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	**000-14247**	**41-1458152**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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)

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.

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^{131} 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^{131}) 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^{90}), 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^{90} 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^{131}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^{131}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^{131} isotope has specific clinical advantages for treating cancer over Iodine (I-125 or I^{125}) and Palladium (Pd-103 or Pd^{103}), the other isotopes commonly used in brachytherapy procedures. IsoRay Medical believes that the short half life and high-energy characteristics of Cs^{131} 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^{103} and 60 days for I^{125}) 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^{131} 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^{90} are underway in the U.S. Also, Y^{90} 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^{90} for medical applications during the mid-1990s. Currently over 90 percent of the Y^{90} used in the U.S. is imported. IsoRay Medical's management believes there is an immediate market opportunity for a highly purified Y^{90}.

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^{131}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.

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"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^{131}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^{131} 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^{131}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^{131} 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^{131} 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^{131}, 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^{131} therapies for other solid cancer tumors*. IsoRay Medical intends to partner with other companies to develop the appropriate delivery technology and therapeutic delivery systems for treatment of other solid cancer tumors such as breast, 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^{90} 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^{131} 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.

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Products

IsoRay Medical markets the Cs^{131}seed and intends to market Yttrium-90 and other radioactive isotopes in the future. Additionally, it will attempt to create a market, primarily in clinical trials, for the liquid Cs-131 isotope, which is created in the production of IsoRay Medical's Cs^{131}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^{131}seed

Competitive Advantages of Cs-131

Cs^{131} 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^{131} will increase industry growth and facilitate meaningful penetration into the treatment of other forms of cancer tumors such as breast cancer.

Brachytherapy Isotope Comparison

	Cesium-131	Palladium-103	Iodine-125
Half Life	9.7 Days	17.5 days	60 days
Energy	29 KeV	22 KeV	28 KeV
Dose Delivery			