IsoRay, Inc.
Form 10KSB/A
May 09, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 10-KSB/A
Amendment No. 1

(Mark one)

o **Annual Report Under Section 13 or 15(d) of The Securities Exchange Act of 1934**

For the fiscal year ended _____

x **Transition Report Under Section 13 or 15(d) of The Securities Exchange Act of 1934**

For the transition period from October 1, 2004 to June 30, 2005

Commission File Number: 0-14247

IsoRay, Inc.
(Exact name of small business issuer as specified in its charter)

Minnesota	41-1458152
(State of incorporation)	(IRS Employer ID Number)

350 Hills Street, Suite 106, Richland, WA 99354
(Address of principal executive offices)

(509) 375-1202
(Issuer's telephone number)

Securities registered under Section 12 (b) of the Exchange Act - None

Securities registered under Section 12(g) of the Exchange Act - Common Stock - $0.001 par value

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Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. o

Check whether the issuer has (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period the Company was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes xNo o

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will be contained, to the best of Company's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. o

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act):

Yes o No x

The issuer's revenues for the nine month transitional period ended June 30, 2005 were $-0-.

The aggregate market value of voting common equity held by non-affiliates as of September 30, 2005 was approximately $34,372,217.

As of September 30, 2005, there were 9,060,221 shares of Common Stock issued and outstanding.

Transitional Small Business Disclosure Format: Yes o No x

IsoRay, Inc.
(formerly Century Park Pictures Corporation)

Transitional Report on Form 10-KSB
for the period from October 1, 2004 through June 30, 2005

Table of Contents

Caution Regarding Forward-Looking Information

All statements contained in this Form 10-KSB, other than statements of historical facts, that address future activities, events or developments are forward-looking statements, including, but not limited to, statements containing the words "believe," "anticipate," "expect" and words of similar import. These statements are based on certain assumptions and analyses made by us in light of our experience and our assessment of historical trends, current conditions and expected future developments as well as other factors we believe are appropriate under the circumstances. However, whether actual results will conform to the expectations and predictions of management is subject to a number of risks and uncertainties that may cause actual results to differ materially.

Such risks include, among others, the following: international, national and local general economic and market conditions: our ability to sustain, manage or forecast our growth; raw material costs and availability; new product development and introduction; existing government regulations and changes in, or the failure to comply with, government regulations; adverse publicity; competition; the loss of significant customers or suppliers; fluctuations and difficulty in forecasting operating results; changes in business strategy or development plans; business disruptions; the ability to attract and retain qualified personnel; the ability to protect technology; and other factors referenced in this and previous filings.

Consequently, all of the forward-looking statements made in this Form 10-KSB are qualified by these cautionary statements and there can be no assurance that the actual results anticipated by management will be realized or, even if substantially realized, that they will have the expected consequences to or effects on our business operations.

As used in this Form 10-KSB, unless the context requires otherwise, "we" or "us" or the "Company" means IsoRay, Inc. (formerly Century Park Pictures Corporation).

PART I

ITEM 1 - DESCRIPTION OF BUSINESS

General

The Company was organized under Minnesota law in 1983.

The Company had no operations, assets or liabilities since its fiscal year ended September 30, 1999 through June 30, 2005.

On May 27, 2005, the Company, a newly-formed, wholly-owned subsidiary, Century Park Transitory Subsidiary, Inc., a Delaware corporation, Thomas Scallen and Anthony Silverman, shareholders of the Company, and IsoRay Medical, Inc., a Delaware corporation entered into a Merger Agreement ("Merger"). On July 28, 2005, the Merger closed. As a result of the Merger, IsoRay Medical, Inc. became a wholly-owned subsidiary of the Company. The Company concurrently changed its name to IsoRay, Inc. In the Merger, the IsoRay stockholders received approximately 82% of the then outstanding securities of the Company, as described below.

The Company issued 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 Company's common stock for each share of IsoRay Medical, Inc. stock. Options and warrants to purchase common and preferred stock of IsoRay Medical, Inc. were also converted at the same rate into options and warrants to purchase common and preferred stock of the Company. At the

time of the Merger and following its recent 1:30 reverse stock split, the Company had 2,498,319 shares of common stock outstanding. Following the Merger, the Company had 10,237,797 shares of common and preferred stock outstanding. The total amount of shares outstanding, on a fully-diluted basis, post merger was 13,880,822, which included not only shares of common stock, but also shares of preferred stock, warrants, options and convertible debentures that could be exercised or converted into shares of common stock. Following the Merger, on a fully diluted basis, the shareholders of IsoRay Medical, Inc. owned approximately 82% of the Company's outstanding securities.

Description of Former Business Operations

Certain Defined Terms

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

"EBRT" (external beam radiation therapy) is the external treatment of prostate cancer using an x-ray-like machine that targets a beam of radiation at the cancer site. The treatment damages genetic material within the cancer cells, which prevents the cells from growing and the affected cells eventually die. Treatments are generally performed at an outpatient center five days a week for seven or eight weeks.

"Half-life" means the time required for a radioisotope to decay to one-half of its previous activity. The amount of radiation emitted thus decreases to 25% of original activity in two half-lives, 12.5% in three half-lives, and so on.

"Isotope" refers to atoms of the same element that have different atomic masses. The word "isotope" means "same place," referring to the fact that isotopes of a given element have the same atomic number and hence occupy the same place in the Periodic Table of the Elements. Thus, they are very similar in their chemical behavior.

"^{131}Cs seed" is the name by which IsoRay Medical's first product, the Cesium-131-based brachytherapy seed, is currently known.

"Pure-beta particle emitter" is a radioisotope whose only emissions during radioactive decay are beta particles (electrons). Beta particles can travel several millimeters in tissue.

"RP" (radical prostatectomy or prostatectomy) is the complete surgical removal of the prostate, under significant anesthesia. Two main types of surgery have evolved: nerve-sparing and non nerve-sparing. The nerve-sparing surgery is designed to minimize damage to the nerves that control penile erection.

"Radiobiologic" is characteristic of the effects of radiation on organisms or tissues, most commonly the effectiveness of therapeutic radiation in interrupting cell growth and replication.

"Radioisotope" is a natural or man-made isotope of an element that spontaneously decays while emitting ionizing radiation.

"Seed" is a common term for small radiation sources consisting of a radioisotope sealed within a biocompatible capsule such as gold or titanium, suitable for temporary or permanent brachytherapy implantation.

"Therapeutic radiation" refers to ionizing radiation with sufficient energy to disrupt basic biological processes of cells.

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

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

2

Overview

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

IsoRay Medical intends to utilize its patented radioisotope technology, experienced chemists and engineers, and management team to create a major therapeutic medical isotope and medical device company with a goal of providing improved patient outcomes in the treatment of prostate cancer and other solid cancer tumors. IsoRay Medical began production and sales of its initial Food and Drug Administration ("FDA") approved product, the IsoRay ^{131}Cs brachytherapy seed, in October 2004 for the treatment of prostate cancer. Management believes its technology will allow it to capture a leadership position in an expanded brachytherapy market. The more clinically beneficial characteristics of the Cesium-131 (Cs-131 or ^{131}Cs) isotope are expected to decrease radiation exposure to the patient and reduce the severity and duration of side effects, while treating cancer cells as effectively, if not more so than other isotopes used in seed brachytherapy. Cesium-131 could also enable meaningful penetration in other solid tumor applications such as breast, lung, liver, brain and pancreatic cancer, expanding the total available market opportunity. The second radioisotope, Yttrium-90 (Y-90 or ^{90}Y), is currently being used in the treatment of non-Hodgkin's lymphoma and is in clinical trials for other applications. Other manufacturers have received FDA approval for ^{90}Y and IsoRay Medical believes production will not require clinical trials or an extensive FDA application process. Production is expected to begin in 2006.

