IsoRay, Inc.
Form 10KSB
September 28, 2007

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-KSB

x **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, 2007

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. 001-33407

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

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

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

Securities registered under Section 12 (b) of the Exchange Act – Common Stock – $0.001 par value
(American Stock Exchange)

Securities registered under Section 12(g) of the Exchange Act – Series C Preferred Share Purchase Rights

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

Class	Outstanding as of September 12, 2007
Common stock, $0.001 par value	23,033,108

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 – $5,738,033.

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 - $77,633,857 as of September 12, 2007.

Documents incorporated by reference – none.

Transitional Small Business Disclosure Format: Yes o No x

ISORAY, INC.

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Caution Regarding Forward-Looking Information

In addition to historical information, this Form 10-KSB contains certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA). This statement is included for the express purpose of availing IsoRay, Inc. of the protections of the safe harbor provisions of the PSLRA.

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," "expect," "anticipate," "intends," "estimate," "forecast," "project," and similar expressions. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any statements of the plans, strategies and objectives of management for future operations; any statements concerning proposed new products, services, developments or industry rankings; any statements regarding future revenue, economic conditions or performance; any statements of belief; and any statements of assumptions underlying any of the foregoing. 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 21 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. Readers are cautioned not to place undue reliance on such forward-looking statements as they speak only of the Company's views as of the date the statement was made. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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 malignant diseases. Medical is headquartered in Richland, Washington.

Available Information

The Company electronically files its annual reports on Form 10-KSB, quarterly reports on Form 10-QSB, current reports on Form 8-K, and all amendments to these reports and other information with the Securities and Exchange Commission (SEC). These reports can be obtained by accessing the SEC's website at www.sec.gov. The public can also obtain copies by visiting the SEC's Public Reference Room at 100 F Street NE, Washington, DC 20549 or by calling the SEC at 1-800-SEC-0330. In addition, the Company makes copies of its annual and quarterly reports available to the public at its website at www.isoray.com. Information on this website is not a part of this report.

Business Operations

Overview

IsoRay is utilizing its patented radioisotope technology, experienced chemists and engineers, and management team to produce a major therapeutic medical isotope with a goal of providing improved patient outcomes in the treatment of prostate cancer and other malignant disease. IsoRay began production and sales of Proxcelan Cesium-131 (Cs-131) brachytherapy seed, in October 2004 for the treatment of prostate cancer after clearance of its premarket notification (510(k)), by the Food and Drug Administration (FDA). Cs-131 could also enable meaningful market penetration for other solid tumor applications such as breast, lung, liver, brain and pancreatic cancer, expanding the total available market opportunity for brachytherapy. Management believes this technology will allow it to capture a leadership position in an expanded brachytherapy market. The beneficial characteristics of the Cs-131 isotope are expected to result in decreased radiation exposure to the patient and reduced severity and duration of side effects, while treating cancer cells as effectively, if not more so than, other isotopes used in seed brachytherapy.

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. The brachytherapy procedure places radioactive seeds as close as possible to (in or near) the cancerous tumor (the word "brachytherapy" means close therapy). The seeds deliver therapeutic radiation thereby killing the cancerous tumor cells while minimizing exposure to adjacent healthy tissue. This procedure allows doctors to administer a higher dose of radiation direct to the tumor than is possible with external beam radiation. Each seed contains a radioisotope sealed within a welded titanium capsule. Approximately 70 to 120 seeds are permanently implanted in the prostate in an outpatient procedure lasting less than one hour. The isotope decays over time and eventually 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 or chemotherapy, or as treatment for residual disease after excision of primary tumors.

Management believes that the IsoRay Proxcelan Cesium-131 brachytherapy seed represents the first major advancement in brachytherapy technology in over 20 years with attributes that could make it the long term "seed of choice" for internal radiation therapy procedures. The Cs-131 seed has an FDA cleared 510(k) 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.

Increasingly, prostate cancer patients and their doctors who decide on seed brachytherapy choose Cs-131 because of its significant advantages over Palladium-103 (Pd-103) and Iodine-125 (I-125), two other isotopes currently in use. These advantages include:

Higher Energy

Cs-131 has a higher average energy than any other commonly used prostate brachytherapy isotope on the market. Energy is a key factor in how uniformly the radiation dose can be delivered throughout the prostate. This is known as homogeneity. Early studies demonstrate Cs-131 implants are able to deliver the required dose while maintaining homogeneity across the gland itself and potentially reducing unnecessary dose to critical structures such as the urethra

and rectum. (Prestidge B.R., Bice W.S., Jurkovic I., *et al.* Cesium-131 Permanent Prostate Brachytherapy: An Initial Report. *Int. J. Radiation Oncology Biol. Phys*. 2005: 63 (1) 5336-5337.)

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Shorter Half-Life

Cs-131 has the shortest half-life of any commonly used prostate brachytherapy isotope at 9.7 days. Cs-131 delivers 90% of the prescribed dose in just 33 days compared to 58 days for Pd-103 and 204 days for I-125. The short half-life of Cs-131 reduces the duration of time during which the patient experiences the irritating effects of the radiation. Early studies demonstrate that Cs-131 is well tolerated with minimal to moderate urinary symptoms that resolve relatively rapidly, within approximately 4-8 weeks. (Prestidge B.R., Bice W.S., Jurkovic I., *et al.* Cesium-131 Permanent Prostate Brachytherapy: An Initial Report. *Int. J. Radiation Oncology Biol. Phys*. 2005: 63 (1) 5336-5337.)

