IsoRay, Inc.
Form 10KSB
September 28, 2006

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, d.c. 20549

FORM 10-KSB

þ Annual Report of Small Business Issuers under Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended June 30, 2006

or

¨ Transition Report of Small Business Issuers under Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from _____ to _____

Commission File No. 000-14247

ISORAY, INC.
(Exact name of registrant as specified in its charter)

Minnesota (State of incorporation)	41-1458152 (I.R.S. Employer Identification No.)
350 Hills St., Suite 106 Richland, Washington 99354 (Address of principal executive offices)	(509) 375-1202 (Registrant's telephone number)

Issuer's telephone number, including area code: (509) 375-1202

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

Number of shares outstanding of each of the issuer's classes of common equity:

Class	Outstanding as of September 15, 2006
Common stock, $0.001 par value	15,802,394

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 x No 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

State issuer's revenues for its most recent fiscal year - $1,994,306.

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked prices of such common equity, as of a specified date within the past 60 days - $44,717,880 as of September 15, 2006.

Documents incorporated by reference - none.

Transitional Small Business Disclosure Format : Yes o No x

ISORAY, INC.
(formerly Century Park Pictures Corporation)

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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 described under "Risk Factors" beginning on page 22 below that may cause actual results to differ materially.

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.

PART I

As used in this Form 10-KSB, unless the context requires otherwise, "we" or "us" or the "Company" means IsoRay, Inc. and its subsidiary.

ITEM 1 - DESCRIPTION OF BUSINESS

General

Century Park Pictures Corporation ("Century") was organized under Minnesota law in 1983. Century had no operations since its fiscal year ended September 30, 1999 through June 30, 2005.

On July 28, 2005, IsoRay Medical, Inc. ("Medical") became a wholly-owned subsidiary of Century pursuant to a merger. Century changed its name to IsoRay, Inc. ("IsoRay" or the "Company"). In the merger, the Medical stockholders received approximately 82% of the then outstanding securities of the Company.

Medical, a Delaware corporation, was incorporated effective June 15, 2004 to develop, manufacture and sell isotope-based medical products and devices for the treatment of cancer and other diseases. Medical is headquartered in Richland, Washington.

Medical was formed for the purpose of combining the operations of IsoRay, Inc. (a former Washington corporation) ("IsoRay (WA)") and its subsidiary, IsoRay Products LLC, two companies that shared common ownership and management with Medical. Medical's management initiated a merger transaction effective October 1, 2004, to combine operations.

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. 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", "^{131}Cs" or **"Cs-131"** 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'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.

Overview

IsoRay 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 tumor cancers. IsoRay began production and sales of its Food and Drug Administration ("FDA") cleared 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.

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

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

The ^{131}Cs isotope appears to have specific advantages for treating cancer over Iodine-125 (I-125 or ^{125}I) and Palladium-103 (Pd-103 or ^{103}Pd), the other isotopes commonly used in brachytherapy procedures. IsoRay 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 such as breast cancer. The shorter half-life of 9.7 days for ^{131}Cs (versus 17 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 compared to Pd-103, 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 and its predecessor companies have accomplished the following key milestones:

- Treated 500th patient (September 2006);
- 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 the ^{131}Cs process (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, allowing initial production of seeds through 2006 at PNNL (April 2004);
- Raised over $23.0 M in debt and equity funding (September 2003 - August 2006)
- Obtained favorable Medicare reimbursement codes for the Cs-131 brachytherapy seed (November 2003);
- Obtained FDA 510(k) approval to market the first product: the ^{131}Cs brachytherapy seed (March 2003);

- Completed initial radioactive seed production, design verification, computer modeling of the radiation profile, and actual dosimetric data compiled by the National Institute of Standards and Technology and PNNL (October 2002); and
- Obtained initial patent for ^{131}Cs isotope separation and purification (May 2000).

Industry Information

Incidence of Prostate Cancer

Excluding skin cancer, prostate cancer is the most common form of cancer, and the second leading cause of cancer deaths in men. The American Cancer Society estimated there will be about 234,460 new cases of prostate cancer diagnosed and an estimated 27,350 deaths associated with the disease in the United States during 2006. Because of early detection techniques (e.g., screening for prostate specific antigen, or PSA) approximately 70% (164,100) 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.

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. 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.

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 seed implant brachytherapy.

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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 breast enlargement. Common side effects of chemotherapy are nausea, hair loss and fatigue.

"Watchful waiting" or "active surveillance", 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 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 I-125 brachytherapy seed. His company, Lawrence Soft Ray Inc., provided the world's supply of seeds from 1967 to 1978 until the 3M Corporation purchased the technology. Eventually 3M sold the business to Amersham 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.

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

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

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

There is a large and growing potential market for the Company's products. Several significant clinical and market factors are contributing to the increasing popularity of the brachytherapy procedure. In Europe brachytherapy is growing in excess of 25% per year and it is expected that market growth in the U.S. will also increase dramatically. In 1996 only 4% of prostate cancer cases were treated with brachytherapy, or about 8,000 procedures. In 2005, it was estimated that over 60,000 brachytherapy procedures were performed for prostate cancer. Brachytherapy as a treatment is now more common than radical prostatectomy and has become the treatment of choice for early-stage prostate cancer. Considerable attention is now being given to high risk and faster growing prostate cancers as well. Brachytherapy has significant advantages over competing treatments including lower cost, better survival data, fewer side effects, a faster recovery time and the convenience of a single outpatient procedure that generally lasts 45 minutes (Merrick, et al., *Techniques in Urology*, Vol. 7, 2001; Potters, et al., *Journal of Urology*, May 2005; Sharkey, et al., *Current Urology Reports*, 2002).

Clinical Results

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

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

- In September 2006 a 5 year prospective study to assess the impact of interstitial brachytherapy on the quality of life of patients with localized prostate cancer was published. The results of the present study confirm that the impact of interstitial brachytherapy on the patients' quality of life is low despite its transient negative effects on some function, and extend existing knowledge concerning quality of life after interstitial brachytherapy. *International Journal of Radiation Oncology; Volume 66; 1;31-37.*
- A twelve-year clinical study published in the 2004 Supplement of the *International Journal of Radiation Oncology, Biology and Physics*, reported relative survival rate of 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.

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- 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 Pd-103 seeds 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 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'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 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 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 intends to design and create a proprietary separation process to manufacture enriched barium, a key source material for ^{131}Cs, to ensure adequate supply and greater manufacturing efficiencies.
- *Introduce Cesium-131 therapies for other cancers*. IsoRay intends to partner with other companies to develop the appropriate delivery technology and therapeutic delivery systems for treatment of other solid tumors such as breast, lung, liver, pancreas, neck, and brain cancer. IsoRay'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.
- *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 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's core radioisotope technology.

Management believes there is a large and growing addressable market for IsoRay's products. Several factors appear to contribute to the increasing popularity of the brachytherapy procedure. Long-term survival data are now available for brachytherapy (other than with respect to treatment from Cs-131 seeds). Brachytherapy has become the treatment of choice for not only early-stage prostate cancer but is now being considered for treatment of fast growing, aggressive tumors. For the treatment of prostate cancer, seed brachytherapy is now more common than surgery (radical prostatectomy). Seed brachytherapy has significant advantages over competing treatments including lower cost, better survival data, fewer side effects, a faster recovery time and the convenience of an outpatient procedure that generally lasts 45 minutes. Over 60,000 procedures were forecasted to occur in the U.S. in 2005. At the June 30, 2006 Cs-131 seed price of $55, this represents a potential $330 million market for seeds 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'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 markets the Cesium-131 seed and intends to market 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'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 capsule. In prostate cancer procedures, approximately 85 to 135 seeds are permanently implanted in a 45-minute outpatient procedure. The isotope decays over time, and the seeds become inert. The seeds may be used as a primary treatment or in conjunction with other treatment modalities such as external beam radiation therapy, chemotherapy, or as treatment for residual disease after excision of primary tumors.

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

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

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

Competitive Advantages of Cs-131

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

Brachytherapy Isotope Comparison

	Cesium-131	Palladium-103	Iodine-125
Half Life	9.7 Days	17.5 days	60 days
Avg. Energy	30.4 KeV+	21 KeV+	28.5 KeV+
Dose Delivery	90% in 33 days	90% in 58 days	90% in 204 days
Total Dose	115 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).