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

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

The ^{131}Cs isotope appears to have specific clinical advantages for treating cancer over Iodine-125 (I-125 or ^{125}I) and Palladium-103 (Pd-103 or ^{103}Pd), the other isotopes commonly used in brachytherapy procedures. IsoRay Medical believes that the short half-life and higher dose rate characteristics of ^{131}Cs will expand industry applications and facilitate meaningful penetration into the treatment of other forms of cancer tumors such as breast cancer. The shorter half-life of 9.7 days for ^{131}Cs (versus 17.5 days for ^{103}Pd and 60 days for ^{125}I) mitigates negative effects of long radiation periods on healthy tissue and is believed to reduce the duration of certain side effects. The higher initial dose rate is believed to be more effective on fast growing cancers by aggressively attacking cancer cells and disrupting cancer cell re-population cycles. The characteristics of ^{131}Cs may result in the use of 10-30% fewer seeds per procedure thereby reducing the total physical radiation dose to the patient and reducing the costs of the procedure for both third party payers and the patient.

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

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

· Opened a new manufacturing and production facility (October 2005);

· Deployed a direct sales force to the market (July 2004 - July 2005);

· Developed a treatment protocol for prostate cancer with a leading oncologist (January 2005);

· Treated the first patient (October 2004);

· Commenced production of the ^{131}Cs seed (August 2004);

· Filed five additional patent applications for ^{131}Cs and ^{90}Y processes (November 2003 - August 2004);

· Obtained a Nuclear Regulatory Commission Sealed Source and Device Registration required by the Washington State Department of Health and the FDA (September 2004);

· Received a Radioactive Materials License from the Washington State Department of Health (July 2004);

· Implemented an ISO-9000 Quality Management System and production operating procedures (under continuing development);

· Signed a Commercial Work for Others Agreement between Battelle (manager of the Pacific Northwest National Laboratory or PNNL) and IsoRay Medical, allowing initial production of seeds through 2006 at PNNL (April 2004);

· Raised over $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);

· Obtained FDA 510(k) approval to market the first product: the ^{131}Cs brachytherapy seed (March 2003);

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

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

Industry Information

Incidence of Prostate Cancer

Excluding skin cancer, prostate cancer is the most common form of cancer, and the second leading cause of cancer deaths in men. The American Cancer Society estimated there will be about 232,090 new cases of prostate cancer diagnosed and an estimated 30,350 deaths associated with the disease in the United States during 2005. Because of early detection techniques (e.g., screening for prostate specific antigen, or PSA) approximately 70% (162,400) of these cases are potentially treatable with seed brachytherapy, when the cancers are still locally confined within the prostate.

The prostate is a walnut-sized gland surrounding the male urethra, located below the bladder and adjacent to the rectum. The two most prevalent prostate diseases are benign prostatic hyperplasia (BPH) and prostate cancer. BPH is

a non-cancerous enlargement of the innermost part of the prostate. Prostate cancer is a malignant tumor that begins most often in the periphery of the gland and, like other forms of cancer, may spread beyond the prostate to other parts of the body.

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

In addition to age, other risk factors are linked to prostate cancer, such as genetics. Men who have relatives that have been affected, especially if the relatives were young at the time of diagnosis, have an even higher risk of contracting the disease. Researchers have discovered that changes in certain genes, influenced by DNA mutations inherited from a parent, may cause some men to be more inclined to develop prostate cancer. It has also been suggested that environmental factors such as exposure to cancer-causing chemicals or radiation may cause DNA mutations in many organs, but this theory has not been confirmed. Another factor that may contribute to prostate cancer is diet, with diets high in fat and high in calcium possibly increasing the risk of prostate cancer.

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

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

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

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

Treatment Options and Protocol

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

Radical Prostatectomy. Historically the most common treatment option for prostate cancer, radical prostatectomy is an invasive surgical procedure in which the entire prostate gland is removed. RP is performed under general anesthesia and typically involves a hospital stay of several days for patient observation and recovery. This procedure is often associated with relatively high rates of impotence and incontinence. For instance, a study published in the *Journal of the American Medical Association* in January 2000 reported that approximately 60% of men who had received RP reported erectile dysfunction as a result of surgery. The same report found that approximately 40% of the patients studied reported at least occasional incontinence. New bilateral nerve-sparing techniques are currently being used more frequently in order to address these side effects, but these techniques require a high degree of surgical skill. RP is typically more expensive than other common treatment modalities.

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

Intensity Modulated Radiation Therapy. IMRT is a newer, more advanced form of EBRT in which sophisticated computer control is used to aim the beam at the target volume from multiple different angles and to vary the intensity of the beam. Thus, damage to normal tissue and critical structures is minimized by distributing the unwanted radiation over a larger geometric area. The course of treatment is similar to EBRT and requires daily doses over a period of seven to eight weeks to deliver the total dose of radiation prescribed to kill the tumor. IMRT is relatively new and thus not widely available for use as a treatment modality. As a result fewer clinical data regarding treatment effectiveness and the incidence of side effects are available. One advantage of IMRT, and to some extent EBRT, is the ability to treat cancers that have begun to spread from the tumor site. An increasingly popular therapy for patients with more advanced prostate cancer is a combination of IMRT with seed implant brachytherapy (which until protocols are developed, does not include the Cesium-131 seed).

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

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

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

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

Origin of Brachytherapy seeds

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

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

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

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

There is a large and growing potential market for the Company's products. Several significant clinical and market factors are contributing to the increasing popularity of the brachytherapy procedure. In Europe brachytherapy is growing in excess of 20% per year and it is expected that market growth in the U.S. will also increase dramatically. In 1996 only 4% of prostate cancer cases were treated with brachytherapy, or about 8,000 procedures. In 2005, it is estimated that over 60,000 brachytherapy procedures will be performed for prostate cancer. Brachytherapy as a treatment is now more common than radical prostatectomy and has become the treatment of choice for early-stage prostate cancer. Considerable attention is now being given to high risk and faster growing prostrate cancers as well. Brachytherapy has significant advantages over competing treatments including lower cost, better survival data, fewer side effects, a faster recovery time and the convenience of a single outpatient procedure that generally lasts 45 minutes (Merrick, et al., *Techniques in Urology*, Vol. 7, 2001; Potters, et al., *Journal of Urology*, May 2005; Sharkey, et al., *Current Urology Reports*, 2002).

Clinical Results

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

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

- A twelve-year clinical study published in the 2004 Supplement of the *International Journal of Radiation Oncology, Biology and Physics*, reported that the relative survival rate is 84% for low risk cancer patients, 78% for intermediate risk cancer patients and 68% for high risk cancer patients. The study was conducted by Dr. Lou Potters, et al. of the New York Prostate Institute and included 1,504 patients treated with brachytherapy between 1992 and 2000.

- A study published in the January 2004 issue of the *International Journal of Radiation Oncology, Biology and Physics*, reported that brachytherapy, radical prostatectomy, high-dose external beam radiation therapy and combined therapies produced similar cure rates. The study was conducted by Dr. Patrick Kupelian, Dr. Louis Potters, et al. and included 2,991 patients with Stage T1 or T2 prostate cancer. Of these patients, 35% of patients underwent surgery, 16% received low-dose EBRT, 10% received high-dose EBRT, 7% received combination therapy and 32% received brachytherapy. After five years, the biochemical relapse-free survival rate was 83% for brachytherapy, 81% for radical prostatectomy, 81% for high-dose EBRT, 77% for combination therapy and 51% for low-dose EBRT.

- A nine-year clinical study published in the March 2000 issue of the *International Journal of Radiation Oncology, Biology and Physics*, reported that 83.5% of patients treated with the Pd-103 device were cancer-free at nine years. The study was conducted by Dr. John Blasko of the Seattle Prostate Institute and included 230 patients with clinical stage T1 and T2 prostate cancer. Only 3% experienced cancer recurrence in the prostate.

- Results from a 10-year study conducted by Dr. Datolli and Dr. Wallner published in the *International Journal of Radiation Oncology, Biology and Physics* in September 2002, were presented at the October 2002 American Society for Therapeutic Radiology and Oncology (ASTRO) conference confirming the effectiveness of the Pd-103 seed in patients with aggressive cancer who previously were considered poor candidates for brachytherapy. The 10-year study was comprised of 175 patients with Stage T2-T3 prostate cancer treated from 1991 through 1995. Of these patients, 79 percent remained completely free of cancer without the use of hormonal therapy or chemotherapy.