Higher Biologically Effective Dose

Another benefit to the short half-life of Cs-131 is what is known as the "biological effective dose" or BED. BED is a way for health care providers to predict how an isotope will perform against slow versus fast growing tumors. Studies have shown Cs-131 is able to deliver a higher BED across a wide range of tumor types than either I-125 or Pd-103. Although prostate cancer is typically viewed as a slow growing cancer it can present with aggressive features. Cs-131's higher BED may be particularly beneficial in such situations. (Armpilia CI, Dale RG, Coles IP *et al.* The Determination of Radiobiologically Optimized Half-lives for Radionuclides Used in Permanent Brachytherapy Implants. *Int. J. Radiation Oncology Biol. Phys*. 2003; 55 (2): 378-385.)

IsoRay and its predecessor companies have accomplished the following key milestones (listed in reverse chronological order):

- Opened a new manufacturing and production facility at the Applied Process Engineering Laboratory to replace the PEcoS-IsoRay Radioisotope Laboratory (PIRL) facility (September 2007);
- Treated over 1,600 patients with Proxcelan Cs-131 seeds (October 2004 to September 2007);
- Deployed and grew the direct sales force to 11 people in the market (July 2007);
- Branded Cs-131 seeds as Proxcelan Cesium-131 brachytherapy seeds (July 2007);
- Developed a dual therapy treatment protocol with 9 centers participating (June 2007);
- Raised over $42 million in debt and equity funding (September 2003 - June 2007);
- Filed additional patent applications for the production of purified Cs-131 (November 2003 – February 2007);
- Completed the monotherapy treatment protocol for prostate cancer (February 2007);
- Obtained FDA 510(k) clearance to market preloaded brachytherapy seeds (preloaded Mick cartridges, strands, and needles) (November 2006);
- Opened a manufacturing and production facility at PIRL (October 2005);
- Treated the first patient with Cs-131 seeds (October 2004);
- Commenced production of the Cs-131 seed (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);
- 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);
- Obtained Medicare reimbursement codes for the Cs-131 brachytherapy seed (November 2003);
- Obtained FDA 510(k) clearance to market the first product: the Cs-131 brachytherapy seed (March 2003);

- Implemented a quality management system and production operating procedures that are compliant with the FDA's Quality System Regulation (QSR) (January 2003);
- Completed prototype 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 the initial patent for Cs-131 isotope separation and purification (May 2000).

Industry Information

Incidence of Prostate Cancer

According to the American Cancer Society, prostate cancer is the most common form of cancer in men after skin cancer, and the second leading cause of cancer deaths in men. The American Cancer Society estimates there will be about 218,890 new cases of prostate cancer diagnosed and an estimated 27,050 deaths associated with the disease in the United States in 2007. Because of early detection techniques (e.g., screening for prostate specific antigen, or PSA) approximately 70% (153,200) 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. 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. According to the American Cancer Society, approximately one man in six will be diagnosed with prostate cancer during his lifetime.

The American Cancer Society lists the following factors that can increase the risk of developing prostate cancer:

- Age – about 2 out of every 3 prostate cancers are found in men over the age of 65;
- Race – prostate cancer is more prevalent in African-American men who are also twice as likely to die of the disease;
- Nationality – prostate cancer is most common in North America and northwestern Europe;
- Family history – men are more likely to have prostate cancer if a close relative had the disease and especially if the relatives were young at the time of diagnosis;
- Diet – men who eat more red meat or high-fat dairy products seem to have a greater chance of getting prostate cancer; and
- Exercise – men over the age of 65 who exercised vigorously had a lower rate of prostate cancer.

Prostate cancer incidence and mortality increase with age. 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. 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 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.

Brachytherapy

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.

Management believes that brachytherapy in Europe is growing aggressively each year, with the use of I-125 growing by approximately 30% in 2006. Management expects that market growth in the U.S. will increase at the rate of 5% per year through 2011.

In 1996 only 4% of prostate cancer cases were treated with brachytherapy, or about 8,000 procedures. The number of brachytherapy cases has consistently increased and in 2006 it was estimated that over 60,000 brachytherapy procedures were performed to treat prostate cancer.

Management believes that 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 higher risk and faster growing prostate cancers as well. Brachytherapy has significant advantages over competing treatments including lower cost, equal or better survival data, fewer side effects, faster recovery time and the convenience of a single outpatient implant procedure that generally lasts less than one hour (Merrick, et al., Techniques in Urology, Vol. 7, 2001; Potters, et al., Journal of Urology, May 2005; Sharkey, et al., Current Urology Reports, 2002).

Treatment Options and Protocol

In addition to brachytherapy, localized prostate cancer can be treated with radical prostatectomy (RP), external beam radiation therapy (EBRT), intensity modulated radiation therapy (IMRT), dual or combination therapy, high dose rate brachytherapy (HDR), cryosurgery, hormone therapy, and watchful waiting. The success of any treatment is measured by the feasibility of the procedure for the patient, morbidities associated with the treatment, overall survival, and cost. When the cancerous tissue is not completely eliminated, the cancer typically returns to the primary site, often with metastases to other areas of the body.