Higher energy. The Cs-131 isotope average decay energy of 30.4 KeV (versus 21 KeV for Pd-103 and 28.5 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 but the higher energy of Cs-131 does make the isotope more "forgiving" for treatment planning purposes.

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

Figure 2: Cs-131 seed Autoradiograph

Shape of radiation field. The shape of the radiation field generated by a ^{131}Cs seed is more uniform than most brachytherapy seed designs, and this uniformity may result in better radiation dose coverage and improved therapeutic effectiveness. Figure 2 shows 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 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'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

Since formation of the Company, management had intended to introduce a second product, Yttrium 90, sometime in 2006. However, management now intends to focus all of its efforts on manufacturing and marketing Cs-131 as it now believes that Yttrium 90 will require far too much capital and distract management from its core business at a time when it believes it can gain valuable market share for Cs-131.

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 isotope of Cs-131. The overall 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). Due to the short half-life of both the Ba-131 and Cs-131 isotopes, potential suppliers must be capable of removing irradiated materials from the reactor core on a routine basis for subsequent processing to produce ultra-pure Cs-131. The Company has identified more than five reactor facilities in the U.S., Europe and the former Soviet Union that are capable of meeting these requirements. As of the date of this report, IsoRay has agreements in place with two suppliers of irradiated Ba-131 or Cs-131. The Company's agreement with Russia's Institute of Nuclear Materials (which commenced as of August 25, 2005 and ends August 25, 2012) 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 isotope projected to be delivered in the first full year of production, although neither of these amounts are obligations to purchase any given quantity of the isotopes in a particular time period. Through June 30, 2006, the Company had paid approximately $74,000 to the Institute of Nuclear Materials. 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 is incorporated into an internal assembly that contains a binder, spacer and a gold 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, each seed is laser welded to produce a sealed radioactive source and biocompatible medical device. This manufacturing technology requires: accurate placement of seed components with respect to the welding head, accurate control of welding parameters to ensure uniform temperature and depth control of the weld, quality control assessment of the weld integrity, and removal of the finished product for downstream processing or rejection of unacceptable materials to waste. Inspection systems are capable of identifying and classifying these variations for quality control and to ensure low scrap rates. Finally, the rapid placement and removal of components from the welding zone affects 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 has implemented a just-in-time production process that is keenly responsive to customer input and orders to ensure that individual customers receive a higher level of customer service from us than from existing seed suppliers who have the luxury of longer lead times due to longer half-life products. Time from order confirmation to completion of product manufacture can be reduced to several working days, including receipt of irradiated barium (from a supplier's reactor), separation of Cs-131 (at our facilities), isotope labeling of the core, and loading of cores into pre-welded titanium "cans" for final welding, testing, quality assurance and shipping.

It is up to each physician to determine the dosage necessary for implants and acceptable dosages vary among physicians. Many of the physicians who order our seeds order more seeds than necessary but wish to assure themselves that they have a sufficient amount. Upon receipt of an order, the Company either delivers the seeds from its facility directly to the physician using Federal Express or sends the order to an independent preloading service which delivers the seeds preloaded into needles just 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 has held discussions with leading designers and manufacturers of automated seed manufacturing equipment that have manufactured, installed and deployed automated production lines in Europe and the United States. In addition, IsoRay engaged in preliminary discussions with another seed manufacturer regarding obtaining an existing automated seed production line. Based on technical evaluations and on site reviews of both options, IsoRay elected to automate its current manufacturing process in phases. Current production rates with IsoRay's semi automated seed welding equipment exceed those attainable with fully automated lines. Phased implementation of automation is expected to be less costly than fully automated production lines and will benefit IsoRay by reducing labor costs and helping to ensure consistent manufacturing quality.

Manufacturing Facility

The initial production of the IsoRay Cs-131 brachytherapy seed commenced at PNNL in 2004. IsoRay 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 began 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 production facility. No agreements have been reached for any possible facilities outside of Washington.

Isotope Testing in Idaho

On December 14, 2005, IsoRay and Idaho's Advanced Test Reactor ("ATR") entered into a collaboration and partnership agreement for the design, analysis and fabrication of a capsule containing barium carbonate, to be irradiated at the ATR and then shipped to IsoRay for processing and analysis of the ^{131}Cs product. As an adjunct to this testing, IsoRay and the Pocatello Development Authority entered into an Economic Development Agreement, dated December 14, 2005, under which the Pocatello Development Authority provided IsoRay with $200,000 (subject to repayment under certain conditions) to use toward the cost of testing at the ATR. During July 2006, several capsules were irradiated and shipped to IsoRay's PIRL facility for analysis. The results of the analyses indicate the capsule performed as designed and that a planned capsule shuttle system will provide adequate conditions for ^{131}Cs production that will enhance IsoRay's overall production capacity.

Repackaging Services

Most brachytherapy manufacturers offer their seed product to the end user packaged in four principal 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 (20%), pre-loaded needles (30%) 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 preloading service is to package, assay and certify the contents of the final product configuration shipped to the customer. A commonly used method of providing this service is through independent radiopharmacies such as Anazao Healthcare and Advanced Care Medical Inc. Manufacturers send loose seeds along with the physician's instructions to the radiopharmacy who, in turn, loads needles and/or strands the seeds according to the doctor's instructions. These pharmacies then sterilize the product and certify the final packaging prior to shipping directly to the end user.

IsoRay has held discussions with the major independent radiopharmacies and determined the additional time required for delivery of loose seeds to an off-site radiopharmacy for subsequent assay, preloading and sterilization creates additional loss of our isotope due to decay and is prohibitive on a long-term basis. However, to increase sales in the near-term we are using these services until our own custom preloading operation comes fully on-line in 2006. On March 1, 2006, the Company entered into a Service Agreement with Advanced Care Medical, Inc. for preloading

services. The term of the Service Agreement is one year, with automatic one year extensions unless terminated, and prices vary from $6-18 per seed depending on how the seeds are packaged. In late March 2006, the Company's stranding service became operational but stranding activity was suspended pending FDA 510(k) clearance of preloaded seed configurations as devices rather than convenience kits for seeds. The 510(k) filing for the stranding activity was submitted to the FDA in August 2006 and the Company expects to receive clearance in the second quarter of fiscal 2007.

The Company currently loads Mick cartridges in our own facility which in recent months accounted for more than 65% of total seed orders. The Company has retained a consultant to assist with implementation of the custom preloading service and expects to begin offering its seed in all four of the commonly used packaging configurations to the rest of its customer base within forty-five to sixty days, pending FDA 510(k) clearance of selected preloaded seed configurations. Providing this service in-house will reduce the current cycle time for any given customer order by three to four days by eliminating the need to ship loose seeds to a third-party provider. This reduction in cycle time will eliminate approximately 25% loss in isotope activity due to radioactive decay. The cost of priority overnight shipment of each order of seeds to a third-party provider is also eliminated. However, we will continue to utilize the independent radiopharmacies in the future both as a backup to our own preloading operation and to handle periodic increases in demand.

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

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

Management estimates the cost of establishing the custom preloading service in its new, leased facility to be approximately $250,000, most of which has already been spent on capital equipment. The custom preloading area has been created in the facility and the necessary equipment has been delivered and installed. Operating procedures are in place, staff members have been trained, and process validation activities have been completed. Technicians have been added to the staff to handle the seed loading and stranding operations. As the Company is not currently performing the stranding function pending FDA 510(k) clearance, these staff members are currently being utilized in our seed production process. PNNL will continue to provide independent third-party assay of the seeds for the foreseeable future. Our customer service staff will provide assistance with shipping, documentation and tracking of all orders from the repackaging service to the end user.

Barium Enrichment Device

Barium-130 is the original source material for Cs-131. When Ba-130 is put into a nuclear reactor it becomes Ba-131, the radioactive material that is the parent isotope 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 are using until the barium enrichment device is developed.

Marketing and Sales

Marketing Strategy

The Company intends to position Cs-131 as the isotope of choice for prostate brachytherapy. Based on preliminary clinical studies, management believes there is no apparent clinical reason to use other isotopes when Cesium-131 is available. The advantages associated with a higher energy and shorter 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 their brachytherapy seed treatment. The potential negative effects of the prolonged radiation times associated with the long half-life of Iodine-125 make this isotope less attractive than Cesium-131.