- A study by the Northwest Prostate Institute in Seattle, Washington reported 79% disease-free survival at 12 years for brachytherapy in combination with external beam radiation (Ragde, *et al*., *Cancer,* July 2000). The chance of cure from brachytherapy is nearly 50% higher than for other therapies for men with large cancers (PSA 10-20) and over twice as high as other therapies for men with the largest cancers (PSA 20+) (K. Wallner, *Prostate Cancer: A Non-Surgical Perspective,* Smart Medicine Press, 2000).

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

Favorable Market Factors

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

Favorable Demographics. Prostate cancer incidence and mortality increase with age. Prostate cancer is found most often in men who are over the age of 50. The National Cancer Institute has reported that the incidence of prostate cancer increases dramatically in men over the age of 55. Currently, one out of every six men is at lifetime risk of developing prostate cancer. More than seven out of ten men diagnosed with prostate cancer are over the age of 65. At

the age of 70, the chance of having prostate cancer is 12 times greater than at age 50. According to the American Cancer Society, prostate cancer incidence rates increased between 1988 and 1992 due to earlier diagnosis in men who otherwise had no sign of symptoms. Early screening has fostered a decline in the prostate cancer death rate since 1990.

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

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

Our Strategy

The key elements of IsoRay Medical's strategy include:

- *Continue to introduce the IsoRay ^{131}Cs seed into the U.S. brachytherapy market*. Utilizing a direct sales organization and selected channel partners, IsoRay Medical intends to capture a leadership position by expanding overall use of the brachytherapy procedure for prostate cancer, capturing much of the incremental market growth and taking market share from existing competitors.

- *Create a state-of-the-art manufacturing process*. IsoRay Medical has constructed a state-of- the-art manufacturing facility in Richland, Washington in its newly leased facility, to implement our proprietary manufacturing process which is designed to improve profit margins and provide adequate manufacturing capacity to support future growth and ensure quality control. If Initiative 297 presents a strategic roadblock to the Company, IsoRay plans to construct a permanent manufacturing facility in another state. Working with leading scientists, IsoRay Medical intends to design and create a proprietary separation process to manufacture enriched barium, a key source material for ^{131}Cs, to ensure adequate supply and greater manufacturing efficiencies. 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 consistent quality and improve profitability.

- *Introduce Cesium-131 therapies for other solid cancer tumors*. IsoRay Medical intends to partner with other companies to develop the appropriate delivery technology and therapeutic delivery systems for treatment of other solid cancer tumors such as breast, lung, liver, pancreas, neck, and brain cancer. IsoRay Medical's management believes that the first major opportunities may be for the use of Cesium-131 in adjunct therapy for the treatment of residual lung and breast cancers.

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

- *Support clinical research and sustained product development*. The Company plans to structure and support clinical studies on the therapeutic benefits of Cs-131 for the treatment of solid tumors and other patient benefits. We are and

will continue to support clinical studies with several leading radiation oncologists to clinically document patient outcomes, provide support for our product claims and compare the performance of our seeds to competing seeds. IsoRay Medical plans to sustain long-term growth by implementing research and development programs with leading medical institutions in the U.S. to identify and develop other applications for IsoRay Medical's core radioisotope technology.

Management believes there is a large and growing addressable market for IsoRay Medical's products. Several factors appear to contribute to the increasing popularity of the brachytherapy procedure. Long-term survival data are now available for brachytherapy (other than with respect to treatment from Cs-131 seeds). Brachytherapy has become the treatment of choice for not only early-stage prostate cancer but is now being considered for treatment of fast growing, aggressive tumors. Brachytherapy is now more common than surgery (prostatectomy). Brachytherapy has significant advantages over competing treatments including lower cost, better survival data, fewer side effects, a faster recovery time and the convenience of an outpatient procedure that generally lasts 45 minutes. Over 60,000 procedures were forecasted to occur in the U.S. in 2005. At the October 6, 2005 Cs-131 seed price of $55, this represents a potential $330 million seed market that is forecast to grow substantially by 2009 according to a recent market survey performed by Frost & Sullivan, a nationally recognized market research firm. IsoRay Medical's management believes that the ^{131}Cs seed will add incremental growth to the existing brachytherapy seed market as physicians who are currently reluctant to recommend brachytherapy for their prostate patients due, in part, to side effects caused by longer-lived isotopes, become comfortable with the shorter half-life of ^{131}Cs, and the anticipated reduction of side effects.

Products

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

Cs-131 Seed Product Description and Use in Cancer Treatment

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

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

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

Figure 1: Cross section of ^{131}Cs seed

Competitive Advantages of Cs-131

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

Brachytherapy Isotope Comparison

	Cesium-131	**Palladium-103**	**Iodine-125**
Half Life	9.7 Days	17.5 days	60 days
Energy	29 KeV+	22 KeV+	28 KeV+
Dose Delivery	90% in 33 days	90% in 58 days	90% in 204 days
Total Dose	100 Gy	125 Gy	145 Gy
Anisotropy Factor*	.969	.877 (TheraSeed® 2000)	.930 (OncoSeed® 6711)
*Degree of symmetry of therapeutic dose, a factor of 1.00 indicates symmetry. +KeV = kiloelectron volt, a standard unit of measurement for electrical energy.			

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

High energy. The Cs-131 isotope decay energy of 29 KeV (versus 22 KeV for Pd-103 and 28 KeV for I-125) generates a therapeutic radiation field that extends beyond the current dosimetry reference point of 1 cm. Pd-103 seeds emit radiation that does not penetrate as far in tissue (up to 40% lower than Cs-131). To compensate for this more Pd-103 seeds are required to attain the equivalent dose as if Cs-131 seeds were used. This increase in the number of seeds implanted increases the time and cost required to perform Pd-103-based procedures. The lower energy from ^{103}Pd seeds may also result in greater non-uniformity of the implant dose as dose rates near the surface of each seed must be higher to compensate for lower doses at greater distances from each seed. The high energy of Cs-131 can result in radiation toxicity if the dosage is not properly calculated by the implanting physician and staff.

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

Figure 2. Cs-131 seed Autoradiograph

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

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

Yttrium-90

Y-90 and Cs-131 are short-lived isotopes that are well suited to treatment of tumors by cell-directed therapy. The Company plans to introduce its second product, Yttrium-90, in 2006. Y-90 is already available from other companies. When used in combination with molecular targeting agents, Y-90 is proving to be an ideal isotope to provide localized radiation therapy for various types of cancer, such as non-Hodgkin's lymphoma, leukemia, ovarian and prostate cancers, osteosarcomas, and tumors of the breast, lung, kidney, colon, and brain. Y-90's properties of short half-life, high specific activity, high energy and pure beta-emissions can be chemically attached to targeting agents that are highly selective for specific tumors. These targeting agents may include monoclonal antibodies, molecules derived from antibodies, peptides, or other tumor-specific molecules. Most Y-90 currently used in the U.S. is imported with varying degrees of quality. IsoRay Medical has developed a proprietary separation process that produces Y-90 that management believes will meet or exceed the purity and quality required for clinical trials and medical applications.

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

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

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

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

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

Cs-131 Manufacturing Process

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

- *Isotope Generation*. The radioactive isotope Cs-131 is normally produced by placing a quantity of stable non-radioactive barium (ideally pure Ba-130) into the neutron flux of a nuclear reactor. The irradiation process converts a small fraction of this material into a radioactive form of barium (Ba-131). The Ba-131 decays by electron capture to the radioactive isotope of interest (Cs-131). IsoRay Medical has evaluated several international nuclear reactors and a few potential facilities in the United States. Due to the short half-life of both the Ba-131 and Cs-131 isotopes, these facilities must be capable of removing irradiated materials from the reactor core on a routine (e.g. weekly) basis. Reactor personnel will ship the irradiated barium on a pre-determined schedule to our facilities for subsequent separation, purification and seed assembly. The Company has identified more than five reactors in the U.S., Europe and the former Soviet Union that are capable of meeting these requirements. This routine isotope generation cycle at supplier reactors will allow significant quantities of Ba-131 to be on hand at our facilities for the completion of the rest of the manufacturing process. To ensure reliability of supply, we intend to seek agreements with multiple facilities to produce Ba-131. As of the date of this report, IsoRay Medical has agreements in place with two suppliers of irradiated Ba-131. The Company's agreement with Russia's Institute of Nuclear Materials for irradiated Ba-131 has a seven year term (ending August 25, 2012) and allows the Company to purchase irradiated Ba-131 for $300.00 per Curie of the isotope. The projected value of the agreement over its term is $30,000,000, with $300,000 worth of irradiated Ba-131 projected to be delivered in the first year. In addition, the Company is engaged in the development of a barium enrichment device that, if successful, should reduce the cost of producing Cs-131 while maintaining the purity and consistency required in the end product.