Radical Prostatectomy. Historically the most common treatment option for prostate cancer, radical prostatectomy is the removal of the prostate gland and some surrounding tissue through an invasive surgical procedure. RP is performed under general anesthesia and involves a hospital stay of three days on average for patient observation and recovery. Possible side affects of RP include impotence and incontinence. According to a study published in the *Journal of the American Medical Association* in January 2000 approximately 60% of men who had a RP reported erectile dysfunction as a result of surgery. This same study stated that approximately 40% of the patients observed reported at least occasional incontinence. New methods such as laparoscopic radical prostatectomy are currently being used more frequently in order to minimize the nerve damage that leads to impotence and incontinence, but these techniques require a high degree of surgical skill. RP is generally more expensive than other common treatment modalities.

External Beam Radiation Therapy. EBRT involves directing a beam of radiation from outside the body at the prostate gland in order to destroy cancerous tissue. EBRT treatments are received on an outpatient basis 5 days a week usually over a period of 8 or 9 weeks. Some 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. Side effects of EBRT can include diarrhea, rectal leakage, irritated intestines, frequent urination, burning while urinating, and blood in the urine. Also the incidence of incontinence and impotence 5 to 6 years after EBRT is comparable to that for surgery.

Intensity Modulated Radiation Therapy. IMRT is a relatively new treatment modality and considered a more advanced form of EBRT in which sophisticated computer control is used to aim the beam at the prostate 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. Because IMRT is a new treatment, less clinical data regarding treatment effectiveness and the incidence of side effects is 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 brachytherapy, known as combination or dual therapy.

Dual or Combination Therapy. Dual therapy is the combination of IMRT or 3-dimensional conformal external beam radiation and seed brachytherapy to treat extra-prostatic extensions or high risk prostate cancers that have grown outside the prostate. Combination therapy treats high risk patients with a full course of IMRT or EBRT over a period of several weeks. When this initial treatment is completed the patient must then wait for several more weeks to months to have the prostate seed implant.

With the arrival of Proxcelan Cs-131, with its short half life, patients may now complete their course of treatment sooner and have shorter duration of side-effects. Management estimates that at least 30% of all prostate implants are now dual therapy cases.

High Dose Rate Temporary Brachytherapy. HDR temporary brachytherapy involves placing very tiny plastic catheters into the prostate gland, and then giving a series of radiation treatments through these catheters. The catheters are then removed, and no radioactive material is left in the prostate gland. A computer-controlled machine inserts a single highly radioactive iridium seed into the catheters one by one. This procedure is typically repeated at least three times while the patient is hospitalized for at least 24 hours.

Cryosurgery. Cryosurgery involves placing cold metal probes into the prostate and freezing the tissue in order to destroy the tumor. Cryosurgery patients typically stay in the hospital for a day or two and have had higher rates of impotence and other side effects than seed implant brachytherapy.

Additional Treatments. Additional treatments include hormone therapy and chemotherapy. Hormone therapy is generally used to shrink the tumor or make it grow more slowly but will not eradicate the cancer. Likewise, chemotherapy will not eradicate the cancer but can slow the tumor growth. Generally, these treatment alternatives are used by doctors to extend patients' lives once the cancer has reached an advanced stage or in conjunction with other treatment methods. Hormone therapy can cause impotence, decreased libido, and breast enlargement. Most recently hormone therapy has been linked to an increased risk of cardiovascular disease in men with certain pre-existing conditions such as heart disease or diabetes. Chemotherapy can cause anemia, nausea, hair loss, and fatigue.

Watchful Waiting. Watchful waiting is not a treatment but might be suggested by some healthcare providers depending on the age and life expectancy of the patient. Watchful waiting may be recommended if the cancer is diagnosed as localized and slow growing, and the patient is asymptomatic. Generally, this approach is chosen when patients are trying to avoid the side affects associated with other treatments or when they are not candidates for current therapies due to other health issues. Healthcare providers will carefully monitor the patient's PSA levels and other symptoms of prostate cancer and may decide on active treatments at a later date.

Brachytherapy Clinical Results

Long term survival data are now available for brachytherapy with I-125 and Pd-103, 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 primarily on results from brachytherapy with I-125 and Pd-103, management believes that these data are also relevant for brachytherapy with Cs-131, and that Cs-131 appears to offer improved clinical outcomes over I-125 and Pd-103, given its shorter half-life and higher energy.

Improved patient outcomes. A number of published studies on the use of I-125 and Pd-103 brachytherapy in the treatment of early-stage prostate cancer have been very positive.

- 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 study confirm the low impact of interstitial brachytherapy on the patients' quality of life despite its transient negative effects on some functions (Caffo, O., et al. *International Journal of Radiation Oncology; Volume 66; 1;31-37).*

- Results of a trial published in 2007 in the International Journal of Radiation Oncology looking at 15-year survival in 223 patients with stage T1-T3 prostate cancer and treated with brachytherapy in combination with external beam and demonstrated excellent long-term biochemical control. Fifteen-year biochemical relapse free survival (BRFS) for the entire treatment group was 74%. BRFS using the Memorial Sloan-Kettering risk cohort analysis (95% confidence interval) were as follows: low risk 88%, intermediate risk 80%, and high risk 53% (Sylvester J. et al. "15-year biochemical relapse free survival in clinical stage T1-T3 prostate cancer following combined external beam radiotherapy and brachytherapy; Seattle experience", Int. J. Rad. Onc. Biol., Vol. 67, 2007, 57-64.).

