

IsoRay, Inc.  
Form 10KSB  
September 28, 2007

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

FORM 10-KSB

**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  
(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 – 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:

<u>Class</u>	<u>Outstanding as of September 12, 2007</u>
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  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

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Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes  No

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  No

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**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](http://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](http://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.)

### 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 effects 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*).



§ 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 49<sup>th</sup> 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

	<b>Cesium-131</b>	<b>Palladium-103</b>	<b>Iodine-125</b>
<b>Half Life</b>	9.7 Days	17.5 days	60 days
<b>Avg. Energy</b>	30.4 keV <sup>+</sup>	20.8 keV <sup>+</sup>	28.5 keV <sup>+</sup>
<b>Dose Delivery</b>	90% in 33 days	90% in 58 days	90% in 204 days
<b>Total Dose</b>	115 Gy	125 Gy	145 Gy
<b>Anisotropy Factor*</b>	0.969	0.877 (TheraSeed® 200)	0.930 (OncoSeed® 6711)

\*Degree of symmetry of therapeutic dose, a factor of 1.00 indicates symmetry.

<sup>+</sup>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.





*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.



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.





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](http://www.isoray.com), [www.cesium.com](http://www.cesium.com), and [www.proxcelan.com](http://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 28<sup>th</sup> through November 1<sup>st</sup>, 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:



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.

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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.

#### *Seasonality*

The Company believes that some seed implantation procedures are deferred around physician vacations (particularly in the summer months), holidays, and medical conventions and conferences resulting in a seasonal influence on the Company's business. These factors cause a momentary decline in revenue which management believes is ultimately realized later.



### *Employees*

As of September 4, 2007, IsoRay employed 66 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 fiscal year 2008.

### *Competition*

The Company competes in a market characterized by technological innovation, extensive research efforts, and significant competition. In general, the Proxcelan Cesium-131 brachytherapy 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 but has declined in recent years. 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 Proxcelan Cesium-131 brachytherapy 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, better quality of life outcomes, 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 about 35% of the market with the original I-125 seed. Theragenics Corp., which introduced the original Pd-103 seed, currently claims (through CR Bard and direct distribution) over 50% of the Pd-103 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 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 clearances before marketing a competing device.

Several companies have obtained regulatory clearance to produce and distribute Pd-103 and I-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 GE Healthcare), 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., CR Bard, 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) clearance to market a Cs-131 seed on June 6, 1993 but to date has not produced 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 for prostate brachytherapy to Russia, Europe, Canada, and other international markets, introducing Cs-131-based therapies for other indications such as lung cancer and ocular melanoma, and through the marketing of other radioactive isotopes. These growth initiatives appear to be significant incremental opportunities.

The Company plans to introduce Cs-131 for prostate brachytherapy 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 clearance 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 residual lung cancer and ocular melanoma. The Company has had discussions with prominent physicians and is looking at 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 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 Proxcelan Cs-131 brachytherapy 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, Europe, and Russia; 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 Cs-131 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 Cleared To Treat Any Malignant Tissue, Our Sole Product Is Currently Used To Treat One Type Of Cancer.* Currently, the Proxcelan Cs-131 seed is used exclusively for the treatment of prostate cancer. We believe the Proxcelan Cs-131 seed will be used to treat cancers of other sites as well, as is currently the case with our competitors' I-125 and Pd-103 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 Increasing Cash Requirements.* IsoRay has generated material operating losses since inception. We expect to continue to experience net operating losses. However, in March 2007, we completed a public equity offering and a warrant call that raised gross proceeds of approximately \$20 million. Due to raising this additional capital, management believes cash and cash equivalents on hand at June 30, 2007 will be sufficient to meet our anticipated cash requirements for operations, debt service, and capital expenditure requirements through at least the next twelve

months. While we are generating significantly more revenue, if operating costs expand proportionately with revenue increases, other applications are pursued for seed usage outside the prostate market, if protocols are expanded supporting the integrity of our product, and marketing expenses increased, management believes approximately \$2 million in monthly revenue will be needed to reach break-even. However, there is no assurance as to when break-even will occur. 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.

*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. Over eighty percent (80%) of our cesium is now supplied through the Institute of Nuclear Materials (INM) located in Russia. This percentage will continue to increase as demand for our products increases. Management expects that we will be able to supplement our supply of cesium with deliveries under our recent contract with the Russian Research Institute of Atomic Reactors (RIAR). Although deliveries have not yet begun under this contract, production capabilities at RIAR are well under development. With the development of barium enrichment capabilities, the Company plans to expand Cs-131 manufacturing capability at the MURR reactor and create production capabilities at Idaho's Advanced Test Reactor (ATR). This strategy will reduce the risk associated with concentrating isotope production at a single reactor facility. Failure to obtain deliveries of cesium from these sources could have a material adverse effect on seed production and there may be a delay before we could locate alternative suppliers. We may not be able to locate suppliers outside of Russia capable of producing the level of output of cesium at the quality standards we require. 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 and our suppliers' control.

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. To mitigate any potential interruptions, the Company continually evaluates its inventory levels and management believes that the Company maintains a sufficient quantity on hand to alleviate any potential disruptions.

*Future Production Increases Will Depend on Our Ability to Acquire Larger Quantities of Cs-131 and Hire More Employees.* IsoRay currently obtains Cs-131 through its contract with INM and through reactor irradiation of natural barium and subsequent separation of cesium from the irradiated barium targets. The amount of Cs-131 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 Ba-130. 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 exclusive agreements with the INM and the RIAR in Russia to provide Cs-131 in quantities sufficient to supply a significant percentage of future demand for this isotope. Delivery of the isotope from INM began in January 2006 and delivery of initial quantities of the isotope from RIAR is expected to begin within the next six months. INM has unique capabilities due to its large irradiation capacity which will allow the Company to meet all of its Cs-131 demands without the use of enriched material for the foreseeable future. Due to the purchase of enriched barium in June 2007, IsoRay now has access to sufficient quantities of enriched barium that may be recycled to increase the production of Cs-131. Although the agreements provide for supplying Cs-131 in significant quantities, there is no assurance that this will result in IsoRay gaining access to a continuing sufficient supply of enriched barium feedstock and if sufficient supplies are attained, we will need to increase our manufacturing staff. If we were unable to obtain supplies of isotopes from Russia in the future, our overall supply of cesium and barium would be reduced significantly unless the Company has a source of enriched barium for utilization in domestic reactors.

*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 and private health insurance plans. Currently, Medicare reimburses hospitals, clinics and physicians for the cost of seeds used in brachytherapy procedures on a pass through 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, we applied to the Centers for Medicare and Medicaid Services (CMS) and received a reimbursement code for use of our Cs-131 seed. As of July 1, 2007, CMS revised the coding system for brachytherapy seeds and separated the single code into two codes - one code for loose seeds and a second code for stranded seeds. This methodology was applied to all companies manufacturing and distributing brachytherapy seeds. Reimbursement amounts are reviewed and revised annually. 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.

*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 facility;
- § the amount and timing of sales orders;
- § rate and success of future product approvals;
- § timing of FDA clearance, 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 Have Limited Data on the Clinical Performance of Cs-131.* As of September 1, 2007, the Proxcelan Cs-131 seed has been implanted in over 1,600 patients and research papers are beginning to be published on the use of the Proxcelan seed. However, we have less statistical data than is available for I-125 and Pd-103 seeds. While this limited data 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 I-125 and Pd-103 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 Cs-131 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.

*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 production facility will 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 appealed this 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 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 Proxcelan Cs-131 seed, and on other third parties, including various radiopharmacies, to package our Proxcelan Cs-131 seed in certain specialized packaging forms requested by customers. 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.

*It Is Possible That Other Treatments May Be Deemed Superior To Brachytherapy.* Our Proxcelan Cs-131 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 device industry is intensely competitive. We compete with both public and private medical device, biotechnology and pharmaceutical companies that have been established longer than we have, have a greater number of products on the market, have greater financial and other resources, and have other technological or competitive advantages. In addition, centers that wish to offer the Proxcelan Cs-131 seed must comply with licensing requirements specific to the state in which they do business and these licensing requirements may take a considerable amount of time to comply with. Certain centers may choose to not offer our Proxcelan Cs-131 seed due to the time required to obtain necessary license amendments. 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 Cs-131 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.

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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.

*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 Cs-131, our patent pending on the manufacture of the brachytherapy seed, our patent applications on additional methods for producing Cs-131 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.

*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 Proxcelan Cs-131 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 Proxcelan Cs-131 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. If we lose the services of several 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.

*Our Ability To Operate In 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 Cs-131 from Russia under our contracts with INM and RIAR. If the strategic alliance with IBT is ultimately consummated, it will allow the Company to obtain access to various foreign countries through IBT distribution channels and customer relationships and leverage IBT's international regulatory expertise.



*Our Ability To Expand Operations And Manage Growth Is Uncertain.* Our efforts to expand our operations 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 Proxcelan Cs-131 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. The Company will no longer qualify as a small business issuer under the federal securities laws for fiscal year 2008 and will therefore need to implement additional provisions of the Sarbanes Oxley Act during the next fiscal year. These reporting obligations will increase our operating costs.

*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.

*Future Sales By Shareholders, Or The Perception That Such Sales May Occur, May Depress The Price Of Our Common Stock.* The sale or availability for sale of substantial amounts of our shares in the public market, including shares issuable upon conversion of outstanding preferred stock or exercise of warrants and options, or the perception that such sales could occur, could adversely affect the market price of our common stock and also could impair our ability to raise capital through future offerings of our shares. As of June 30, 2007, we had 22,789,324 outstanding shares of common stock, and the following additional shares were reserved for issuance: 3,683,439 shares upon exercise of outstanding options, 3,627,764 shares upon exercise of outstanding warrants, and 59,065 shares upon conversion of preferred stock. Any decline in the price of our common stock may encourage short sales, which could place further downward pressure on the price of our common stock and may impair our ability to raise additional capital through the sale of equity securities.

*The Issuance Of Shares Upon Exercise Of Derivative Securities May Cause Immediate And Substantial Dilution To Our Existing Shareholders.* The issuance of shares upon conversion of the preferred stock and the exercise of warrants and options may result in substantial dilution to the interests of other shareholders since these selling shareholders may ultimately convert or exercise and sell all or a portion of the full amount issuable upon exercise. If all derivative securities were converted or exercised into shares of common stock, there would be an approximate additional 7,300,000 shares of common stock outstanding as a result. The issuance of these shares will have the effect of further diluting the proportionate equity interest and voting power of holders of our common stock.

*We Do Not Expect To Pay Any Dividends For The Foreseeable Future.* We do not anticipate paying any dividends to our shareholders for the foreseeable future. The terms of certain of our and our subsidiary's outstanding indebtedness substantially restrict the ability of either company to pay dividends. Accordingly, shareholders must be prepared to rely on sales of their common stock after price appreciation to earn an investment return, which may never occur. Any determination to pay dividends in the future will be made at the discretion of our Board of Directors and will depend on our results of operations, financial conditions, contractual restrictions, restrictions imposed by applicable law and other factors our Board deems relevant.

*Certain Provisions of Minnesota Law and Our Charter Documents Have an Anti-Takeover Effect.* There exist certain mechanisms under Minnesota law and our charter documents that may delay, defer or prevent a change of control. Anti-takeover provisions of our articles of incorporation, bylaws and Minnesota law could diminish the opportunity for shareholders to participate in acquisition proposals at a price above the then-current market price of our common stock. For example, while we have no present plans to issue any preferred stock, our Board of Directors, without further shareholder approval, may issue shares of undesignated preferred stock and fix the powers, preferences, rights and limitations of such class or series, which could adversely affect the voting power of the common shares. In addition, our bylaws provide for an advance notice procedure for nomination of candidates to our Board of Directors that could have the effect of delaying, deterring or preventing a change in control. Further, as a Minnesota corporation, we are subject to provisions of the Minnesota Business Corporation Act, or MBCA, regarding "business combinations," which can deter attempted takeovers in certain situations. Pursuant to the terms of a shareholder rights plan adopted in February 2007, each outstanding share of common stock has one attached right. The rights will cause substantial dilution of the ownership of a person or group that attempts to acquire the Company on terms not approved by the Board of Directors and may have the effect of deterring hostile takeover attempts. The effect of these anti-takeover provisions may be to deter business combination transactions not approved by our Board of Directors, including acquisitions that may offer a premium over the market price to some or all shareholders. We may, in the future, consider adopting additional anti-takeover measures. The authority of our Board to issue undesignated preferred or other capital stock and the anti-takeover provisions of the MBCA, as well as other current and any future anti-takeover measures adopted by us, may, in certain circumstances, delay, deter or prevent takeover attempts and other changes in control of the company not approved by our Board of Directors.

## **ITEM 2 - DESCRIPTION OF PROPERTY**

The Company's executive offices are located at 350 Hills Street, Suite 106, Richland, WA 99354, (509) 375-1202, where IsoRay currently leases approximately 19,330 square feet of office and laboratory space for approximately \$26,700 per month plus monthly janitorial expenses of approximately \$700 from Energy Northwest, the owner of the Applied Process Engineering Laboratory (the APEL facility). The Company is not affiliated with this lessor. The monthly rent is subject to annual increases based on the Consumer Price Index. The current lease was entered into in May 2007, expires on April 30, 2010, and has two three-year renewal options. Additional office space will be needed as other general and administrative employees are hired and will be secured in the Richland area.

In February 2005, the Company entered into a lease agreement for leased space at the PEcoS-IsoRay Radioisotope Laboratory (PIRL) in which it established production facilities. The lease was for 4,400 total square feet and the term commenced on regulatory licensing approval, which was obtained in October 2005. The lease had a base term of one year with a one year renewal option. The first year of rent was paid by issuing 24,000 shares of the Company's common stock. The Company has agreed to rent of \$5,000 per month for the renewal term. However, if the Company fails to decommission this site and complete the required regulatory "clean-up" by January 1, 2008, the Company will face stiff fines and penalties for holding over. The Company is not affiliated with the lessor.

In September 2007, the Company moved all manufacturing operations to the APEL facility after completing the necessary improvements and installing the required equipment and will vacate its leased space at PIRL. The APEL facility has over 19,000 square feet and includes space for isotope separation, seed production, order dispensing, a clean room for preloading seeds into strands, needles, and cartridges, 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 believes that the APEL facility will be used through April 2016 which is the end of the original lease term plus the two three-year renewal options. Other facilities could be necessary to produce additional Cs-131 products for the prostate and other organ cancer markets in other regions of the country or the world if demand continues to grow.

The Company has used Pacific Northwest National Laboratory (PNNL) to provide third-party assay of its products but has otherwise vacated PNNL facilities.

The Company intends to establish a new facility in Russia to produce Cs-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 started negotiations with any third-parties.

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 4, 2007, we had 23,033,108 outstanding shares of Common Stock and 59,065 outstanding shares of Preferred Stock.

On April 19, 2007, our common stock began trading on the American Stock Exchange (AMEX) under the symbol "ISR." Prior to this our common stock was quoted on the OTC Bulletin Board and the Pink Sheets under the symbols "ISRY.OB" and "ISRY.PK," respectively. Even though we have now obtained our AMEX listing, at times there is still limited trading activity in our securities

The following table sets forth, for the fiscal quarters indicated, the high and low sales prices for our common stock as reported on the American Stock Exchange, the OTC Bulletin Board, and the Pink Sheets. The OTC Bulletin Board and Pink Sheet quotations are high and low last reported bid prices representing 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. In the past, there was an absence of an established trading market for the Company's common stock, as the market was limited, sporadic and highly volatile, which may have affected the prices listed

below.

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<b>Year ended June 30, 2007</b>	<b>High</b>	<b>Low</b>
First quarter	\$ 3.50	\$ 2.75
Second quarter	6.00	3.00
Third quarter	4.90	3.80
Fourth quarter	5.18	3.51

<b>Year ended June 30, 2006</b>	<b>High</b>	<b>Low</b>
First quarter	\$ 5.95	\$ 1.00
Second quarter	8.25	4.50
Third quarter	7.25	6.20
Fourth quarter	6.40	3.25

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. On February 1, 2007, the Board of Directors declared a dividend on the Series B Preferred Stock of all outstanding and cumulative dividends through December 31, 2006. There is no Series A Preferred Stock outstanding. The total Series B dividends of \$38,458 were paid on February 15, 2007. The Company does not plan on paying any cash dividends on the Series B Preferred Stock in the foreseeable future.

As of September 4, 2007, we had approximately 880 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. Each of the Plans has subsequently been amended. 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 American Stock Exchange or the OTC Bulletin Board) on the date of the grant, and with varying vesting periods as determined by the Board.

As of June 30, 2007, the following options had been granted under the option plans.

<b>Plan Category</b>	<b>Number of securities to be issued on exercise of outstanding options, warrants and rights</b>	<b>Weighted-average exercise price of outstanding options, warrants and rights</b>	<b>Number of securities remaining available for future issuance under equity compensation plans</b>
	<b>#</b>	<b>\$</b>	
Equity compensation plans approved by shareholders	N/A	N/A	N/A
Equity compensation plans not approved by shareholders	3,683,439	\$ 2.86	259,778

Total	3,683,439	\$	2.86	259,778
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Sales of Unregistered Securities

All sales of unregistered securities were previously reported.

**ITEM 6 - MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION**Critical Accounting Policies and Estimates

Management's discussion and analysis of the Company's financial condition and results of operations is 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.

Short-Term Investments

The Company invests certain excess cash in marketable securities consisting primarily of commercial paper, auction rate securities, and money market funds. The Company classifies all debt securities as "available-for-sale" and records the debt securities at fair value with unrealized gains and losses included in shareholders' equity.

The Company's short-term investments consisted of the following at June 30, 2007 and 2006:

	2007	2006
Municipal debt securities	\$ 3,000,000	\$ —
Corporate debt securities	6,942,840	—
	\$ 9,942,840	\$ —

At June 30, 2007, all of the Company's corporate debt securities mature within fiscal year 2008. All municipal debt consists of auction rate securities that may have maturity dates exceeding 5 years, however, they reset each month. Based on the frequency of the auction reset periods, the fair market value approximates cost.

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 or market. Cost of raw materials is determined using the weighted average method. Cost of work in process and finished goods is computed using standard cost, which approximates actual cost, on a first-in, first-out basis. As the Company has had minimal gross margin throughout the past fiscal years, inventories have generally been recorded at market or net realizable value.

### Fixed Assets

Fixed assets are carried at the lower of cost or net realizable value. Production equipment with a cost of \$2,500 or greater and other fixed assets with a cost of \$1,500 or greater are capitalized. Major betterments that extend the useful lives of assets are also capitalized. Normal maintenance and repairs are charged to expense as incurred. When assets are sold or otherwise disposed of, the cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized in operations.

Depreciation is computed using the straight-line method over the following estimated useful lives:

Production equipment	3 to 7 years
Office equipment	2 to 5 years
Furniture and fixtures	2 to 5 years

Leasehold improvements and capital lease assets are amortized over the shorter of the life of the lease or the estimated life of the asset.

The Company has adopted the provisions of Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. The provisions of SFAS No. 144 require that an impairment loss be recognized when the estimated future cash flows (undiscounted and without interest) expected to result from the use of an asset are less than the carrying amount of the asset. Measurement of an impairment loss is based on the estimated fair value of the asset if the asset is expected to be held and used.

Management of the Company periodically reviews the net carrying value of all of its equipment on an asset by asset basis. These reviews consider the net realizable value of each asset, as measured in accordance with the preceding paragraph, to determine whether an impairment in value has occurred, and the need for any asset impairment write-down.

Although management has made its best estimate of the factors that affect the carrying value based on current conditions, it is reasonably possible that changes could occur which could adversely affect management's estimate of net cash flows expected to be generated from its assets, and necessitate asset impairment write-downs.

### Deferred Financing Costs

Financing costs related to the acquisition of debt are deferred and amortized over the term of the related debt using the effective interest method. Deferred financing costs include the fair value of common shares issued to certain shareholders for their guarantee of certain Company debt in accordance with APB 21 and EITF Issue 95-13. The value of the shares issued was the estimated market price of the shares as of the date of issuance. Amortization of deferred financing costs, totaling \$178,633 and \$296,608 for the years ended June 30, 2007 and 2006, respectively, is included in financing expense on the statements of operations.



