FORM 10-K

IsoRay, Inc. - ISR

Filed: September 23, 2009 (period: June 30, 2009)

Annual report with a comprehensive overview of the company

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

FORM 10-K

☑ **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the fiscal year ended June 30, 2009

or

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the transition period from _____ to _____

Commission File No. 001-33407

ISORAY, INC.

(Exact name of registrant as specified in its charter)

Minnesota	41-1458152
(State of incorporation)	(I.R.S. Employer Identification No.)
350 Hills St., Suite 106 Richland, Washington (Address of principal executive offices)	99354 (Zip code)

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

Securities registered pursuant to Section 12(b) of the Exchange Act – Common Stock – $0.001 par value
(NYSE Amex)

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

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

Class	Outstanding as of September 14, 2009
Common stock, $0.001 par value	22,942,088

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

INDICATE BY CHECK MARK WHETHER THE REGISTRANT (1) HAS FILED ALL REPORTS REQUIRED TO BE FILED BY SECTION 13 OR 15(D) OF THE EXCHANGE ACT OF 1934 DURING T PRECEDING 12 MONTHS (OR FOR SUCH SHORTER PERIOD THAT THE REGISTRANT WAS REQUIRED TO FILE SUCH REPORTS), AND (2) HAS BEEN SUBJECT TO SUCH FILING REQUIREMENTS F the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on ITS CORPORATE WEB SITE, IF ANY, EVERY INTERACTIVE DATA FILE REQUIRE be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements INCORPORATED BY REFERENCE IN PART III OF THIS FORM 10-K OR ANY AMENDMENT TO THIS Form 10-K. ☐

Indicate BY CHECK MARK WHETHER THE REGISTRANT IS A LARGE ACCELERATED FILER, AN ACCELERATED FILER, A NON-ACCELERATED FILER, OR A SMALLER REPORTING COMPANY. SEE THE definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐
Smaller reporting company ☒

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

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 T COMMON EQUITY WAS LAST SOLD, OR THE AVERAGE BID AND ASKED PRICE OF SUCH COMMON EQUITY, AS OF THE LAST BUSINESS DAY OF THE REGISTRANT'S MOST RECEN completed second fiscal quarter – $4,509,712 as of December 31, 2008.

Documents incorporated by reference – none.

ISORAY, INC.

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Caution Regarding Forward-Looking Information

In addition to historical information, this Form 10-K 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-K, 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 Item 1A – Risk Factors beginning on page 23 below that may cause actual results to differ materially.

Consequently, all of the forward-looking statements made in this Form 10-K 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-K, unless the context requires otherwise, “we” or “us” or the “Company” means IsoRay, Inc. and its subsidiaries.

ITEM 1 – 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 on 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.

IsoRay International LLC (International), a Washington limited liability company, was formed on November 27, 2007 and is a wholly-owned subsidiary of the Company. International has not had any significant transactions since its inception.

Available Information

The Company electronically files its annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to th reportsand other information with the Securities and Exchange Commission (SEC).These reports can be obtained by accessing the SEC's website a 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 SEC at 1-800-SEC-0330. In addition, the Company makes copies of its annual and quarterly reports available to the public at its websitewww.isoray.com. Information on this website is not a part of this report.

Business Operations

Overview

In 2003, IsoRay obtained clearance from the FDA for treatment for all solid tumorapplications using Cesium-131 (Cs-131). Such applications include prostate cancer; ocular melanoma; head, neck and lung tumors; and breast, liver, brand pancreatic cancer. The seed may be used in surface, interstital a intracavity applications for tumors with known radio sensitivity.Management believes its Cs-131 technology will allow it to become a leader the brachytherapy market. Management believes that the IsoRay Proxcelesium-131 brachytherapy seed represents the first major advancement brachytherapy technology in over 21 years with attributes that could make it the long-term "seed of choice" for internal radiation therapy procedures.

IsoRay began production and sales of Proxcelan Cesium-131 brachytherapy seeds October 2004 for the treatment of prostate cancer after clearance premarket notification (510(k)) by the Food and Drug Administration (FDA).In December 2007, IsoRay began selling its Proxcelan Cs-131 seeds for t treatment of ocular melanoma. On June 1, 2009, the Company again expanded its application of Cs-131 with the treatment of a head and neck tumor t couldnot be accessed by other treatment modalities. More recently the Companyas focused on other applications which require revising the delive system from those historically used by the Company.