- A study of 367 patients with localized prostate cancer treated using real-time intraoperative planning technique with median follow up of 63 months demonstrated this technique consistently achieved optimal coverage of the prostate with concomitant low doses delivered to the urethra and rectum. Biochemical control outcomes were excellent at 5 years (Zelefsky M, et al. "Five-year outcome of intraoperative conformal permanent I-125 interstitial implantation for patient with clinically localized prostate cancer', Int. J. Rad. Onc. Biol., Vol. 67, 2007, 65-70.).

- A 1700 patient case review over 12 years was conducted by J. Sharkey and published in the August 2004 edition of Brachytherapy. The review of patients diagnosed with T1 or T2 adenocarcinoma of the prostate and treated with either radical prostatectomy or brachytherapy showed superiority of brachytherapy over prostatectomy. Low risk brachytherapy resulted in 99% freedom from PSA failure while surgery showed results of 97% (Sharkey J, et al. "Pd-103 brachytherapy versus radical prostatectomy in patient with clinically localized prostate cancer: a 12-year experience from a single group practice". Brachytherapy, 4, 2005.).

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 Proxcelan Cesium-131 brachytherapy 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 or isotopes. Additionally when side effects do occur, they should resolve more rapidly than those experienced with I-125 and Pd-103 isotopes.

Cs-131 Clinical Results and Ongoing Trials

A Cs-131 monotherapy trial for the treatment of prostate cancer was fully enrolled in February 2007. The trial was a 100 patient multi-institutional study to observe the dosimetric characteristics of Cs-131 and its side effect profile. The results of the monotherapy trial have demonstrated that Cs-131 is a viable alternative as an isotope for permanent seed prostate brachytherapy. Some of the significant and specific findings were as follows:

- Patient reported symptoms (IPSS Scores) were mild to moderate with relatively rapid resolution within 4-6 months.
- Prostate Specific Antigen, or PSA, response over 12 months was very encouraging, i.e. low levels with no failures per the nadir definition. (Prestidge BR, Bice WS, "Clinical outcomes of a Phase II, multi-institutional Cesium-131 permanent prostate brachytherapy trial". *Brachytherapy*, *Volume 6, Issue 2*, *April-June 2007*, Page 78) (Moran BJ, Braccioforte MH, "Cesium-131 prostate brachytherapy: An early experience". *Brachytherapy*, *Volume 6, Issue 2*, *April-June 2007*, Page 80).

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- The resolution of acute side effects proved to be much quicker with Cs-131 compared to I-125 thus validating the theoretical argument that dose related side effects dissipate faster with shorter lived isotopes. (Prestidge BR, "Cesium-131; the isotope of choice in permanent prostate brachytherapy". Oral Presentation at the American Brachytherapy Society annual conference, April 2007.).
- The dosimetric observations of the trial demonstrated that it was possible to deliver adequate dose to the prostate while maintaining dose uniformity across the gland. The dose delivered to critical structures was well within acceptable limits. (Bice WS, Prestidge BR, "Cesium-131 permanent prostate brachytherapy: The dosimetric analysis of a multi-institutional Phase II trial". Brachytherapy 2007(6); 88-89.).

The monotherapy Cs-131 trial will continue to follow patients with annual updates on IPSS and patient long-term survival data.

A second prospective randomized monotherapy trial is underway at The Chicago Prostate Cancer Center. Headed by Dr. Brian Moran, this trial directly compares Cs-131 and I-125 treatment related morbidities such as sexual dysfunction and incontinence following brachytherapy for localized carcinoma of the prostate in low to intermediate risk patients.

A third ongoing study first presented at the American Association of Physicists in Medicine (AAPM) meeting in July 2007 compared the dosimetry of Cesium-131 and Palladium-103 directly. The study showed a 17.5% reduction in the number of seeds, 6% reduction in planned needles, 35.5% reduction in V150 (percent of gland that receives more than 150% of the prescription dose), and 44.2% reduction in R100 (percent of rectal tissue that receives the full prescription dose of radiation). (Musmacher, J., "Dosimetric comparison of Cesium-131 and Palladium-103 for permanent prostate brachytherapy", poster presented at 49th AAPM Annual Conference, Minneapolis, MN, April 22-26, 2007.)

The Company has also commissioned a dual therapy protocol. This multi-institutional trial observes the dosimetric characteristics of Cs-131 and health related quality of life (HRQOL) results following combined Cs-131 transperineal permanent prostate brachytherapy and external beam radiotherapy in patients with intermediate to high risk prostate cancer. This protocol is being conducted to confirm clinically what radiobiological data suggests regarding this treatment modality. The quantified dosimetric variables collected will be correlated to the reported HRQOL data and ultimately compared to existing data in the literature for similar investigations using I-125 and Pd-103. Patient enrollment for this study began in April 2007.