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

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

We are seeking to promote the advantages of Cs-131's unique combination of high energy and short half-life 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 implant sites. We also emphasize the prolonged radiation times and the high doses of radiation given to the patient by the iodine isotope and the possible negative effects of this prolonged radiation to the adjacent healthy tissues. We believe that this is an important marketing message because clinicians generally agree the radiation given by Iodine has little or no clinical benefit after 120 to 150 days.

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

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

Because of this market factor, we also promote our products directly to the general population. The audience targeted will be the prostate cancer patient, his spouse, family and care givers. The marketing message to this segment of the market emphasizes the specific advantages of Cs-131, including fewer side effects, less total radiation, and shorter period of radiation. The Company is targeting 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 is to validate and support all product claims with well-designed and executed clinical studies that support the efficacy and positive patient outcomes of our Cs-131 seed. We intend to sponsor physician-directed studies that will compare the performance of our seeds to Pd-103 and I-125 seeds. During the remainder of 2006 and into 2007, IsoRay plans to continue its collaboration with leading physicians to develop clinical data on the efficacy of Cs-131 seeds. Noted contributors from the medical physics community will be consulted regarding the benefits of brachytherapy using shorter half-life, improved dosimetry, and higher decay energy seeds. Articles will be submitted to professional journals such as *Medical Physics* and the *International Journal of Radiation Oncology, Biology, and Physics*.

Sales and Distribution

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

IsoRay has a direct sales organization to introduce Cs-131 to radiation oncologists and medical physicists. During 2006, IsoRay 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 September 1, 2006, the Company had supplied the ^{131}Cs seed to 27 well-known implant centers strategically located throughout the U.S.

The Company will expand its U.S. sales force as it expands the customer base. If the Company implements its plans to expand 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 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's predecessor's filing for an Additional Device Category, CMS (Centers for Medicare and Medicaid Services) approved a HCPCS/CPT code for Cs-131 brachytherapy seeds of $44.67 per seed. This is the same price as awarded to Pd-103 seeds, and compares favorably to the $37.34 price granted to I-125 seeds. Medicare is the most significant U.S. payer for prostate brachytherapy services, and is the payer in approximately 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 but we plan to increase this price to $59.00 as of October 1, 2006.

Prostate brachytherapy is typically performed in an 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, management believes that prices of

brachytherapy seeds will stabilize and increase over the next few years.

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, 2006 include:

Community Hospital of Los Gatos	Los Gatos, CA	20.1% of revenue
Chicago Prostate Cancer Center	Westmont, IL	18.7% of revenue
Mills Peninsula Health Center	San Mateo, CA	10.4% 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 was 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. IsoRay's predecessor also filed for patent protection in four European countries under the Patent Cooperation Treaty. Those patents have been assigned to IsoRay.

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's procedures and documentation. In June and July of 2004, three patent applications were filed relating to methods of deriving Cs-131 developed by IsoRay employees. The Company is currently working on developing and patenting additional methods of deriving Cs-131 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 reassigns the Royalty Agreement to another company, these royalties increase to 2%. The Royalty Agreement has an anti-shelving clause which requires IsoRay to return the patent if IsoRay 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 (a predecessor company) in

exchange for a membership interest. The license agreement was transferred to IsoRay through a series of mergers and the reverse acquisition.

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, 2006, IsoRay and its predecessor companies incurred more than $2.25 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's predecessor obtained FDA 510(k) clearance in March 2003 to market the IsoRay ^{131}Cs seed for the treatment of localized solid tumors.

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 byproduct 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. In June 2006, a U.S. District court judge ruled that Initiative 297 was unconstitutional in its entirety. However, the state of Washington has indicated that it would appeal the decision. If this decision is overturned and Initiative 297 is enforced it could impact our ability to manufacture our seeds, whether at PNNL or elsewhere in the State of Washington.

Seasonality

The Company is now aware of a seasonal influence on its business. During the months of July and August, physicians take vacations and defer seed implantation surgeries causing a momentary decline in revenue which management believes is ultimately realized later.

Employees

As of September 1, 2006, IsoRay employed 53 full-time individuals 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. None of the Company's employees are represented by any collective bargaining unit. IsoRay estimates that successful implementation of its growth plan would result in up to 30 additional employees by the end of calendar year 2007.

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 currently claims nearly 30% 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 may 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. Six of those companies represent nearly 100% of annual brachytherapy seed sales worldwide: CR Bard, Inc., Oncura (part of Galil), Theragenics Corp., North American Scientific, Inc., Mentor Corp., and Best Medical International, Inc. The top three - CR Bard, Inc., Oncura and Theragenics - currently garner over 80% of annual sales.

It is possible that three or four of the current I-125 or Pd-103 seed manufacturers (e.g., 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. 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 Independent Accountants Have Expressed Doubt About Our Ability To Continue As A Going Concern. IsoRay has generated material operating losses since inception. We expect to continue to experience net operating losses. Our ability to continue as a going concern is subject to our ability to obtain necessary funding from outside sources, including obtaining additional funding from the sale of our securities or obtaining loans and grants from various financial institutions where possible. The substantial doubt expressed by IsoRay's auditors about its ability to continue as a going concern increases the difficulty in meeting such goals. IsoRay began generating revenue in October 2004 and is in the early stages of marketing its IsoRay ^{131}Cs seed. IsoRay has limited historical, operating or financial information upon which to evaluate its 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 September 1, 2006, the IsoRay ^{131}Cs seed has been implanted in over 500 patients. While this 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 executives and increasing production requirements significantly increased IsoRay's monthly cash requirements since August 2005. Monthly operating cash requirements as of September 1, 2006 were approximately $800,000, 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 associated with our public reporting status have resulted in greater amounts of short-term cash demands. IsoRay 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 $3.2 million of additional capital to fund working capital needs through the end of fiscal year 2007. IsoRay currently has a manufacturing and production facility located in Richland, Washington that its management believes will provide adequate space to manufacture the ^{131}Cs seed product for the prostate and other organ cancer markets until late 2007.

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

The Passage Of Initiative 297 In Washington May Result In The Relocation Of Our Manufacturing Operations. Washington voters approved Initiative 297 in late 2004, which may impose restrictions on sites at which mixed radioactive and hazardous wastes are generated and stored. IsoRay has been assured by the Attorney General's office of the State of Washington that medical isotopes are not included in Initiative 297 and that manufacturing in IsoRay's new production facility would not be interrupted, but there is no assurance that this interpretation of Initiative 297 by the Attorney General's Office will continue to exclude medical isotopes. In June 2006, a U.S. District court judge ruled that Initiative 297 was unconstitutional in its entirety. However, the state of Washington has indicated that it may appeal the decision. If this decision is overturned and Initiative 297 is enforced it could impact our ability to manufacture our seeds in the State of Washington.

Management believes that we will be able to continue our manufacturing operations in the State of Washington for the foreseeable future. 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 have experience primarily in research and development of products and our experience in commercial-scale manufacturing is limited. IsoRay began commercial production of the ^{131}Cs seed in the fourth quarter of 2004. Although IsoRay'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 has developed and deployed semi-automated laser welding equipment that can produce seeds faster than fully-automated equipment the Company has reviewed that would cost several million dollars to design and fabricate. IsoRay believes it will continually find more efficient means of welding the titanium seeds; however, there is a possibility that future demand will outstrip our ability to produce seeds using the semi-automated process. With its new facility, IsoRay's management believes that IsoRay will be able to meet future demand unless demand greatly exceeds management's current projections, which management does not believe will occur. IsoRay has entered into a lease agreement and has relocated to a manufacturing and production facility located in Richland, Washington that management believes will provide adequate space to manufacture ^{131}Cs seed product for the prostate and other organ cancer markets until late

2007.