The Company's deferred financing costs consisted of the following at June 30, 2007 and 2006:

	2007	2006
<b>Value of shares issued to guarantors:</b>		
Benton-Franklin Economic Development District (83,640 shares)	\$ 138,006	\$ 138,006
Columbia River Bank line of credit (127,500 shares)	–	210,375
Benton-Franklin Economic Development District loan fees	3,450	3,450
Columbia River Bank line of credit loan fees	–	500
Convertible debentures issuance costs	–	30,047
Hanford Area Economic Investment Fund Committee loan fees	22,128	22,128
Less amortization	(67,859)	(130,148)
	<b>\$ 95,725</b>	<b>\$ 274,358</b>

In June 2007, the Company elected not to renew its line of credit with Columbia River Bank due to the Company's current cash position. The Company wrote off the remaining net deferred financing charges of \$98,409 relating to this line of credit.

#### Licenses

Amortization of licenses is computed using the straight-line method over the estimated economic useful lives of the assets. In fiscal year 2006, the Company entered into an agreement with IBt, SA, a Belgian company (IBt) to use IBt's proprietary "Ink Jet" production process and its proprietary polymer seed technology for use in brachytherapy procedures using Cs-131. The Company paid license fees of \$275,000 during fiscal year 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 incorporating the technology 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. The IBt license is being amortized over the 15-year term of the license agreement.

In the fourth quarter of fiscal year 2007, the Company reviewed the carrying values of licenses. 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 license agreement and other business arrangements.

Amortization of licenses was \$23,426 and \$20,530 for the years ended June 30, 2007 and 2006, respectively. Based on the licenses recorded at June 30, 2007, and assuming no subsequent impairment of the underlying assets, the annual amortization expense for each fiscal year ending June 30, is expected to be as follows: \$30,795 for 2008, \$18,770 for 2009, \$18,481 for 2010, \$18,333 for 2011, \$18,333 for 2012, and \$157,363 thereafter.

#### Other Assets

Other assets, which include deferred charges and patents, are stated at cost, less accumulated amortization. Amortization of patents is computed using the straight-line method over the estimated economic useful lives of the assets. The Company periodically reviews the carrying values of patents and any impairments are recognized when the expected future operating cash flows to be derived from such assets are less than their carrying value.

Based on the patents and other intangible assets recorded in other assets at June 30, 2007, and assuming no subsequent impairment of the underlying assets, the annual amortization expense for each fiscal year ending June 30, is expected to be as follows: \$30,155 for 2008, \$2,632 for 2009, \$2,632 for 2010, \$2,632 for 2011, \$2,632 for 2012, and \$12,192

thereafter.

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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 they are 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.

In fiscal year 2006, the Company 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 and property leases. This amount was determined based on discussions with qualified production personnel and on historical evidence. During fiscal year 2007, the Company reevaluated its obligations based on discussions with the Washington Department of Health and determined that the initial asset retirement obligation should be increased by an additional \$56,120. The Company anticipates spending most of the amounts represented by this accrual in fiscal year 2008. In addition, another asset retirement obligation will be established in the first quarter of fiscal year 2008 representing obligations at its new production facility. This new asset retirement obligation will be for obligations to remove any residual radioactive materials and to remove any unwanted leasehold improvements.

During the years ended June 30, 2007 and 2006, the asset retirement obligation changed as follows:

	2007	2006
Beginning balance	\$ 67,425	\$ —
New obligations	—	63,040
Changes in estimates of existing obligations	56,120	—
Accretion of discount	7,597	4,385
Ending balance	\$ 131,142	\$ 67,425

Financial Instruments

The Company discloses the fair value of financial instruments, both assets and liabilities, recognized and not recognized in the balance sheet, for which it is practicable to estimate the fair value. The fair value of a financial instrument is the amount at which the instrument could be exchanged in a current transaction between willing parties, other than a forced liquidation sale.

The carrying amounts of financial instruments, including cash and cash equivalents; short-term investments; accounts receivable; accounts payable; notes payable; capital lease obligations; and convertible debentures payable, approximated their fair values at June 30, 2007 and 2006.

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*, that 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) collectability is reasonably assured.



Revenue for the fiscal years ended June 30, 2007 and 2006 was derived solely from sales of the Proxcelan Cs-131 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. Although the Company does not have an extensive operating history upon which to develop sales returns estimates, we have used the expertise of our management team, particularly those with extensive industry experience and knowledge, to develop a proper methodology for estimating returns.

### Stock-Based Compensation

Prior to July 1, 2006, the Company accounted for share-based employee compensation, including stock options, using the method prescribed in Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* and related interpretations (APB 25). Under APB 25, for stock options granted at market price, no compensation cost was recognized and a disclosure was made regarding the pro forma effect on net earnings assuming compensation cost had been recognized in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123). On December 16, 2004, the Financial Accounting Standards Board issued SFAS No. 123 (Revised 2004), *Share Based Payment* (SFAS 123R), which requires companies to measure and recognize expense for all share-based payments at fair value. SFAS 123R eliminates the ability to account for share-based compensation transactions using APB 25 and generally requires that such transactions be accounted for using prescribed fair-value-based methods. SFAS 123R permits public companies to adopt its requirements using one of two methods: (a) a “modified prospective” method in which compensation costs are recognized beginning with the effective date based on the requirements of SFAS No. 123R for all share-based payments granted or modified after the effective date, and based on the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date or (b) a “modified retrospective” method which includes the requirements of the modified prospective method described above, but also permits companies to restate based on the amounts previously recognized under SFAS No. 123 for purposes of pro forma disclosures either for all periods presented or for prior interim periods of the year of adoption. Effective July 1, 2006, the Company adopted SFAS 123R using the modified prospective method. No share-based employee compensation cost was reflected in the statement of operations prior to the adoption of SFAS No. 123R. Results for prior periods have not been restated.

The following table presents the share-based compensation expense recognized in accordance with SFAS 123R during the year ended June 30, 2007 and in accordance with APB 25 during the year ended June 30, 2006:

	Year ended June 30,	
	2007	2006
Cost of product sales	\$ 120,710	\$ —
Research and development	41,481	—
Sales and marketing	216,432	—
General and administrative	1,449,491	—
Total share-based compensation	\$ 1,828,114	\$ —

The total value of the stock options awards is expensed ratably over the service period of the employees receiving the awards. As of June 30, 2007, total unrecognized compensation cost related to stock-based options and awards was \$1,707,843 and the related weighted-average period over which it is expected to be recognized is approximately 1.23 years.

### Research and Development Costs

Research and development costs, including salaries, research materials, administrative expenses and contractor fees, are charged to operations as incurred. The cost of equipment used in research and development activities that has alternative uses is capitalized as part of fixed assets and not treated as an expense in the period acquired. Depreciation of capitalized equipment used to perform research and development is classified as research and development expense in the year computed.

### 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, environmental matters, and a variety of other matters. The Company is also 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 or compliance issues, the Company believes that when it relocates its production facilities then certain decommissioning expenses will be incurred and has recorded an asset retirement obligation for these expenses.

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 probable 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.

### Income Taxes

Income taxes are accounted for under the liability method. Under this method, the Company provides deferred income taxes for temporary differences that will result in taxable or deductible amounts in future years based on the reporting of certain costs in different periods for financial statement and income tax purposes. This method also requires the recognition of future tax benefits such as net operating loss carryforwards, to the extent that realization of such benefits is more likely than not. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment of the change.

### Income (Loss) Per Common Share

The Company accounts for its income (loss) per common share according to SFAS No. 128, *Earnings Per Share*. Under the provisions of SFAS No. 128, primary and fully diluted earnings per share are replaced with basic and diluted earnings per share. Basic earnings per share is calculated by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding, and does not include the impact of any potentially dilutive common stock equivalents. Common stock equivalents, including warrants to purchase the Company's common stock and common stock issuable upon the conversion of notes payable, are excluded from the calculations when their effect is antidilutive. At June 30, 2007 and 2006, the calculation of diluted weighted average shares does not include preferred stock, options, or warrants that are potentially convertible into common stock as those would be antidilutive due to the Company's net loss position.

Securities that could be dilutive in the future as of June 30, 2007 and 2006 are as follows:

	2007	2006
Preferred stock	59,065	144,759
Preferred stock warrants	–	179,512
Common stock warrants	3,627,764	2,502,769
Common stock options	3,683,439	3,129,692
Convertible debentures	–	109,639
<b>Total potential dilutive securities</b>	<b>7,370,268</b>	<b>6,066,371</b>

## **Results of Operations**

### **Financial Presentation**

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, 2007 and 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, 2007 compared to year ended June 30, 2006**

**Product sales.** Revenues for the year ended June 30, 2007 were \$5,738,033 compared to revenues of \$1,994,306 for the year ended June 30, 2006. The increase of \$3,743,727 or 188% is due to increased sales volume of the Company's Proxcelan (Cs-131) seed. All of the Company's revenues were generated through sales of its Proxcelan (Cs-131) seeds for the treatment of prostate cancer. The number of medical centers that purchased Proxcelan seeds during the fiscal year ended June 30, 2007 has grown to 59 as compared to 26 medical centers that ordered seeds in the fiscal year ended June 30, 2006.

**Cost of product sales.** Cost of product sales was \$5,792,630 for the year ended June 30, 2007 compared to cost of product sales of \$3,815,122 for the year ended June 30, 2006. The increase of \$1,977,508 or 52% was mainly due to higher production levels during the year ended June 30, 2007 which were related to the increase in sales volume over the corresponding period from 2006. The major components of the increase were wages, benefits and related taxes, materials, depreciation, preload expenses, and share-based compensation. Wages, benefits, and related taxes increased about \$753,000 for the year ended June 30, 2007 due to the hiring of additional production employees to support the higher production levels. Materials costs increased about \$201,000 due to increased sales volume. Depreciation and amortization expense increased about \$245,000 due to the addition of equipment that was placed in service in fiscal year 2006 or 2007. Preload expenses increased about \$301,000 due to higher sales volumes. Share-based compensation expense was about \$121,000 in fiscal year 2007 as the Company implemented SFAS No. 123R on July 1, 2006. These increases were partially offset by a decrease in payments to Pacific Northwest National Laboratory (PNNL). During part of fiscal year 2006, the Company used PNNL for manufacturing and other ancillary services. The Company stopped using PNNL to produce the seeds during fiscal year 2006 but continues to use PNNL for certain analytical support functions.

**Gross loss.** Gross loss for the year ended June 30, 2007 was \$54,597 compared to gross loss of \$1,820,816 for the year ended June 30, 2006. The decrease of \$1,766,219 or 97% was due to higher revenues offsetting fixed production costs and increased production efficiency.



**Research and development.** Research and development expenses for the year ended June 30, 2007 were \$1,345,163 which represents an increase of \$894,738 or 199% over the research and development expenses of \$450,425 for the corresponding period of 2006. The major components of the increase were wages, benefits and related taxes, consulting, legal expenses, share-based compensation, and protocol expenses. Wages, benefits and related taxes were approximately \$294,000 and \$77,000 for the years ended June 30, 2007 and 2006, respectively as the Company hired research scientists and associated personnel. Consulting expenses increased during 2007 due to a project to increase the efficiency of isotope production. The Company incurred approximately \$245,000 of legal expense related to patents and trademarks that were expensed. Share-based compensation expense was approximately \$41,000 and \$0 for the years ended June 30, 2007 and 2006, respectively, as the Company implemented SFAS No. 123R on July 1, 2006. Clinical study protocol expenses were approximately \$227,000 and \$116,000 for the years ended June 30, 2007 and 2006, respectively, due to payments to clinics for participation in the Company's protocols.

**Sales and marketing expenses.** Sales and marketing expenses were \$3,384,472 for the year ended June 30, 2007. This represents an increase of \$1,963,972 or 138% compared to the year ended June 30, 2006 sales and marketing expenses of \$1,420,500. Wages, benefits, payroll taxes, travel, and office and other support expenses on behalf of our sales, marketing, and customer service staff increased about \$1,100,000 due to the hiring of additional sales and marketing personnel. Conventions and tradeshow increased by about \$217,000 due to the Company's continued and expanding presence at these events in an effort to expand its market share. Marketing and advertising expenses increased about \$149,000 as the Company has created and distributed brochures, videos, and other promotional literature designed to promote the benefits of our product. Consulting expenses increased about \$151,000 due to consultants hired to assist with protocols, develop a branding strategy, and increase brand awareness. Share-based compensation expense was about \$216,000 in fiscal year 2007 as the Company implemented SFAS No. 123R on July 1, 2006.

**General and administrative expenses.** General and administrative expenses for the year ended June 30, 2007 were \$4,915,598 compared to general and administrative expenses of \$3,503,522 for the corresponding period of 2006. The increase of \$1,412,076 or 40% is primarily due to approximately \$1,449,000 of share-based compensation expense related to the implementation of SFAS No. 123R on July 1, 2006, approximately \$440,000 of increased payroll costs due to a higher headcount, and approximately \$243,000 relating to investor relations and other public company expenses. These increased expenses were partially offset by a reduction in consulting fees of approximately \$455,000 including \$330,000 which represented merger consulting fees incurred in the three months ended September 30, 2005. Other consulting fees were reduced as the Company used less external resources. Legal expenses and audit fees decreased approximately \$160,000 as the Company had more regulatory and other filings in fiscal year 2006 due to the merger, private placements, and registration statement filings.

**Operating loss.** Due to our rapid structural growth and related need to capture additional market share, product revenues not covering production costs, and significant research and development expenditures, we have not been profitable, and have generated operating losses since our inception. In the year ended June 30, 2007, the Company had an operating loss of \$9,699,830 which is an increase of \$2,504,567 or 35% over the operating loss of \$7,195,263 for the year ended June 30, 2006. Included in the operating loss for the year ended June 30, 2007 is share-based compensation of \$1,828,114 due to the implementation of SFAS No. 123R on July 1, 2006. Without the share-based compensation expense, our operating loss would have only increased by \$676,453 or 9%.

**Interest income.** Interest income was \$406,921 for the year ended June 30, 2007 compared to interest income of \$51,744 for the year ended June 30, 2006. Interest income is mainly derived from excess funds held in money market and investment accounts. The increase of \$355,177 or 686% was due to the additional cash and investment balances held by the Company due to the additional capital raised throughout the year ended June 30, 2007.



**Financing expense.** Financing expense for the year ended June 30, 2007 was \$312,246 or a decrease of \$376,854 or 55% from financing expense of \$689,100 for the corresponding period in 2006. Included in financing expense is interest expense of approximately \$134,000 and \$332,493 for the years ended June 30, 2007 and 2006, respectively. The decrease in interest expense is due to the conversion of debentures to common stock during the fiscal year ended June 30, 2006 partially offset by interest expense related to the Hanford Area Economic Investment Fund Committee (HAEIFC) loan that was entered into in June 2006. The remaining balance of financing expense represents the amortization of deferred financing costs which decreased due to the write-off in fiscal year 2006 of the deferred financing costs relating to the debentures that were converted to common stock, partially offset by the amortization of the HAEIFC deferred financing costs and the write-off in fiscal year 2007 of the deferred financing costs relating to the Columbia River Bank line of credit that the Company elected not to renew.

**Debt conversion expense.** Debt conversion expense for the year ended June 30, 2006 relates to the one-time recognition of \$385,511 expense in short-term inducement to convert debentures.

**Liquidity and capital resources.** We have historically financed our operations through cash investments from shareholders. During fiscal year 2007 our primary source of cash was an institutional round of financing (August 2006), a public direct equity offering (March 2007), and the exercise of common stock warrants and options and preferred stock warrants.

*Cash flows from operating activities*

Cash used in operating activities was \$7.3 million in fiscal year 2007 compared to \$7.0 million in fiscal year 2006, an increase of approximately \$300,000. Cash used by operating activities is net loss adjusted for non-cash items and changes in operating assets and liabilities. The increase is mainly related to an increase in net loss of approximately \$600,000. The large increase due to the higher accounts payable balance is partially offset by the large decrease related to higher inventory levels and mainly results from the accrual of approximately \$470,000 for the purchase of enriched barium in June 2007. This invoice was paid in July 2007. The remaining increase in accounts payable is due to higher production and operating levels.

*Cash flows from investing activities*

In 2007, the Company invested its excess cash generated from shareholder investments. During 2007, the Company purchased \$10.9 million of various short-term investments (mainly commercial paper and municipal auction rate securities). One of these investments valued at approximately \$1.0 million matured and was subsequently reinvested. As of June 30, 2007, short-term investments held by the Company amounted to \$9.9 million.

Cash expenditures for fixed assets were \$2.4 million in fiscal 2007 and \$475,000 in fiscal 2006. The large increase is mainly due to construction of our new facility and equipment purchases for the new facility. The Company expects to spend approximately \$4.0 to \$5.0 million during fiscal year 2008 for capital expenditures to complete the construction of our new facility and purchase other equipment.

*Cash flows from financing activities*

In August 2006, the Company completed an institutional round of financing. Pursuant to the round of institutional financing 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 common stock issued provided approximately \$4.7 million, net of offering costs. All of the warrants were exercised prior to the call date of March 26, 2007 which provided an additional \$6.8 million of cash.



In March 2007, the Company issued 4,130,500 shares of common stock at a price of \$4.00 per share, 826,100 common stock warrants with an exercise price of \$5.00 per share, and 206,526 common stock warrants representing placement agent warrants with an exercise price of \$4.40 per share. This public direct equity offering provided approximately \$15.1 million, net of offering costs.

Additionally, the Company issued 781,705 shares of common stock pursuant to the exercise of common stock options and warrants (excluding the warrants issued pursuant to the round of institutional financing) and preferred stock warrants, which were exchanged for common stock immediately upon exercise. The Company received approximately \$900,000 in cash pursuant to these exercises.

#### *Projected 2008 Liquidity and Capital Resources*

At June 30, 2007, cash and cash equivalents amounted to \$9,335,730 and short-term investments amounted to \$9,942,840 compared to \$2,207,452 of cash and cash equivalents at June 30, 2006.

The Company had approximately \$6.9 million of cash and \$10.1 million of short-term investments as of September 4, 2007. As of that date management believes that the Company's monthly required cash operating expenditures were approximately \$600,000. Management believes that approximately \$4.0 to \$5.0 million will be spent on capital expenditures during fiscal year 2008.

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.

During fiscal year 2008, the Company intends to continue its existing protocol studies as well as initiate new protocols for additional therapies. Due to this, the cost of protocols is currently budgeted to be about \$800,000 in fiscal year 2008.

Sales and marketing and general and administrative expenses are anticipated to increase about \$1.0 million during fiscal year 2008 mainly due to additional sales personnel and sales related activities.

Assuming operating costs expand proportionately with revenue increases, other applications are pursued for seed usage outside the prostate market, protocols are expanded supporting the integrity of our product and marketing expenses are increased, management believes the Company will reach breakeven with revenues of approximately \$2 million per month. Based on the foregoing assumptions, management believes cash, cash equivalents, and short-term investments on hand at June 30, 2007 will be sufficient to meet our anticipated cash requirements for operations, debt service, and capital expenditure requirements through at least the next twelve months. Management's plans to attain breakeven and generate additional cash flows include increasing revenues from both new and existing customers, developing additional therapies, and maintaining cost control. However, there can be no assurance that the Company will attain profitability or that the Company will be able to attain its aggressive revenue targets. If we do not experience the necessary increases in sales or if we experience unforeseen manufacturing constraints, we may need to obtain additional funding.

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.



*Long-Term Debt and Capital Lease Agreements*

IsoRay has two loan facilities in place as of June 30, 2007. The first 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, 2007, the principal balance owed was \$185,848. 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 second loan is from the Hanford Area Economic Investment Fund 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, 2007, the Company has taken only a partial draw of \$418,670 on the facility and the remaining facility of \$981,330 is available to purchase equipment. The principal balance owed on the loan as of June 30, 2007 was \$391,610. This loan is secured by receivables, equipment, materials and inventory, and certain life insurance policies and also required personal guarantees.