In addition to establishing the dosimetric and quality of life impact of Proxcelan Cesium-131 brachytherapy seeds in different treatment modalities, all trials have been designed to collect ongoing PSA results for the purposes of establishing long-term survival rates using Cs-131 seed implant brachytherapy.

Our Strategy

The key elements of IsoRay's strategy for fiscal year 2008 include:

- *Continue to introduce the Proxcelan Cs-131 brachytherapy seed into the U.S. market*. Utilizing our direct sales organization and selected channel partners, IsoRay intends to continue expanding the use of Proxcelan Cs-131 seeds in brachytherapy procedures for prostate cancer, by increasing the number of treatment centers offering Cs-131 and increasing the number of patients treated at each center using Cs-131. IsoRay hopes to capture much of the incremental market growth in seed implant brachytherapy and take market share from existing competitors.

- *Move our state-of-the-art manufacturing process to a new facility*. IsoRay has completed construction of a new manufacturing facility in Richland, Washington in its recently leased facility at the Applied Process Engineering Laboratory (APEL facility). This facility replaces our currently leased production facility (PIRL facility). The new facility is four times larger than the size of our former facility and will allow production to expand as sales orders increase.

- *Develop an enriched barium manufacturing process*. Working with leading scientists, IsoRay is working to design and create a proprietary process for manufacturing enriched barium, a key source material for Cs-131. This will ensure adequate future supply of Cs-131 and greater efficiencies in producing the isotope.

- *Introduce Cs-131 therapies for other cancers*. IsoRay intends to partner with other companies to develop the appropriate technologies and therapeutic delivery systems for treatment of other solid tumors such as breast, lung, liver, ocular, pancreas, neck, and brain cancers. IsoRay's management believes that the first major opportunities may be for the use of Cs-131 for ocular melanoma and as adjunct therapy for lung cancer (treating the surgical margins).

- *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. and other countries to identify and develop other applications for IsoRay's core radioisotope technology.

- *Diversify our supply of Cs-131.* Currently, the Company relies heavily on Cs-131 from its primary Russian supplier. This supplier has significant capacity for producing Cs-131 with higher quality than currently available from other sources. The Company is actively developing the capability to produce multi-curie quantities of Cs-131 from several reactor sources located both abroad and domestically.

- *Introduce Proxcelan Cesium-131 brachytherapy seeds to the European and Russian markets.* The Company is currently working to obtain the European CE Mark and certification to ISO 13485 to enable the sale of our product in the European Union. If the proposed strategic alliance with IBt, SA, a Belgian company, is ultimately consummated, it will allow the Company to obtain access to various foreign countries through IBt distribution channels and leverage IBt's international regulatory expertise.

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 Proxcelan 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. Seed brachytherapy has significant advantages over competing treatments including lower cost, 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 2006. (At the June 30, 2007 average Proxcelan seed price of $72, this represents a potential market of over $300 million for seeds that is forecast to grow substantially by 2009 according to a 2004 market survey performed by Frost & Sullivan, a nationally recognized market research firm.) IsoRay's management believes that the Proxcelan seed will add incremental growth to the existing brachytherapy seed market as physicians who are currently reluctant to recommend brachytherapy for their prostate patients due, in part, to side effects caused by longer-lived isotopes, become comfortable with the shorter half-life of Cs-131, and the anticipated related reduction of side effects that it offers.

Products

IsoRay markets the Proxcelan Cesium-131 brachytherapy seed for the treatment of prostate cancer and intends to market Cs-131 for the treatment of other malignant disease in the future. Additionally, the Company may market other radioactive isotopes in the future.

Competitive Advantages of Proxcelan Cs-131

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

Brachytherapy Isotope Comparison

	Cesium-131	Palladium-103	Iodine-125
Half Life	9.7 Days	17.5 days	60 days
Avg. Energy	30.4 keV[+]	20.8 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[*]	0.969	0.877 (TheraSeed® 200)	0.930 (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 Cs-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 Proxcelan 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 Pd-103 seeds may also result in lesser homogeneity 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 higher 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.

Quality of Life. Because IsoRay's Proxcelan Cesium-131 brachytherapy seed 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. Initial results indicated that the side effects experienced, if any, are mild to moderate and urinary symptoms resolve more rapidly, within 4-6 months, when compared to I-125. Management believes that as the data matures it will continue to support fewer and less severe side effects and complications when compared to other conventional therapies.

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Shape of radiation field. The shape of the radiation field generated by a Proxcelan seed is more uniform than most brachytherapy seed designs, and this uniformity may result in better radiation dose coverage and improved therapeutic effectiveness. IsoRay has conducted extensive computer modeling of the seed design. The dosimetric characteristics of the Cs-131 seed were recently confirmed through American Association of Physicists in Medicine (AAPM) evaluations of the seed design (Med Phys, 34:2). The results of these tests showed superior dose characteristics relative to the leading I-125 and Pd-103 seeds. The IsoRay seed has also met all Nuclear Regulatory Commission (NRC) requirements for sealed radioactive sources.