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

- *Internal Seed Core Technology*. The purified Cs-131 isotope will be incorporated into an internal assembly that contains a binder, spacer and X-ray marker. This internal core assembly is subsequently inserted into a titanium case. The dimensional tolerance for each material is extremely important. Several carrier materials and placement methods have been evaluated, and through a process of elimination, we have developed favored materials and methods during our laboratory testing. The equipment necessary to produce the internal core includes accurate cutting and gauging devices, isotope incorporation vessels, reaction condition stabilization and monitoring systems, and tools for placing the core into the titanium tubing prior to seed welding.

- *Seed Welding*. Following production of the internal core and placement into the titanium capsule, a seed is hermetically sealed to produce a sealed radioactive source and biocompatible medical device. This manufacturing technology requires: accurate placement of seed components with respect to the welding head, accurate control of welding parameters to ensure uniform temperature and depth control of the weld, quality control assessment of the weld integrity, and removal of the finished product for downstream processing or rejection of unacceptable materials to waste. Inspection systems 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 have established procedures and controls to meet all FDA and ISO 9001:2000 Quality Standards. Product quality and reliability will be secured by utilizing multiple sources of irradiation services, feedstock material, and other seed manufacturing components. An intensive production line preventive maintenance and spare parts program will be implemented. Also, an ongoing training program will be established for customer service to ensure that all regulatory requirements for the FDA, DOT and applicable nuclear radiation and health authorities are fulfilled.

The Company intends to implement a just-in-time production capability that is keenly responsive to customer input and orders to ensure that individual customers receive a higher level of customer service from us than from existing seed suppliers who have the luxury of longer lead times due to longer half-life products. Time from order 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.

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

Automated Manufacturing Process

IsoRay Medical has 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 may benefit IsoRay because of potentially reduced labor 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 and completed construction (tenant improvements) of a new interim production facility in Richland, Washington that received final regulatory approval on October 6, 2005 and will begin radioactive production operations shortly thereafter. The Company is also considering another state as a location for a future facility, either as the Company's sole manufacturing facility or as a secondary facility. No agreements have been reached for any possible facilities outside of Washington.

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, based on internal management studies of the market, for each of the four packaging types are: loose seeds (negligible amount) Mick cartridges (30%), pre-loaded needles (20%) and strands (50%). Market trends indicate significant movement toward the stranded configuration, as there are some clinical data suggesting less potential for post-implant seed migration when a stranded configuration is used

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

IsoRay Medical has held discussions with the major independent radiopharmacies and determined the 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. However, to increase sales in the near-term we are using one of these services on an interim basis until our own custom preloading operation comes on-line late in 2005. The Company intends to market its seeds to the end user in all four of the commonly used packaging configurations, and has retained an experienced consultant to assist in the development of this value-added repacking service.

Prior to the establishment of a custom preloading service, IsoRay Medical is offering loose seeds which will require the implant center to load the seeds into their preferred implant configuration. IsoRay is currently loading Mick cartridges in its new facility 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 custom preloading service is operational, the Company will add pre-loaded needles and strands in sterile and non-sterile package configurations. Management believes the custom preloading 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 reduces 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 an additional revenue stream and incremental margins to the Company through the pricing premiums that can be charged. The end users of these packaging options are willing to pay a premium because of the savings realized by eliminating the need for loose seed handling and loading capabilities on site, eliminating the need for additional staffing to load and sterilize seeds and needles, and eliminating the expense of additional assaying of the seeds.

Management estimates the cost of establishing a custom preloading service in its new, leased facility to be approximately $250,000. Space for this custom preloading operation has been reserved in the facility and most of the necessary equipment has been delivered and installed. Preloading procedures have been drafted, staff are being trained, and process validation activities are scheduled for the 4th quarter of 2005. 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 identified sources of enriched barium, including in the former Soviet Union, that we believe we can use until the barium enrichment device is developed.

Marketing and Sales

Marketing Strategy

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

We 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 advantages of Cs-131’s unique combination of high energy and short half-life will be heavily promoted within the clinical market. Because we believe there is no apparent clinical reason to choose other isotopes over Cesium, we have and will continue to target those high volume users of other isotopes as our first implant sites. We 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: attendance at the major brachytherapy-related clinical conferences to exhibit our products and provide marketing information for annual meetings, conferences and other forums of the various professional societies; print advertising in brachytherapy clinical journals; and promoting clinical presentations by experts in the field at major conferences.

In today’s U.S. health care market patients are more informed and involved in the management of their health and any treatments required. Many physicians relate incidents of their patients coming for consultations armed with articles researched on the Internet and other sources describing new treatments and medications. In many cases, these patients

are demanding a certain therapy or drug and the physicians are complying when medically appropriate.

Because of this market factor, we will also promote our products directly to the general population. The audience targeted will be the prostate cancer patient, his spouse, family and care givers. The marketing message to this segment of the market 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, 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 Pd-103 and I-125 seeds. During the remainder of 2005 and into 2006, IsoRay Medical plans to continue its collaboration with leading physicians to develop clinical data on the efficacy of Cs-131 seeds. Noted contributors from the medical physics community will be consulted regarding the benefits of brachytherapy using shorter half-life, improved dosimetry, and higher decay energy seeds. Articles will be submitted to professional journals such as *Medical Physics* and the *International Journal of Radiation Oncology, Biology, and Physics*.

Sales and Distribution

According to a recent industry survey, approximately 2,000 hospitals and free standing clinics are currently offering radiation oncology services in the United States. Not all of these facilities offer seed brachytherapy services. These institutions are staffed with radiation oncologists and medical physicists who provide expertise in radiation therapy treatments and serve as consultants for urologists and prostate cancer patients. We 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 started to build a direct sales organization to introduce Cs-131 to radiation oncologists and medical physicists. In August 2004 IsoRay Medical hired two highly successful sales professionals from the brachytherapy industry that bring well established relationships with key radiation oncologists and medical physicists, and in 2005, IsoRay Medical expanded its sales force to four experienced individuals. By hiring experienced and successful brachytherapy sales people, the Company reduces the risk of delay in penetrating the market due to a lack of knowledge of the industry or unfamiliarity with the key members of the brachytherapy community.

The initial response to our new isotope from prominent radiation oncologists, medical physicists and urologists in the US has been very positive. As of October 6, 2006, the Company had supplied the ^{131}Cs seed to thirteen well-known implant centers strategically located throughout the U.S. Implant centers are currently located in the states of Arizona, California, Illinois, Pennsylvania, Tennessee, New York, Texas, Washington and Wisconsin, which have implanted our seed into 75 patients as of October 6, 2005. As production increases, additional centers will be added. Clinical results from the patients implanted through October 6, 2005, while perhaps not a large enough group to draw 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 should reduce the time and expense required to identify, train and penetrate the key implant centers and establish relationships with the key opinion leaders in these markets. Using established distributors also should reduce the time spent acquiring the proper radiation handling licenses and other regulatory requirements of these markets.

Pricing

Payment for IsoRay Medical products comes from third-party 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. payor for prostate brachytherapy services, and is the payor in close to 70% of all U.S. prostate brachytherapy cases. CMS reviews and adjusts outpatient reimbursement on a periodic and ad hoc basis, but no changes are expected for 2006. As of July 31, 2005, the price for our loose seeds

was $55 per seed.

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

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

Other Information

Customers

Customers representing ten percent or more of total Company sales for the twelve months ended June 30, 2005 include:

Chicago Prostate Cancer Center	Westmont, IL	18.5% of revenue
Western Cancer Center	San Diego, CA	30.6% of revenue
Texas Cancer Center	San Antonio, TX	21.8% of revenue

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

Proprietary Rights

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

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

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

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

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

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

Research And Development

From inception (December 17, 2001) through June 30, 2005, IsoRay Medical and its predecessor companies incurred more than $1.8 million in costs related to research and development activities. The Company expects to continue to have employees working on activities that will be classified as research or development for the foreseeable future.