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, 2008 and also excuses non-compliance with covenants prohibiting fixed asset or 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 had a line of credit from Columbia River Bank, which provided credit in the amount of \$375,000. This line expired on March 1, 2007. Although the bank offered to extend this credit line, the Company elected to not extend the line of credit as part of its overall review of its banking and cash management relationships.

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 all capital lease obligations at June 30, 2007 was \$220,415.

Principal maturities on notes payable are due as follows:

Year ending June 30,	
2008	\$ 49,212
2009	53,609
2010	182,566
2011	38,436
2012	41,983
Thereafter	211,652
	\$ 577,458

Future minimum lease payments under capital lease obligations are as follows:

Year ending June 30,	
2008	\$ 214,269
2009	27,626
Total future minimum	241,895

lease payments Less amounts representing interest	(21,480)
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Present value of net minimum lease payments	220,415
Less amounts due in one year	(194,855)

Amounts due after one year	\$ 25,560
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*Other Commitments and Contingencies*

As of September 1, 2007, the Company had issued purchase orders for approximately \$681,000 of production and office equipment and inventory materials that were not yet received. The Company anticipates financing most of these purchases through its cash reserves.

On May 2, 2007, Medical entered into a lease for its new production facility with Energy Northwest, the owner of the Applied Process Engineering Laboratory (the APEL lease). The APEL lease has a three year term expiring on April 30, 2010, an option to renew for two additional three-year terms, and monthly rent of approximately \$26,700, subject to annual increases based on the Consumer Price Index, plus monthly janitorial expenses of approximately \$700. This new facility became operational in September 2007.

The Company's lease agreement with PEcoS IsoRay Radioisotope Laboratory (PIRL) is scheduled to expire in October 2007 but has been extended through December 2007 at a monthly rent of \$5,000.

Future minimum lease payments under operating leases including the two three-year renewals of the APEL lease are as follows:

Year ending		
June 30,		
2008	\$	372,118
2009		338,496
2010		338,354
2011		337,925
2012		328,749
Thereafter		1,260,206
	\$	2,975,848

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 Cs-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.

In September 2007, the Company entered into a letter of intent with IBt to enter into a Global Strategic Alliance incorporating various cooperative initiatives which will be the subject of a number of subsequent agreements and transactions. The proposed initiatives, each of which are subject to Board approval by each respective party, include:

§ An amendment to IsoRay's license agreement with IBt for use of its polymer seed technology whereby IsoRay would pay the remaining \$225,000 license fee but would not be subject to ongoing royalty payments. IsoRay would purchase polymer seed components at cost plus a profit margin to be determined.

§ The Company would grant IBt an exclusive license to distribute Cs-131 brachytherapy seeds in certain markets outside of North and South America, including the European Union.

§ The Company would receive the exclusive right to manufacture and distribute polymer I-125 brachytherapy seeds in North and South America.

§ The Company would also receive IBt's US subsidiary's customer list and the right to offer employment to certain IBt US employees.





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 or compliance issues, the Company believes that when it relocates its current production facilities then certain decommissioning expenses will be incurred. Therefore, the Company established in fiscal year 2006 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 and property leases. This amount was determined based on discussions with qualified production personnel and on historical evidence. During fiscal year 2007, the Company reevaluated its obligations based on discussions with the Washington Department of Health and determined that the initial asset retirement obligation should be increased by an additional \$56,120. The Company anticipates spending most of the amounts represented by this accrual in fiscal year 2008. In addition, another asset retirement obligation will be established in the first quarter of fiscal year 2008 representing obligations at its new production facility. This new asset retirement obligation will be for obligations to remove any residual radioactive materials and to remove any unwanted leasehold improvements.

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 has no off-balance sheet arrangements.

#### *Related Party Transactions*

The Company received legal services from a law firm in which Stephen Boatwright, a member of the Board of Directors, is one of the firm's partners. The total amounts paid in 2007 and 2006 to the law firm were \$458,534 and \$390,000, respectively. The 2007 amount includes approximately \$18,000 accrued in accounts payable as of June 30, 2007.

#### **Inflation**

Management does not believe that the current levels of inflation in the United States have had a significant impact on the operations of the Company. If current levels of inflation hold steady, management does not believe future operations will be negatively impacted.

### **New Accounting Standards**

In July 2006, the FASB issued Financial Accounting Standard Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48). FIN 48 is an interpretation of SFAS 109 and it seeks to reduce the diversity in practice associated with certain aspects of measurement and recognition in accounting for income taxes. In addition, FIN 48 requires expanded disclosure with respect to uncertainties in income taxes. The Company does not believe the adoption of FIN 48 on July 1, 2007 will have a material effect on its consolidated financial statements.

In September 2006, the FASB issued statement No. 157, Fair Value Measurements, (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007, with earlier application encouraged. Any amounts recognized upon adoption as a cumulative effect adjustment will be recorded to the opening balance of retained earnings in the year of adoption. The Company is currently evaluating the impact this statement will have on its financial statements.

In February 2007, the FASB issued statement No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115 (SFAS 159). The statement allows entities to value financial instruments and certain other items at fair value. The statement provides guidance over the election of the fair value option, including the timing of the election and specific items eligible for the fair value accounting. Changes in fair values would be recorded in earnings. The statement is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact this statement will have on its financial statements.

### **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., then 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 prior 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, 2007. 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) As previously reported, our independent registered public accounting firm, in connection with the review of our consolidated financial statements for the period ended September 30, 2005, 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 weaknesses to be significant deficiencies 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.

During the second quarter of fiscal year 2007, the Company completed the implementation of the following control improvements to remediate the two material weaknesses:

### ***Lack of segregation of duties***

- § Reviewed the duties of all accounting personnel and reassigned any conflicting duties to other personnel;
- § Established daily management reviews of cash and accounts receivable activities and positions;
- § Distributed monthly operating results for review by management in an appropriate time frame; and
- § Established monthly reconciliation procedures including review by the appropriate supervisor.

### ***Financial reporting procedures***

- § Established monthly reconciliation procedures including review by the appropriate supervisor;
- § Established and implemented various accounting policies and procedures; and
- § Distributed monthly operating results for review by management in an appropriate time frame.

Based on the evaluation completed in the fourth quarter of fiscal year 2007, the Company has concluded that these control improvements are properly designed and operating effectively as of June 30, 2007, and the two significant deficiencies that previously existed have been substantially remediated.

**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, 2007 that have not been already disclosed on a Form 8-K filed with the SEC.

**PART III****ITEM 9 – DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS, CONTROL PERSONS, AND CORPORATE GOVERNANCE; COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT**

Effective as of July 28, 2005 (the closing date of the Merger), 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), Robert Kauffman, and Dwight Babcock, and a Compensation Committee consisting of Dwight Babcock (Chairman) and Albert Smith. No other committees have been formed.

*Audit Committee*

The Audit Committee Charter was established on December 8, 2006. The Audit Committee Charter lists the purposes of the Audit Committee as overseeing the accounting and financial reporting processes of the Company and audits of the financial statements of the Company and providing assistance to the Board of Directors in monitoring (1) the integrity of the Company's financial statements, (2) the Company's compliance with legal and regulatory requirements, (3) the independent auditor's qualifications and independence, and (4) the performance of the Company's internal audit function, if any, and independent auditor.

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 each Audit Committee member is 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.

*Executive Officers and Directors*

The executive officers and directors serving the Company as of June 30, 2007 were as follows:

Name	Age	Position Held	Term*
Roger Girard	64	Chairman, President, CEO	Annual
Jonathan Hunt	40	Chief Financial Officer – Treasurer	
David Swanberg	51	Executive Vice President – Operations	Annual

		and Corporate Secretary, Director	
Lori Woods	45	Vice President	
Dwight Babcock	59	Director	Annual
Stephen Boatwright	43	Director	Annual
Robert Kauffman	66	Director	Annual
Thomas LaVoy	47	Director	Annual
Albert Smith	63	Director	Annual

\* For directors only

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Roger Girard – In addition to serving as President, Chairman and CEO for the Company, Mr. Girard is also the CEO, President and Chairman of the Board of IsoRay Medical, Inc., and has served in these positions since the formation of IsoRay Medical, Inc. Mr. Girard was CEO and Chairman of IsoRay's predecessor company from August of 2003 until October 1, 2004. Mr. Girard has been actively involved in the management and the development of the management team at IsoRay, and his experienced leadership has helped drive IsoRay's development to date. From June 1998 until August of 2003, Mr. Girard served as President of Strategic Financial Services, a business consulting company based in Seattle, Washington designed to help wealthy individuals and companies with strategic planning and financial strategy. Strategic Financial Services previously provided its services to another medical device company. Mr. Girard served as its sole employee. Mr. Girard also served as the managing partner for the Northwest office of Capital Consortium, another business consulting company based in Seattle, during this time. Capital Consortium employed four people and analyzed business market potential for start-ups and early stage companies. Mr. Girard has knowledge, experience and connections to private, institutional and public sources of capital and is experienced in managing and designing capital structures for business organizations as well as organizing and managing the manufacturing process, distribution, sales, and marketing, based on his 35 years of experience.

Jonathan Hunt – Mr. Hunt has over 10 years of finance and accounting experience, including financial reporting, SEC knowledge, and operational analysis. Before joining IsoRay, he was employed by Hypercom Corporation, a global provider of electronic payment solutions and manufacturer of credit card terminals, serving as its Assistant Corporate Controller from 2005 to 2006. His finance background also includes serving as both a Manager and Director of Financial Reporting and a Director of Operational Planning and Analysis for Circle K Corporation and its affiliates from 2000 to 2005 and working for PricewaterhouseCoopers LLP from 1992 to 1999 where his last position held was Business Assurance Manager. Mr. Hunt holds Masters of Accountancy and Bachelor of Science degrees from Brigham Young University and is a Certified Public Accountant.

David Swanberg - Mr. Swanberg has more than 22 years experience in engineering and materials science, nuclear waste and chemical processing, aerospace materials and processes, and environmental technology development and environmental compliance. Beginning in November 1995 and until January 2004, Mr. Swanberg was employed full time as Sr. Chemical/Environmental Engineer for Science Applications International Corporation working on a variety of projects including nuclear waste research and development. Mr. Swanberg joined IsoRay's predecessor company in March of 1999 on a part-time basis and has held management positions in the IsoRay companies since 2000. Mr. Swanberg began full-time employment with IsoRay in February 2004. He has been instrumental in development of IsoRay's initial product, the Cs-131 brachytherapy seed, including interfaces with technical, regulatory, and quality assurance requirements. With IsoRay and its predecessor companies, he has managed the development and production of radioactive seeds to support testing to meet NRC and FDA requirements, provided technical guidance for characterization of the IsoRay seed to meet AAPM Task Group 43 protocols, and coordinated production and testing of non-radioactive seeds to conform to ISO standards for brachytherapy devices. He is President of the Nuclear Medicine Research Council. He holds an MS in Chemical Engineering, is a licensed Chemical Engineer, and a certified Level II Radiation Worker.

Lori Woods – Ms. Woods joined the Company in July 2006 and has over 20 years experience in medical device technology and healthcare services. Ms. Woods served as the CEO of Pro-Qura, a medical services company focusing on brachytherapy quality assurance and education, from 2002 until joining the Company. During her tenure at Pro-Qura, Ms. Woods developed its business strategy, expanded its business portfolio in quality assurance beyond prostate brachytherapy into other areas of cancer, and increased funding by 50%. Prior to this, she served as the Vice President of Sales at ATI Medical in 2002, Vice President of Sales - West and Vice President of Marketing and Business Development for Imagyn Medical Technologies from 2000 to 2002, Director of Business Development for Seattle Prostate Institute from 1998 to 2000, and Regional Vice President and Regional Manager of Interdent from 1994 to 1998. Ms. Woods holds a Bachelor of Science degree in Business Administration - Marketing from Loma Linda University.





Dwight Babcock – Mr. Babcock has served as Chairman and Chief Executive Officer of Apex Data Systems, Inc. an information technology company, since 1975. Apex Data Systems automates the administration and claims adjudication needs of insurance companies both nationally and internationally. Mr. Babcock was formerly President and CEO of Babcock Insurance Corporation (BIC) from 1974 until 1985. BIC was a nationally recognized third party administrator operating within 35 states. Mr. Babcock has knowledge and experience in the equity arena and has participated in various activities within the venture capital, private and institutional capital markets. Mr. Babcock studied marketing and economics at the University of Arizona where he currently serves on the University of Arizona Astronomy Board.

Stephen Boatwright – Mr. Boatwright has been a member of Keller Rohrback, PLC in Phoenix, Arizona since 2005. From 1997 through 2005, Mr. Boatwright was a partner at Gammage & Burnham, PLC, also in Phoenix, Arizona. Throughout his career, he has provided legal counsel to both private and public companies in many diverse industries. In recent years, Mr. Boatwright’s legal practice has focused on representing technology, biotechnology, life science and medical device companies for their securities, corporate and intellectual property licensing needs. Mr. Boatwright earned both a J.D. and an M.B.A. from the University of Texas at Austin, and holds a B.A. in Philosophy from Wheaton College.

Robert Kauffman – Mr. Kauffman has served as Chief Executive Officer and Chairman of the Board of Alanco Technologies, Inc. (NASDAQ: ALAN), an Arizona-based information technology company, since July 1, 1998. Mr. Kauffman was formerly President and Chief Executive Officer of NASDAQ-listed Photocomm, Inc., from 1988 until 1997 (since renamed Kyocera Solar, Inc.). Photocomm was the nation’s largest publicly owned manufacturer and marketer of wireless solar electric power systems with annual revenues in excess of \$35 million. Prior to Photocomm, Mr. Kauffman was a senior executive of the Atlantic Richfield Company (ARCO) whose varied responsibilities included Senior Vice President of ARCO Solar, Inc., President of ARCO Plastics Company and Vice President of ARCO Chemical Company. Mr. Kauffman earned an M.B.A. in Finance at the Wharton School of the University of Pennsylvania, and holds a B.S. in Chemical Engineering from Lafayette College, Easton, Pennsylvania.

Thomas LaVoy – Mr. LaVoy has served as Chief Financial Officer of SuperShuttle International, Inc., since July 1997 and as Secretary since March 1998. SuperShuttle is one of the largest providers of shuttle services in major cities throughout the West and Southwest regions of the United States. He has also served as a director of Alanco Technologies, Inc. (NASDAQ: ALAN) since 1998. From September 1987 to February 1997, Mr. LaVoy served as Chief Financial Officer of NASDAQ-listed Photocomm, Inc. Mr. LaVoy was a Certified Public Accountant with the firm of KPMG Peat Marwick from 1980 to 1983. Mr. LaVoy has a Bachelor of Science degree in Accounting from St. Cloud University, Minnesota, and is a Certified Public Accountant.

Albert Smith – Mr. Smith was the co-founder of and served as Vice Chairman of CSI Leasing, Inc., a private computer leasing company from 1972 until March 2005. He founded Extreme Video, LLC a private video conferencing company in Scottsdale, Arizona in December 2005 where he presently serves as CEO and President. Mr. Smith presently serves as a director for Center for Arizona Policy (Scottsdale) and Doulos Ministries (Denver). Mr. Smith has extensive experience in marketing and sales having managed a national sales force of over fifty people while at CSI Leasing, Inc. Mr. Smith holds a BS in Business Administration from Ferris State College.

The Company’s directors, as named above, will serve until the next annual meeting of the Company’s shareholders or until their successors are duly elected and have qualified. Directors will be elected for one-year terms at the annual shareholders meeting. There is no arrangement or understanding between any of the directors or officers of the Company and any other person pursuant to which any director or officer was or is to be selected as a director or officer, and there is no arrangement, plan or understanding as to whether non-management shareholders will exercise their voting rights to continue to elect the current directors to the Company’s board. There are also no arrangements, agreements or understandings between non-management shareholders that may directly or indirectly participate in or influence the management of the Company’s affairs.



There are no agreements or understandings for any officer or director to resign at the request of another person, and none of the officers or directors are acting on behalf of, or will act at the direction of, any other person. There are no family relationships among our executive officers and directors.

*Significant Employees*

Certain significant employees of our subsidiary, IsoRay Medical, Inc., and their respective ages as of the date of this report are set forth in the table below. Also provided is a brief description of the experience of each significant employee during the past five years.

Name	Age	Position Held and Tenure
Fredric Swindler	59	VP, Regulatory Affairs and Quality Assurance
Lane Bray	79	Chemist
Oleg Egorov	37	Director of Research and Development

Fredric Swindler – Mr. Swindler joined the Company in October 2006 and has over 30 years experience in manufacturing and regulatory compliance. Mr. Swindler served as VP, Quality Assurance and Regulatory Affairs for Medisystems Corporation, a manufacturer and distributor of medical devices, from 1994 until joining the Company. During his tenure at Medisystems Corporation, Mr. Swindler developed a quality system to accommodate vertically integrated manufacturing, developed regulatory strategies, policies and procedures, and submitted nine pre-market notifications (510(k)) to the FDA. Prior to this, Mr. Swindler held various positions with Marquest Medical Products from 1989 to 1994, Sherwood Medical Products from 1978 to 1989, Oak Park Pharmaceuticals in 1978, and Mead Johnson & Company from 1969 to 1978. Mr. Swindler holds a Bachelor of Science degree in Biomedical Engineering from Rose Hulman Institute of Technology and a Masters of Business Administration from the University of Evansville.

Lane Bray – Mr. Bray is known nationally and internationally as a technical expert in separations, recovery, and purification of isotopes and is a noted authority in the use of cesium and strontium ion exchange for Department of Energy’s West Valley and Hanford nuclear waste cleanup efforts. In 2000, Mr. Bray received the ‘Radiation Science and Technology’ award from the American Nuclear Society. Mr. Bray has authored or co-authored over 110 research publications, 12 articles for 9 technical books, and holds 24 U.S. and foreign patents. Mr. Bray patented the USDOE/PNNL process for purifying medical grade Yttrium-90 that was successfully commercialized in 1999. Mr. Bray also recently invented and patented the proprietary isotope separation and purification process that is assigned to IsoRay. Mr. Bray was elected ‘Tri-Citizen of the Year’ in 1988, nominated for ‘Engineer of the Year’ by the American Nuclear Society in 1995, and was elected ‘Chemist of the Year for 1997’ by the American Chemical Society, Eastern Washington Section. Mr. Bray retired from the Pacific Northwest National Laboratory in 1998. Since retiring in 1998, Mr. Bray worked part time for PNNL on special projects until devoting all of his efforts to IsoRay in 2004. Mr. Bray has been a Washington State Legislator, a Richland City Councilman, and a Mayor of Richland. Mr. Bray has a B.A. in Chemistry from Lake Forest College.

Oleg Egorov – Dr. Egorov is recognized nationally and internationally for his work in radiochemistry, radioanalytical chemistry, analytical chemistry and instrumentation. Prior to joining IsoRay in December of 2005 as Director of Radiochemical Development and then Director of Research and Development, Dr. Egorov worked from May 1998 as a Senior Research Scientist at the Pacific Northwest National Laboratory (PNNL). Prior to that time, he served the Environmental Molecular Sciences Laboratory at PNNL as a Graduate Research Fellow from August 1994 to May 1998 and as a Graduate Research Assistant to the University of Washington’s Center for Process Analytical Chemistry from September 1992 to August 1993. Former positions included a tenure as a Research Engineer at the Department of Radiochemistry at the Moscow State University, Moscow, Russia between September 1998 to August 1992, and Field Chemist at the Institute of Volcanology, at the Russian Academy of Science at Petropavlovsk-Kamchatsky, Russia, during the summers of 1989 and 1990 concurrent to studies that lead to his acquisition of Master of Science in Radiochemistry from the Moscow State University. During his tenure at PNNL, Dr. Egorov had led world-class basic and applied R&D programs directed at new chemistries and instrumentation for automated production of short-lived medical isotopes for the treatment of cancer, automated process monitoring, radionuclide sensors for groundwater monitoring, and laboratory automation. Dr. Egorov pioneered the application of flow-based techniques for automating radiochemical analyses of nuclear wastes, renewable surface sensing and separations, and equilibration-based radionuclide sensing. He has authored/co-authored numerous peer-reviewed publications in these areas, including several book chapters. Dr. Egorov holds four U.S./international patents, three of which have been licensed to industry. Dr. Egorov has been a recipient of numerous outstanding performance and key contributor awards. In 2003, Dr. Egorov was nominated for the American Chemical Society Arthur F. Findeis Award for Achievements by a Young Analytical Scientist. In 2004, Dr. Egorov was a recipient of a Federal Laboratory Consortium Award for Excellence in Technology Transfer for “Alpha Particle Immunotherapy for Treating Leukemia and Solid-Tumor Metastases”. Dr. Egorov holds a M.S. in Radiochemistry from Moscow State University, Moscow, Russia; a M.S. in Environmental and Analytical Chemistry and a Ph.D. in Analytical Chemistry from the University of Washington.

#### Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 (the Exchange Act) requires the Company’s directors and executive officers, and persons who beneficially own more than ten percent of a registered class of our equity securities, to file with the Securities and Exchange Commission (the Commission) initial reports of beneficial ownership and reports of changes in beneficial ownership of our Common Stock. The rules promulgated by the Commission under Section 16(a) of the Exchange Act require those persons to furnish us with copies of all reports filed with the Commission pursuant to Section 16(a). The information in this section is based solely upon a review of Forms 3, Forms 4, and Forms 5 received by us.

We believe that IsoRay’s executive officers, directors and 10% shareholders timely complied with their filing requirements during the year ended June 30, 2006 except as follows: David Swanberg (two Form 4s). We believe all of these forms have been filed as of the date of this Report.

#### Code of Ethics

We have adopted a Code of Conduct and Ethics that applies to all of our officers, directors and employees and a separate Code of Ethics for Chief Executive Officer and Senior Financial Officers that supplements our Code of Conduct and Ethics. The Code of Conduct and Ethics was previously filed as Exhibit 14.1 to our Form 10-KSB for the period ended June 30, 2006, and the Code of Ethics for Chief Executive Officer and Senior Financial Officers was previously filed as Exhibit 14.2 to this same report. The Code of Ethics for Chief Executive Officer and Senior Financial Officers is also available to the public on our website at <http://www.isoray.com/ethicsForCeo.htm>. Each of these policies comprises written standards that are reasonably designed to deter wrongdoing and to promote the behavior described in Item 406 of Regulation S-B promulgated by the Securities and Exchange Commission.

#### Nominating Procedures

There have been no material changes to the procedures by which our shareholders may recommend nominees to the Board of Directors during our last fiscal year.

**ITEM 10 – EXECUTIVE COMPENSATION**

The following summary compensation table sets forth information concerning compensation for services rendered in all capacities during our past two fiscal years awarded to, earned by or paid to each of the following individuals. Salary and other compensation for these officers are set by the Compensation Committee of the Board of Directors.

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### Summary Compensation Table

Name and principal position	Year	Salary (\$)	Bonus (\$)	Stock awards (\$)	Option	Nonequity	Nonqualified	All other	Total (\$)
					awards (\$)	incentive	plan	compensation	
				(1)	(2)	(3)	(4)		
Roger Girard, Chairman and CEO (2)	2007	298,042	-	-	600,500	-	-	-	898,542
	2006	199,231	-	-	-	-	-	-	199,231
David Swanberg, Executive Vice President - Operations (2) (3)	2007	161,539	-	-	372,228	-	-	-	533,767
	2006	120,000	25,000	-	79,500	-	-	-	224,500
Lori Woods, Vice President (4)	2007	155,692	-	-	327,150	-	-	-	482,842
	2006	-	-	-	-	-	-	-	-
Jonathan Hunt, Chief Financial Officer (5)	2007	120,000	-	-	205,650	-	-	24,266	349,916
	2006	60,000	-	-	58,512	-	-	-	118,512
Michael Dunlop, former Chief Financial Officer (6)	2007	30,660	-	-	-	-	-	288,000	318,660
	2006	80,167	-	-	79,500	-	-	-	159,667

- (1) Amounts represent the FAS 123R valuation for the fiscal year ended June 30, 2007 and 2006, respectively. All such options were awarded under one of the Company's stock option plans. All options awarded (with the exception of Mr. Swanberg's and Mr. Dunlop's fiscal year 2006 stock option grants that were immediately vested on the grant date) vest in three equal annual installments beginning with the first anniversary from the date of grant and expire ten years after the date of grant. All options were granted at the fair market value of the Company's stock on the date of grant and the Company used a Black-Scholes methodology as discussed in the footnotes to the financial statements to value the options.
- (2) Mr. Girard and Mr. Swanberg were granted 150,000 and 100,000 options, respectively, on June 1, 2007. These options have an exercise price of \$4.14 and vest over 3 years. On July 25, 2007, the Board discussed the issue of director compensation and each director (including Mr. Girard and Mr. Swanberg) elected to cancel 50,000 of their options from the June 1, 2007 grant. After the cancellation, Mr. Girard and Mr. Swanberg had 100,000 and 50,000 options, respectively, from the June 1, 2007 grant. The terms of these options were not changed as part of the cancellation. Under FAS 123R, the value of the cancelled options to Mr. Girard and Mr. Swanberg were \$128,500 each. The value of these options has been included in the table above.
- (3) The value of Mr. Swanberg's options includes \$7,728 relating to options granted to his wife who is also an employee of the Company.
- (4) Ms. Woods became an employee of the Company on July 5, 2006.
- (5) Mr. Hunt became an employee of the Company on May 1, 2006. The Company reimbursed Mr. Hunt for certain of his relocation costs and this amount is included in the "All other compensation" column for fiscal year 2007.
- (6) Mr. Dunlop left the Company in September 2006. As part of his employment agreement, Mr. Dunlop was entitled to a severance payment of \$288,000 and this amount is included in the "All other compensation" column.

Mr. Girard and Ms. Woods, have employment contracts with the Company. Mr. Swanberg had an employment agreement with the Company's subsidiary that expired on September 1, 2007. The Company and Mr. Swanberg are negotiating terms for a new employment agreement as of the date of this report.



Mr. Girard's employment agreement is dated October 6, 2005 and expires on October 6, 2009. The agreement will be automatically extended at the end of the fourth year for one year on each anniversary date unless the agreement is modified at least 90 days prior to the anniversary date. Effective July 1, 2006, the agreement calls for an annual salary of \$300,000 with increases as determined by the Compensation Committee of the Board and a bonus plan as determined by the Board. Under the terms of the agreement, if Mr. Girard is terminated without cause or he terminates his employment for good reason then he is entitled to receive his continued salary and benefits for a one year period. Good reason is defined in the agreement to mean a reduction of salary or benefits, a change in Mr. Girard's title, position, authority, or responsibilities, or any breach by the Company of this agreement. In the event of disability, Mr. Girard is entitled to his continued salary and benefits for a one year period. The agreement also includes certain restrictive covenants that prohibit Mr. Girard from providing services to a competing business for the period of this agreement plus one year.

Mr. Swanberg's employment agreement was with IsoRay Medical, Inc. and was dated September 1, 2004. The agreement had a term of three years and expired on September 1, 2007. Mr. Swanberg is due \$50,000 under this agreement as a bonus from August 2007.

Ms. Woods' employment agreement dated February 14, 2007, is for an initial term of two years but will be automatically extended for an additional year on each anniversary date unless terminated in accordance with the provisions of the agreement. The agreement entitles Ms. Woods to a salary of at least \$160,000 with increases as determined by the Compensation Committee of the Board and annual bonus payments under a bonus plan as established by the Compensation Committee. In the event that Ms. Woods is terminated without cause, becomes disabled, or terminates her employment for good reason, she will be entitled to her salary and benefits for the remaining term of the agreement or 18 months, whichever is shorter. Good reason is defined in the agreement to mean a reduction of salary or benefits, a change in Ms. Woods' title, position, authority, or responsibilities, causing Ms. Woods to relocate, or any breach by the Company of this agreement. If Ms. Woods is terminated within one year of a change of control then she shall be entitled to her salary and benefits for the remaining term of the agreement or 18 months, whichever is longer, in addition to a one-time payment equal to her most recently received bonus. In the event of Ms. Woods' termination without cause or termination within one year of a change of control, all of her unvested stock options shall immediately vest in full and shall be exercisable as provided in the applicable stock option plan. The agreement also includes certain restrictive covenants that prohibit Ms. Woods from providing services to a competing business for the period of this agreement plus one year.



### Outstanding Equity Awards at Fiscal Year-End

Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option awards Equity incentive plan awards:		
			Number of securities underlying unexercised unearned options (#)	Option exercise price (\$)	Option expiration date
Roger Girard, Chief Executive Officer (Principal Executive Officer)	513,840	-	-	1.19	8/1/2015
	-	100,000 <sup>(1)</sup>	-	3.11	8/15/2016
	-	150,000 <sup>(2)</sup>	-	4.14	6/1/2017
David Swanberg, Executive Vice President - Operations	150,000	-	-	1.00	8/18/2015
	-	50,000 <sup>(1)</sup>	-	3.11	8/15/2016
	-	100,000 <sup>(2)</sup>	-	4.14	6/1/2017
Lori Woods, Vice President	-	50,000 <sup>(3)</sup>	-	3.50	7/5/2016
	-	50,000 <sup>(4)</sup>	-	3.10	10/17/2016
	-	15,000 <sup>(5)</sup>	-	4.40	3/2/2017
	-	20,000 <sup>(6)</sup>	-	4.14	6/1/2017
Jonathan Hunt, Chief Financial Officer		<sup>(7)</sup>			
	10,000	20,000	-	5.50	5/1/2016
	-	50,000 <sup>(4)</sup>	-	3.10	10/17/2016
	-	15,000 <sup>(5)</sup>	-	4.40	3/2/2017
	-	20,000 <sup>(6)</sup>	-	4.14	6/1/2017
Michael Dunlop, former Chief Financial Officer	-	-	-	-	-

(1) Represents the August 15, 2006 grant, one-third of which became exercisable on August 15, 2007, one-third of which will become exercisable on August 15, 2008, and the final third will become exercisable on August 15, 2009.

(2) Mr. Girard and Mr. Swanberg were granted 150,000 and 100,000 options, respectively, on June 1, 2007. These options have an exercise price of \$4.14 and vest over 3 years. On July 25, 2007, the Board discussed the issue of director compensation and each director (including Mr. Girard and Mr. Swanberg) elected to cancel 50,000 of their options from the June 1, 2007 grant. After the cancellation, Mr. Girard and Mr. Swanberg had 100,000 and 50,000 options, respectively, from the June 1, 2007 grant. The terms of these options was not changed as part of the cancellation. These cancelled options have been included in the table above as they were outstanding on June 30, 2007.

(3) Represents a July 5, 2006 grant, one-third of which became exercisable on July 1, 2007, one-third of which will become exercisable on July 1, 2008, and the final third will become exercisable on July 1, 2009.

(4) Represents the October 17, 2006 grant, one-third of which will become exercisable on October 17, 2007, one-third of which will become exercisable on October 17, 2008, and the final third will become exercisable on October 17, 2009.

(5)

- Represents the March 2, 2007 grant, one-third of which will become exercisable on March 2, 2008, one-third of which will become exercisable on March 2, 2009, and the final third will become exercisable on March 2, 2010.
- (6) Represents the June 1, 2007 grant, one-third of which will become exercisable on June 1, 2008, one-third of which will become exercisable on June 1, 2009, and the final third will become exercisable on June 1, 2010.

(7) Represents the final two-thirds vesting of a May 1, 2006 grant, half of which will become exercisable on May 1, 2008 and the other half will become exercisable on May 1, 2009.

The Company has a 401(k) plan that commenced in fiscal year 2007. The 401(k) plan covers all eligible full-time employees of the Company. Contributions to the 401(k) plan are made by participants to their individual accounts through payroll withholding. Additionally, the 401(k) plan provides for the Company to make contributions to the 401(k) plan in amounts at the discretion of management. The Company has not made any contributions to the 401(k) plan and does not maintain any other retirement plans for its executives or employees.

### Non-Employee Director Compensation

Name	Fees earned or paid in cash (\$)		Option awards (\$)		Non-equity incentive plan compensation (\$)	Non-qualified deferred compensation earnings (\$)	All other compensation (\$)	Total (\$)
	(1)	Stock awards (\$)	(2)	(3)	(4)	(5)	(6)	
Dwight Babcock	8,000	-	236,000	-	-	-	-	244,000
Stephen Boatwright	8,000	-	236,000	-	-	-	-	244,000
Robert Kauffman	8,000	-	236,000	-	-	-	-	244,000
Thomas LaVoy	7,000	-	236,000	-	-	-	-	243,000
Albert Smith	7,000	-	236,000	-	-	-	-	243,000

- (1) In fiscal year 2007, each non-employee director received cash compensation of \$1,000 per meeting attended. Beginning in fiscal year 2008, each non-employee director will receive cash compensation of \$3,000 per month, except for Mr. Boatwright who will receive \$1,000 per month. In addition, each non-employee director will receive \$1,000 per Board meeting attended in person or \$500 per Board meeting attended via telephone and \$500 per committee meeting attended.
- (2) This represents the value determined in accordance with FAS 123R for the option grant of August 15, 2006. Each non-employee director also received a grant of 50,000 options with an exercise price of \$4.14 per share on June 1, 2007. After a discussion of director compensation with the entire Board, each Board member elected to cancel their June 1, 2007 option grant on July 25, 2007 in exchange for the additional cash compensation discussed in (1) above. Under FAS 123R, these options were valued at \$128,500 per director. The value of these options has been included in the table above and in the financial statements as they were fully vested on the day of grant.
- (3) Each director had stock options to purchase 200,000 shares of the Company's common stock outstanding as of June 30, 2007 including the June 1, 2007 grant (for 50,000 shares per director) that was subsequently cancelled on July 25, 2007.

### ITEM 11 – SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following tables set forth certain information regarding the beneficial ownership of the Company's common stock and preferred stock as of September 12, 2007 for (a) each person known by the Company to be a beneficial owner of five percent or more of the outstanding common or preferred stock of the Company, (b) each executive officer, director and nominee for director of the Company, and (c) directors and executive officers of the Company as a group. As of September 12, 2007, the Company had 23,033,108 shares of common stock and 59,065 shares of preferred stock outstanding.

**Common Stock Share Ownership**

Name of Beneficial Owner	Common Shares Owned	Common Stock Options Exercisable Within 60 Days	Common Warrants	Percent of Class (1)
Roger Girard	368,534	547,173	-	3.98%
David Swanberg (2)	324,327	179,999	5,500	2.21%
Lori Woods	3,000	33,332	-	—%
Jonathan Hunt	-	26,666	-	—%
Michael Dunlop	195,050	-	-	—%
Dwight Babcock (3)	61,002	150,000	12,500	—%
Stephen Boatwright (4)	60,000	150,000	-	—%
Robert Kauffman	43,802	150,000	-	—%
Thomas LaVoy	8,423	150,000	-	—%
Albert Smith	108,947	150,000	12,500	1.18%
Directors and Executive Officers as a group	1,173,085	1,537,170	30,500	11.90%

- (1) Percentage ownership is based on 23,033,108 shares of Common Stock outstanding on September 12, 2007. Shares of Common Stock subject to stock options which are currently exercisable or will become exercisable within 60 days after September 12, 2007 are deemed outstanding for computing the percentage ownership of the person or group holding such options, but are not deemed outstanding for computing the percentage ownership of any other person or group.
- (2) Mr. Swanberg's options include 13,333 options granted to his spouse.
- (3) Mr. Babcock's common shares owned include 2,695 shares owned by his spouse.
- (4) Mr. Boatwright's common shares owned are held by an entity controlled by Mr. Boatwright.

**Preferred Stock Share Ownership**

Name of Beneficial Owner	Preferred Shares Owned	Percent of Class (1)
Aissata Sidibe (2)	20,000	33.86%
William and Karen Thompson Trust (3)	14,218	24.07%
Jamie Granger (4)	10,529	17.83%
Hostetler Living Trust (5)	9,479	16.05%
Leslie Fernandez (6)	3,688	6.24%

- (1) Percentage ownership is based on 59,065 shares of Preferred Stock outstanding on September 12, 2007.
- (2) The address of Ms. Sidibe is 229 Lasiandra Ct, Richland, WA 99352.
- (3) The address of the William and Karen Thompson Trust is 285 Dondero Way, San Jose, CA 95119.
- (4) The address of Jamie Granger is 53709 South Nine Canyon Road, Kennewick, WA 99337.
- (5) The address of the Hostetler Living Trust is 9257 NE 175th Street, Bothell, WA 98011.
- (6) The address of Leslie Fernandez is 2615 Scottsdale Place, Richland, WA 99352.

No officers or directors beneficially own shares of Preferred Stock.

## **ITEM 12 – CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE**

IsoRay Medical, Inc.'s patent rights to its Cs-131 process were acquired from Lane Bray, a shareholder and employee of the Company, and are subject to a 1% royalty on gross profits and certain contractual restrictions. Pursuant to the royalty agreement, the Company must also pay a royalty of 2% of Gross Sales, as defined, for any sub-assignments of the aforesaid patented process to any third parties. The royalty agreement will remain in force until the expiration of the patents on the assigned technology, unless earlier terminated in accordance with the terms of the underlying agreement. During fiscal year 2007, the Company achieved its first gross margin and began making quarterly payments to Mr. Bray as outlined in the royalty agreement. The Company recorded royalty expense of \$2,161 for fiscal year 2007 related to these payments.

On January 16, 2005, in addition to certain other shareholders, the following current and former officers and directors of the Company were awarded shares of common stock for guaranteeing a loan with the Benton Franklin Economic Development District (BFEDD) in the amount of \$230,000, which was funded in December 2004, and a line of credit with Columbia River Bank in the amount of \$395,000: Michael Dunlop guaranteed \$15,000 of the BFEDD loan and \$30,000 of the Columbia River Bank line of credit, for which he received 12,888 post-merger shares; Roger Girard guaranteed \$20,000 of the BFEDD loan, for which he received 5,728 post-merger shares; John Hrobsky guaranteed \$15,000 of the Columbia River Bank line of credit, for which he received 4,296 post merger shares; and David Swanberg guaranteed \$30,000 of the Columbia River Bank line of credit, for which he received 8,592 post-merger shares. During fiscal year 2006, certain original guarantors, including John Hrobsky, declined to continue guaranteeing the loans and forfeited the shares which had been granted to them. Due to this the following officers agreed to increase the amount of their guarantees as follows: Michael Dunlop guaranteed an additional \$5,000 of the Columbia River Bank line of credit, for which he received an additional 1,432 common shares; and Roger Girard guaranteed an additional \$105,000 of the Columbia River Bank line of credit, for which he received an additional 30,072 common shares.

Mr. Stephen Boatwright, a Company director, has been actively involved in providing various legal services to the Company and IsoRay Medical, Inc. through the law firm of Keller Rohrback, PLC. During the fiscal years ended June 30, 2007 and 2006, the Company paid Keller Rohrback, PLC approximately \$459,000 and \$390,000, respectively, for legal services. In addition, the Company had accrued at June 30, 2007 approximately \$18,000 in legal fees to be paid.

Certain members of management, including Roger Girard and David Swanberg, personally guaranteed a loan from HAEIFC, in exchange for which they have a contractual right to receive their pro rata portion of the 70,455 shares that will be issued to the guarantors of this loan.

On May 27, 2005, the Company, Century Park Transitory Subsidiary, Inc., a Delaware corporation, Thomas Scallen and Anthony Silverman (shareholders of the Company), and IsoRay Medical, Inc., a Delaware corporation, entered into a Merger Agreement. Pursuant to the Merger Agreement, Century Park Transitory Subsidiary, Inc. was merged with and into IsoRay Medical, Inc. and IsoRay Medical, Inc. became a wholly-owned subsidiary of the Company. The Merger Agreement was subject to the satisfaction of certain conditions, including the granting of certain "piggy-back" and demand registration rights to the purchasers of certain convertible debentures of IsoRay Medical, Inc., Anthony Silverman and certain other affiliates of the Company; the agreements of the officers and directors of IsoRay Medical, Inc. to lock-up the shares of common stock of the Company they received in the merger for a period of one year from the closing of the merger; the agreements of Thomas Scallen and Anthony Silverman to escrow certain shares of common stock of the Company; and the receipt by IsoRay Medical, Inc. from Anthony Silverman or his associates of one million dollars as the purchase price of certain securities of IsoRay Medical, Inc. before the closing. These conditions were satisfied prior to the closing of the merger, which occurred on July 28, 2005.