Cs-131 Manufacturing Process

Overview. Cs-131 is a radioactive isotope that can be produced by the neutron bombardment of Barium-130 (Ba-130). When Ba-130 is put into a nuclear reactor and is exposed to a flux of neutrons it becomes Ba-131, the radioactive material that is the parent isotope of Cs-131. The radioactive isotope Cs-131 is normally produced by placing a quantity of stable non-radioactive barium (ideally barium enriched in isotope 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. In addition, the supplier's nuclear reactor facility must have sufficient irradiation capacity to accommodate barium targets and the nuclear reactors must have sufficient neutron flux to economically produce commercially viable quantities of Cs-131. Ideally, the irradiation facility will also have a radiochemical separation infrastructure to carry out the initial separation steps. The Company has identified key reactor facilities in the U.S. and the former Soviet Union that are capable of meeting these requirements.

As of the date of this report, IsoRay has exclusive agreements in place with three suppliers of irradiated Ba-131 or Cs-131. During fiscal year 2007, the Company obtained approximately 80% of its isotope from the Institute of Nuclear Materials (INM) located in Russia. The Company has an exclusive supply agreement with INM that originally commenced August 25, 2005 and was amended on September 3, 2006 and February 2, 2007. The agreement has a ten-year term but is not an obligation to purchase any given quantity of the isotope; however, if the Company does not purchase certain minimum levels, then INM is no longer bound by the exclusivity portion of the agreement. Even if INM were to become the sole supplier, INM has sufficient irradiation capacity to meet the Company's Cs-131 anticipated demand through fiscal year 2009 without the use of enriched barium. However, the Company is actively seeking other suppliers in order to diversify its supply of Cs-131.

During fiscal year 2007, the Company also obtained irradiated barium from the University of Missouri under an agreement originally signed on August 9, 2005. The Company also has an exclusive agreement in place with the Russian Institute of Atomic Reactors (RIAR) for supply of Cs-131. The production development activities at RIAR are under way and the Company currently anticipates accepting deliveries of Cs-131 within the next six months, but there is no assurance as to this delivery schedule.

To produce the Proxcelan seed, the purified Cs-131 isotope is absorbed onto a ceramic core containing a gold X-ray marker. This internal core assembly is subsequently inserted into a titanium capsule that is then welded shut and becomes a sealed radioactive source and a biocompatible medical device. The dimensional tolerances for the ceramic core, gold X-ray marker, and the titanium capsule are extremely important. To date the Company has used sole-source providers for certain components such as the gold X-ray marker and the titanium capsule as these suppliers have been validated by our quality department and they have been cost effective.

We have established procedures and controls to comply with the FDA's Quality System Regulation. The Company constantly monitors these procedures and controls to ensure that they are operating properly thereby working to maintain a high-quality product. Also, the quality, production, and customer service departments maintain open

communications 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 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 is 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 quantity. Upon receipt of an order, the Company either delivers the seeds from its facility directly to the physician or sends the order to an independent preloading service that delivers the seeds preloaded into needles or cartridges 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.

Due to the lead time for obtaining and processing the Cs-131 isotope and the short half-life, the Company relies on sales forecasts and historical knowledge to estimate the proper inventory levels of isotope in order to be able to fulfill all customer orders. Consequently, some portion of the isotope is written off to current period costs as it decays and is not used in an end product.

Automated Manufacturing Process

Based on evaluations of automation options by management, IsoRay has elected to automate its current manufacturing process in phases. Management believes that current production rates with the Company's semi-automated seed welding equipment exceed those attainable with fully automated lines that the Company has evaluated. 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. The Company has purchased some automation equipment and is reviewing options for the development of additional automated equipment. The Company also has a contract with a third party to outsource certain sub-processes.

Manufacturing Facility

The Company has replaced the manufacturing facility located at PEcoS-IsoRay Radioisotope Laboratory (PIRL) with a new production facility located at Applied Process Engineering Laboratory (APEL). The APEL facility became operational in September 2007, which was three months earlier than the original scheduled opening. The facility has over 19,000 square feet and includes space for isotope separation, seed production, order dispensing, a clean room for radiopharmacy work, and a dedicated shipping area. A description of the lease terms for the APEL facility is located in the Other Commitments and Contingencies section of Item 6 below. The Company now plans to decommission the PIRL facility and return it to the landlord by the end of calendar year 2007. Management believes that the APEL facility will be utilized for manufacturing space through fiscal year 2016 which is the original lease term plus the two three-year renewal options. Management currently anticipates exercising both three-year renewal options to extend the APEL facility lease through April 2016.

The Company has used Pacific Northwest National Laboratory (PNNL) to provide third-party assay of its products but has otherwise vacated PNNL facilities. Management is currently setting up facilities to move the independent assay of its products to its new production facility and will utilize in-house resources which will reduce isotope depletion and also minimize assay expenditures.

The Company intends to establish a new facility in Russia to produce Proxcelan Cesium-131 brachytherapy seeds. This new facility is part of the Company's strategy to expand into the Russian and European markets. The Company has not entered into any agreements concerning this facility and has not begun any negotiations with any third-parties.