Government Regulation

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

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

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

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

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

As a registered medical device manufacturer with the FDA, we are subject to inspection to ensure compliance with their current Good Manufacturing Practices, or cGMP. These regulations require that we and any of our contract manufacturers' design, manufacture and service products and maintain documents in a prescribed manner with respect to manufacturing, testing, distribution, storage, design control and service activities. Modifications or enhancements that could significantly affect the safety or effectiveness of a device or that constitute a major change to the intended use of the device require a new 510(k) notice for any product modification. We may be prohibited from marketing the modified product until the 510(k) notice is cleared by the FDA.

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

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

In the United States, as a manufacturer of medical devices and devices utilizing radioactive by product material, we are subject to extensive regulation by not only federal governmental authorities, such as the FDA, but also by state and local governmental authorities, such as the Washington State Department of Health, to ensure such devices are safe and effective. In Washington State, the Department of Health, by agreement with the federal Nuclear Regulatory Commission ("NRC"), regulates the possession, use, and disposal of radioactive byproduct material as well as the manufacture of radioactive sealed sources to ensure compliance with state and federal laws and regulations. Our ^{131}Cs brachytherapy seeds constitute both medical devices and radioactive sealed sources and are subject to these regulations.

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

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

Seasonality

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

Employees

As of September 30, 2005, IsoRay Medical employed twenty-four full-time individuals, one occasional individual and one part-time individual. 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 30 additional employees by the end of 2006.

Competition

The Company competes in a market characterized by technological innovation, extensive research efforts and significant competition. In general, the IsoRay seed competes with conventional methods of treating localized cancer, including, but not limited to, radical prostatectomy and external beam radiation therapy which includes intensity modulated radiation therapy, as well as competing permanent brachytherapy devices. RP has historically represented

the most common medical treatment for early-stage, localized prostate cancer. EBRT is also a well-established method of treatment and is widely accepted for patients who represent a poor surgical risk or whose prostate cancer has advanced beyond the stage for which surgical treatment is indicated. Management believes that if general conversion from these treatment options (or other established or conventional procedures) to the IsoRay seed does occur, such conversion will likely be the result of a combination of equivalent or better efficacy, reduced incidence of side effects and complications, lower cost, quality of life issues and pressure by health care providers and patients.

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

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

Several companies have obtained regulatory approval to produce and distribute Palladium-103 and Iodine-125 seeds, which compete directly with our seed. Ten of those companies represent nearly 100% of annual brachytherapy seed sales worldwide: ONCURA (part of General Electric Company), Theragenics Corp., North American Scientific, Inc., Mentor Corp., Implant Sciences Corp., International Brachytherapy S.A., Cardinal Health, Inc., C.R. Bard, Inc., 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 Canada, Europe and other international markets, introducing Cs-131-based therapies for other forms of solid tumors focusing first on breast tumors, and through the marketing of other radioactive isotopes. These growth initiatives are in the early stages of planning and appear to be significant incremental opportunities.

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

Risk Factors

Our Subsidiary's Independent Accountants Have Expressed Doubt About Its Ability To Continue As A Going Concern. IsoRay Medical has generated material operating losses since inception and has a shareholders' 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 doubt expressed by

IsoRay Medical's auditors about its ability to continue as a going concern increases the difficulty in meeting such goals. IsoRay Medical began generating revenue in October 2004, has generated revenue of approximately $410,000 through September 30, 2005, and is in the early stages of marketing its IsoRay ^{131}Cs seed. IsoRay Medical and the Company have limited historical, operating or financial information upon which to evaluate their performance. There can be no assurance that the Company will attain profitability.

Our Revenues Depend Upon One Product. Until such time as we develop additional products, our revenues depend upon the successful production, marketing, and sales of the IsoRay ^{131}Cs seed. The rate and level of market acceptance of this product may vary depending on the perception by physicians and other members of the healthcare community of its safety and efficacy as compared to that of competing products, if any; the clinical outcomes of the patients treated; the effectiveness of our sales and marketing efforts in the United States and Europe; any unfavorable publicity concerning our product or similar products; our product's price relative to other products or competing treatments; any decrease in current reimbursement rates from the Centers for Medicare and Medicaid Services or third party payers; regulatory developments related to the manufacture or continued use of the product; availability of sufficient supplies of enriched barium for ^{131}Cs seed production; ability to produce sufficient quantities of this product; and the ability of physicians to properly utilize the device and avoid excessive levels of radiation to patients. Because of our reliance on this product as the sole source of our revenue, any material adverse developments with respect to the commercialization of this product may cause us to continue to incur losses rather than profits in the future.

Although Approved To Treat Any Malignant Tissue, Our Sole Product Is Currently Used To Treat One Type Of Cancer. Currently, the IsoRay ^{131}Cs seed is used exclusively for the treatment of prostate cancer. We believe the ^{131}Cs seed will be used to treat cancers of other sites as well, as is currently the case with our competitors'^{125}I and ^{103}Pd seeds. However, we believe that clinical data gathered by select groups of physicians under treatment protocols specific to other organs, will be needed prior to widespread acceptance of our product for treating other cancer sites. If our current and future products do not become accepted in treating cancers of other sites, our sales will depend solely on treatment of prostate cancer and will require ever increasing market share to increase revenues.

We Have Limited Data On The Clinical Performance Of ^{131}Cs. As of October 6, 2005, the IsoRay ^{131}Cs seed has been implanted in 75 patients. While this limited number of patients may prevent us from drawing statistically significant conclusions, the side effects experienced by these patients were less severe than side effects observed in seed brachytherapy with ^{125}I and ^{103}Pd and in other forms of treatment such as radical prostatectomy These early results indicate that the onset of side effects generally occurs between one and three weeks post-implant, and the side effects are resolved between five and eight weeks post-implant, indicating that, at least for these initial patients, side effects resolved more quickly than the side effects that occur with competing seeds or with other forms of treatment. These limited findings support management's belief that the^{131}Cs seed will result in less severe side effects than competing treatments, but we may have to gather data on outcomes from additional patients before we can establish statistically valid conclusions regarding the incidence of side effects from our seeds.

We Will Need To Raise Additional Capital. 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 requirements since August 2004. Monthly operating cash requirements as of the date of this filing were approximately $500,000, excluding capitalized items. Capital expenditures typically include the purchase or capital lease of equipment, with a life-expectancy of more than 12 months, costing in excess of $2,500, which would include among other things: analytical systems, improved packaging for final products and, new production systems which increase manufacturing throughput. Ongoing requirements to meet greater payroll obligations coupled with legal and accounting fees related to completing the recent merger with IsoRay, Inc. and public reporting status have resulted in greater amounts of short-term cash demands. IsoRay Medical was actively raising capital prior to the merger and we will need to continue to raise capital.

We will also need substantial funds to complete the development, manufacturing, and marketing of our current and future products. Consequently, we will seek to raise additional capital through not only public and private offerings of equity and debt securities, but also collaborative arrangements, strategic alliances, or from other sources. We will need to raise at least $5.5 million of additional capital to fund working capital needs through the end of 2006. IsoRay Medical has entered into a lease agreement and has constructed a manufacturing and production facility located in Richland, Washington that its management believes will provide adequate space to manufacture the ^{131}Cs seed product for the prostate and other organ cancer markets until late 2007.

22

We may be unable to raise additional capital on commercially acceptable terms, if at all, and if we raise capital through additional equity financing, existing shareholders may have their ownership interests diluted. Our failure to be able to generate adequate funds from operations or from additional sources would harm our business.