Sales And Marketing Experience. IsoRay'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 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 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. 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. As an example, on January 5, 2006, IsoRay was notified by one of its primary customers, Chicago Prostate Cancer Center ("CPCC"), that it would no longer accept ^{131}Cs products from the radiopharmacy exclusively used by IsoRay at that time due to quality control concerns. The role of the radiopharmacy is to provide third-party assay, preloading, and sterilization of the ^{131}Cs seeds which are then shipped directly to customers for use in patient implants. IsoRay immediately began working to bring these functions in house. On March 28, 2006, following commencement of operations of the Company's pre-load department, which performs third-party assay, preloading and sterilization of the ^{131}Cs seeds, CPCC resumed ordering from us. Initial shipments of ^{131}Cs seeds, custom-loaded to this customer's specifications, met the quality control guidelines established by CPCC. Although the temporary three month suspension of seed orders by CPCC had a negative impact on revenue in the quarter ended March 31, 2006, the Company's management believes any long-term impact will be nominal.

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

- our achievement of product development objectives and milestones;
- demand and pricing for the Company's products;
- effects of aggressive competitors;
- hospital, clinic and physician buying decisions;
- research and development and manufacturing expenses;
- patient outcomes from our therapy;
- physician acceptance of our products;
- government or private healthcare reimbursement policies;
- our manufacturing performance and capacity;
- incidents, if any, that could cause temporary shutdown of our manufacturing facilities;
- the amount and timing of sales orders;
- rate and success of future product approvals;

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- 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. Delivery of the isotopes from the Institute of Nuclear Materials began in January 2006. IsoRay believes this supplier may also provide access to sufficient quantities of enriched barium that may be recycled for use in other reactors to increase the production of ^{131}Cs. Although the agreement provides for supplying ^{131}Cs in significant quantities, there is no assurance that this will result in IsoRay gaining access to a sufficient supply of enriched barium feedstock and if sufficient supplies are attained we will need to increase our manufacturing staff.

We Are Subject To Uncertainties Regarding Reimbursement For Use Of Our Products. Hospitals and freestanding clinics may be less likely to purchase our products if they cannot be assured of receiving favorable reimbursement for treatments using our products from third-party 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, 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 to the Company.

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. At our leased facility we 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 has an employment agreement with Roger Girard, its Chief Executive Officer, and its subsidiary has employment agreements with most of its executive officers and key scientific personnel. If we lose the services of several of these officers or key scientific personnel, our business could be harmed. Our success also will depend upon our ability to attract and retain other highly qualified scientific, managerial, sales, and manufacturing personnel and their ability to develop and maintain relationships with key individuals in the industry. Competition for these personnel and relationships is intense and we compete with numerous pharmaceutical and biotechnology companies as well as with universities and non-profit research organizations. We may not be able to continue to attract and retain qualified personnel.

The Value Of Our Granted Patent, and Our Patents Pending, Is Uncertain. Although our management strongly believes that our patent on the process for producing ^{131}Cs, our patent pending on the manufacture of the brachytherapy seed, our patent applications on additional methods for producing ^{131}Cs and other isotopes 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 Over-The-Counter Bulletin Board, a market with limited liquidity and minimal listing standards, under the symbol "ISRY.OB." While management has plans to apply for listing on the American Stock Exchange, the Company currently does not meet the applicable requirements and is uncertain as to when it will be able to do so. 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. 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 Is Subject To Penny Stock Regulation. As the market price of our shares has declined below $5.00 per share, our shares are now 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 Company's net tangible assets; or exempted from the definition by the SEC. As our shares are now deemed to be "penny stocks", trading in the shares are subject to additional sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. This classification also makes our shares ineligible for market coverage by many established brokerage firms.

ITEM 2 - DESCRIPTION OF PROPERTY

Subsequent to June 2005, the Company's executive offices are located at 350 Hills Street, Suite 106, Richland, WA 99354, (509) 375-1202, where IsoRay currently leases approximately 3,765 square feet of office and laboratory space for $5,144 per month from Energy Northwest. The lease expires December 31, 2006, 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 fiscal year 2007, 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.

We have entered into a lease, which commenced as of regulatory licensing approval on October 6, 2005, for a facility located in Richland, Washington that management believes will provide adequate space to manufacture the Cs-131 product for the prostate cancer markets until late 2007, with a maximum manufacturing capacity of approximately 60,000 seeds per month and total square footage of 4,400 feet. The lease is for a term of twelve months following regulatory licensing approval, with a twelve-month extension option. Payment for the initial lease term was the issuance of 24,007 shares of IsoRay, Inc. 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 (PEcoS), and the Company is not affiliated with this lessor. Equipment installed at this facility includes a hot cell, a glove box, three fume-hoods, laser welders and laser welding tooling, which complete the laser sealing of the seeds; sophisticated testing equipment that allows us to test materials used at several stages of the production process and assay the completed seeds prior to shipment; and sterilizing and packaging systems that allow the seeds to be pre-loaded into delivery systems according to customer specifications. We believe we will need to add to the capital production equipment installed at this facility within the next six to twelve months to meet increasing demand for our product, and have adequate room at the facility to install equipment that would approximately double the production capacity up to 60,000 seeds per month (approximately 600 patient treatments). If additional production space is needed it is available at the PEcoS facility.

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 Annual Report.

PART II

ITEM 5 - MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDERS' MATTERS

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. As of September 18, 2006, we had 15,802,394 outstanding shares of Common Stock and 122,543 outstanding shares of Preferred Stock.

Our common stock is quoted on the OTC Bulletin Board under the symbol "ISRY.OB" and on the Pink Sheets under the symbol "ISRY.PK." There is limited trading activity in our securities, and there can be no assurance a regular trading market for our common stock will be sustained. We resumed trading on the Pink Sheets on August 18, 2005, after a period of no trading activity from February 18, 2005 until August 18, 2005. We also had a period of no trading activity from July 2003 until February 7, 2005. On November 2, 2005, we began trading on the OTC Bulletin Board. The following table sets forth, for the calendar periods indicated, the range of the high and low last reported bid prices of our common stock from October 1, 2003 through December 31, 2005, as reported by the Pink Sheets and the OTC Bulletin Board. The quotations represent inter-dealer prices without retail mark-ups, mark-downs or commissions, and may not necessarily represent actual transactions. The quotations may be rounded for presentation. There is an absence of an established trading market for the Company's common stock, as the market is limited, sporadic and highly volatile, which may affect the prices listed below.

The following table sets forth, for the fiscal quarters indicated, the high and low sales prices for our common stock as reported on the OTC Bulletin Board and the Pink Sheets.

Year ended June 30, 2006	**High**	**Low**
First quarter	$ 5.95	$ 1.00
Second quarter	8.25	4.50
Third quarter	7.25	6.20
Fourth quarter	6.40	3.25
Year ended June 30, 2005	**High**	**Low**
First quarter	$ N/A	$ N/A
Second quarter	*	*
Third quarter[1]	N/A	N/A

* Less than $0.01.

[1] Due to our change of fiscal year end from September 30 to June 30, our 2005 fiscal year was only nine months long.

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.

As of September 15, 2006, we had approximately 890 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. On August 15, 2006, the Company adopted the 2006 Director Stock Option Plan (the “Director Plan”) pursuant to which it may grant equity awards to eligible persons. The Option Plan allows the Board of Directors to grant options to purchase up to 1,800,000 shares of common stock to directors, officers, key employees and service providers of the Company, and the Employee Plan allows the Board of Directors to grant options to purchase up to 2,000,000 shares of common stock to officers and key employees of the Company. The Director Plan allows the Board of Directors to grant options to purchase up to 1,000,000 shares of common stock to directors of the Company. Options granted under all of the Plans 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 OTC Bulletin Board) on the date of the grant, and with varying vesting periods as determined by the Board.

As of June 30, 2006, the following options had been granted under the option plans.

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	3,257,592	$ 2.11	333,982
Total	3,257,592	$ 2.11	333,982

Sales of Unregistered Securities

During the last fiscal year, the following sales of unregistered securities were completed by the Company and not previously reported:

- On October 6, 2005, the Company issued 24,007 shares of common stock to Nuvotec USA, Inc. as payment for one year's lease of the PIRL facilities pursuant to the exemption from registration provided by Section 4(2) of the Securities Act.