Patent and Know-How Royalty License Agreement

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 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. .

Director Independence

Using the standards of the American Stock Exchange, the Company's Board has determined that Mr. Babcock, Mr. Kauffman, Mr. LaVoy, and Mr. Smith each qualify under such standards as an independent director. Mr. Kauffman and Mr. LaVoy each meet the American Stock Exchange listing standards for independence both as a director and as a member of the Audit Committee, and Mr. Babcock and Mr. Smith each meet the American Stock Exchange listing standards for independence both as a director and as a member of the Compensation Committee. No other directors are independent under these standards. The Company did not consider any relationship or transaction between itself and these independent directors not already disclosed in this report in making this determination.

**ITEM 13 – EXHIBITS AND REPORTS ON FORM 8-K**

**(except as otherwise indicated, all exhibits were previously filed)**

<b>Exhibit #</b>	<b>Description</b>
2.1	Merger Agreement dated as of May 27, 2005, by and among Century Park Pictures Corporation, Century Park Transitory Subsidiary, Inc., certain shareholders and IsoRay Medical, Inc. incorporated by reference to the Form 8-K filed on August 3, 2005.
2.2	Certificate of Merger, filed with the Delaware Secretary of State on July 28, 2005 incorporated by reference to the Form 8-K filed on August 3, 2005.
3.1	Articles of Incorporation and By-Laws are incorporated by reference to the Exhibits to the Company's Registration Statement of September 15, 1983.
3.2	Certificate of Designation of Rights, Preferences and Privileges of Series A and B Convertible Preferred Stock, filed with the Minnesota Secretary of State on June 29, 2005 incorporated by reference to the Form 8-K filed on August 3, 2005.
3.3	Restated and Amended Articles of Incorporation incorporated by reference to the Form 10-KSB filed on October 11, 2005.
3.4	Text of Amendments to the Amended and Restated By-Laws of the Company, incorporated by reference to the Form 8-K filed on February 7, 2007.
4.2	Form of Lock-Up Agreement for Certain IsoRay Medical, Inc. Shareholders incorporated by reference to the Form 8-K filed on August 3, 2005.

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- 4.3 Form of Lock-Up Agreement for Anthony Silverman incorporated by reference to the Form 8-K filed on August 3, 2005.
- 4.4 Form of Registration Rights Agreement among IsoRay Medical, Inc., Century Park Pictures Corporation and the other signatories thereto incorporated by reference to the Form 8-K filed on August 3, 2005.
- 4.5 Form of Escrow Agreement among Century Park Pictures Corporation, IsoRay Medical, Inc. and Anthony Silverman incorporated by reference to the Form 8-K filed on August 3, 2005.



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- 4.6 Form of Escrow Agreement among Century Park Pictures Corporation, IsoRay Medical, Inc. and Thomas Scallen incorporated by reference to the Form 8-K filed on August 3, 2005.
- 4.7 Amended and Restated 2005 Stock Option Plan incorporated by reference to the Form S-8 filed on August 19, 2005.
- 4.8 Amended and Restated 2005 Employee Stock Option Plan incorporated by reference to the Form S-8 filed on August 19, 2005.
- 4.9 Form of Registration Right Agreement among IsoRay Medical, Inc., Meyers Associates, L.P. and the other signatories thereto, dated October 15, 2004, incorporated by reference to the Form SB-2 filed on November 10, 2005.
- 4.10 Form of Registration Rights Agreement among IsoRay, Inc., Meyers Associates, L.P. and the other signatories thereto, dated February 1, 2006, incorporated by reference to the Form SB-2/A1 filed on March 24, 2006.
- 4.11 Form of IsoRay, Inc. Common Stock Purchase Warrant, incorporated by reference to the Form SB-2/A1 filed on March 24, 2006.
- 4.12 2006 Director Stock Option Plan, incorporated by reference to the Form S-8 filed on August 18, 2006.
- 4.13 Form of Registration Rights Agreement among IsoRay, Inc. and the other signatories thereto, dated August 9, 2006, incorporated by reference to the Form 8-K filed on August 18, 2006.
- 4.14 Form of IsoRay, Inc. Common Stock Purchase Warrant, dated August 9, 2006, incorporated by reference to the Form 8-K filed on August 18, 2006.
- 4.15 Form of Registration Rights Agreement among IsoRay, Inc., Meyers Associates, L.P. and the other signatories thereto, dated October 17, 2005, incorporated by reference to the Form SB-2 filed on October 16, 2006.
- 4.16 Amended and Restated 2006 Director Stock Option Plan, incorporated by reference to the Form S-8/A1 filed on December 18, 2006.
- 4.17 Amended and Restated 2005 Stock Option Plan, incorporated by reference to the Form S-8/A1 filed on December 18, 2006.
- 4.18 Intentionally omitted.
- 4.19 Rights Agreement, dated as of February 1, 2007, between the Computershare Trust Company N.A., as Rights Agent, incorporated by reference to Exhibit 1 to the Company's Registration Statement on Form 8-A filed on February 7, 2007.
- 4.20 Certificate of Designation of Rights, Preferences and Privileges of Series C Junior Participating Preferred Stock, incorporated by reference to Exhibit 1 to the Company's Registration Statement on Form 8-A filed February 7, 2007.
- 10.2 Universal License Agreement, dated November 26, 1997 between Donald C. Lawrence and William J. Stokes of Pacific Management Associates Corporation, incorporated by reference to the Form SB-2 filed on November 10, 2005.
- 10.3 Royalty Agreement of Invention and Patent Application, dated July 12, 1999 between Lane A. Bray and IsoRay LLC, incorporated by reference to the Form SB-2 filed on November 10, 2005.
- 10.4 Tri-City Industrial Development Council Promissory Note, dated July 22, 2002, incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.
- 10.5 Section 510(k) Clearance from the Food and Drug Administration to market Lawrence CSERION Model CS-1, dated March 28, 2003, incorporated by reference to the Form SB-2 filed on November 10, 2005.
- 10.6

- Battelle Project No. 45836 dated June 20, 2003, incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.
- 10.7 Applied Process Engineering Laboratory APEL Tenant Lease Agreement, dated April 23, 2001 between Energy Northwest and IsoRay, LLC, incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.
- 10.8 Work for Others Agreement No. 45658, R2, dated April 27, 2004 between Battelle Memorial Institute, Pacific Northwest Division and IsoRay Products LLC, incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.
- 10.9 Development Loan Agreement for \$230,000, dated September 15, 2004 between Benton-Franklin Economic Development District and IsoRay Medical, Inc., incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.

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- 10.10 Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Sealed Source, dated September 17, 2004, incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.
- 10.11 CRADA PNNL/245, "Y-90 Process Testing for IsoRay", dated December 22, 2004 between Pacific Northwest National Laboratory and IsoRay Medical Inc., including Amendment No. 1, incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.
- 10.12 Intentionally Omitted
- 10.13 Amendment 1 to Agreement 45658, dated February 23, 2005 between Battelle Memorial Institute Pacific Northwest Division and IsoRay Medical, Inc., incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.
- 10.14 Equipment Lease Agreement dated April 14, 2005 between IsoRay Medical, Inc. and Nationwide Funding, LLC, incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.
- 10.15 Lease Agreement, Rev. 2, dated November 1, 2005 between Pacific EcoSolutions, Inc. and IsoRay Medical, Inc., incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.
- 10.16 Master Lease Agreement Number 5209, dated May 7, 2005 between VenCore Solutions LLC and IsoRay Medical, Inc., incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.
- 10.17 Contract #840/08624332/04031 dated August 25, 2005 between IsoRay, Inc. and the Federal State Unitary Enterprise << Institute of Nuclear Materials >>, Russia, incorporated by reference to the Form SB-2 filed on November 10, 2005.
- 10.18 State of Washington Radioactive Materials License dated October 6, 2005, incorporated by reference to the Form SB-2 filed on November 10, 2005.
- 10.19 Express Pricing Agreement Number 219889, dated October 5, 2005 between FedEx and IsoRay Medical, Inc., incorporated by reference to the Form 10-QSB filed on November 21, 2005.
- 10.20 Girard Employment Agreement, dated October 6, 2005 between Roger E. Girard and IsoRay, Inc., incorporated by reference to the Form 10-QSB filed on November 21, 2005.
- 10.21 Contract Modification Quality Class G, dated October 25, 2005 to Contract Number X40224 between Energy Northwest and IsoRay, Inc., incorporated by reference to the Form 10-QSB filed on November 21, 2005.
- 10.22 Agreement dated August 9, 2005 between the Curators of the University of Missouri and IsoRay Medical, Inc., incorporated by reference to the Form SB-2/A2 filed on April 27, 2006 (confidential treatment requested).
- 10.23 SICAV ONE Securities Purchase Agreement, dated December 7, 2005, by and between IsoRay, Inc. and Mercatus & Partners, Ltd., incorporated by reference to the Form 8-K filed on December 12, 2005.
- 10.24 SICAV TWO Securities Purchase Agreement, dated December 7, 2005, by and between IsoRay, Inc. and Mercatus & Partners, Ltd., incorporated by reference to the Form 8-K filed on December 12, 2005.
- 10.25 Economic Development Agreement, dated December 14, 2005, by and between IsoRay, Inc. and the Pocatello Development Authority, incorporated by reference to the Form 8-K filed on December 20, 2005.
- 10.26 License Agreement, dated February 2, 2006, by and between IsoRay Medical, Inc. and IBt SA, incorporated by reference to the Form 8-K filed on March 24, 2006 (confidential treatment requested).

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- 10.27 Benton Franklin Economic Development District Loan Covenant Waiver Letter, dated as of March 31, 2005, incorporated by reference to the Form SB-2/A3 filed on May 12, 2006.
- 10.28 Service Agreement between IsoRay, Inc. and Advanced Care Medical, Inc., dated March 1, 2006, incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.
- 10.29 Business Loan Agreement between IsoRay Medical, Inc. and Columbia River Bank, dated March 1, 2006, incorporated by reference to the Form SB-2/A4 filed on May 26, 2006.
- 10.30 Letter from HAEIFC to IsoRay Medical, Inc. dated April 26, 2006, incorporated by reference to the Form SB-2/A5 filed on June 6, 2006.

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- 10.31 Loan Agreement, dated June 15, 2006, by and between IsoRay Medical, Inc. and the Hanford Area Economic Investment Fund Committee, incorporated by reference to the Form 8-K filed on June 21, 2006.
- 10.32 Commercial Security Agreement, dated June 15, 2006, by and between IsoRay Medical, Inc. and the Hanford Area Economic Investment Fund Committee, incorporated by reference to the Form 8-K filed on June 21, 2006.
- 10.33 Common Stock and Warrant Purchase Agreement among IsoRay, Inc. and the other signatories thereto, dated August 9, 2006, incorporated by reference to the Form 8-K filed on August 18, 2006.
- 10.34 Benton Franklin Economic Development District Loan Covenant Waiver Letter, dated September 26, 2006, filed herewith.
- 10.35 Form of Officer and Director Indemnification Agreement, incorporated by reference to the Form SB-2 Post Effective Amendment No. 2 filed on October 13, 2006.
- 10.36 Contract No. 840/20553876/11806-32, dated October 6, 2006, by and between IsoRay Medical, Inc. and FSUE "SSC-Research Institute of Atomic Reactors," incorporated by reference to the Form 8-K filed on November 6, 2006 (confidential treatment requested for redacted portions).
- 10.37 Agreement for Exclusive Right to Buy, dated October 6, 2006, by and between IsoRay Medical, Inc. and FSUE "SSC-Research Institute of Atomic Reactors," incorporated by reference to the Form 8-K filed on November 6, 2006 (confidential treatment requested for redacted portions).
- 10.38 Form of Securities Purchase Agreement by and among IsoRay, Inc. and the Buyers dated March 22, 2007, incorporated by reference to the Form 8-K filed on March 23, 2007.
- 10.39 Form of Common Stock Purchase Warrant dated March 21, 2007, incorporated by reference to the Form 8-K filed on March 23, 2007.
- 10.40 Placement Agent Agreement by and between the Company and Punk, Ziegel & Company, L.P. dated March 14, 2007, incorporated by reference to the Form 8-K filed on March 23, 2007.
- 10.41 Placement Agent Agreement by and between the Company and Maxim Group LLC dated February 2, 2006, incorporated by reference to the Form 8-K filed on March 23, 2007.
- 10.42 APEL - Tenant Lease Agreement Revision No. 11 dated as of May 2, 2007 with an effective date of May 1, 2007 between Energy Northwest and IsoRay Medical, Inc., incorporated by reference to the Form 8-K filed on May 8, 2007.
- 10.43 Loan Covenant Waiver Letter dated September 24, 2007 from the Hanford Area Economic Investment Fund Committee, filed herewith.
- 10.44 Loan Covenant Waiver Letter dated September 26, 2007 from the Benton-Franklin Economic Development District, filed herewith.
- 16.1 Letter from S.W. Hatfield, CPA to the SEC dated December 13, 2005, incorporated by reference to the Form 8-K filed on December 14, 2005.
- 21.1 Subsidiaries of the Company, incorporated by reference to the Form 10-KSB filed on October 11, 2005.
- 23.1 Consent of DeCoria, Maichel & Teague, P.S., filed herewith.
- 31.1 Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 - Chief Executive Officer, filed herewith.
- 31.2 Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 - Chief Financial Officer, filed herewith.
- 32.1

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Certifications Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, filed  
herewith.

Reports on Form 8-K

On April 4, 2007, the Company filed a Current Report on Form 8-K announcing that as a result of its warrant call on March 26, 2007, the Company received \$4,989,000 of capital from warrant exercises.

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On May 8, 2007, the Company filed a Current Report on Form 8-K announcing its subsidiary, IsoRay Medical, Inc., entered into a new lease for 19,328 square feet to be used for its new production facility.

**ITEM 14 – PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The Company paid or accrued the following fees in each of the prior two fiscal years to its principal accountant, DeCoria, Maichel & Teague, P.S. and to its previous principal accountant, S. W. Hatfield, CPA:

	Year ended June 30, 2007	Year ended June 30, 2006
1. Audit fees <sup>(1)</sup>	\$ 41,016	\$ 72,292
2. Audit-related fees	1,800	1,150
3. Tax fees	4,250	2,750
4. All other fees	-	-
<b>Totals</b>	<b>\$ 47,066</b>	<b>\$ 76,192</b>

- (1) Fees for the year ended June 30, 2006 were as follows: \$49,125 paid to DeCoria, Maichel & Teague, P.S. and \$23,167 paid to S. W. Hatfield, CPA.

As part of its responsibility for oversight of the independent registered public accountants, the Audit Committee has established a pre-approval policy for engaging audit and permitted non-audit services provided by our independent registered public accountants, DeCoria, Maichel & Teague, P.S. In accordance with this policy, each type of audit, audit-related, tax and other permitted service to be provided by the independent auditors is specifically described and each such service, together with a fee level or budgeted amount for such service, is pre-approved by the Audit Committee. The Audit Committee has delegated authority to its Chairman to pre-approve additional non-audit services (provided such services are not prohibited by applicable law) up to a pre-established aggregate dollar limit. All services pre-approved by the Chairman of the Audit Committee must be presented at the next Audit Committee meeting for review and ratification. All of the services provided by DeCoria, Maichel & Teague, P.S. described above were approved by our Audit Committee.

The Company's principal accountant, DeCoria, Maichel & Teague P.S., did not engage any other persons or firms other than the principal accountant's full-time, permanent employees.



**IsoRay, Inc.**  
**Index to Financial Statements**

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**Report of Independent Registered Public Accounting Firm**

Board of Directors and Shareholders  
IsoRay, Inc.  
Richland, Washington

We have audited the accompanying consolidated balance sheets of IsoRay, Inc. and Subsidiary (“the Company”) (see Note 1) as of June 30, 2007 and 2006, and the related consolidated statements of operations, changes in shareholders’ equity and cash flows for the years then ended. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion the financial statements referred to above present fairly, in all material respects, the consolidated financial position of IsoRay, Inc. and Subsidiary as of June 30, 2007 and 2006, and the consolidated results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ DeCoria, Maichel & Teague, P.S.

Spokane, Washington  
September 28, 2007

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**IsoRay, Inc. and Subsidiary  
Consolidated Balance Sheets**

	2007	June 30,	2006
<b>ASSETS</b>			
Current assets:			
Cash and cash equivalents	\$ 9,355,730	\$	2,207,452
Short-term investments	9,942,840		-
Accounts receivable, net of allowance for doubtful accounts of \$99,789 and \$85,183, respectively	1,092,925		596,447
Inventory	880,834		161,381
Prepaid expenses and other current assets	458,123		161,546
<b>Total current assets</b>	<b>21,730,452</b>		<b>3,126,826</b>
Fixed assets, net of accumulated depreciation	3,665,551		1,642,293
Deferred financing costs, net of accumulated amortization	95,725		274,358
Licenses, net of accumulated amortization	262,074		273,475
Other assets, net of accumulated amortization	322,360		338,987
<b>Total assets</b>	<b>\$ 26,076,162</b>	<b>\$</b>	<b>5,655,939</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>			
Current liabilities:			
Accounts payable and accrued expenses	\$ 1,946,042	\$	584,296
Accrued payroll and related taxes	459,068		614,645
Accrued interest payable	1,938		11,986
Deferred revenue	23,874		-
Notes payable, due within one year	49,212		51,351
Capital lease obligations, due within one year	194,855		183,554
Convertible debentures payable, due within one year	-		455,000
Asset retirement obligation, current portion	131,142		-
<b>Total current liabilities</b>	<b>2,806,131</b>		<b>1,900,832</b>
Notes payable, due after one year	528,246		581,557
Capital lease obligations, due after one year	25,560		220,415
Asset retirement obligation	-		67,425
<b>Total liabilities</b>	<b>3,359,937</b>		<b>2,770,229</b>
Commitments and contingencies (Note 16)			
Shareholders' equity:			
Preferred stock, \$.001 par value; 6,000,000 shares authorized:			
Series A: 1,000,000 shares allocated; no shares issued and outstanding	-		-
Series B: 5,000,000 shares allocated; 59,065 and 144,759 shares issued and outstanding	59		145

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Common stock, \$.001 par value; 194,000,000 shares authorized; 22,789,324 and 15,157,901 shares issued and outstanding	22,789	15,158
Subscriptions receivable	-	(6,122,007)
Additional paid-in capital	45,844,793	22,538,675
Accumulated deficit	(23,151,416)	(13,546,261)
Total shareholders' equity	22,716,225	2,885,710
Total liabilities and shareholders' equity	\$ 26,076,162	\$ 5,655,939

The accompanying notes are an integral part of these financial statements.

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**IsoRay, Inc. and Subsidiary**  
**Consolidated Statements of Operations**

	<b>Year ended June 30,</b>	
	<b>2007</b>	<b>2006</b>
Product sales	\$ 5,738,033	\$ 1,994,306
Cost of product sales	5,792,630	3,815,122
Gross loss	(54,597)	(1,820,816)
Operating expenses:		
Research and development	1,345,163	450,425
Sales and marketing expenses	3,384,472	1,420,500
General and administrative expenses	4,915,598	3,503,522
Total operating expenses	9,645,233	5,374,447
Operating loss	(9,699,830)	(7,195,263)
Non-operating income (expense):		
Interest income	406,921	51,744
Financing expense	(312,246)	(689,100)
Debt conversion expense (Note 10)	-	(385,511)
Non-operating income (expense), net	94,675	(1,022,867)
Net loss	\$ (9,605,155)	\$ (8,218,130)
Basic and diluted loss per share	\$ (0.54)	\$ (0.68)
Weighted average shares used in computing net loss per share:		
Basic and diluted	17,827,522	12,051,964

The accompanying notes are an integral part of these financial statements.