The Passage Of Initiative 297 In Washington May Result In The Relocation Of Our Manufacturing Operations. Washington voters approved Initiative 297 in late 2004, which may impose restrictions on sites at which mixed radioactive and hazardous wastes are generated and stored, including the PNNL, which is where our ^{131}Cs seed product has been manufactured to date. We are currently in the process of transitioning from PNNL to full production in our new, leased facility outside of PNNL. IsoRay has been assured by the Attorney General's office of the State of Washington that medical isotopes are not included in Initiative 297 and that manufacturing in IsoRay's new production facility would not be interrupted, but there is no assurance that this interpretation of Initiative 297 by the Attorney General's Office will continue to exclude medical isotopes. The U.S. Secretary of Energy is a party to litigation challenging the constitutionality of Initiative 297 in U.S. District Court. Due to this litigation, the State of Washington and the U.S. Justice Department have agreed to delay any implementation of Initiative 297 for an indefinite period of time. Thus, we have the ability to continue manufacturing seeds at PNNL for some period of time if needed as a back-up to our new IsoRay production facility, or to conduct further development activities there. If the State of Washington begins enforcement of the initiative, we may be unable to conduct any future activities at PNNL that would generate mixed radioactive and hazardous wastes.

Management believes that we will be able to continue our manufacturing operations in the State of Washington for the foreseeable future, whether at PNNL or at our new leased facility, which is now operational. In the event Initiative 297 is enforced against us, management may consider establishing an alternate manufacturing facility outside of Washington, and we may consider moving all or part of our operations to another state even if Initiative 297 is not enforced against us.

We Have Limited Manufacturing Experience And May Not Be Able To Meet Demand. The existing management team and staff of IsoRay Medical and the Company have experience primarily in research and development of products and our experience in commercial-scale manufacturing is limited. IsoRay Medical began commercial production of the ^{131}Cs seed in the fourth quarter of 2004 and has completed 45 production-scale ^{131}Cs separation runs as of October 3, 2005. IsoRay Medical recently demonstrated production of ^{90}Y using a process suitable for weekly production of commercial-scale quantities of this isotope. Although IsoRay Medical's management team has significant radiochemistry experience, there is a possibility that production demands may result in challenges that may be too difficult or expensive to overcome. IsoRay Medical has developed and deployed semi-automated laser welding equipment that can produce seeds faster than a certain fully-automated line of equipment the Company has reviewed that would cost several million dollars to design and fabricate. IsoRay Medical believes it will continually find more efficient means of welding the titanium seeds; however, there is a possibility that future demand will outstrip our ability to produce seeds using the semi-automated process. We cannot ensure that either IsoRay Medical's manufacturing processes or its ability to sustain ongoing production of its products will be able to meet demand.

Sales And Marketing Experience. IsoRay Medical's sales and marketing team has extensive experience in successfully establishing and training domestic and international sales forces as well as successfully introducing new medical devices to the market, but we have limited specific experience with commercial sales and marketing of the Cesium-131 radioisotope. IsoRay Medical has employed marketing professionals with extensive experience selling medical devices, including radioisotopes for large, international companies. Our initial marketing activities have been targeted to a limited number of physicians and treatment centers, and we will need to recruit additional employees to assist in expanding our customer base. We have developed in-house customer service, order entry, shipping, billing, and sales support. In addition, the Company has engaged a nationally recognized reimbursement specialist Kathy Francisco, of the Pinnacle Health Group, with over 25 years of healthcare reimbursement experience, to assist with reimbursement questions and to provide reimbursement guidelines and appropriate insurance coding numbers needed to obtain reimbursement for seed costs and the implant procedure by our customers. This consulting project was completed by the spring of 2005 and cost IsoRay approximately $7,500 plus travel-related expenses. Although, this

group and other consultants continue to be available to support the Company in its reimbursement and marketing programs, we cannot be certain that our products will be marketed and distributed in accordance with our expectations or that our market research will be accurate. We also cannot be certain that we will be able to develop our own sales and marketing capabilities to the extent anticipated by management. We may choose to add third-party distribution channels, but we may not be able to maintain satisfactory arrangements with the third parties upon whom we rely.

We Are Subject To The Risk That Certain Third Parties May Mishandle Our Product. We rely on third parties, such as Federal Express, to deliver our ^{131}Cs seed, and on other third parties, including various radiopharmacies, to package our ^{131}Cs seed in certain specialized packaging forms that, as of the date of this report, we do not provide at our own facilities. We are subject to the risk that these third parties may mishandle our product, which could result in adverse effects, particularly given the radioactive nature of our product.

Our Operating Results Will Be Subject To Significant Fluctuations. Our quarterly revenues, expenses, and operating results are likely to fluctuate significantly in the future. Fluctuation may result from a variety of factors, which are discussed in detail throughout this "RISK FACTORS" section, including:

· our achievement of product development objectives and milestones;

· demand and pricing for the Company's products;

· effects of aggressive competitors;

· hospital, clinic and physician buying decisions;

· research and development and manufacturing expenses;

· patient outcomes from our therapy;

· physician acceptance of our products;

· government or private healthcare reimbursement policies;

· our manufacturing performance and capacity;

· incidents, if any, that could cause temporary shutdown of our manufacturing facilities;

· the amount and timing of sales orders;

· rate and success of future product approvals;

· timing of FDA approval, if any, of competitive products and the rate of market penetration of competing products;

· seasonality of purchasing behavior in our market;

· overall economic conditions; and

· the successful introduction or market penetration of alternative therapies.

We Rely Heavily On A Limited Number Of Suppliers. Some materials used in our products are currently available only from a limited number of suppliers. For example, virtually all titanium tubing used in brachytherapy seed manufacture comes from a single source, Accellent Corporation. We currently obtain a key component of our seed core from a single supplier. We do not have formal written agreements with either this key supplier or with Accellent Corporation. Any interruption or delay in the supply of materials required to produce our products could harm our business if we were unable to obtain an alternative supplier or substitute equivalent materials in a cost-effective and timely manner. Additional factors that could cause interruptions or delays in our source of materials include limitations on the availability of raw materials or manufacturing performance experienced by our suppliers and a breakdown in our commercial relations with one or more suppliers. Some of these factors may be completely out of our control and our

suppliers' control.

Future Production Increases Will Depend on Our Ability to Acquire Larger Quantities of ^{131}Cs and Hire More Employees. IsoRay currently obtains ^{131}Cs through reactor irradiation of natural barium and subsequent separation of cesium from the irradiated barium targets. The amount of ^{131}Cs that can be produced from a given reactor source is limited by the power level and volume available within the reactor for irradiating targets. This limitation can be overcome by utilizing barium feedstock that is enriched in the stable isotope ^{130}Ba. However, the number of suppliers of enriched barium is limited and they may be unable to produce this material in sufficient quantities at a reasonable price.

IsoRay has entered into an exclusive agreement with the Institute of Nuclear Materials in the former Soviet Union to provide irradiated barium and ^{131}Cs in quantities sufficient to supply a significant percentage of future demand for ^{131}Cs. IsoRay believes this supplier may also provide access to sufficient quantities of enriched barium that may be recycled for use in other reactors to increase the production of ^{131}Cs. Although the agreement provides for supplying ^{131}Cs in significant quantities, there is no assurance that this will result in IsoRay gaining access to a sufficient supply of enriched barium feedstock and if sufficient supplies are attained we will need to increase our manufacturing staff.

We Are Subject To Uncertainties Regarding Reimbursement For Use Of Our Products. Hospitals and freestanding clinics may be less likely to purchase our products if they cannot be assured of receiving favorable reimbursement for treatments using our products from third-party payers, such as Medicare, Medicaid and private health insurance plans. Currently, Medicare reimburses hospitals, clinics and physicians for the cost of seeds used in brachytherapy procedures on a per seed basis. Historically, private insurers have followed Medicare guidelines in establishing reimbursement rates. However, third-party payers are increasingly challenging the pricing of certain medical services or devices, and we cannot be sure that they will reimburse our customers at levels sufficient for us to maintain favorable sales and price levels for our products. There is no uniform policy on reimbursement among third-party payers, and we can provide no assurance that our products will continue to qualify for reimbursement from all third-party payers or that reimbursement rates will not be reduced. A reduction in or elimination of third-party reimbursement for treatments using our products would likely have a material adverse effect on our revenues.

In 2003, IsoRay applied to the Centers for Medicare and Medicaid Services (CMS) and received reimbursement codes for use of our ^{131}Cs seed (HCPCS code C2633 and APC code 2633). However, since January 1, 2004 hospitals and clinics ordering brachytherapy seeds have been reimbursed for the cost of the seeds plus a fixed mark-up at a rate prescribed by CMS. Reimbursement amounts are reviewed and revised periodically, and on an ad hoc basis. Although the Company is not currently aware of any changes to CMS reimbursement rates that would have a material effect on our ability to maintain our pricing structure, adjustments could be made to these reimbursement amounts or policies, which could result in reduced reimbursement for brachytherapy services, which could negatively affect market demand for our products.