In addition, during the last fiscal year, the following sales of unregistered securities were completed by IsoRay Medical, Inc. and not previously reported:

- Between January 31, 2005 and July 10, 2005, IsoRay Medical, Inc. sold approximately $4,137,875 in principal amount of 8% convertible debentures (less commissions of ten percent on securities placed by broker/dealers), in reliance on the exemption from registration provided by Rule 506 of Regulation D of the Securities Act, that subsequent to the merger between the Company and IsoRay Medical, Inc. were convertible into 995,882 shares of common stock of the Company. On December 13, 2005, the Board of Directors of the Company announced a short-term conversion inducement to current holders of these convertible debentures. Holders were permitted two conversion options: 1) convert under the original terms of the debenture to the Company's common stock at a $4.15 conversion price, and include the newly issued shares in the Company's registration statement on Form SB-2, or 2) convert under terms essentially identical to those offered to purchasers of Units in the Company's October 2005 Offering: a $4.00 conversion price and one callable warrant to purchase one share of the Company's common stock at an exercise price of $6.00 per share for each share issued upon conversion (waiving registration rights for approximately one year). Holders of $3,682,875 of debentures converted to common stock of the Company. The Company issued 911,276 shares of common stock, and 659,469 warrants to purchase shares of common stock, exercisable at $6.00 per share, leaving $455,000 in principal amount of debentures unconverted. Of the 911,276 shares of common stock issued pursuant to conversion of the debentures, 251,800 shares were included in the Company's Form SB-2 filing (file number 333-129646) which became effective on June 8, 2006.

ITEM 6 - MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

Critical Accounting Policies and Estimates

The discussion and analysis of the Company's financial condition and results of operations are based upon its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related

disclosure of contingent liabilities. On an on-going basis, management evaluates past judgments and estimates, including those related to bad debts, inventories, accrued liabilities, and contingencies. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The Company believes the following critical accounting policies affect its more significant judgments and estimates used in the preparation of its consolidated financial statements.

Accounts Receivable

Accounts receivable are stated at the amount that management of the Company expects to collect from outstanding balances. Management provides for probable uncollectible amounts through an allowance for doubtful accounts. Additions to the allowance for doubtful accounts are based on management's judgment, considering historical write-offs, collections and current credit conditions. Balances which remain outstanding after management has used reasonable collection efforts are written off through a charge to the allowance for doubtful accounts and a credit to the applicable accounts receivable. Payments received subsequent to the time that an account is written off are considered bad debt recoveries.

Inventory

Inventory is reported at the lower of cost, determined using the weighted average method, or net realizable value.

Asset Retirement Obligation

SFAS No. 143, *Asset Retirement Obligations*, establishes standards for the recognition, measurement and disclosure of legal obligations associated with the costs to retire long-lived assets. Accordingly, under SFAS No. 143, the fair value of the future retirement costs of the Company's leased assets are recorded as a liability on a discounted basis when it is incurred and an equivalent amount is capitalized to property and equipment. The initial recorded obligation, which has been discounted using the Company's credit-adjusted risk free-rate, will be reviewed periodically to reflect the passage of time and changes in the estimated future costs underlying the obligation. The Company amortizes the initial amount capitalized to property and equipment and recognizes accretion expense in connection with the discounted liability over the estimated remaining useful life of the leased assets.

Revenue Recognition

The Company applies the provisions of SEC Staff Accounting Bulletin ("SAB") No. 104, *Revenue Recognition*. SAB No. 104, which supersedes SAB No. 101, *Revenue Recognition in Financial Statements*, provides guidance on the recognition, presentation and disclosure of revenue in financial statements. SAB No. 104 outlines the basic criteria that must be met to recognize revenue and provides guidance for the disclosure of revenue recognition policies. The Company recognizes revenue related to product sales when (i) persuasive evidence of an arrangement exists, (ii) shipment has occurred, (iii) the fee is fixed or determinable, and (iv) collectibility is reasonably assured.

Revenue for the fiscal years ended June 30, 2006 and 2005 was derived solely from sales of the ^{131}Cs brachytherapy seed, which is used in the treatment of cancer. The Company recognizes revenue once an order has been received and shipped to the customer. Prepayments, if any, received from customers prior to the time that products are shipped are recorded as deferred revenue. In these cases, when the related products are shipped, the amount recorded as deferred revenue is recognized as revenue. The Company accrues for sales returns and other allowances at the time of shipment.

Legal Contingencies

In the ordinary course of business, the Company is involved in legal proceedings involving contractual and employment relationships, product liability claims, patent rights, and a variety of other matters. The Company records contingent liabilities resulting from asserted and unasserted claims against it, when it is probable that a liability has been incurred and the amount of the loss is reasonably estimable. The Company discloses contingent liabilities when there is a reasonable possibility that the ultimate loss will exceed the recorded liability. Estimating probable losses requires analysis of multiple factors, in some cases including judgments about the potential actions of third-party claimants and courts. Therefore, actual losses in any future period are inherently uncertain. Currently, the Company does not believe any of its pending legal proceedings or claims will have a material impact on its financial position or results of operations. However, if actual or estimated probable future losses exceed the Company's recorded liability for such claims, it would record additional charges as other expense during the period in which the actual loss or change in estimate occurred.

Results of Operations

Financial Presentation

Statement of Financial Accounting Standards (SFAS) No. 141, *Business Combinations*, requires that following a merger the accounting acquirer's financial statements should be used for historical comparisons. Although the legal acquirer was Century, for accounting purposes Medical was the acquirer and as such Medical's historical financial statements are shown for comparative purposes. Also for accounting purposes, the merger was accounted for as though it happened on July 1, 2005.

The following sets forth a discussion and analysis of the Company's financial condition and results of operations for the two years ended June 30, 2006. This discussion and analysis should be read in conjunction with our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-KSB. The following discussion contains forward-looking statements. Our actual results may differ significantly from the results discussed in such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in "Item 1 — Risk Factors" of this Annual Report on Form 10-KSB.

Year ended June 30, 2006 compared to year ended June 30, 2005

Product sales. Revenues for the year ended June 30, 2006 were $1,994,306, an increase of $1,792,575 over sales for the year ended June 30, 2005 of $201,731. All of the Company's revenues were generated through sales of its ^{131}Cs seeds. IsoRay began sales of its ^{131}Cs seed on October 26, 2004 with one medical center customer. By June 30, 2006 the number of medical center customers who had ordered the ^{131}Cs seed had grown to 26.

Gross loss. Gross loss was $1,820,816 for the year ended June 30, 2006 or an increase of $548,296 as compared to a gross loss of $1,272,520 for the year ended June 30, 2005. Cost of products sold was $3,815,122 for the year ended June 30, 2006 or an increase of $2,340,871 over the $1,474,251 incurred for the year ended June 30, 2005. During the year ended June 30, 2006, the Company paid $868,650 to Pacific Northwest National Laboratory (PNNL) under our contract with them for use of their facilities and personnel to support production. During the fourth quarter of fiscal year 2006, we paid approximately $110,000 for quality assurance support and as a deposit to extend our contract through December 31, 2007. The Company is currently using PNNL for certain research and development and quality assurance activities. Also during fiscal 2006, the Company paid approximately $1 million in wages, benefits, and related taxes for production personnel and approximately $1.6 million in direct and indirect material costs. These costs increased due to a larger staff and material and supply costs related to an increase in sales during fiscal year 2006.

Also included in cost of products sold during 2006 were over $109,000 for production and small tools, none of which individually exceeded the $2,500 threshold we use in determining whether to capitalize production equipment. These materials and small tools were needed to commence production in our independent production facility, the PEcoS-IsoRay Radioisotope Laboratory ("PIRL"). Most are long-lived items and will not need replacing in the next fiscal year. The Company has moved essentially all of its Cs-131 production operations to PIRL.

Research and development. Research and development expenses for the year ended June 30, 2006 were $450,425 an increase of $312,893 over research and development expenses of $137,532 for the year ended June 30, 2005. During 2006, $116,200 was spent on protocol studies of patients that have been implanted with the Company's ^{131}Cs brachytherapy seeds. Also during 2006, $144,588 was spent on research to improve Cs-131 production.

Sales and marketing expenses. Sales and marketing expenses were $1,420,500 for the year ended June 30, 2006. This represents an increase of $718,678 over the expense of $701,822 for the year ended June 30, 2005. During fiscal 2006, approximately $994,000 was spent on wages, travel, office, and other support expenses on behalf of the sales and marketing and customer service staff. The balance was spent on advertising, market research and trade shows and conferences. The increases are due to increased marketing of the Company's ^{131}Cs seed since introduction of our product to the market in October 2004.