The Company is also considering another state as a location for a future facility 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 Cs-131 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 Cs-131 production that will enhance IsoRay's overall production capacity. ATR has now obtained the funding to design and implement the necessary capsule shuttle system and IsoRay has collaborated with ATR on its design and testing. The Company is seeking to enter into a contract with ATR in fiscal year 2008 to produce irradiated barium but there is no assurance that this will ultimately occur

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)

No single package configuration dominates the market at this point. In 2007, the Millenium Research Group reported that the estimated market shares for each of the four packaging types are: loose seeds (9.5%), Mick cartridges (29.1%), pre-loaded needles (19.4%) and all strand configurations (42.0%). 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. 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 radiopharmacies then sterilize the product and certify the final packaging prior to shipping directly to the end user.

IsoRay currently has agreements with several independent radiopharmacies to assay, preload, and sterilize our loose seeds. This 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 our new APEL facility. Once our custom preloading operation comes fully on-line, we anticipate completing most of the assay, preload, and sterilization in-house rather than relying on independent radiopharmacies.

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The Company currently loads most Mick cartridges in our own facility which in recent months accounted for more than 65% of total seed orders. Currently, PNNL provides independent third-party assay of seeds for customers who request this service. The Company expects to begin offering a 100% confirmation assay in Q2 of FY2008 performed by in-house analytical services. Providing the assay and preloading services in-house allows the Company to reduce the time to process an order by two to four days as the additional shipping and third-party handling time are eliminated. This reduction in order processing time eliminates 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.

Barium Enrichment Device

Ba-130 is the original source material for Cs-131. When Ba-130 is put into a nuclear reactor it becomes Ba-131 which is the radioactive material that is the parent isotope of Cs-131. Natural barium contains only 0.1% of Ba-130 with six other isotopes making up the other 99.9%. The Company is currently developing an enrichment device to produce “enriched barium” having a higher concentration of the Ba-130 isotope than is found in naturally occurring barium. Irradiating enriched barium will result in higher yields of Cs-131. The Company anticipates the use of enriched barium will also streamline the manufacturing process and reduce Cs-131 production costs. In June 2007, the Company purchased approximately 6 grams of Ba-130 (metal equivalent) that will be used in future production of Cs-131. The enriched barium is being stored in Russia and is included in raw materials at June 30, 2007.

Marketing and Sales

Marketing Strategy

The Company has worked to position Proxcelan Cesium-131 brachytherapy seeds as the seed of choice for prostate brachytherapy. Based on current and preliminary clinical studies, management believes there is no apparent clinical reason to use other isotopes when Cs-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 I-125 make this isotope less attractive than Cs-131. The low energy of Pd-103 creates potential cold or hot areas in the treatment plan and requires more seeds to optimize the implant.

IsoRay has chosen to identify its proprietary Cs-131 seed with the brand of “Proxcelan.” Management is using this brand to differentiate Cs-131 seeds from seeds using the other isotopes. We continue to 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.

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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 has developed a customized brand message for each audience. For medical professionals, IsoRay has created print and visual medias (including physician brochures discussing the clinical advantages of Cs-131, clinical information binders, informational DVDs, single sheet glossies with targeted clinical data, etc.), advertisements in the leading medical journals and a physician targeted website. In addition, the Company attends national professional meetings, including the following:

- § American Brachytherapy Society (ABS),
- § American Society for Therapeutic Radiation and Oncology (ASTRO),
- § American Urological Association (AUA),
- § Association of American Physicists in Medicine (AAPM), and
- § various other professional society meetings.

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 the Proxcelan Cesium-131 brachytherapy seed, including fewer side effects, less total radiation, and a shorter period of radiation exposure. The Company is targeting this market through its websites (located at www.isoray.com, www.cesium.com, and www.proxcelan.com), advertising in magazines read by prostate cancer patients and their care givers, through patient advocacy efforts, informational patient brochures and DVDs with patient testimonials, and advertisements in specific markets supporting brachytherapy, etc.

In addition, the Company continues to promote the clinical findings of the various protocols through presentations by respected thought leaders. The Company will continually review and update all marketing materials as more clinical information is gathered from the protocols and studies.

During fiscal year 2007, the first abstracts were published on the results of clinical studies of Cs-131 treatments. In fiscal year 2008, the Company will continue its collaboration with leading physicians to develop clinical data on the efficacy of Cs-131 seeds including the dual therapy protocol and the prospective randomized trial. In addition, the Company continues to consult with noted contributors from the medical physics community and will have articles submitted to professional journals such as *Medical Physics* and the *International Journal of Radiation Oncology, Biology, and Physics* regarding the benefits of and clinical trials involving Cs-131.

At ASTRO 2007 to be held in Los Angeles on October 28th through November 1st, the following abstracts related to Cs-131 have been accepted:

1. Urinary Morbidity Following Cs-131 Brachytherapy for Localized Prostate Cancer
(Brian Moran, M.D., Chicago Prostate Cancer Center, Chicago, IL)
2. Results of a Multi-Institutional Trial Using Cesium-131 Permanent Prostate Brachytherapy
(Brad Prestidge, M.D., Texas Cancer Clinic, San Antonio, TX)
3. BED as a Predictive Tool for the Outcome of a Permanent Prostate Brachytherapy Trial Using Cesium-131 as Monotherapy
(William Bice, PhD, Texas Cancer Clinic, San Antonio, TX)
4. Dosimetric Comparison of Cesium-131 and Palladium-103 for Permanent Prostate Brachytherapy
(J. S. Musmacher, North Shore Medical Accelerator, Smithtown, NY)

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 Proxcelan Cesium-131 brachytherapy seeds to radiation oncologists and medical physicists. During 2007 IsoRay expanded its sales force to eleven sales people. These sales people include those experienced in the brachytherapy market and the medical device market.

