granted under the Option Plan and options to purchase 888,865 shares had been granted under the Employee Plan as part of the Merger.

<b>Plan Category</b>	<b>Number of securities to be issued upon exercise of outstanding options, warrants and rights (#)</b>	<b>Weighted-average exercise price of outstanding options, warrants and rights (\$)</b>	<b>Number of securities remaining available for future issuance under equity compensation plans</b>
Equity compensation plans approved by shareholders	N/A	N/A	N/A
Equity compensation plans not approved by shareholders	2,069,337	\$1.33	930,663
<b>Total</b>	<b>2,069,337</b>	<b>\$1.33</b>	<b>930,663</b>

### ***Recent Sales of Unregistered Securities***

In addition to the securities issued pursuant to the Merger, the Company issued an aggregate of 2,500,000 shares of common stock in April 2005 (prior to the 30:1 reverse stock split) for cash proceeds of \$85,000. These securities were sold to Andrew Eccelstone (1,470,000 shares), Gary Boster (882,000 shares) and Philip and Stephanie Rogers (148,000 shares). Mr. Rogers served as the Company's President prior to the Merger. The Company relied upon § 4(2) of the Securities Act of 1933, as amended, as the exemption from registration for this transaction. No underwriters were used in connection with this transaction.

### **ITEM 5.01 Changes in Control of Registrant**

Following the Merger, the holders of all of the common stock of IsoRay before the Merger only own 28.07% of the common stock, and 24.41% of the combined voting stock of the Company. The former holders of voting stock in IsoRay Medical now own 71.93% of the common stock, and 75.59% of the combined voting stock of the Company.

### **ITEM 5.02 Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers**

In conjunction with the Merger, and effective as of July 28, 2005 (the closing date of the Merger), Thomas Scallen resigned from his positions as Chief Executive Officer and Chairman of the Board, Philip Rogers resigned from his position as President and a director, and Wally Bietak resigned from his position as a director of the Registrant.

Effective as of July 28, 2005, Roger Girard and David Swanberg were appointed as directors by the resigning Board, and, also effective as of July 28, 2005, they appointed Robert Kauffman, Thomas LaVoy and Stephen Boatwright to fill the remaining three vacant Board positions. The Board has not yet determined on which Board committees these five directors will serve, although it expects to do so at its next scheduled meeting after the Board establishes which committees the Company will form. Further information about the new Board members may be found below.

Effective as of July 28, 2005, Roger Girard was appointed as Chief Executive Officer and President of the Registrant and Michael Dunlop was appointed as Chief Financial Officer and Treasurer of the Company. Also effective July 28, 2005, John Hrobsky was appointed Vice President, Sales and Marketing and David Swanberg was appointed Secretary and Vice President, Operations. The Registrant has not entered into employment agreements with any of these officers as of the date of this filing. Further information about these officers may be found below.

### **Management**

IsoRay's management and directors 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 director and officer during the past five years and directorships (if any) held by each director in other companies.

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Name	Age	Position
Roger Girard	61	CEO, President, Chairman
John Hrobsky	55	VP - Sales and Marketing
Michael Dunlop	53	CFO, Treasurer
David J. Swanberg	48	VP-Operations, Secretary, Director
Robert Kauffman	64	Director
Thomas LaVoy	45	Director
Stephen Boatwright	41	Director

**Roger Girard:** In addition to serving as President, Chairman and CEO for the Registrant, Mr. Girard is currently 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 company designed to help wealthy individuals and companies with strategic planning and financial strategy. Mr. Girard also served as the managing partner for the Northwest office of Capital Consortium during this time. 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.

**John Hrobsky:** Prior to joining IsoRay's predecessor company as Executive Vice President of Sales and Marketing in 2004, Mr. Hrobsky was President, CEO and a director of Advanced Cochlear Systems, positions he held beginning in 2001. From 1999 to 2001, Mr. Hrobsky served as President, CEO and a director of Zaxis International, Inc., a biotechnology company. Prior to 1999, Mr. Hrobsky served as a senior executive or CEO of a number of biotech and medical device companies. IsoRay Medical products with which Mr. Hrobsky has experience include a medical device for restoring neuro-control after spinal cord injury, the leading cochlear implant worldwide, and radiology and imaging equipment. Notably, Mr. Hrobsky served as Vice President of Sales for Cochlear Corporation, the U.S. subsidiary of Cochlear Ltd., an Australian based manufacturer of cochlear implants. Cochlear Ltd. is the world's leading provider of cochlear implants commanding approximately 60% of the market. Mr. Hrobsky earned a B.S. in IsoRay Medical Technology in 1971 from the University of Wisconsin - Eau Claire, and has earned credits toward an MBA from Regis University, Denver, CO.