General and administrative expenses. General and administrative expenses were $3,503,522 for the year ended June 30, 2006 or an increase of $1,632,197 as compared to $1,871,325 for the year ended June 30, 2005. Included in general and administrative expenses in 2006 is $330,000 relating to consulting fees for the reverse acquisition that was paid with the issuance of common stock (see Item 1). The increases over the prior periods are due to supporting the Company's increased manufacturing and sales activities. These activities have increased as the Company has only been manufacturing and selling its product since October 2004. Additionally, increased expenses in the 2006 fiscal year were due to compliance with SEC regulations following the July 28, 2005 merger. Significant components of general and administrative expenses include $838,797 in consulting expense, payroll and related expenses of $866,863 and professional fees, including accounting and legal fees of $522,318. Consulting services increased in connection with the establishment of the independent PIRL production facilities, which commenced production in the late Fall of 2005, and associated equipment installation, customization and validation; review and advice on business and capital strategies, and the addition of a medical director who serves as a consultant. Professional fees increased due to the Company's July 28, 2005 merger, SEC compliance activities including the Company's registration statement on Form SB-2 filed that was effective in June 2006, and other general business activities.

Operating loss. Due to the Company's significant research and develop expenditures, additional responsibilities as a reporting company, rapid structural growth, and nominal product revenues, the Company has not been profitable, and has generated operating losses since inception. For the year ended June 30, 2006, the Company had an operating loss of $7,195,263. This represents an increased loss of $3,212,064 in comparison with the year ended June 30, 2005 operating loss of $3,983,199.

Interest income. Interest income increased by $49,350 to $51,744 for the year ended June 30, 2006. Interest income is mainly derived from excess funds held in certain near-liquid accounts.

Financing expense. Financing expense for the year ended June 30, 2006 includes $332,493 of interest expense incurred on long-term debt and convertible debentures outstanding. The interest expense increased over the prior year due to interest payments on the convertible debentures that were sold as part of the January 1, 2005 PPM, computed interest expense on the capital leases entered into during fiscal 2006, and interest expense on other loans that were initiated in January 2005. The remaining balance of financing expense represents amortization of deferred financing costs primarily related to the January 2005 issuance of common stock to guarantors of certain loans made to the Company, commissions and legal costs paid in conjunction with the issuance of convertible debentures, issuance of warrants as an inducement for a note payable, and costs associated with the initiation of the Hanford Area Economic

Investment Fund Committee (HAEIFC) note payable. During 2006, $89,516 of deferred financing costs were expensed relating to debentures that were converted to common stock.

Debt conversion expense. This amount of approximately $385,000 relates to the one-time, non-cash expense resulting from the short-term inducement offered to debenture holders to their convert debentures to common stock (see Note 11). This expense was recognized in accordance with Statement of Financial Accounting Standard No. 84, *Induced Conversions of Convertible Debt*.

Year ended June 30, 2005 compared to year ended June 30, 2004

Product sales. Revenues for the year ended June 30, 2005 were $201,731. The Company did not have any revenues for the year ended June 30, 2004. IsoRay began sales of its ^{131}Cs seed on October 26, 2004 with one medical center customer. All of the Company's sales in 2005 were generated through sales of its^{131}Cs seeds.

Gross loss. Gross loss was $1,272,520 and cost of products sold was $1,474,251 for the year ended June 30, 2005. The Company did not have any gross loss or cost of products sold for the year ended June 30, 2005. During the year ended June 30, 2005, the Company paid $574,225 to Pacific Northwest National Laboratory (PNNL) under our contract with them for use of their facilities and personnel to support production. The Company was using PNNL for production of its seeds and other activities.

Research and development. Research and development expenses for the year ended June 30, 2005 were $137,532 an increase of $95,206 over research and development expenses of $42,326 for the year ended June 30, 2004. The change is due to research to improve Cs-131 production and of other isotopes.

Sales and marketing expenses. Sales and marketing expenses were $701,822 for the year ended June 30, 2005. This represents an increase of $620,336 over the expense of $81,486 for the year ended June 30, 2004. Most of the 2005 expenses were spent on wages, travel, office, and other support expenses on behalf of the sales and marketing and customer service staff. The increases are due to hiring sales personnel during 2005 to market the Company's^{131}Cs seed which was only introduced to the market in October 2004.

General and administrative expenses. General and administrative expenses were $1,871,325 for the year ended June 30, 2005 as compared to $650,161 for the year ended June 30, 2004. The increase is due to increased salaries for officers who were foregoing salaries or were paid under market and the hiring of additional staff as the Company began manufacturing and selling its product. Approximately $870,000 was spent on payroll, benefits, and related employment costs during fiscal year 2005. Other significant components of general and administrative expenses included about $178,000 in consulting services and $269,000 of professional fees. Consulting expenses increased as the Company hired advisors for operations, business and capital strategies. Professional fees increased due to the merger of the two predecessor companies into IsoRay Medical, Inc. as well as the Company's private placements and other general business matters.

Operating loss. Due to the Company's significant research and development expenditures, large general and administrative expenses and payroll related to properly staffing the Company for anticipated further growth coupled with nominal product revenues, the Company generated operating losses. For the year ended June 30, 2005, the Company had an operating loss of $3,983,199. This represents an increased loss of $3,209,226 in comparison with the year ended June 30, 2004 operating loss of $773,973.

Interest income. Interest income was $2,394 for the year ended June 30, 2005 which was an increase of $496 over interest income of $1,898 for the year ended June 30, 2004.

Financing expense. Financing expense for the year ended June 30, 2005 includes amortization of deferred financing costs and interest expense incurred on long-term debt and convertible debentures outstanding. The deferred financing costs relate primarily to the January 2005 issuance of common stock to guarantors of certain loans made to the Company and commissions and legal costs paid in conjunction with the issuance of convertible debentures. Amortization of these costs amounted to $76,746 during 2005. The remaining balance relates to interest expense which increased due to the issuance of the convertible debentures in 2005.

Loss on disposal of fixed assets. This loss in 2005 relates to the write-off of certain rudimentary production equipment that was replaced by complex production equipment that improves the manufacturing process.

Liquidity and capital resources. At June 30, 2006, cash and cash equivalents amounted to $2,207,452. During the year ended June 30, 2006, the Company issued 1,768,889 shares of common stock pursuant to two private placements, which raised $6,516,350 of cash, net of legal costs and commissions paid. Additionally, the Company issued 666,691 shares of common stock pursuant to the exercise of common stock options and warrants and preferred stock warrants, which were exchanged for common stock immediately upon exercise. These option and warrant exercises were paid in cash and by surrendering a partial note payable. The Company received $1,400,114 in cash and forgiveness of $48,313 of notes payable pursuant to these exercises. During 2006, the Company exchanged $3,682,875 of convertible debentures for 911,271 common shares and 659,469 warrants. This conversion allowed the Company to alleviate approximately $3.68 million of indebtedness at a favorable equity exchange rate. The Company also issued 207,479 shares of common stock for $515,035 of consulting services, production equipment repair and maintenance, production equipment, and production rent.

On August 17, 2006, the Company closed a round of institutional funding that provided approximately $5 million, net of offering costs. The Company issued 2,063,000 shares of common stock at a price of $2.50 per share and 2,269,300 common stock warrants (including broker warrant commissions) with an exercise price of $3.00 per share. The warrants have a call feature which the Company can trigger once the stock trades above $4.50 per share for a specified period of time.

The Company had approximately $5.9 million of cash on hand as of September 1, 2006. As of that date management believes that the Company's monthly required cash operating expenditures were approximately $800,000. This recent increase in monthly expenditures is primarily a result of the addition of various protocols for seed applications and the obsolescence of the Company's oversupply of Cesium resulting from an inability to forecast demand after the slower than anticipated months of July and August. Management is focused on achieving better forecasting demand models to alleviate loss of viable seeds due to a half life which results in quick obsolescence and believes that increases in demand will lessen the impact of overoptimistic forecasts. The Company has issued purchase orders for additional production equipment that will allow it to expand production capacity in its current facility. The total of these purchase orders is approximately $260,000 and it is anticipated that about $225,000 of this equipment will be funded with the HAEIFC loan. As of September 1, 2006, management believes that assuming expenditures continue at approximately the same monthly rate and that it is able to fund a portion of its equipment purchases with the HAEIFC loan that the Company's cash on hand will fund operating expenditures through the beginning of March 2007. This is based on the Company attaining its current revenue targets and the ability to efficiently manufacture our product. If

we should experience disruptions in our revenues then our monthly cash requirements would increase and necessitate that we obtain additional funding prior to March 2007.