In August 2009, IsoRay Medical received clearance from the FDA for its Premarket Notification (510(k)) for Proxcelan™ Cesium-131 brachytherapy see that are preloaded into bioabsorbable braided strands. This clearance permits the product to be commercially distributed for treatment of lung, head and n tumors as well as tumors in other organs. While Cs-131 brachytherapy seeds themselves have been cleared for treatment in all organs since 2003, this 51 allows Cs-131 seeds to be delivered in a convenient and sterile format that can be implanted without additional seed loading by the facility. The 510(k) also clears the application of braided strands onto a bioabsorbable mesh matrix to further facilitate the implant procedure.

Brachytherapyseeds are small devices used in an interstital radiation procedure. The procedure has become one of the primary treatments for prost cancer. The brachytherapy procedure places radioactive seeds as close as possible to (or near) the cancerous tumor (the word "brachytherapy" means cl 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 directly to the tumor. Each seed contains a radioisotope sealed within a welded titanium capsule. When brachytherapy is the only treatment (monotherapy), approximately 70 to 120 seeds are permanently implanted in the prostate in an outpatien procedure lasting less than one hour. The number of seeds used varies based on the size of the prostate and the activity level specified by the physician. When brachytherapy is combined with external beam radiation or intensity modulated radiation therapy (dual therapy), the approximately 40-80 seeds are used in the procedure. The isotope decaysover time and eventually the seeds become inert. The seeds may be used as a primary treatment or in conjunctio with other treatment modalities, such as chemotherapy, or as treatment for residual disease after excision of primary tumors. The number of seeds for othe treatment sites will vary from as few as 10-12 to as many at 80-100 depending on the location of the tumor being treated.

Brachytherapy Isotope Comparison

INCREASINGLY, PROSTATE CANCER PATIENTS AND THEIR DOCTORS WHO DECIDE ON SEED BRACHYTHERAPY CHOOSE CS-131 BECAUSE OF ITS SIGNIFICANT ADVANTAGES OVE 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 HO UNIFORMLY THE RADIATION DOSE CAN BE DELIVERED THROUGHOUT THE PROSTATE. THIS QUALITY OF A PROSTATE IMPLANT IS KNOWN AS HOMOGENEITY. EARLY STUDIE DEMONSTRATE CS-131 IMPLANTS ARE ABLE TO DELIVER THE REQUIRED DOSE WHILE MAINTAINING HOMOGENEITY ACROSS THE GLAND ITSELF AND POTENTIALLY REDUC UNNECESSARY DOSE TO CRITICAL STRUCTURES SUCH AS THE URETHRA AND RECTUM. (PRESTIDGE B.R., BICE W.S., JURKOVIC I., *et al.* CESIUM-131 PERMANENT PROSTAT 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 I JUST 33 DAYS COMPARED TO 58 DAYS FOR PD-103 AND 204 DAYS FOR I-125. BY FAR THE MOST COMMONLY REPORTED SIDE EFFECTS OF PROSTATE BRACHYTHERAPY A IRRITATIVE AND OBSTRUCTIVE SYMPTOMS IN THE ACUTE PHASE POST-IMPLANT (NEILL B, ET AL. THE NATURE AND EXTENT OF URINARY MORBIDITY IN RELATION PROSTATE BRACHYTHERAPY URETHRAL DOSIMETRY. BRACHYTHERAPY 2007:6(3)173-9.). THE SHORT HALF-LIFE OF CS-131 REDUCES THE DURATION OF TIME DURIN which the patient experiences the irritating effects of the radiation.

Improved Coverage of the Prostate

Permanent PROSTATE BRACHYTHERAPY UTILIZING CS-131 SEEDS ALLOWS FOR BETTER DOSE HOMOGENEITY AND SPARING OF THE URETHRA AND RECTUM WHILE PROVIDI COMPARABLE PROSTATE COVERAGE COMPARED TO I-125 OR PD-103 SEEDS WITH COMPARABLE OR FEWER SEEDS AND NEEDLES. SEVERAL STUDIES HAVE DEMONSTRAT DOSIMETRIC ADVANTAGES OF CS-131 OVER THE OTHER COMMONLY USED PROSTATE BRACHYTHERAPY ISOTOPES. (MUSMACHER JS, ET AL. DOSIMETRIC COMPARISON OF CESIUM-131 AND PALLADIUM-103 FOR PERMANENT PROSTATE BRACHYTHERAPY. INT. J. RADIATION ONCOLOGY BIOL. PHYS. 2007:69(3)S730-1.) (YAPARPALVI R, ET AL. IS CS-131 OR I-125 OR PD-103 THE "IDEAL" ISOTOPE FOR PROSTATE BOOST BRACHYTHERAPY? A DOSIMETRIC VIEW POINT. INT. J. RADIATION ONCOLOGY BIOL PHYS. 2007:69(3)S677-8) (SUTLIEF S, ET AL. CS-131 PROSTATE BRACHYTHERAPY AND TREATMENT PLAN PARAMETERS. MEDICAL PHYSICS 2007:34(6)2431.) (YANG R, ET AL. DOSIMETRIC COMPARISON OF PERMANENT PROSTATE BRACHYTHERAPY PLANS UTILIZING CS-131, I-125 AND PD-103 SEEDS. MEDICAL PHYSIC 2008:35(6)2734.)