**IsoRay, Inc. and Subsidiary**  
**Consolidated Statement of Changes in Shareholders' Equity (Deficit)**

	IsoRay, Inc. (MN)		IsoRay Medical, Inc.		Series B Preferred Stock		Common Stock		Subscriptions Receivable	Additional Paid-in Capital	Accumulated Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
30,	-	\$ -	-	\$ -	1,338,167	\$ 1,338	6,163,623	\$ 6,164	\$ -	3,805,773	\$ (5,328,132)
y,											
tures											
Inc.,											
sh	1,338,132	1,338	6,163,518	6,164	(1,338,167)	(1,338)	(6,163,623)	(6,164)			
eld											
of											
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r the											
on			2,498,534	2,499						8,733	
mon											
at for											
g			168,472	169						329,831	
eu											
nal										(734)	
rred											
nts	8,708	8								6,977	
rred											
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ng a											
ble	44,788	45								48,268	
mon											
nts			84,147	84						49,866	
mon											
ns			101,284	101						119,476	
o	(1,246,869)	(1,246)	1,246,869	1,246							
			911,271	911						3,681,964	

able to												
ants -term												
es												385,511
ants r m Note												60,000
mon the vate			1,500,000	1,500								5,406,626
mon the vate			268,889	269								1,107,955
mon s			1,748,146	1,748				(6,122,007)				6,120,259
ment non t of			39,007	39								184,996
mon the nt ion, sts			427,764	428								1,223,174
												(8,218,13)
30,	144,759	145	15,157,901	15,158	-	-	-	-	(6,122,007)	22,538,675	(13,546,20	
rred												
ants	37,322	37										41,642
mon			2,295,506	2,295								6,857,385
ants non			755,499	755								873,937
ns	(123,016)	(123)	123,016	123								

mon											
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ment		(1,748,146)	(1,748)				6,122,007	(6,120,259)			
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ment,											
osts		2,063,000	2,063					4,700,870			
mon											
the											
net											
(see		4,130,500	4,131					15,112,900			
lend											
								(38,458)			
								1,828,114			
									(9,605,15		
30,	59,065 \$	59	22,789,324 \$	22,789	- \$	-	- \$	- \$	- \$	45,844,793 \$	(23,151,41

The accompanying notes are an integral part of these financial statements.



**IsoRay, Inc. and Subsidiary**  
**Consolidated Statements of Cash Flows**

	<b>Year ended June 30,</b>	
	<b>2007</b>	<b>2006</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (9,605,155)	\$ (8,218,130)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization of fixed assets	491,643	271,060
Amortization of deferred financing costs and other assets	223,604	384,266
Accretion of asset retirement obligation	7,597	4,385
Share-based compensation (Note 11)	1,828,114	-
Merger consulting fees paid by issuance of common stock	-	330,000
Consulting and repair fees paid by issuance of common stock	-	39,750
Rent expense paid by issuance of common stock	-	90,026
Debt conversion expense (Note 10)	-	385,511
Changes in operating assets and liabilities:		
Accounts receivable, net	(496,478)	(546,478)
Inventory	(719,453)	(79,455)
Prepaid expenses	(296,577)	41,252
Accounts payable and accrued expenses	1,361,746	(132,646)
Accrued payroll and related taxes	(10,577)	456,721
Accrued interest payable	(10,048)	(29,339)
Deferred revenue	23,874	-
Net cash used by operating activities	(7,201,710)	(7,003,077)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of fixed assets	(2,445,850)	(474,795)
Additions to licenses and other assets	(29,874)	(395,201)
Purchase of short-term investments	(10,931,920)	-
Proceeds from the sale or maturity of short-term investments	989,080	-
Cash acquired in reverse acquisition (Note 1)	-	32,587
Net cash used by investing activities	(12,418,564)	(837,409)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of notes payable, net of financing costs	-	646,542
Proceeds from sales of convertible debentures payable	-	550,000
Repayment of convertible debentures payable	(405,001)	-
Principal payments on notes payable	(55,450)	(592,790)
Principal payments on capital lease obligations	(183,554)	(124,688)
Proceeds from cash sales of common shares, net of offering costs	19,819,964	6,516,350
Proceeds from cash sales of preferred stock, pursuant to exercise of warrants	41,679	6,985
Proceeds from cash sales of common stock, pursuant to exercise of warrants	6,859,680	49,950
	729,692	119,577

Proceeds from cash sales of common stock, pursuant to exercise of options		
Proceeds from cash sales of common stock, pursuant to June 2006 warrant exercises	-	1,223,602
Payments of dividends to preferred shareholders	(38,458)	-
Payments to common shareholders in lieu of issuing fractional shares	-	(734)
Net cash provided by financing activities	26,768,552	8,394,794
Net increase in cash and cash equivalents	7,148,278	554,308
Cash and cash equivalents, beginning of period	2,207,452	1,653,144
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 9,355,730</b>	<b>\$ 2,207,452</b>
Supplemental disclosures of cash flow information:		
Cash paid for interest	\$ 143,662	\$ 361,832
Non-cash investing and financing activities:		
Cashless exercise of common stock options in lieu of severance pay	\$ 145,000	\$ -
Exchange of convertible debentures payable for shares of common stock	49,999	3,682,875
Fixed assets acquired by capital lease obligations	-	507,947
Increase in PP&E related to asset retirement obligation	56,120	63,040
Issuance of common shares as partial payment for production equipment	-	25,248
Issuance of common shares as partial payment of notes payable	-	48,313
Liabilities acquired in acquisition	-	21,355
Prepaid rent paid by issuance of common stock	-	120,036
Issuance of warrants as an inducement for a note payable	-	60,000

The accompanying notes are an integral part of these financial statements.

**IsoRay, Inc.**  
**Notes to Consolidated Financial Statements**  
**For the years ended June 30, 2007 and 2006**

**1. Organization**

Historical Organization

Century Park Pictures Corporation (Century) was organized under Minnesota law in 1983. Century is a public company subject to the periodic reporting requirements of the Securities Exchange Act of 1934.

Century had no operations since its fiscal year ended September 30, 1999 through June 30, 2005.

Merger Transaction

On May 27, 2005, IsoRay Medical, Inc. (Medical) entered into a merger agreement with Century to merge with Century's newly-formed, wholly-owned subsidiary.

On July 28, 2005, the merger transaction closed. As a result of the merger, Medical became a wholly-owned subsidiary of Century, which concurrently changed its name to IsoRay, Inc. (IsoRay or the Company).

IsoRay issued shares of its common and preferred stock to the holders of common and preferred stock of Medical at a rate of 0.842362 share of IsoRay's stock for each share of Medical's stock. Options and warrants to purchase common and preferred stock of Medical were also converted at the same rate into options and warrants to purchase common and preferred stock of IsoRay, Inc. On a fully-diluted basis, Medical's shareholders owned approximately 82% of IsoRay's outstanding securities following the merger.

Management believes the transaction was structured to qualify as a non-taxable reorganization under Section 368(a)(1)(A) of the Internal Revenue Code of 1986, as amended.

As part of the reverse merger, Medical acquired cash of \$32,587 and accounts payable of \$21,355.

**2. Summary of Significant Accounting Policies**

Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary (collectively the Company). All significant intercompany accounts and transactions have been eliminated.

Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents.

Short-Term Investments

The Company invests certain excess cash in marketable securities consisting primarily of commercial paper, auction rate securities, and money market funds. The Company classifies all debt securities as "available-for-sale" and records the debt securities at fair value with unrealized gains and losses included in shareholders' equity.

The Company's short-term investments consisted of the following at June 30, 2007 and 2006:

	2007	2006
Municipal debt securities	\$ 3,000,000	\$ —
Corporate debt securities	6,942,840	—
	\$ 9,942,840	\$ —

At June 30, 2007, all of the Company's corporate debt securities mature within fiscal year 2008. All municipal debt consists of auction rate securities that may have maturity dates exceeding 5 years, however, they reset each month. Based on the frequency of the auction reset periods, the fair market value approximates cost.

#### 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 or market. Cost of raw materials is determined using the weighted average method. Cost of work in process and finished goods is computed using standard cost, which approximates actual cost, on a first-in, first-out basis. As the Company has had minimal gross margin throughout the past fiscal years, inventories have generally been recorded at market or net realizable value.

#### Fixed Assets

Fixed assets are carried at the lower of cost or net realizable value. Production equipment with a cost of \$2,500 or greater and other fixed assets with a cost of \$1,500 or greater are capitalized. Major betterments that extend the useful lives of assets are also capitalized. Normal maintenance and repairs are charged to expense as incurred. When assets are sold or otherwise disposed of, the cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized in operations.

Depreciation is computed using the straight-line method over the following estimated useful lives:

Production	3 to 7
equipment	years
Office	2 to 5
equipment	years
Furniture	2 to 5
and	years
fixtures	

Leasehold improvements and capital lease assets are amortized over the shorter of the life of the lease or the estimated life of the asset.

The Company has adopted the provisions of Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. The provisions of SFAS No. 144 require that an

impairment loss be recognized when the estimated future cash flows (undiscounted and without interest) expected to result from the use of an asset are less than the carrying amount of the asset. Measurement of an impairment loss is based on the estimated fair value of the asset if the asset is expected to be held and used.

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Management of the Company periodically reviews the net carrying value of all of its equipment on an asset by asset basis. These reviews consider the net realizable value of each asset, as measured in accordance with the preceding paragraph, to determine whether an impairment in value has occurred, and the need for any asset impairment write-down.

Although management has made its best estimate of the factors that affect the carrying value based on current conditions, it is reasonably possible that changes could occur which could adversely affect management's estimate of net cash flows expected to be generated from its assets, and necessitate asset impairment write-downs.

#### Deferred Financing Costs

Financing costs related to the acquisition of debt are deferred and amortized over the term of the related debt using the effective interest method. Deferred financing costs include the fair value of common shares issued to certain shareholders for their guarantee of certain Company debt (see Notes 7 and 8) in accordance with APB 21 and EITF Issue 95-13. The value of the shares issued was the estimated market price of the shares as of the date of issuance. Amortization of deferred financing costs, totaling \$178,633 and \$296,608 for the years ended June 30, 2007 and 2006, respectively, is included in financing expense on the statements of operations.

The Company's deferred financing costs consisted of the following at June 30, 2007 and 2006:

	2007	2006
<b>Value of shares issued to guarantors:</b>		
Benton-Franklin Economic Development District (83,640 shares)	\$ 138,006	\$ 138,006
Columbia River Bank line of credit (127,500 shares)	–	210,375
Benton-Franklin Economic Development District loan fees	3,450	3,450
Columbia River Bank line of credit loan fees	–	500
Convertible debentures issuance costs	–	30,047
Hanford Area Economic Investment Fund Committee loan fees	22,128	22,128
Less amortization	(67,859)	(130,148)
	\$ 95,725	\$ 274,358

In June 2007, the Company elected not to renew its line of credit with Columbia River Bank due to the Company's current cash position. The Company wrote off the remaining net deferred financing charges of \$98,409 relating to this line of credit.

#### Licenses

Amortization of licenses is computed using the straight-line method over the estimated economic useful lives of the assets. In fiscal year 2006, the Company entered into an agreement with IBt, SA, a Belgian company (IBt) to use IBt's proprietary "Ink Jet" production process and its proprietary polymer seed technology for use in brachytherapy procedures using Cesium-131 (Cs-131). The Company paid license fees of \$275,000 during fiscal year 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 incorporating the technology 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. The IBt license is being amortized over the 15-year term of the license agreement.

In the fourth quarter of fiscal year 2007, the Company reviewed the carrying values of licenses. 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 license agreement and other business arrangements (see Note 19).

Amortization of licenses was \$23,426 and \$20,530 for the years ended June 30, 2007 and 2006, respectively. Based on the licenses recorded at June 30, 2007, and assuming no subsequent impairment of the underlying assets, the annual amortization expense for each fiscal year ending June 30 is expected to be as follows: \$30,795 for 2008, \$18,770 for 2009, \$18,481 for 2010, \$18,333 for 2011, \$18,333 for 2012, and \$157,363 thereafter.

#### Other Assets

Other assets, which include deferred charges and patents, are stated at cost, less accumulated amortization. Amortization of patents is computed using the straight-line method over the estimated economic useful lives of the assets. The Company periodically reviews the carrying values of patents and any impairments are recognized when the expected future operating cash flows to be derived from such assets are less than their carrying value.

Based on the patents and other intangible assets recorded in other assets at June 30, 2007, and assuming no subsequent impairment of the underlying assets, the annual amortization expense for each fiscal year ending June 30 is expected to be as follows: \$30,155 for 2008, \$2,632 for 2009, \$2,632 for 2010, \$2,632 for 2011, \$2,632 for 2012, and \$12,192 thereafter.

#### 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 they are 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.

In fiscal year 2006, the Company 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 and property leases. This amount was determined based on discussions with qualified production personnel and on historical evidence. During fiscal year 2007, the Company reevaluated its obligations based on discussions with the Washington Department of Health and determined that the initial asset retirement obligation should be increased by an additional \$56,120. The Company anticipates spending most of the amounts represented by this accrual in fiscal year 2008. In addition, another asset retirement obligation will be established in the first quarter of fiscal year 2008 representing obligations at its new production facility. This new asset retirement obligation will be for obligations to remove any residual radioactive materials and to remove any unwanted leasehold improvements.

During the years ended June 30, 2007 and 2006, the asset retirement obligation changed as follows:

	2007	2006
Beginning balance	\$ 67,425	\$ —
New obligations	—	63,040
Changes in estimates of existing obligations	56,120	—
Accretion of discount	7,597	4,385
Ending balance	\$ 131,142	\$ 67,425

### Financial Instruments

The Company discloses the fair value of financial instruments, both assets and liabilities, recognized and not recognized in the balance sheet, for which it is practicable to estimate the fair value. The fair value of a financial instrument is the amount at which the instrument could be exchanged in a current transaction between willing parties, other than a forced liquidation sale.

The carrying amounts of financial instruments, including cash and cash equivalents; short-term investments; accounts receivable; accounts payable; notes payable; capital lease obligations; and convertible debentures payable, approximated their fair values at June 30, 2007 and 2006.

### 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) collectability is reasonably assured.

Revenue for the fiscal years ended June 30, 2007 and 2006 was derived solely from sales of the Proxcelan Cs-131 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. Although the Company does not have an extensive operating history upon which to develop sales returns estimates, we have used the expertise of our management team, particularly those with extensive industry experience and knowledge, to develop a proper methodology.

### Stock-Based Compensation

Prior to July 1, 2006, the Company accounted for share-based employee compensation, including stock options, using the method prescribed in Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* and related interpretations (APB 25). Under APB 25, for stock options granted at market price, no compensation cost was recognized and a disclosure was made regarding the pro forma effect on net earnings assuming compensation cost had been recognized in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123). On December 16, 2004, the Financial Accounting Standards Board issued SFAS No. 123 (Revised 2004), *Share Based Payment* (SFAS 123R), which requires companies to measure and recognize expense for all share-based payments at fair value. SFAS 123R eliminates the ability to account for share-based compensation transactions using APB 25 and generally requires that such transactions be accounted for using prescribed fair-value-based methods. SFAS 123R



permits public companies to adopt its requirements using one of two methods: (a) a “modified prospective” method in which compensation costs are recognized beginning with the effective date based on the requirements of SFAS No. 123R for all share-based payments granted or modified after the effective date, and based on the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date or (b) a “modified retrospective” method which includes the requirements of the modified prospective method described above, but also permits companies to restate based on the amounts previously recognized under SFAS No. 123 for purposes of pro forma disclosures either for all periods presented or for prior interim periods of the year of adoption. Effective July 1, 2006, the Company adopted SFAS 123R using the modified prospective method. No share-based employee compensation cost was reflected in the statement of operations prior to the adoption of SFAS No. 123R. Results for prior periods have not been restated (see Note 11).

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### Research and Development Costs

Research and development costs, including salaries, research materials, administrative expenses and contractor fees, are charged to operations as incurred. The cost of equipment used in research and development activities which has alternative uses is capitalized as part of fixed assets and not treated as an expense in the period acquired. Depreciation of capitalized equipment used to perform research and development is classified as research and development expense in the year computed.

### Advertising and Marketing Costs

Advertising costs are expensed as incurred except for the cost of tradeshow and related marketing materials which are deferred until the tradeshow occurs. Advertising and marketing costs expensed (including tradeshow) were \$441,196 and \$292,351 for the years ended June 30, 2007 and 2006, respectively. Marketing costs of \$162,307 are capitalized at June 30, 2007.

### Shipping and Handling Costs

Shipping and handling costs are expensed as incurred and included in cost of product sales.

### 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, environmental matters, and a variety of other matters. The Company is also 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 or compliance issues, the Company believes that when it relocates its current production facilities then certain decommissioning expenses will be incurred and has recorded an asset retirement obligation for these expenses.

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 probable 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.

Income Taxes

Income taxes are accounted for under the liability method. Under this method, the Company provides deferred income taxes for temporary differences that will result in taxable or deductible amounts in future years based on the reporting of certain costs in different periods for financial statement and income tax purposes. This method also requires the recognition of future tax benefits such as net operating loss carryforwards, to the extent that realization of such benefits is more likely than not. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment of the change.

Income (Loss) Per Common Share

The Company accounts for its income (loss) per common share according to SFAS No. 128, *Earnings Per Share*. Under the provisions of SFAS No. 128, primary and fully diluted earnings per share are replaced with basic and diluted earnings per share. Basic earnings per share is calculated by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding, and does not include the impact of any potentially dilutive common stock equivalents. Common stock equivalents, including warrants to purchase the Company's common stock and common stock issuable upon the conversion of notes payable, are excluded from the calculations when their effect is antidilutive. At June 30, 2007 and 2006, the calculation of diluted weighted average shares does not include preferred stock, options, or warrants that are potentially convertible into common stock as those would be antidilutive due to the Company's net loss position.

Securities that could be dilutive in the future as of June 30, 2007 and 2006 are as follows:

	2007	2006
Preferred stock	59,065	144,759
Preferred stock warrants	–	179,512
Common stock warrants	3,627,764	2,502,769
Common stock options	3,683,439	3,129,692
Convertible debentures	–	109,639
<b>Total potential dilutive securities</b>	<b>7,370,268</b>	<b>6,066,371</b>

Use of Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management of the Company to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Accordingly, actual results could differ from those estimates and affect the amounts reported in the financial statements.

### 3. Inventory

Inventory consists of the following at June 30, 2007 and 2006:

	2007	2006
Raw materials	\$ 682,327	\$ 61,531
Work in process	120,242	67,906
Finished goods	78,265	31,944
	\$ 880,834	\$ 161,381

The cost of materials and production costs contained in inventory that are not useable due to the passage of time, and resulting loss of bio-effectiveness, are written off to cost of product sales at the time it is determined that the product is not useable.

In June 2007, the Company purchased \$469,758 of enriched barium that will be used in future production of our isotope. The enriched barium is held by a Russian vendor and is included in raw materials at June 30, 2007.

### 4. Prepaid Expenses

Prepaid expenses consist of the following at June 30, 2007 and 2006:

	2007	2006
Prepaid contract work	\$ -	\$ 7,913
Prepaid insurance	37,001	21,340
Prepaid rent	26,693	30,009
Other prepaid expenses	249,184	21,200
Other current assets	145,245	81,084
	\$ 458,123	\$ 161,546

### 5. Fixed Assets

Fixed assets consist of the following at June 30, 2007 and 2006:

	2007	2006
Production equipment	\$ 807,838	\$ 590,908
Office equipment	111,218	70,060
Furniture and fixtures	118,227	100,653
Leasehold improvements	522,951	652,404
Capital lease assets (a)	655,858	599,738
Construction in progress	2,217,372	34,254
	4,433,464	2,048,017
Less accumulated depreciation	(767,913)	(405,724)
	\$ 3,665,551	\$ 1,642,293

(a) Balance includes asset retirement addition of \$119,160 and \$63,040 as of June 30, 2007 and 2006, respectively.