Our growth plans for fiscal 2007 include expanding sales to new customers, growing sales volume with existing customers, and expanding production capability through the purchase of additional equipment. The Company has also begun a review of its current facilities and future needs. The Company continues to use PNNL to provide third-party assay of its products, but has otherwise vacated PNNL facilities. This review includes evaluating the Company's need for space given its growth projections. It is anticipated that additional employees and production equipment will be needed to meet future growth. This could create the need for additional production and office space that would be leased through an operating lease.

IsoRay has four loans outstanding as of June 30, 2006. The first from Tri-City Industrial Development Council, with an original principal amount of $40,000, was funded in 2001 and required a final principal-only payment of $10,000 which was paid in August 2006. It was non-interest bearing and unsecured. The second loan is from the Benton-Franklin Economic Development District ("BFEDD") in an original principal amount of $230,000 and was funded in December 2004. It bears interest at eight percent and has a sixty month term with a final balloon payment. As of June 30, 2006, the principal balance owed was $204,237. This loan is secured by certain equipment, materials and inventory of IsoRay, and also required personal guarantees, for which the guarantors were issued approximately 70,455 shares of common stock. The third loan is a line of credit from Columbia River Bank, which provides credit in the amount $395,000. It bears interest at a floating prime plus two percent rate, and is secured by certain accounts receivable and inventory and personal guarantees, for which the guarantors were issued approximately 107,401 shares of common stock. As of June 30, 2006, no balance was outstanding on the line of credit. The line of credit expires on March 1, 2007. The fourth loan is from the Hanford Area Economic Fund Investment Committee and was originated in June 2006. The loan has a total facility of $1,400,000 and bears interest at nine percent. As of June 30, 2006, the Company has taken only a partial draw of $418,670 on the facility and the remaining facility of $981,330 is available to use to purchase equipment. This loan is secured by receivables, equipment, materials and inventory of IsoRay, and certain life insurance policies.

The BFEDD has granted IsoRay a waiver from enforcing violations of paying officers in excess of $100,000 per year and maintaining a certain current asset ratio. The waiver is effective through June 30, 2007 and also excuses non-compliance with covenants prohibiting fixed asset of lease obligations in excess of $24,000 per year, covenants prohibiting mergers, and covenants requiring maintenance of a certain long-term debt to equity ratio. Management believes that if the BFEDD accelerates repayment that it has sufficient cash resources to satisfy this obligation.

The Company has certain capital leases for production and office equipment that expire at various times from March 2008 to April 2009. These leases currently call for total monthly payments of $19,361. The total of capital lease obligations at June 30, 2006 was $403,969.

At June 30, 2006, the Company had outstanding $455,000 of convertible debentures. These debentures could be converted into 109,639 shares of common stock at a conversion rate of $4.15 per share. Each debenture bears interest at an annual rate of eight percent (not compounded) with accrued interest paid quarterly. The debentures mature at various times from February 2007 to June 2007.

Through September 1, 2006, the Company had issued purchase orders for approximately $260,000 of production and office equipment. The Company anticipates financing most of these purchases through the HAEIFC facility.

In February 2006, the Company signed a license agreement with International Brachytherapy s.a. ("IBt") covering North America and providing the Company with access to IBt's Ink Jet production process and its proprietary polymer seed technology for use in brachytherapy procedures using Cesium-131. The Company paid license fees of $275,000 during 2006 and another payment of $225,000 was to be made in August 2006 pursuant to the license agreement. Royalty payments based on net sales revenue are also required, with minimum quarterly royalties ranging from $100,000 to $200,000 and minimum annual royalties ranging from $400,000 to $800,000 over the term of the agreement. Management is engaged in further negotiations with IBt and may ultimately terminate this agreement,

although management has not yet decided on a course of action.

As of the date of this report, the August 2006 payment has not been made as the Company has been in continued negotiations with IBt concerning the amount and timing of future royalty payments due to the low market acceptance of the polymer seed technology.

In September 2006, the Company entered into a settlement agreement with a former executive. As part of the settlement the Company agreed to pay the former executive $100,000 in September 2006 and $215,000 in January 2007. As the former executive's employment with the Company ended in March 2006, the full amount of both payments was accrued as of June 30, 2006 in accrued payroll.

The Company is subject to various local, state, and federal environmental regulations and laws due to the isotopes used to produce the Company's product. As part of normal operations, amounts are expended to ensure that the Company is in compliance with these laws and regulations. While there have been no reportable incidents, the Company believes that were it to discontinue or relocate its current production facilities then certain remediation expenses would be incurred. Therefore, the Company has established an initial asset retirement obligation of $63,040 which represents the discounted cost of cleanup that the Company anticipates it will have to incur at the end of its equipment leases. This amount was determined based on discussions with qualified production personnel and on historical evidence. The Company does not believe that any amount of this accrual will be spent during fiscal year 2007.

The industry that the Company operates in is subject to product liability litigation. Through its production and quality assurance procedures, the Company works to mitigate the risk of any lawsuits concerning its product. The Company also carries product liability insurance to help protect it from this risk.

The Company expects to finance its future cash needs through the sale of equity securities, solicitation to warrant holders to exercise their warrants, and possibly strategic collaborations or debt financing or through other sources that may be dilutive to existing shareholders. If the Company needs to raise additional money to fund its operations, funding may not be available to it on acceptable terms, or at all. If the Company is unable to raise additional funds when needed, it may not be able to market its products as planned or continue development and regulatory approval of its future products. If the Company raises additional funds through equity sales, these sales may be dilutive to existing investors.

The Company has no off-balance sheet arrangements.

Going Concern Issues

Our financial statements have been prepared assuming we will continue as a going concern. We had net losses of $8,218,130 and $4,269,188 for the years ended June 30, 2006 and 2005 and an accumulated deficit of $13,546,261 at June 30, 2006. These factors, among others, raise substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustment that might result from the outcome of this uncertainty. Management plans to obtain the necessary financing and to continue to grow revenues in order to achieve profitability but no assurances can be given that management will be able to obtain additional financing or grow revenues to a profitable level.

If we are unable to generate profits and unable to obtain additional financing to meet our working capital requirements, we may have to curtail our business or cease operations. Our continuation as a going concern is dependent upon our ability to generate sufficient cash flow to meet our obligations on a timely basis, to obtain additional financing, and, ultimately, to attain profitability. Should any of these events not occur, the accompanying financial statements will be adversely effected and we may have to cease operations.

Inflation

Inflation and changing prices are not anticipated to have a significant impact on the future operations of the Company.

Recent Accounting Pronouncements

In December 2004, the FASB issued SFAS 123(Revised), *Share-Based Payment* ("SFAS 123R"), which replaces SFAS 123 and supersedes APB 25. On April 14, 2005, the Securities and Exchange Commission adopted a new rule that amends the compliance dates for SFAS 123R. Under the new rule, we are required to adopt SFAS 123R for the three-month period commencing July 1, 2006. SFAS 123R requires all share-based payments to employees, including grants of employee stock options, be recognized as compensation cost in the financial statements based on their fair values. As such, reporting employee stock options under the intrinsic value-based method prescribed by APB 25 will no longer be allowed. We have historically elected to use the intrinsic value method and have not recognized expense for employee stock options granted. We plan to adopt SFAS 123R on July 1, 2006 on a prospective basis. Upon adoption, all future employee stock option grants plus the balance of the non-vested grants awarded prior to July 1, 2006, will be expensed over the stock option vesting period based on the fair value at the date the options are granted. We estimate that the impact of adoption will be an additional expense of $189,430 for employee stock options granted prior to June 30, 2006.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections — A Replacement of APB Opinion No. 20 and FASB Statement No. 3* ("SFAS 154"). SFAS 154 requires the retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impractical to determine either the period-specific effects or cumulative effect of the accounting change. SFAS No. 154 also requires that a change in depreciation, amortization, or depletion method for long-lived non-financial assets be accounted for as a change in accounting estimate affected by a change in accounting principle. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005 and we will adopt this provision, as applicable, during fiscal year 2007.