Rapid Resolution of Side effects

STUDIES DEMONSTRATE THAT OBJECTIVE MEASURES OF COMMON SIDE-EFFECTS SHOWED AN EARLY PEAK IN SYMPTOMS IN THE 2-WEEK TO 1-MONTH TIME FRAME. RESOLUTION OF MORBIDITY RESOLVED RAPIDLY WITHIN 4-6 MONTHS. (PRESTIDGE B, ET. AL. CLINICAL OUTCOMES OF PHASE-II, MULTI-INSTITUTIONAL CESIUM-13 Permanent Prostate Brachytherapy Trial. *Brachytherapy.* 2007: 6 (2)78.) (Moran B, et al. Cesium-131 Prostate Brachytherapy: An Early Experience. BRACHYTHERAPY 2007:6(2)80.) (JONES A, ET AL. IPSS TRENDS FOR CS-131 PERMANENT PROSTATE BRACHYTHERAPY. BRACHYTHERAPY 2008:7(2)194.) (DEFOE ET AL. IS THERE DECREASED DURATION OF ACUTE URINARY AND BOWEL SYMPTOMS AFTER PROSTATE BRACHYTHERAPY WITH CESIUM 131 RADIOISOTOPE? INT. RADIATION ONCOLOGY BIOL. PHYS. 2008:72(S1)S317.) MORE STRINGENT STUDIES ARE UNDERWAY TO MORE FULLY CHARACTERIZE ANY ADVANTAGE IN SIDE EFF resolution experienced by patients undergoing Cs-131 prostate brachytherapy versus brachytherapy with other isotopes.

Higher Biologically Effective Dose

Another benefit to the short half-life of Cs-131 is what is known as the "biologically effective dose" or BED. BED is a way for health care providers to predict how an isotope will perform against cancers exhibiting different characteristics, for instance, 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.)

PSA Control

Investigators tracking PSA in both single arm and randomized trials have concluded Cs-131's PSA response rates show similar early tumor control to I-125, long considered the gold standard in permanent seed brachytherapy. Longitudinal PSA measurements from ongoing Cs-131 clinical series demonstrate trends very similar to those seen with other isotopes. (Moran B, et. al. Cesium-131 Prostate Brachytherapy" An Early Experience *Brachytherapy*. 2007:6(2)80.) (Bice W, et. al. Recommendations for permanent prostate brachytherapy with 131Cs: a consensus report from the Cesium Advisory Group. Brachytherapy 2008:7(4)290-296.) (Platta CS, et al. Early Outcomes of Prostate Seed Implants with 131Cs: Toxicity and Initial PSA Dynamics from a Single Institution. Int. J. Radiation Oncology Biol. Phys. 2008:72(S1)S323-4.)

Industry Information

Incidence of Prostate Cancer

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 in six men will be diagnosed with prostate cancer during his lifetime. It is the most common form of cancer in men after skin cancer, and the second leading cause of cancer deaths in men following lung and bronchus cancers that account for 30% of deaths from cancer in men. The American Cancer Society estimates there will be about 192,280 new cases of prostate cancer diagnosed and an estimated 27,360 deaths associated with the disease in the United States in 2009. Because of early detection techniques (e.g., screening for prostate specific antigen, or PSA), approximately nine out of ten prostate cancers are found in the local and regional stages (local means it is still confined to the prostate; regional means it has spread from the prostate to nearby areas, but not to distant sites, such as bone).

Prostate cancer accounts for about 9% of cancer related deaths in men. 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. At the age of 70, the chance of having prostate cancer is 12 times greater than at age 50.

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. Early screening has fostered a decline in the prostate cancer death rate since 1990. When compared to men of the same age and race who do not have cancer (called relative survival), the 5-year relative survival rate for men when the cancer is found in the local and regional stages is nearly 100%. During this past year the national press publicized a meeting among urologists at the annual American Urology Association meeting debating the need for annual PSA testing. Results of this publicity may result in future recommendations to begin testing at a later age and not test annually unless there are risk factors. Based on its own industry knowledge, management believes this could lead to an increase in prostate cancer, which has not been experienced since 2000.