The initial response to our new isotope from prominent radiation oncologists, medical physicists and urologists in the US has been very positive and the number of surgical centers and clinics using the Proxcelan seed continues to increase.

The Company expects to expand its customer base in fiscal year 2008. When 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 expenses 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.

Reimbursement

Payment for IsoRay products comes from third-party payers including the Centers for Medicare and Medicaid Services (CMS) and private insurance companies. These payers reimburse the hospitals and clinics via well-established payment procedures. In 2003, the Company was approved for an initial HCPCS code for Cs-131 brachytherapy seeds. In July 2007 CMS divided the HCPCS code into two codes for all manufacturers of brachytherapy seeds. The current method has assigned one HCPCS code for loose seeds and a second HCPCS code for stranded 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.

Prostate brachytherapy is typically performed in an outpatient setting, and as such, is covered by the CMS Outpatient Prospective Payment System. Currently, when charges for the seeds are correctly submitted to CMS, the total cost of the seeds is reimbursed to the hospital or clinic by CMS. CMS reviews and adjusts outpatient reimbursement on a periodic basis and is currently reviewing the reimbursement rates that will be effective beginning January 1, 2008. CMS has proposed that a fixed price per seed be reimbursed and the Company is working to ensure that the proposed amounts are adequate to reimburse hospitals or clinics for the full amount of the seeds. The US House of Representatives has passed a bill that would continue the pass-through reimbursement of brachytherapy seeds during 2008. However, the US Senate version of the bill did not contain the same provisions. The Company believes that the final calendar year 2008 reimbursement rates will not be known until November or December 2007. Other insurance companies have historically followed CMS’s reimbursement policies.

Other Information

Customers

Customers representing ten percent or more of total Company sales for the twelve months ended June 30, 2007 include:

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Community Hospital of Los Gatos	Los Gatos, CA	24.5% of revenue
Chicago Prostate Cancer Center	Westmont, IL	13.2% of revenue

The loss of any of these significant customers would have an 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, Chief Chemist and 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 2004, July 2004, and February 2007, five 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 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. During fiscal years 2007 and 2006, the Company recorded royalty expense of $2,161 and $0, respectively.

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, management believes that there have been no product sales incorporating the "know-how" and that therefore no royalty is due pursuant to the terms of the agreement. Management believes that ultimately no royalties should be paid under this agreement as there is no intent to use this "know-how" in the future.

The licensor of the Lawrence "know-how" has disputed management's contention that it is not using this "know-how". On September 25, 2007, the Company participated in nonbinding mediation and no settlement was reached. The parties

have agreed to extend mediation discussions until early October, 2007. If no settlement is reached, the parties may demand binding arbitration.

Research and Development

During the three-year period ended June 30, 2007, IsoRay and its predecessor companies incurred more than $1.8 million in costs related to research and development activities. The Company expects to continue to devote employees to ongoing research and development activities for the foreseeable future.

The Company anticipates finishing its major research and development project to develop a proprietary separation process to manufacture enriched barium and thereby increase isotope production efficiency during fiscal year 2008. The remaining project costs are anticipated to be approximately $400,000.

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 Quality System Regulations, also known as the Good Manufacturing Practices, which include extensive record keeping and periodic inspections of manufacturing facilities. IsoRay's predecessor obtained FDA 510(k) clearance in March 2003 to market the Proxcelan Cs-131 seed for the treatment of localized solid tumors and other malignant disease and IsoRay obtained FDA 510(k) clearance in November 2006 to market preloaded brachytherapy seeds.

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.

In the United States, medical devices are classified into three different categories over which the 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 Proxcelan Cs-131 seed is a Class II device and received 510(k) clearance in March 2003.

Approval of new Class III medical devices is a lengthy procedure and can take a number of years and require the expenditure of significant resources. There is a shorter FDA review and clearance process for Class II medical devices, the premarket notification or 510(k) process, whereby a company can market certain Class II medical devices that can be shown to be substantially equivalent to other legally marketed devices. Since brachytherapy seeds have been classified by the FDA as a Class II device, we have been able to achieve market clearance for our Cs-131 seed using the 510(k) process.

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 are 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 support of IsoRay's global strategy to expand marketing to other countries such as Europe, Canada, as well as other foreign markets, we have initiated a project to obtain the European CE Mark, Canadian registration, and certification to ISO 13485, an internationally recognized quality system. European law requires that medical devices sold in any EU member state comply with the requirements of the European Medical Device Directive (MDD). Compliance with the MDD and obtaining a CE Mark involves being certified to ISO 13485 and obtaining approval of the product technical file by a notified body that is recognized by competent authorities of a member state. Compliance with ISO 13485 is also required for registration of a company for sale of its products in Canada. Many of the recognized EU Notified Bodies are also recognized by Health Canada to conduct the ISO 13485 inspections for Canadian registration.

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 Cs-131 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 appealed 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.