Depreciation and amortization expense related to fixed assets totaled \$491,643 and \$271,060 for 2007 and 2006, respectively. Accumulated amortization of capital lease assets totaled \$198,171 and \$55,644 at June 30, 2007 and 2006, respectively.

## 6. Other Assets

Other assets, net of accumulated amortization, consist of the following at June 30, 2007 and 2006:

	2007	2006
Deferred charges	\$ 297,008	\$ 318,885
Patents and trademarks, net of accumulated amortization of \$16,463 and \$13,831	25,352	20,102
	\$ 322,360	\$ 338,987

Deferred charges consist of prepaid legal fees for patents which have not yet been obtained, and prepayments and deposits on fixed assets and contracts. Amortization of patents and trademarks was \$2,632 and \$1,513 for the years ended June 30, 2007 and 2006, respectively.

## 7. Bank Line of Credit

The Company had a \$375,000 revolving line of credit with Columbia River Bank that expired on March 1, 2007. The Company intended to renew the line of credit and received a proposal from the bank. In June 2007, the Company decided not to renew this line of credit as part of its overall review of its banking and cash management relationships. The Company had no borrowings under the line of credit during the fiscal year ended June 30, 2007.

## 8. Notes Payable

Notes payable consist of the following at June 30, 2007 and 2006:

	2007	2006
Tri-City Industrial Development Council (TRIDEC) note payable (a)	\$ -	\$ 10,000
Benton-Franklin Economic Development District (BFEDD) note payable (b)	185,848	204,237
Hanford Area Economic Investment Fund Committee (HAEIFC) note payable (c)	391,610	418,671
	577,458	632,908
Less amounts due within one year	(49,212)	(51,351)
Amounts due after one year	\$ 528,246	\$ 581,557

- (a) This is a non-interest bearing note, due in annual installments of \$10,000 that matured in August 2006. The note payable to TRIDEC did not bear interest, but was not discounted because the note was exchanged solely for cash.
- (b) The note payable to BFEDD, which is collateralized by substantially all of the Company's assets, and guaranteed by certain shareholders, was executed pursuant to a Development Loan Agreement. The note contains certain restrictive covenants relating to: working capital; levels of long-term debt to equity; incurrence of additional indebtedness; payment of compensation to officers and directors; and payment of dividends. The note is payable in monthly installments including interest at 8.0% per annum with a final balloon payment due in October 2009.

At June 30, 2007, the Company was not in compliance with certain of the covenants. The Company has obtained a waiver from BFEDD, relating to these covenants, through June 30, 2008.

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(c) In June 2006, the Company entered into a note payable with HAEIFC, which is collateralized by receivables, inventory, equipment, and certain life insurance policies. The total note payable facility is for \$1.4 million and is to be used to purchase production equipment. In June 2006, the Company requested an initial disbursement of approximately \$400,000. The note contains certain restrictive covenants relating to: financial ratios; payment of compensation to officers and directors; and payment of dividends. The note accrues interest at 9% and is payable in monthly installments with the final installment due in July 2016. At June 30, 2007, the Company was not in compliance with certain of the covenants. The Company has obtained a waiver from HAEIFC, relating to these covenants, through June 30, 2008.

On October 14, 2005, the Company borrowed \$250,000 under a short-term note payable from a shareholder who was later appointed to the Board of Directors in April 2006. The note, which bore interest at the rate of 10.0%, was paid in full on its due date of December 1, 2005. In connection with the loan, the Company granted a warrant to purchase 12,500 shares of common stock at an aggregate total exercise price of \$10. The Company recorded financing expenses of \$60,000 related to the issuance of these warrants.

Principal maturities on notes payable are due as follows:

Year ending June 30,	
2008	\$ 49,212
2009	53,609
2010	182,566
2011	38,436
2012	41,983
Thereafter	211,652
	\$ 577,458

## 9. Capital Lease Obligations

The Company leases certain equipment under long-term agreements that represent capital leases. Future minimum lease payments under capital lease obligations are as follows:

Year ending June 30,	
2008	\$ 214,269
2009	27,626
Total future minimum lease payments	241,895
Less amounts representing interest	(21,480)
Present value of net	220,415



minimum lease payments	
Less amounts due within one year	(194,855)
Amounts due after one year	\$ 25,560

#### **10. Convertible Debentures Payable**

Through June 30, 2005, the Company had sold \$3,587,875 of convertible debentures pursuant to the January 31, 2005 Offering (see Note 12). In July 2005, the Company sold an additional \$550,000 of these convertible debentures. The debentures, which bore interest at 8% and matured two years from the date of issuance (through June 2007), could be converted into shares of the Company's common stock at a rate of \$4.15 per share plus, at the discretion of the Company, either a cash payment for accrued interest, or that number of common shares equal to the amount of unpaid accrued interest at \$4.15 per share. Based upon reviews of SFAS 133, EITF 00-19, and EITF 98-5, the Company determined that the conversion feature did not have a derivative value.

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On December 13, 2005, the Board of Directors announced a short-term conversion inducement to current holders of the convertible debentures, originally issued in conjunction with the January 31, 2005 Private Placement Offering. 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 register the newly issued shares in the Form SB-2 Registration Statement filed with the SEC on November 10, 2005, or 2) convert under terms essentially identical to those offered to purchasers of Units in the Offering of October 17, 2005 – 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).

As of June 30, 2006, holders of \$3,682,875 of debentures had converted to common stock of the Company, responding to the inducement of the second exercise method described above. As of June 30, 2006, the Company had issued 911,271 shares of common stock (including approximately 23,840 incremental shares not previously available to holders of debentures under the original conversion terms), and 659,469 warrants to purchase shares of common, exercisable at \$6.00 per share. During the fiscal year ended June 30, 2006, the Company recognized \$385,511 in non-cash short-term inducement expense, in accordance with SFAS No. 84. The Company reviewed SFAS 133 and EITF 00-19 and determined that the warrants issued in connection with the short-term conversion inducement did not have derivative value.

The remaining convertible debentures matured during the fiscal year ended June 30, 2006. One \$50,000 convertible debenture holder converted into 12,048 common shares and the remaining balance and accrued interest was paid in cash. All other debenture holders elected to receive cash payments of their principal and accrued interest on the maturity dates.

## 11. Share-Based Compensation

Prior to July 1, 2006, the Company accounted for share-based employee compensation, including stock options, using the method prescribed by APB 25. Under APB 25, for stock options granted at market price, no compensation cost was recognized, and a disclosure was made regarding the pro forma effect on net earnings assuming compensation cost had been recognized in accordance with SFAS 123. Effective July 1, 2006, the Company adopted SFAS 123R using the modified prospective method.

The following table presents the share-based compensation expense recognized in accordance with SFAS 123R during the year ended June 30, 2007 and in accordance with APB 25 during the year ended June 30, 2006:

	Year ended June 30,	
	2007	2006
Cost of product sales	\$ 120,710	\$ –
Research and development	41,481	–
Sales and marketing expenses	216,432	–
General and administrative expenses	1,449,491	–
Total share-based compensation	\$ 1,828,114	\$ –

The adoption of SFAS 123R reduced net income for the year ended June 30, 2007 by \$1,828,114. Basic loss per common share for the year ended June 30, 2007 would have been \$0.44 if the Company had not adopted SFAS 123R, compared to reported basic loss per common share of \$0.54. The total value of the stock options awards is expensed ratably over the service period of the employees receiving the awards. As of June 30, 2007, total unrecognized compensation cost related to stock-based options and awards was \$1,707,843 and the related weighted-average period over which it is expected to be recognized is approximately 1.23 years.



The Company currently provides share-based compensation under three equity incentive plans approved by the Board of Directors: the Amended and Restated 2005 Stock Option Plan (the Option Plan), the Amended and Restated 2005 Employee Stock Option Plan (the Employee Plan), and the 2006 Director Stock Option Plan (the Director Plan). 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. 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 on the date of the grant, and varying vesting periods as determined by the Board. For stock options with graded vesting terms, the Company recognizes compensation cost on a straight-line basis over the requisite service period for the entire award.

On June 1, 2007, the Company issued an option grant to employees and directors. The options had an exercise price of \$4.14 which was the closing market price of the Company's stock. The options issued to the employees vest over 3 years while the options granted to the non-employee directors were immediately vested.

The Company's CEO, who also serves as Chairman of the Board, was granted 150,000 options, the Executive Vice President Operations (EVP-Operations), who also serves as a Director, was granted 100,000 options, and all non-employee directors were granted 50,000 options each. On July 25, 2007, the Board discussed the issue of director compensation and each director (including the employee directors) elected to cancel 50,000 of their options from the June 1, 2007 grant. After the cancellation, the CEO and EVP-Operations had 100,000 and 50,000 options, respectively, and the non-employee directors had no options from the June 1, 2007 grant. The terms of these remaining options for the CEO and EVP- Operations were not changed as part of the cancellation.

In accordance with SFAS 123R, all of the options that were cancelled have been accounted for as cancellation of options with no consideration. No additional compensation cost associated with the CEO's and EVP-Operations's options will be recognized after the cancellation date of July 25, 2007. Cancelled options that had been granted to non-employee directors were immediately vested on the date of grant; therefore all related compensation cost was recognized in fiscal year 2007. Under SFAS 123R, the value of the cancelled options to each non-employee director was \$128,500.

All of these subsequently cancelled options are included in the options granted and outstanding as of June 30, 2007.

A summary of stock option activity within the Company's share-based compensation plans for the year ended June 30, 2007 is as follows:

	Shares	Price (a)	Life (b)	Value (c)
Outstanding at June 30, 2007	3,683,439	\$ 2.86	8.67	\$ 8,259,814
Vested and expected to vest at June 30, 2007	3,270,441	\$ 2.85	8.68	\$ 8,150,622
Vested and exercisable at June 30, 2007	2,278,172	\$ 2.45	8.42	\$ 6,726,822

(a) Weighted average price per share.  
 (b) Weighted average remaining contractual life.  
 (c) Aggregate intrinsic value.

The aggregate intrinsic value of options exercised during the years ended June 30, 2007 and 2006 was \$2,286,370 and \$391,908, respectively. The Company's current policy is to issue new shares to satisfy option exercises.

The weighted average fair value of stock option awards granted and the key assumptions used in the Black-Scholes valuation model to calculate the fair value are as follows for the year ended June 30, 2007 and 2006:

	Year ended June 30,	
	2007	2006
Weighted average fair value of options granted	\$ 2.29	\$ 1.38
Key assumptions used in determining fair value:		
Weighted average risk-free interest rate	4.86%	4.67%
Weighted average life of the option (in years)	5.58	7.31
Weighted average historical stock price volatility	69.87%	31.24%
Expected dividend yield	0.00%	0.00%

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. Because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options. The risk-free interest rate is based on the U.S. treasury security rate in effect as of the date of grant. The expected lives of options and the volatility are based on historical data of the Company.

The following table illustrates the effect on net loss and net loss per common share for the year ended June 30, 2006 as if the Company had applied the fair value recognition provisions of SFAS 123 to all outstanding stock option awards for periods presented prior to the Company's adoption of SFAS 123R. The fair value of these options was estimated at the date of grant using the Black-Scholes method set forth in SFAS No. 123R.

	2006
Net loss, as reported	\$ 8,218,130
SFAS No. 123 stock option expense	1,167,086
Pro forma net loss	\$ 9,385,216
Net loss per share:	
Basic and Diluted, as reported	\$ 0.68

Basic and Diluted, pro forma

\$ 0.77

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## **12. Shareholders' Equity**

The authorized capital structure of the Company consists of \$.001 par value preferred stock and \$.001 par value common stock.

### Preferred Stock

The Company's Certificate of Incorporation authorizes 6,000,000 shares of \$.001 par value preferred stock available for issuance with such rights and preferences, including liquidation, dividend, conversion, and voting rights, as described below.

#### Series A

Series A preferred shares are entitled to a 10% dividend annually on the stated par value per share. These shares are convertible into shares of common stock at the rate of one share of common stock for each share of Series A preferred stock, and are subject to automatic conversion into common stock upon the closing of an underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933 covering the offer and sale of common stock in which the gross proceeds to the Company are at least \$4 million. Series A preferred shareholders have voting rights equal to the voting rights of common stock, except that the vote or written consent of a majority of the outstanding preferred shares is required for any changes to the Company's Certificate of Incorporation, Bylaws or Certificate of Designation, or for any bankruptcy, insolvency, dissolution or liquidation of the Company. Upon liquidation of the Company, the Company's assets are first distributed ratably to the Series A preferred shareholders. At June 30, 2007, there were no Series A preferred shares outstanding.

#### Series B

Series B preferred shares are entitled to a cumulative 15% dividend annually on the stated par value per share. These shares are convertible into shares of common stock at the rate of one share of common stock for each share of Series B preferred stock, and are subject to automatic conversion into common stock upon the closing of an underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933 covering the offer and sale of common stock in which the gross proceeds to the Company are at least \$4 million. Series B preferred shareholders have voting rights equal to the voting rights of common stock, except that the vote or written consent of a majority of the outstanding preferred shares is required for any changes to the Company's Certificate of Incorporation, Bylaws or Certificate of Designation, or for any bankruptcy, insolvency, dissolution or liquidation of the Company. Upon liquidation of the Company, the Company's assets are first distributed ratably to the Series A preferred shareholders, then to the Series B preferred shareholders.

On February 1, 2007, the Board of Directors declared a dividend on the Series B Preferred Stock of all outstanding and cumulative dividends through December 31, 2006. The total dividends of \$38,458 were paid on February 15, 2007. The Company does not anticipate paying any cash dividends on the Series B Preferred Stock in the foreseeable future. At June 30, 2007, there were 59,065 Series B preferred shares outstanding and cumulative dividends in arrears were \$5,272.

In addition to the shares of common stock and Series B preferred stock issued pursuant to the merger transaction (see Note 1), the Company had the following transactions that affected shareholders' equity during the years ended June 30, 2007 and 2006.

### March 2007 Public Equity Offering

On March 20, 2007, the Company entered into definitive securities purchase agreements (the March 2007 Purchase Agreements) with certain institutional investors pursuant to which the Company agreed to issue and sell an aggregate of 4,130,500 shares of its common stock at \$4.00 per share, through a registered direct offering, for aggregate gross proceeds of approximately \$16,522,000, before deducting estimated fees and expenses associated with the offering (the Offering). As part of the Offering, each purchaser of five shares of common stock received a warrant to purchase one share of common stock at an exercise price of \$5.00 per share with a 4-year term. A total of 826,100 warrants were issued under these terms. The closing took place on March 22, 2007. The shares of common stock offered by the Company in this transaction were registered under the Company's existing shelf registration statement (File No. 333-140246) on Form S-3, which was declared effective by the Securities and Exchange Commission on February 15, 2007, and the prospectus supplement dated March 21, 2007.

Punk, Ziegel & Company, L.P. and Maxim Group LLC (the Placement Agents) acted as the placement agents for the Offering. On March 14, 2007 and February 2, 2006, the Company executed placement agent agreements (the Placement Agent Agreements) by and between the Company and Punk, Ziegel & Company, L.P. and Maxim Group LLC, respectively. The Company paid the Placement Agents an aggregate fee equal to 6% of the gross proceeds of the Offering or approximately \$991,000. In addition, the Placement Agents also received 206,526 warrants with an exercise price of \$4.40 per share and a 5-year term as part of their overall fee.

The warrants issued in the March 2007 Purchase Agreements were not accounted for as derivatives in accordance SFAS 133 paragraph 11(a), SFAS 150, and EITF 00-19.

### March 2007 Warrant Call

As part of the August 2006 Stock Purchase Agreement, the Company issued warrants with an exercise price of \$3.00 per share. The warrants were callable by the Company for 45 days after a period of 60 trading days in which the closing price of the underlying stock was at or above \$4.50 per share for 30 of the 60 days.

As of February 16, 2007, the Company's common stock had traded at or above \$4.50 for 30 of the previous 60 days. On February 21, 2007, the Company sent out notices to the warrant holders establishing a call date of March 26, 2007. The warrant holders had the option to either exercise their warrants or permit the Company to repurchase the warrants for \$.01 per share on the call date. All of the remaining warrants were exercised prior to the call date.

### August 2006 Stock Purchase Agreement

On August 17, 2006, the Company sold certain shares of its common stock and warrants to purchase common stock pursuant to a Common Stock and Warrant Purchase Agreement (the August 2006 Purchase Agreement) dated August 9, 2006. The securities were issued to 25 accredited investors pursuant to the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended. MicroCapital, LLC acted as the lead investor for the transaction. Net proceeds of \$4.7 million were received by the Company in exchange for the issuance of 2,063,000 shares of common stock and warrants to purchase 2,063,000 shares of common stock. In addition, brokers assisting the Company with the capital raise were issued warrants to purchase 206,300 shares of common stock on identical terms as the warrants issued to investors.

Pursuant to the August 2006 Purchase Agreement, the purchase price per share of the Company's common stock was \$2.50, and the accompanying warrants were issued with an exercise price of \$3.00 per share. The warrants and the August 2006 Purchase Agreement contained anti-dilution provisions, including one providing that, if the Company issues stock or rights to acquire stock at a price less than \$2.00 (excluding certain issuances such as options to employees, directors and certain consultants and shares issued in connection with licensing or leasing transactions),



the Company is required to issue to each investor additional shares equal to 25% of what such investor purchased in the original transaction. The warrants were exercisable by the holder (subject to anti-dilution and adjustment provisions) for a period of five years from the date of issuance. The warrants were callable by the Company for 45 days after a period of 60 trading days in which the price of the underlying stock exceeds \$4.50 per share for 30 of the 60 days, and only if a registration statement covering the underlying shares is effective.

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In connection with the August 2006 Purchase Agreement, the Company also entered into a Registration Rights Agreement whereby the Company agreed to file a registration statement to cover the re-sale of the shares of common stock sold and issuable upon exercise of the warrants. Under the Registration Rights Agreement, the Company agreed to file the registration statement within 60 days of the closing, cure any defect causing the registration statement to fail to be effective within 10 business days, and cause suspension periods for the registration statement to not exceed 60 days in any 360 day period. If the Company fails to comply with these provisions, the Company will be required to pay as liquidated damages an amount equal to 2% of the aggregate purchase price paid by the investors for each 30 day period during which the failure continues, not to exceed 10% of the aggregate purchase price. A Form SB-2 Registration Statement to register these shares was filed with the SEC on October 16, 2006 and declared effective on December 5, 2006.

The warrants issued in the August 2006 Purchase Agreement were not accounted for as derivatives in accordance SFAS 133 paragraph 11(a), SFAS 150, and EITF 00-19.

#### IsoRay, Inc. June 2006 Warrant Exercise Solicitation

In June 2006, the Board of Directors approved a limited one-time discount of the exercise price of outstanding warrants (with exercise prices over \$3.00) to \$3.00 per share of common stock if the warrants were exercised on or before June 30, 2006. The warrants exercised as part of this one-time discount were primarily held by investors who purchased them as part of the Company's October 2005 and February 2006 private placement offerings and had original exercise prices of \$6.00 and \$6.50. The change in exercise price was a modification of the original warrant based on market conditions and was accounted for as a financing transaction similar to a modification of the offering price of shares in a stock sale. Therefore there was no effect on the statement of operations as the Company had previously determined that under SFAS 133 and EITF 00-19 these warrants were equity instruments rather than derivatives. The Company issued 427,764 common shares and raised \$1,223,602, net of offering costs, through this warrant exercise solicitation.

#### IsoRay, Inc. February 2006 Private Placement

On February 1, 2006 the Company commenced an offering of Investment Units (Units) for sale, pursuant to a Private Placement Offering (the February 2006 Offering), which management believes was exempt from registration under the Securities Act of 1933 (the Act) pursuant to Section 4(2) of the Act and Rule 506 of Regulation D. The February 2006 Offering consisted of a maximum of 89 Units, each Unit consisting of 5,000 shares of common stock and a warrant to purchase 5,000 shares of common stock at an exercise price of \$6.50 per share. The Units were sold for \$22,500 per Unit. The Company closed this offering on February 24, 2006. Approximately \$1.1 million, net of offering costs, was raised under the February 2006 Offering. The warrants issued in the February 2006 Offering were not accounted for as derivatives in accordance SFAS 133 paragraph 11(a) and EITF 00-19.