**Michael 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 16 years of administrative experience in the healthcare industry. As Director of Contracting and Marketing for Community Choice, PHCO, 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 20 years experience in engineering and materials science, nuclear waste and chemical processing, aerospace materials and processes, and environmental technology development and environmental compliance. During the past five years, 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 and has held management positions in the IsoRay companies since 2000. 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 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 LaVoy:** Mr. LaVoy has served as Chief Financial Officer of SuperShuttle International, Inc., since July 1997 and as Secretary since March 1998. 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 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.

### 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	42	Chief Technology Officer
Keith Welsch	58	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-Citizen 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 is retired from the Pacific Northwest National Laboratory and currently serves as a part time consultant for medical isotope development. 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. 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.

**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. Mr. Welsch received a BA in Business Administration from Washington State University.

### *Executive Compensation*

The following table provides certain summary information concerning the compensation earned by IsoRay Medical's Chief Executive Officer or comparable officer for services rendered in all capacities to IsoRay Medical or its predecessor companies for the calendar years ended December 31, 2002, 2003 and 2004. No other executive officer of IsoRay Medical or its predecessor companies received compensation in excess of \$100,000 during calendar years 2002, 2003 or 2004. The following information includes the dollar value of base salaries, bonus awards, the number of stock options granted and certain other compensation, if any, whether paid or deferred.



**Summary Compensation Table**

		Annual Compensation		Long Term Compensation			All Other Compensation (\$)
		Salary (\$)	Bonus (\$)	Awards		Payouts	
Name and Principal Position	Year			Restricted Stock Awards (\$)	Securities Underlying Options/SARs (#)	LTIP Payouts (\$)	
Donald Segna, President, IsoRay Products LLC	2002	0	0	0	0	0	0
	2003	0	0	0	41,580	0	0
	2004	24,000	0	0	0	0	0
Roger Girard, CEO, IsoRay, Inc. and IsoRay Medical, Inc.	2003	12,000	0	49,900	0	0	0
	2004	97,258	0	9,900	610,000	0	0

**Securities Ownership of Certain Beneficial Owners and Management**

The following tables set forth certain information regarding the beneficial ownership of the Company's common stock and preferred stock as of July 28, 2005 for (a) each person known by the Company to be a beneficial owner of five percent or more of the outstanding common or preferred stock of the Company, (b) each executive officer, director and nominee for director of the Company, and (c) all directors and executive officers of the Company as a group. As of July 28, 2005, the Company had 8,899,629.76 shares of common stock and 1,338,167.05 shares of preferred stock outstanding.

**COMMON STOCK SHARE OWNERSHIP AS OF JULY 28, 2005**

Name and Address of Beneficial Owner <sup>(1)</sup>	Amount of Common Shares Owned	Options or Warrants Exercisable Within 60 Days of July 28, 2005	Total Shares Beneficially Owned	Percent of Common Shares Owned <sup>(2)</sup>
Roger Girard, Chief Executive Officer, President and Chairman	338,492.75	219,014.12	0	6.11%
Michael Dunlop, Chief Financial Officer	136,619.33	0	0	1.54%
John Hrobsky, Vice President	0	234,176.64	0	2.56%
David Swanberg, Vice President	284,609.70	0	0	3.20%
Robert Kauffman, Director	43,802.83	0	0	.49%

Thomas LaVoy, Director	0	0	0	0%
Stephen Boatwright, Director	0	84,236.20	0	.94%
Lawrence Family Trust <sup>(3)</sup>	888,530.20	0	0	9.98%
Donald Segna	511,214.35	0	0	5.74%
Anthony Silverman <sup>(4)</sup>	777,020.84	296,431.89	27,376.77	11.67%
All Officers and Directors as a group (7 persons)	803,494.61	537,426.96	0	14.21%

(1) Except as otherwise noted, the address for each of these individuals is c/o IsoRay, Inc., 350 Hills St., Suite 106, Richland, Washington 99354.

(2) Percentage ownership is based on 8,899,629.76 shares of Common Stock outstanding on July 28, 2005. Shares of Common Stock subject to stock options or warrants which are currently exercisable or will become exercisable within 60 days after July 28, 2005 are deemed outstanding for computing the percentage ownership of the person or group holding such options, but are not deemed outstanding for computing the percentage ownership of any other person or group.

(3) The address of the Lawrence Family Trust is 285 Dondero Way, San Jose, California 95119.

(4) The address of Mr. Silverman is 2747 Paradise Road #903, Las Vegas, Nevada 98109.

## PREFERRED STOCK SHARE OWNERSHIP AS OF JULY 28, 2005

Name and Address of Beneficial Owner <sup>(1)</sup>	Amount of Preferred Shares Owned	Options or Warrants Exercisable Within 60 Days of July 28, 2005	Total Shares Beneficially Owned	Percent of Preferred Shares Owned <sup>(2)</sup>
Lebowitz Living Trust <sup>(3)</sup>	142,189.03	0	0	10.63%
David Swanberg, Vice President	14,218.23	0	0	1.06%
All Officers and Directors as a group (7 persons) <sup>(4)</sup>				
	14,218.23	0	0	1.06%

<sup>(1)</sup> Except as otherwise noted, the address for each of these individuals is c/o IsoRay, Inc., 350 Hills St., Suite 106, Richland, Washington 99354.