ITEM 7 - FINANCIAL STATEMENTS

The required accompanying financial statements begin on page F-1 of this document.

ITEM 8 - CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

The Company's Board of Directors engaged DeCoria, Maichel & Teague, P.S., the independent auditor for the Company's wholly-owned subsidiary, to be its new independent auditor effective November 15, 2005, which was also the effective date of S.W. Hatfield, CPA's dismissal as the Company's certifying accountant by the Board.

Except for an expression of doubt about our ability to continue as a going concern, S.W. Hatfield, CPA's audit reports on the Company's financial statements as of June 30, 2005 and September 30, 2004 did not contain an adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles.

During the two fiscal years ended June 30, 2005 and September 30, 2004, and through November 15, 2005 there were no disagreements with S.W. Hatfield, CPA on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreements, if not resolved to the satisfaction of S.W. Hatfield, CPA would have caused it to make a reference to the subject matter of the disagreements in connection with its report; and there were no reportable events as described in Item 304(a)(1)(iv)(B) of Regulation S-B promulgated by the Securities and Exchange Commission (the "SEC") pursuant to the Securities Exchange Act of 1934, as amended.

During the Company's two most recent fiscal years and through November 15, 2005, the Company did not consult DeCoria, Maichel & Teague, P.S. with respect to the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements, or any other matters or reportable events listed in Item 304(a)(2) of Regulation S-B. However, IsoRay Medical, Inc., the Company's wholly-owned subsidiary, has consulted with DeCoria, Maichel & Teague, P.S., its independent auditor, during these time periods solely in connection with IsoRay Medical, Inc.'s financial statements.

ITEM 8A - CONTROLS AND PROCEDURES

(a) Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined under Rules 13a-14(c) and 15d-14(c) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of June 30, 2006. Based on that evaluation, our principal executive officer and our principal financial officer concluded that the design and operation of our disclosure controls and procedures were effective in timely alerting them to material information required to be included in the Company's periodic reports filed with the SEC under the Exchange Act. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote. However, management believes that our system of disclosure controls and procedure is designed to provide a reasonable level of assurance that the objectives of the system will be met.

(b) In connection with the review of our consolidated financial statements for the period ended September 30, 2005, our independent registered public accounting firm advised the Board of Directors and management of certain significant internal control deficiencies that they considered to be, in the aggregate, a material weakness. In particular, our independent registered public accounting firm identified the following weaknesses in our internal control system: (1) a lack of segregation of duties and (2) a lack of formal procedures relating to all areas of financial reporting. The independent registered public accounting firm indicated that they considered these deficiencies to be reportable conditions as that term is defined under standards established by the American Institute of Certified Public Accountants. A material weakness is a significant deficiency in one or more of the internal control components that alone or in the aggregate precludes our internal controls from reducing to an appropriately low level of risk that material misstatements in our financial statements will not be prevented or detected on a timely basis. The Company considered these matters in connection with the period end closing of accounts and preparation of the related consolidated financial statements and determined that no prior period financial statements were materially affected by such matters. Notwithstanding the material weaknesses identified by our independent registered public accountants, we believe that the financial statements and other financial information included in this report, fairly present in all material respects, the financial condition, results of operation and cash flows of the Company as of, and for, the periods represented in this report.

The size of the Company has previously prevented us from being able to employ sufficient resources at this time to enable us to have an adequate level of supervision and segregation of duties within our internal control system. Set forth below is a discussion of the significant internal control deficiencies that had not been remediated as of the end of the period covered by this report.

Lack of segregation of duties. Our size has prevented us from being able to employ sufficient resources to enable us to have an adequate level of segregation of duties within our internal control system. There is one dedicated employee and three employees that work in accounting and other departments who are involved in the processing of transactions. Due to the small employee base it is difficult to effectively segregate accounting duties. While we strive to segregate duties as much as practicable, budgetary considerations have not previously allowed the addition of full time staff. We are currently reorganizing the accounting department to more effectively segregate duties but we believe additional staff is still needed. We will continue in our attempt to add staff to allow for fuller segregation of

duties, although there is no certainty additional staff can be successfully hired. As a result, this significant internal control deficiency has not been remediated as of the end of the period covered by this report, nor do we know if we will be able to remediate this weakness during the upcoming quarter.

Lack of formal procedures relating to all areas of financial reporting including a lack of review by management. Due to the size of our Company, and as a consequence of the lack segregation of duties, we have not previously had formal month end close procedures. As a result, there has been a lack of timely review of the financial statements. However, near the end of the fiscal year our controller began developing monthly close procedures and these were partially implemented at June 30, 2006. Although this significant internal control deficiency has not been fully remediated as of the end of the period covered by this report, we have made progress and expect to have this fully remediated by the end of the second quarter of fiscal year 2007.

If we are unable to remediate the identified material weaknesses, there is a more than remote likelihood that a material misstatement to our SEC reports will not be prevented or detected, in which case investors could lose confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on our ability to raise additional capital and could also have an adverse effect on our stock price.

ITEM 8B - OTHER INFORMATION

There were no items required to be disclosed in a report on Form 8-K during the fourth quarter of the fiscal year ended June 30, 2006 that have not been properly disclosed on a Form 8-K filed with the SEC.

PART III

ITEM 9 - DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT

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

Effective as of July 28, 2005, Roger Girard and David Swanberg were appointed as directors by the resigning Board, and, also effective as of July 28, 2005, they appointed Robert Kauffman, Thomas LaVoy and Stephen Boatwright to fill the remaining three vacant Board positions. On March 31, 2006, the number of directors was increased to seven and Dwight Babcock and Albert Smith were appointed to fill the newly created positions.

The Board has established an Audit Committee consisting of Thomas LaVoy, (Chairman) and Robert Kauffman, and a Compensation Committee consisting of Dwight Babcock and Al Smith. No other committees have been formed.

The Audit Committee is responsible for assisting the Board of Directors in monitoring and oversight of (1) the integrity of the Company's financial statements and its systems of internal accounting and financial controls and (2) the independence and performance of the Company's independent auditors. The Board of Directors has determined that Mr. LaVoy and Mr. Kauffman are each an "audit committee financial expert" as defined in Item 401 of Regulation S-B promulgated by the Securities and Exchange Commission, and are each independent. The Board's conclusions regarding the qualifications of Mr. LaVoy as an audit committee financial expert were based on his service as a chief financial officer of a public company, his experience as a certified public accountant and his degree in accounting. The Board's conclusions regarding the qualifications of Mr. Kauffman as an audit committee financial expert were based on his service as a chief executive officer of multiple public companies, his active supervision of the principal financial and accounting officers of the public companies for which he served as chief executive officer, and his M.B.A. in Finance.

Effective as of July 28, 2005, Roger Girard was appointed as Chief Executive Officer and President of the Company and Michael Dunlop was appointed as Chief Financial Officer and Treasurer of the Company. Also effective July 28, 2005, John Hrobsky was appointed Vice President, Sales and Marketing and David Swanberg was appointed Secretary and Vice President-Operations.

In March 2006, Mr. Hrobsky's employment was terminated with the Company and in September 2006 the Company reached a settlement agreement with him.

On September 7, 2006, Mr. Dunlop resigned from his position as Chief Financial Officer and Treasurer. Jonathan Hunt, formerly controller of the Company, was appointed as Chief Financial Officer and Treasurer of the Company on September 7, 2006 to succeed Mr. Dunlop.

Further information about the current directors and officers may be found below.

The directors and executive officers serving the Company as of September 7, 2006 were as follows:

Name	Age	Position Held	Term*
Roger Girard	63	Chairman, President, CEO	Annual
Jonathan Hunt	39	Chief Financial Officer - Treasurer	
David Swanberg	50	Executive Vice President - Operations and Corporate Secretary, Director	Annual
Robert Kauffman	65	Director	Annual
Thomas LaVoy	46	Director	Annual
Stephen Boatwright	42	Director	Annual
Dwight Babcock	58	Director	