Furthermore, any federal and state efforts to reform government and private healthcare insurance programs could significantly affect the purchase of healthcare services and products in general and demand for our products in particular. We are unable to predict whether potential healthcare reforms will be enacted, whether other healthcare legislation or regulations affecting the business may be proposed or enacted in the future or what effect any such legislation or regulations would have on our business, financial condition or results of operations.

It Is Possible That Other Treatments May Be Deemed Superior To Brachytherapy. Our ^{131}Cs seed faces competition not only from companies that sell other radiation therapy products, but also from companies that are developing alternative therapies for the treatment of cancers. It is possible that advances in the pharmaceutical, biomedical, or gene therapy fields could render some or all radiation therapies, whether conventional or brachytherapy, obsolete. If alternative therapies are proven or even perceived to offer treatment options that are superior to brachytherapy, physician adoption of our product could be negatively affected and our revenues from our product could decline.

Our Industry Is Intensely Competitive. The medical products industry is intensely competitive. We compete with both public and private medical device, biotechnology and pharmaceutical companies that have been established longer

than we have, have a greater number of products on the market, have greater financial and other resources, and have other technological or competitive advantages. We also compete with academic institutions, government agencies, and private research organizations in the development of technologies and processes and in acquiring key personnel. Although we have patents granted and patents applied for to protect our isotope separation processes and ^{131}Cs seed manufacturing technology, we cannot be certain that one or more of our competitors will not attempt to obtain patent protection that blocks or adversely affects our product development efforts. To minimize this potential, we have entered into exclusive agreements with key suppliers of isotopes and isotope precursors.

We May Be Unable To Adequately Protect Or Enforce Our Intellectual Property Rights Or Secure Rights To Third-Party Patents. Our ability and the abilities of our partners to obtain and maintain patent and other protection for our products will affect our success. We are assigned, have rights to, or have exclusive licenses to patents and patents pending in the U.S. and numerous foreign countries. The patent positions of medical device companies can be highly uncertain and involve complex legal and factual questions. Our patent rights may not be upheld in a court of law if challenged. Our patent rights may not provide competitive advantages for our products and may be challenged, infringed upon or circumvented by our competitors. We cannot patent our products in all countries or afford to litigate every potential violation worldwide.

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

One Of Our Licensed Patents May Be Terminated Under Certain Conditions. Our ^{131}Cs separation patent is essential for the production of Cesium-131. The owner of the patent, Lane Bray, a shareholder of the Company and Chief Chemist of IsoRay Medical, has the right to terminate the license agreement that allows the Company to use this patent if we discontinue production for any consecutive 18 month period. The Company has no plans to discontinue production, and management considers it highly unlikely that production will be discontinued for any significant period at any time in the future.

Failure To Comply With Government Regulations Could Harm Our Business. As a medical device and medical isotope manufacturer, we are subject to extensive, complex, costly, and evolving governmental rules, regulations and restrictions administered by the FDA, by other federal and state agencies, and by governmental authorities in other countries. Compliance with these laws and regulations is expensive and time-consuming, and changes to or failure to comply with these laws and regulations, or adoption of new laws and regulations, could adversely affect our business.

In the United States, as a manufacturer of medical devices and devices utilizing radioactive by-product material, we are subject to extensive regulation by federal, state, and local governmental authorities, such as the FDA and the Washington State Department of Health, to ensure such devices are safe and effective. Regulations promulgated by the FDA under the U.S. Food, Drug and Cosmetic Act, or the FDC Act, govern the design, development, testing, manufacturing, packaging, labeling, distribution, marketing and sale, post-market surveillance, repairs, replacements, and recalls of medical devices. In Washington State, the Department of Health, by agreement with the federal Nuclear Regulatory Commission ("NRC"), regulates the possession, use, and disposal of radioactive byproduct material as well as the manufacture of radioactive sealed sources to ensure compliance with state and federal laws and regulations. Our ^{131}Cs brachytherapy seeds constitute both medical devices and radioactive sealed sources and are subject to these regulations.

Under the FDC Act, medical devices are classified into three different categories, over which the FDA applies increasing levels of regulation: Class I, Class II, and Class III. Our ^{131}Cs seed has been classified as a Class II device and has received clearance from the FDA through the 510(k) pre-market notification process. Although not anticipated, any modifications to the device that would significantly affect safety or effectiveness, or constitute a major change in intended use, would require a new 510(k) submission. As with any submittal to the FDA, there is no assurance that a 510(k) clearance would be granted.

In addition to FDA-required market clearances and approvals for our products, our manufacturing operations are required to comply with the FDA's Quality System Regulation, or QSR, which addresses requirements for a company's quality program such as management responsibility, good manufacturing practices, product and process design controls, and quality controls used in manufacturing. Compliance with applicable regulatory requirements is monitored through periodic inspections by the FDA Office of Regulatory Affairs ("ORA"). We anticipate both announced and unannounced inspections by the FDA. Such inspections could result in non-compliance reports (Form

483) which, if not adequately responded to, could lead to enforcement actions. The FDA can institute a wide variety of enforcement actions, ranging from public warning letters to more severe sanctions such as fines, injunctions, civil penalties, recall of our products, operating restrictions, suspension of production, non-approval or withdrawal of pre-market clearances for new products or existing products, and criminal prosecution. There can be no assurance that we will not incur significant costs to comply with these regulations in the future or that the regulations will not have a material adverse effect on our business, financial condition and results of operations.

The marketing of our products in foreign countries will, in general, be regulated by foreign governmental agencies similar to the FDA. Foreign regulatory requirements vary from country to country. The time and cost required to obtain regulatory approvals could be longer than that required for FDA clearance in the United States and the requirements for licensing a product in another country may differ significantly from FDA requirements. We will rely, in part, on foreign distributors to assist us in complying with foreign regulatory requirements. We may not be able to obtain these approvals without incurring significant expenses or at all, and the failure to obtain these approvals would prevent us from selling our products in the applicable countries. This could limit our sales and growth.

Our Business Exposes Us To Product Liability Claims. Our design, testing, development, manufacture, and marketing of products involve an inherent risk of exposure to product liability claims and related adverse publicity. Insurance coverage is expensive and difficult to obtain, and, although we currently have a five million dollar policy, in the future we may be unable to obtain or renew coverage on acceptable terms, if at all. If we are unable to obtain or renew sufficient insurance at an acceptable cost or if a successful product liability claim is made against us, whether fully covered by insurance or not, our business could be harmed.

Our Business Involves Environmental Risks. Our business involves the controlled use of hazardous materials, chemicals, biologics, and radioactive compounds. Manufacturing is extremely susceptible to product loss due to radioactive, microbial, or viral contamination; material or equipment failure; vendor or operator error; or due to the very nature of the product's short half-life. Although we believe that our safety procedures for handling and disposing of such materials comply with state and federal standards there will always be the risk of accidental contamination or injury. In addition, radioactive, microbial, or viral contamination may cause the closure of the respective manufacturing facility for an extended period of time. By law, radioactive materials may only be disposed of at state-approved facilities. We currently dispose of our radioactive waste through the Battelle managed PNNL site under a one year renewable agreement. At our new, leased facility we 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. IsoRay, Inc. has an employment agreement with Roger Girard, its Chief Executive Officer, and IsoRay Medical has employment agreements with most of its executive officers and key scientific personnel. If we lose the services of several of these officers or key scientific personnel, our business could be harmed. Our success also will depend upon our ability to attract and retain other highly qualified scientific, managerial, sales, and manufacturing personnel and their ability to develop and maintain relationships with key individuals in the industry. Competition for these personnel and relationships is intense and we compete with numerous pharmaceutical and biotechnology companies as well as with universities and non-profit research organizations. We may not be able to continue to attract and retain qualified personnel.