<sup>(2)</sup> Percentage ownership is based on 1,338,167.05 shares of Preferred Stock outstanding on July 28, 2005. Shares of Preferred Stock subject to stock options or warrants which are currently exercisable or will become exercisable within 60 days after July 28, 2005 are deemed outstanding for computing the percentage ownership of the person or group holding such options, but are not deemed outstanding for computing the percentage ownership of any other person or group.

<sup>(3)</sup> The address of the Lebowitz Living Trust is 16123 Greenwood Road, Monte Sereno, California 95030.

<sup>(4)</sup> No officers or directors other than Mr. Swanberg beneficially own shares of Preferred Stock.

### ***Certain Relationships and Related Transactions***

IsoRay Medical's patent rights to its Cesium-131 process were acquired from Lane Bray, a shareholder of the Company, and are subject to a 1% royalty on gross profits and certain contractual restrictions. Additionally, when IsoRay Medical attains a 15% domestic market share, it will pay to the Lawrence Family Trust, a major shareholder of the Company, 1% of the "Factory Price" with a minimum annual royalty of \$4,000, pursuant to an agreement with Don Lawrence. In exchange for consulting services, Quatsch Ventures, LLC, an entity controlled by Stephen Boatwright, one of the Company's directors, received options to purchase 84,236 shares of our common stock in 2004. Mr. Boatwright is a member of Keller Rohrback, PLC, which provides legal services to the Company and IsoRay Medical.

***Indemnification of Directors and Officers***

The Company's Articles of Incorporation provides to directors and officers indemnification to the full extent provided by law, and provide that, to the extent permitted by Minnesota law, a director will not be personally liable for monetary damages to the Company or its shareholders for breach of his or her fiduciary duty as a director, except for liability for certain actions that may not be limited under Minnesota law.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

**ITEM 5.03 Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year**

On June 28, 2005, the Registrant filed a Certificate of Designation with the Minnesota Secretary of State to designate the rights, preferences and privileges of Series A and B Convertible Preferred Stock, as required by the Merger Agreement. The Registrant is now authorized to issue up to 1 million shares of Series A Convertible Preferred Stock and up to 5 million shares of Series B Convertible Preferred Stock. The Series A Preferred carries a dividend of ten percent per year on the stated value per share of \$1.20 through March 31, 2007. The Series B Preferred carries a dividend of fifteen percent per year on the stated value per shares of \$1.20, and accrued but unpaid dividends cumulate. Both series of preferred stock vote equally with the common stock, and may be converted into common stock at a rate of one share of common stock for each one share of preferred stock converted.

On July 29, 2005, the Registrant filed a Certificate of Amendment to its Articles of Incorporation, changing the name of the Registrant from "Century Park Pictures Corporation" to "IsoRay, Inc."

On August 1, 2005, the Registrant determined that it would change its fiscal year end from September 30 to June 30, and by August 15, 2005 the Registrant will file Form 1128 with the Internal Revenue Service (IRS) to effectuate this change. Pending approval from the IRS, the Registrant will file its transition report on Form 10-KSB.

**ITEM 8.01 Other Events**

As a result of the Merger, IsoRay has moved its principal executive offices to 350 Hills Street, Suite 106, Richland, Washington 99354.

**ITEM 9.01 Exhibits**

(a) Financial Statements of Business Acquired

To be filed by amendment.

(b) Pro Forma Financial Information

To be filed by amendment.

(c) Exhibits

2.1 Merger Agreement dated as of May 27, 2005, by and among Century Park Pictures Corporation, Century Park Transitory Subsidiary, Inc., certain shareholders and IsoRay Medical, Inc.

2.2 Certificate of Merger, filed with the Delaware Secretary of State on July 28, 2005

3.1 Certificate of Designation of Rights, Preferences and Privileges of Series A and B Convertible Preferred Stock, filed with the Minnesota Secretary of State on June 29, 2005

3.2 Amendment to Articles of Incorporation, filed with the Minnesota Secretary of State on July 29, 2005

4.1 Form of Lock-Up Agreement for Certain IsoRay Medical, Inc. Shareholders

4.2 Form of Lock-Up Agreement for Anthony Silverman

4.3 Form of Registration Rights Agreement among IsoRay Medical, Inc., Century Park Pictures Corporation and the other signatories thereto

4.4 Form of Escrow Agreement among Century Park Pictures Corporation, IsoRay Medical, Inc. and Anthony Silverman

4.5 Form of Escrow Agreement among Century Park Pictures Corporation, IsoRay Medical, Inc. and Thomas Scallen

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**SIGNATURES**

In accordance with the requirements of the Exchange Act, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

IsoRay, Inc., a Minnesota corporation

Dated: August 3, 2005

By: /s/ Roger Girard

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Roger Girard, CEO