#### IsoRay, Inc. Subscriptions Receivable

On December 7, 2005, the Company entered into a SICAV ONE Securities Purchase Agreement and a SICAV TWO Securities Purchase Agreement (collectively, the December 2005 Purchase Agreements) with Mercatus & Partners, Limited, a United Kingdom private limited company (Mercatus). The December 2005 Purchase Agreements permitted Mercatus to purchase 1,748,146 shares of the Company's common stock at a purchase price of \$3.502 per share subject to receipt of funding. As no funding had been received, on May 18, 2006, the Company requested immediate return of the certificates representing all shares of common stock to which Mercatus had previously subscribed in accordance with the terms of the December 2005 Purchase Agreements. The December 2005 Purchase Agreements called for return of certificates within ten days if funding is not received within two days of receipt of the notice. After significant delay and the Company's attainment of a court order, the share certificates were returned. On August 8, 2006, the share certificates were cancelled and the December 2005 Purchase Agreements were terminated.



IsoRay, Inc. October 2005 Private Placement

On January 30, 2006 the Company closed an offering of Units for sale, pursuant to a Private Placement Offering (the October 2005 Offering) of October 17, 2005, which management believes was exempt from registration under the Act pursuant to Section 4(2) of the Act and Rule 506 of Regulation D. The October 2005 Offering consisted of a maximum of 200 Units, each Unit consisting of 5,000 shares of common stock and a warrant to purchase 5,000 shares of common stock at an exercise price of \$6.00 per share. This maximum was increased, pursuant to the terms of the October 2005 Offering, at the sole discretion of the Company, to a maximum of 300 Units. The Units were sold for \$20,000 per Unit. Approximately \$5.4 million, net of offering costs, was raised under the October 2005 Offering. The warrants issued in the October 2005 Offering were not accounted for as derivatives in accordance SFAS 133 paragraph 11(a) and EITF 00-19.

IsoRay Medical, Inc. January 2005 Private Placement

In January 2005, Medical commenced an offering (the January 2005 Offering) of up to \$2,000,000 of 8% convertible debentures (see Note 10) to accredited investors in a private placement, which management believes was exempt from registration under the Act pursuant to Section 4(2) of the Act and Rule 506 of Regulation D. On May 27, 2005, Medical amended and restated the January 2005 Offering to increase the maximum amount of the offering to \$4,150,000.

Through June 30, 2005, Medical sold debentures totaling \$3,587,875. In connection with the sales of these debentures, Medical paid commissions totaling \$216,783 and legal expenses totaling \$56,470, which amounts have been recorded as deferred financing costs.

In July 2005, Medical sold an additional \$550,000 of debentures pursuant to this offering. The sale of these additional debentures was not subject to payment of commissions.

In 2006, \$3,682,875 of the debentures were converted to common stock pursuant to a short-term conversion inducement (see Note 10).

Issuance of Common Stock in Payment of Consulting Services

During 2006, the Company issued 173,472 shares of its common stock in full satisfaction of consulting services including 168,472 shares that were issued as payment for merger consulting services (see Note 1). The shares were valued using the market price of the stock on the date of issue.

Issuance of Common Stock in Partial Payment of Equipment Purchase

During 2006, the Company issued 10,000 shares of its common stock and paid \$962 of cash in full satisfaction for the purchase of production equipment and repairs and maintenance invoices totaling \$40,962. The shares were valued using the market price of the stock on the date of issue.

Cash Payments for Fractional Shares

During 2006, the Company paid a combined total of \$734 to the former common and preferred shareholders of Medical and Century for fractional shares that resulted from the merger that was effective July 28, 2005 (see Note 1).

Warrants to Purchase Series B Preferred Stock

Pursuant to a private placement of debt units during 2003 and 2004, a predecessor company issued \$365,000 of notes payable to investors and granted warrants for the purchase of 227,750 of its Class A member shares. Through a series of mergers these warrants were exchanged for warrants to purchase 323,830 Series B preferred shares. The warrants activity is summarized as follows:

	2007		2006 (a)	
	Warrants	Price (b)	Warrants	Price (b)
Beginning balance outstanding	179,512	\$ 0.79	233,008	\$ 0.84
Converted to common warrants				
(c)	(142,190)	0.70	—	—
Exercised	(37,322)	1.12	(53,496)	1.03
Ending balance outstanding	—	\$ —	179,512	\$ 0.79

(a) The 2006 beginning balance has been adjusted to reflect the 0.842362 conversion ratio (see Note 1).

(b) Weighted average price per share.

(c) During fiscal year 2007, one preferred warrant holder requested the Board of Directors to extend the expiration date of his warrants and to convert them to common warrants. The Board granted this request and set new expiration dates as noted below. The exercise price was not changed. The change in expiration date and the conversion to common warrants was a modification of the original warrant based on market conditions and was accounted for as a financing transaction similar to a modification of the offering price of shares in a stock sale. Therefore there was no effect on the statement of operations as the Company had previously determined that under SFAS 133 and EITF 00-19 these warrants were equity instruments rather than derivatives.

Number of Warrants	Price	New Expiration Date	Old Expiration Date
56,876	\$ 0.70	October 30, 2007	October 30, 2006
28,438	0.70	January 31, 2009	January 31, 2007
56,876	0.70	March 30, 2010	March 30, 2007
142,190			

Warrants to Purchase Common Stock

In connection with the various common stock offerings and at other times the Company has issued warrants for the purchase of common stock. The warrants activity is summarized as follows:

	2007		2006 (a)	
	Warrants	Price (b)	Warrants	Price (b)
Beginning balance outstanding	2,502,769	\$ 5.73	136,158	\$ 1.20
Warrants issued	3,301,926	3.59	2,878,522	5.85
Converted from preferred (c)	142,190	0.70	-	-
Cancelled/expired	(23,615)	2.54	-	-
Exercised	(2,295,506)	2.99	(511,911)	2.49
Ending balance outstanding	3,627,764	\$ 5.31	2,502,769	\$ 5.73

(a) The 2006 beginning balance has been adjusted to reflect the 0.842362 conversion ratio (see Note 1).

(b) Weighted average price per share.

(c) During fiscal year 2007, one preferred warrant holder requested the Board of Directors to extend the expiration date of his warrants and to convert them to common warrants. The Board granted this request and set new expiration dates as noted in the Preferred Warrants section of this footnote.

The following table summarizes additional information about the Company's common warrants outstanding as of June 30, 2007:

Number of Warrants	Range of Exercise Prices	Expiration Date
277,614	\$4.15	July 2007
12,500	\$0.0008	October 2007
56,876	\$0.70	October 2007
53,000	\$6.00	October 2007
162,500	\$6.00	November 2007
934,469	\$5.75 to \$6.00	December 2007
700,250	\$6.00	January 2008
276,923	\$6.00 to \$6.50	February 2008
5,000	\$7.00	March 2008
5,692	\$4.15	May 2008
28,438	\$0.70	January 2009
56,876	\$0.70	March 2010
826,100	\$5.00	March 2011
206,526	\$4.40	March 2012
25,000	\$2.00	July 2015
3,627,764		

Stock Options

A summary of the Company's stock option activity and related information for the years ended June 30, 2007 and 2006 is as follows:

	2007		2006 (a)	
	Shares	Price (b)	Shares	Price (b)
Beginning balance outstanding	3,129,692	\$ 2.05	2,237,802	\$ 1.31
Granted (c) (d)	1,488,700	3.67	1,189,722	3.23
Cancelled	(179,454)	2.68	(196,548)	1.19
Exercised	(755,499)	1.16	(101,284)	1.18
Ending balance outstanding	3,683,439	\$ 2.86	3,129,692	\$ 2.05
Exercisable at end of year	2,528,172	\$ 2.45	2,649,576	\$ 1.79

(a) The 2006 beginning balances have been adjusted to reflect the 0.842362 conversion ratio (see Note 1).

(b) Weighted average price per share.

(c) All options granted had exercise prices equal to the ending market price of the Company's common stock on the grant date.

(d) Included in options granted are 350,000 options granted with an exercise price of \$4.14 to members of the Board of Directors that were subsequently cancelled on July 25, 2007. 100,000 of these options were granted to the Company's CEO and Executive Vice-President Operations and were to vest over three years. The remaining 250,000 options were granted to non-employee Directors and were immediately vested. See Note 11 for a further discussion of these cancelled options.

The following table summarizes additional information about the Company's stock options outstanding as of June 30, 2007:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Shares	Price (a)	Life (b)	Shares	Price (a)
\$1.00 to \$1.19	1,002,892	\$ 1.16	7.85 yrs	934,322	\$ 1.16
\$1.96 to \$2.00	653,791	1.98	8.09 yrs	653,791	1.98
\$3.10 to \$3.20	676,234	3.12	9.16 yrs	342,075	3.12
\$3.50 to \$3.85	200,000	3.74	9.00 yrs	116,666	3.81
\$4.14 to \$4.15	820,472	4.14	9.54 yrs	334,235	4.14
\$4.40	108,800	4.40	9.68 yrs	-	-
\$5.50 to \$6.50	221,250	6.06	8.65 yrs	147,083	6.18
Total options	3,333,439			2,278,172	

(a) Weighted average exercise price.

(b) Weighted average remaining contractual life.

**13.**

**Income Taxes**

The Company recorded no income tax provision or benefit for the years ended June 30, 2007 and 2006.

The Company had a net deferred tax asset of approximately \$6.7 million and \$3.8 million as of June 30, 2007 and 2006, respectively. The deferred tax asset has arisen principally from net operating loss carryforwards, share-based compensation, depreciation and amortization, and accrued compensation. The deferred tax asset was calculated based on the currently enacted 34% statutory income tax rate. Since management of the Company cannot determine if it is more likely than not that the Company will realize the benefit of its net deferred tax asset, a valuation allowance equal to the full amount of the net deferred tax asset at June 30, 2007 and 2006 has been established.

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At June 30, 2007, the Company had tax basis net operating loss carryforwards of approximately \$19 million available to offset future regular taxable income. These net operating loss carryforwards expire through 2027.

**14. 401(k) and Profit Sharing Plan**

The Company has a 401(k) plan, which commenced in fiscal year 2007, covering all eligible full-time employees of the Company. Contributions to the 401(k) plan are made by the participants to their individual accounts through payroll withholding. The 401(k) plan also allows the Company to make contributions at the discretion of management. To date, the Company has not made any contributions to the 401(k) plan.

**15. Related Party Transactions**

The Company received various legal services for assistance with the common stock and warrant offerings, lease and contract review, and other general counsel support from a law firm in which one of the firm's partners is a member of the Company's Board of Directors. The total amounts paid in 2007 and 2006 to the law firm were \$458,534 and \$390,000, respectively. The 2007 amount includes approximately \$18,000 accrued in accounts payable as of June 30, 2007.

During fiscal year 2006, the Company paid \$60,000 to a shareholder for strategic business and financial consulting.

**16. Commitments and Contingencies**

Royalty Agreement for Invention and Patent Application

A shareholder of the Company previously assigned his rights, title and interest in an invention to IsoRay Products LLC (a predecessor company) in exchange for a royalty equal to 1% of the Gross Profit, as defined, from the sale of "seeds" incorporating the technology. The patent and associated royalty obligations were transferred to the Company in connection with the merger transactions (see Note 1).

The Company must also pay a royalty of 2% of Gross Sales, as defined, for any sub-assignments of the aforesaid patented process to any third parties. The royalty agreement will remain in force until the expiration of the patents on the assigned technology, unless earlier terminated in accordance with the terms of the underlying agreement.

During fiscal years 2007 and 2006, the Company recorded royalty expenses of \$2,161 and \$0, respectively.

Patent and Know-How Royalty License Agreement

IsoRay Products LLC was the holder of an exclusive license to use certain "know-how." This license was transferred to Medical and subsequently to the Company in connection with the merger transactions (see Note 1). The terms of the original license agreement required 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.



Battelle Memorial Institute Production Agreement

In April 2004, IsoRay Products LLC entered into an agreement with Battelle Memorial Institute, Pacific Northwest Division (Battelle), the operator of the Pacific Northwest National Laboratory, for certain production-related services and facilities. This agreement was assumed by Medical and subsequently by the Company following the merger transactions (see Note 1). In accordance with the terms of the agreement, the Company is required to make advance payments, which are then applied against billings by Battelle as services are provided. During the years ended June 30, 2007 and 2006, the Company incurred \$151,065 and \$868,650, respectively, of costs for production-related services and facilities provided by Battelle. At June 30, 2007, accrued liabilities included \$494 related to this agreement. The agreement, which expires December 31, 2007, may be terminated at any time by either party, upon giving a 60-day written notice to the other party.

Operating Lease Agreements

The Company leases office and laboratory space and production and office equipment under noncancelable operating leases. The lease agreements require monthly lease payments and expire on various dates through June 2011. The Company's two significant leases are described below.

On May 2, 2007, Medical entered into a lease for its new production facility with Energy Northwest, the owner of the Applied Process Engineering Laboratory (the APEL lease). The new lease provides the Company with 19,328 square feet of manufacturing and office space and the Company has moved all manufacturing operations to this new leased space as of September 2007 and will vacate its leased space at the PEcoS-IsoRay Radioisotope Laboratory (PIRL). The APEL lease has a three year term expiring on April 30, 2010, an option to renew for two additional three-year terms, and monthly rent of approximately \$26,700, subject to annual increases based on the Consumer Price Index, plus monthly janitorial expenses of approximately \$700. Due to the severe economic penalty associated with not exercising the two lease renewal options, the Company currently intends to exercise both of the three-year renewal options at the appropriate time in the lease.

In February 2005, the Company entered into a lease agreement for leased space at PIRL in which it established production facilities. The lease term commenced on regulatory licensing approval, which was obtained in October 2005. The lease had a base term of one year with a one year renewal option. The first year of rent was paid using 24,000 shares of the Company's common stock which was valued at \$120,035 based on the date of issuance. The Company has agreed to pay \$5,000 per month for its second year of occupancy.

Future minimum lease payments under operating leases including the two three-year renewals of the APEL lease, which the Company intends to exercise, are as follows:

Year ending June 30,	
2008	\$ 372,118
2009	338,496
2010	338,354
2011	337,925
2012	328,749
Thereafter	1,260,206
	\$ 2,975,848

Rental expense (including rent paid with common stock) amounted to \$207,044 and \$155,838 for the years ended June 30, 2007 and 2006, respectively.

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### License Agreement with IBt

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 Cs-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 incorporating the technology 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.

As of the date of this report, the August 2006 payment has not been made. In the fourth quarter of fiscal year 2007, the Company reviewed the carrying values of licenses, including the IBt license. 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 license agreement and other business arrangements (see Note 19).

## **17. Concentrations of Credit and Other Risks**

### Financial Instruments

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents, short-term investments, and accounts receivable.

The Company's cash and cash equivalents are maintained with high-quality financial institutions. The accounts are guaranteed by the Federal Deposit Insurance Corporation (FDIC) up to \$100,000. At June 30, 2007, uninsured cash balances totaled \$9,418,359.

Short-term investments are held by a major, high-quality financial institution. Generally, these securities are traded in a highly liquid market and may be redeemed upon demand and bear minimal risk. Management regularly monitors the composition and maturities of these investments and the Company has not experienced any material loss on its investments.

The Company's accounts receivable result from credit sales to customers. The Company had two and three customers whose sales were greater than 10% for each of the years ended June 30, 2007 and 2006, respectively. These customers represented 37.7% and 49.2% of the Company's total revenues for the years ended June 30, 2007 and 2006, respectively. Those same customers accounted for 25.6% and 47.9% of the Company's net accounts receivable balance at June 30, 2007 and 2006, respectively.

The Company's Proxcelan brachytherapy seed is currently its only product and all of the Company's revenues are derived from sales of the Proxcelan seed in the United States. Sales to the Company's largest customer totaled 24.5% and 20.6% of total revenues in 2007 and 2006, respectively.

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.

The Company routinely assesses the financial strength of its customers and provides an allowance for doubtful accounts as necessary.

### Inventories

Most components used in the Company's product are purchased from outside sources. Certain components are purchased from single suppliers. The failure of any such supplier to meet its commitment on schedule could have a material adverse effect on the Company's business, operating results and financial condition. If a sole-source supplier were to go out of business or otherwise become unable to meet its supply commitments, the process of locating and qualifying alternate sources could require up to several months, during which time the Company's production could be delayed. Such delays could have a material adverse effect on the Company's business, operating results and financial condition.

### **18. New Accounting Standards**

In July 2006, the FASB issued Financial Accounting Standard Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48). FIN 48 is an interpretation of SFAS 109 and it seeks to reduce the diversity in practice associated with certain aspects of measurement and recognition in accounting for income taxes. In addition, FIN 48 requires expanded disclosure with respect to uncertainties in income taxes. The Company does not believe the adoption of FIN 48 on July 1, 2007 will have a material effect on its consolidated financial statements.

In September 2006, the FASB issued statement No. 157, Fair Value Measurements, (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007, with earlier application encouraged. Any amounts recognized upon adoption as a cumulative effect adjustment will be recorded to the opening balance of retained earnings in the year of adoption. The Company is currently evaluating the impact this statement will have on its financial statements.

In February 2007, the FASB issued statement No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115 (SFAS 159). The statement allows entities to value financial instruments and certain other items at fair value. The statement provides guidance over the election of the fair value option, including the timing of the election and specific items eligible for the fair value accounting. Changes in fair values would be recorded in earnings. The statement is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact this statement will have on its financial statements.

### **19. Subsequent Events**

The following events and transactions have occurred subsequent to June 30, 2007:

#### Option Cancellations

On June 1, 2007, the Company issued an option grant to employees and directors. The options had an exercise price of \$4.14 which was the closing market price of the Company's stock. The options issued to the employees vest over 3 years while the options granted to the non-employee directors were immediately vested.

The Company's CEO, who also serves as Chairman of the Board, was granted 150,000 options, the EVP-Operations, who also serves as a Director, was granted 100,000 options, and all non-employee directors were granted 50,000 options each. On July 25, 2007, the Board discussed the issue of director compensation and each director (including the employee directors) elected to cancel 50,000 of their options from the June 1, 2007 grant.

After the cancellation, the CEO and EVP-Operations had 100,000 and 50,000 options, respectively, and the non-employee directors had no options from the June 1, 2007 grant. The terms of these remaining options for the CEO and EVP-Operations were not changed as part of the cancellation.

In accordance with SFAS 123R, all of the options that were cancelled have been accounted for as cancellation of options with no consideration. No additional compensation cost associated with the CEO's and EVP-Operations's options will be recognized after the cancellation date of July 25, 2007. Cancelled options that had been granted to non-employee directors were immediately vested on the date of grant; therefore all related compensation cost was recognized in fiscal year 2007.

All of these subsequently cancelled options are included in the options granted and outstanding as of June 30, 2007.

#### Global Strategic Alliance with IBt

In September 2007, the Company entered into a letter of intent with IBt to enter into a Global Strategic Alliance incorporating various cooperative initiatives which will be the subject of a number of future agreements and transactions. Each of the following proposed initiatives are subject to Board approval by each of the respective parties:

§ An amendment to the IsoRay's license agreement with IBt for the use of its polymer seed technology whereby IsoRay would pay the remaining \$225,000 license fee but would not be subject to ongoing royalty payments.

    IsoRay would purchase polymer seed components at cost plus a profit margin to be determined.

§ The Company would grant IBt an exclusive license to distribute Cs-131 brachytherapy seeds in certain markets outside of North and South America, including the European Union.

§ The Company would receive the exclusive right to manufacture and distribute polymer I-125 brachytherapy seeds in North and South America.

§ The Company would also receive IBt's US subsidiary's customer list and the right to offer employment to certain IBt US employees.

SIGNATURES

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

Dated: September 28, 2007

ISORAY, INC., a Minnesota corporation

By /s/ Roger E. Girard  
Roger E. Girard, Chief Executive Officer

By /s/ Jonathan R. Hunt  
Jonathan R. Hunt, Chief Financial Officer