The Value Of Our Granted Patent, and Our Patents Pending, Is Uncertain. Although our management strongly believes that our patent on the process for producing ^{131}Cs, our patent pending on the manufacture of the brachytherapy seed, our patent applications on additional methods for producing ^{131}Cs and ^{90}Y which have been filed, and anticipated future patent applications, which have not yet been filed, have significant value, we cannot be certain that other like-kind processes may not exist or be discovered, that any of these patents is enforceable, or that any of our patent applications will result in issued patents.

Our Ability To Expand Into Foreign Markets Is Uncertain. Our future growth will depend in part on our ability to establish, grow and maintain product sales in foreign markets, particularly in Europe and Asia. However, we have limited experience in marketing and distributing products in other countries. Any foreign operations would subject us to additional risks and uncertainties, including our customers' ability to obtain reimbursement for procedures using our products in foreign markets; the burden of complying with complex and changing foreign regulatory requirements; language barriers and other difficulties in providing long-range customer service; potentially longer accounts

receivable collection times; significant currency fluctuations, which could cause third party distributors to reduce the number of products they purchase from us because the cost of our products to them could fluctuate relative to the price they can charge their customers; reduced protection of intellectual property rights in some foreign countries; and the possibility that contractual provisions governed by foreign laws would be interpreted differently than intended in the event of a contract dispute. Any future foreign sales of our products could also be adversely affected by export license requirements, the imposition of governmental controls, political and economic instability, trade restrictions, changes in tariffs and difficulties in staffing and managing foreign operations. Many of these factors may also affect our ability to import enriched barium from Russia under our contract with the Institute of Nuclear Materials.

Our Ability To Initiate Operations And Manage Growth Is Uncertain. Our efforts to commercialize our medical products will result in new and increased responsibilities for management personnel and will place a strain upon the entire company. To compete effectively and to accommodate growth, if any, we may be required to continue to implement and to improve our management, manufacturing, sales and marketing, operating and financial systems, procedures and controls on a timely basis and to expand, train, motivate and manage our employees. There can be no assurance that our personnel, systems, procedures, and controls will be adequate to support our future operations. If the IsoRay ^{131}Cs seed were to rapidly become the "seed of choice," it is unlikely that we could meet demand. We could experience significant cash flow difficulties and may have difficulty obtaining the working capital required to manufacture our products and meet demand. This would cause customer discontent and invite competition.

Our Reporting Obligations As A Public Company Are Costly. Operating a public company involves substantial costs to comply with reporting obligations under federal securities laws that are continuing to increase as provisions of the Sarbanes Oxley Act of 2002 are implemented. These reporting obligations will increase our operating costs. We may not reach sufficient business volume to justify our public reporting status.

There Is A Limited Market For Our Common Stock. Currently only a limited trading market exists for our common stock. Our common stock currently trades on the Pink Sheets, a market with very limited liquidity and minimal listing standards, under the symbol "ISRY.PK." Any broker/dealer that makes a market in our stock or other person that buys or sells our stock could have a significant influence over its price at any given time, and quotations are limited and sporadic. We have applied for a listing on the Over-the Counter Bulletin Board, but there can be no assurance that such a listing will be obtained. Even if we are listed on the Over-the-Counter Bulletin Board, shareholders may experience more difficulty in attempting to sell their shares than if the shares were listed on a national stock exchange or quoted on the NASDAQ Stock Market. We cannot assure our shareholders that a market of our stock will be sustained. There is no assurance that our shares will have any greater liquidity than shares that do not trade on a public market.

Our Stock Price Is Likely To Be Volatile. There is generally significant volatility in the market prices and limited liquidity of securities of early stage companies, and particularly of early stage medical product companies. Contributing to this volatility are various events that can affect our stock price in a positive or negative manner. These events include, but are not limited to: governmental approvals, refusals to approve, regulations or actions; market acceptance and sales growth of our products; litigation involving the Company or our industry; developments or disputes concerning our patents or other proprietary rights; changes in the structure of healthcare payment systems; departure of key personnel; future sales of our securities; fluctuations in our financial results or those of companies that are perceived to be similar to us; investors' general perception of us; and general economic, industry and market conditions. If any of these events occur, it could cause our stock price to fall.

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

ITEM 2 - DESCRIPTION OF PROPERTY

The Company leased, prior to July 2005, approximately 1,941 square feet of office space at 4701 IDS Center, Minneapolis, Minnesota 55402. This space was sub-leased to a separate company owned by the Company's then-CEO. The Company incurred no expense related to this lease during any period reflected in this Transitional Report on Form 10-KSB.

Subsequent to June 2005, the Company's executive offices are now located at 350 Hills Street, Suite 106, Richland, WA 99354, (509) 375-1202, where IsoRay Medical currently leases approximately 3,100 square feet of office and laboratory space for $4,196 per month from Energy Northwest. The lease expires December 31, 2005, but is renewable. The Company is not affiliated with its lessor. Additional office space will be needed as employees are hired, and is currently available at this location. The Company believes that its current 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-131 seeds in PNNL until it expires in December 2006. Management believes that IsoRay will have sufficient time prior to this contract's expiration to shift production to IsoRay's new facility, described below.

We have entered into a lease, which commenced as of regulatory licensing approval on October 6, 2005, for a facility located in Richland, Washington that management believes will provide adequate space to manufacture the Cs-131 product for the prostate cancer markets until late 2007. The lease is for a term of twelve months following regulatory licensing approval, 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. The lessor is Pacific EcoSolutions Incorporated, and the Company is not affiliated with this lessor.

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

ITEM 3 - LEGAL PROCEEDINGS

The Company is not involved in any material legal proceedings.

ITEM 4 - SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matter was submitted to a vote of the Company's security holders during the fourth quarter of the fiscal year covered by this Transitional Report.

PART II

ITEM 5 - MARKET FOR COMMON EQUITY, RELATED STOCKHOLDERS' MATTERS AND SMALL BUSINESS ISSUER PURCHASES OF EQUITY SECURITIES

The Company's Articles of Incorporation provide that the Company has the authority to issue 200,000,000 shares of capital stock, which are currently divided into two classes as follows: 194,000,000 shares of common stock, par value of $0.001 per share; and 6,000,000 shares of preferred stock, par value of $0.001 per share. 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.

Our common stock is quoted on the Pink Sheets under the symbol “ISRY.PK.” We resumed trading on the Pink Sheets on August 18, 2005, after a period of no trading activity (under our prior symbol “CPPC.PK”) from February 18, 2005 until August 18, 2005. We also had a period of no trading activity from July 2003 until February 7, 2005. Prior to August 18, 2005, there was an absence of an established trading marking for the Company’s common stock, the market was very limited and sporadic, and no quotations from October 1, 2003 through July 2005 exceeded $0.01 per share.

On October 3, 2005, the last reported bid price of our common stock as reported on the Pink Sheets was $5.50 per share. This quotation represents an inter-dealer price without retail mark-up, mark-down or commissions, and may not necessarily represent an actual transaction.

As of September 30, 2005, we had approximately 811 shareholders of record, exclusive of shares held in street name.

Equity Compensation Plans

On May 27, 2005, the Company adopted the 2005 Stock Option Plan (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. Options granted under either Plan have a ten year maximum term, an exercise price equal to at least the fair market value of the Company’s common stock (based on the trading price on the Pink Sheets or OTC Bulletin Board) on the date of the grant, and with varying vesting periods as determined by the Board. IsoRay Medical, Inc.’s option plans were cancelled and replaced in the merger with the Plans described above, and new options were issued without any change in the material terms of the options, other than acceleration of all unvested options (other than those issued to Mr. Griffiths, Mr. Hrobsky and Mr. Hutchinson which retained their original vesting terms). As of June 30, 2005, no options had been granted under either plan.

Plan Category	Number of securities to be issued on exercise of outstanding options, warrants and rights #	Weighted-average exercise price of outstanding options, warrants, and rights $	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by shareholders	N/A	N/A	N/A
Equity compensation plans not approved by shareholders	N/A	N/A	3,000,000
Total	N/A	N/A	3,000,000

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

Pursuant to the Merger Agreement, all rights and privileges granted to IsoRay shareholders owning common and preferred stock were converted into substantially similar rights and privileges when the shareholders received IsoRay, Inc. shares of common and preferred stock subject solely to the differences between Delaware (IsoRay Medical) and Minnesota (IsoRay) laws.

Preferred Stock