Incidence of Lung Cancer

An estimated 219,440 new cases of lung cancer are expected in 2009, accounting for 15% of all cancer diagnoses in the United States. Lung cancer accou for the most cancer related deaths in both men and women in the United States. An estimated 159,390 deaths, accounting for about 28% of all cancer dea are expected to occur in 2009. This exceeds the combined number of deaths from the leading causes of cancer (breast, prostate, and colon cancers) alo accounts for 6% of all deaths from any source in the United States. (Cancer Management: A Multidisciplinary Approach, 11th Edition (2008). Richar Pazdur, Lawrence R. Coia, William J. Hoskins, Lawrence D. Wagman; American Cancer Society, 2009.)

Cigarette smoking is the most important risk factor for lung cancer. Risk increases with quantity and length of time a person has smoked during his or her lif time. Other risk factors include occupational or environmental exposure to secondhand smoke, radon, asbestos (particularly among smokers), certain meta (chromium, cadmium, arsenic), some organic chemicals, radiation, air pollution, and a history of tuberculosis. Genetic susceptibility plays a contributing role in the development of lung cancer, especially in those who develop the disease at a younger age. (American Cancer Society, 2009)

The 1-year relative survival for lung cancer increased from 35% in 1975-1979 to 41% in 2001-2004, largely due to improvements in surgical techniques an combined therapies. However, the 5-year survival rate for all stages combined is only 15%. The 5-year survival rate is 50% for cases detected when disease is still localized, but only 16% of lung cancers are diagnosed at this early stage. (American Cancer Society, 2009)

Incidence of Head and Neck Cancers

In 2008 it was estimated that there were a total of 47,560 head and neck cancer cases, which includes 22,900 cases of oral cavity cancer, 12,250 cases laryngeal cancer, and 12,410 cases of pharyngeal cancer, diagnosed in the United States. (Cancer Management: A Multidisciplinary Approach, 11th Edition (2008). Richard Pazdur, Lawrence R. Coia, William J. Hoskins, Lawrence D. Wagman; American Cancer Society, 2009.)

Symptoms may include a sore in the throat or mouth that bleeds easily and does not heal, a lump or thickening, ear pain, a neck mass, coughing up blood, and a red or white patch that persists. Difficulties in chewing, swallowing, or moving the tongue or jaws are often late symptoms. (American Cancer Socie 2009)

Known risk factors include all forms of smoked and smokeless tobacco products and excessive consumption of alcohol. Many studies have reported synergism between smoking and alcohol use, resulting in more than a 30-fold increased risk in individuals who both smoke and drink heavily. HPV infection is associated with certain types of oropharyngeal cancer. (American Cancer Society, 2009)

Incidence of Ocular Melanoma

The American Cancer Society estimates that 2,350 new cases of cancers of the eye and orbit (primarily melanoma) will be diagnosed in 2009 and about 23 deaths from cancer of the eye will occur in 2009. Eye cancer can occur at any age but typically occurs in people over 50 years of age. (American Canc Society, 2009)

Eye cancer may not present symptoms unless it grows in certain parts of the eye or in an advanced stage. Some signs and symptoms may include decreased ability to see, floaters or flashes of light, visual field loss, a glowing spot on the iris, change in position of the eyeball within its socket, bulging of the eye, and/or change in the movement of the eye within the socket. Known risk factors for ocular melanoma include sun exposure, certain occupations (e.g. welders, farmers, fishermen, and chemical workers), race/ethnicity/eye color, and certain inherited conditions such as dysplastic nevus syndrome. (American Cancer Society, 2009)

Prostate Brachytherapy

There is a large potential market for the Company's products. Several significant clinical and market factors are contributing to the increasing popularity of the brachytherapy procedure. Over 61,000 procedures were forecasted to occur in the U.S. in 2007 (Source: iData Research, Inc., 2008). 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 2007 approximately 61,000 brachytherapy procedures were performed to treat prostate cancer. (Source: iData Research Inc., 2008)

Minimally invasive 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 prostatectomy surgery (RP for radical prostatectomy), 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.

Prostatectomy Surgery Options. Historically the most common treatment option for prostate cancer, radical prostatectomy is the removal of the prostate gland and some surrounding tissue through an invasive surgical procedure. RP is performed under general anesthesia and involves a hospital stay of three days on average for patient observation and recovery. Possible side affects of RP include impotence and incontinence. According to a study published in the *Journal of the American Medical Association* in January 2000, approximately 60% of men who had a RP reported erectile dysfunction as a result of surgery. This same study stated that approximately 40% of the patients observed reported at least occasional incontinence. New methods such as laparoscopic and robotic prostatectomy surgeries 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 and laparoscopic prostatectomy are projected to decrease approximately 31% in the U.S. from the 2004 high of 66,567 to 20,838 procedures in 2014. However, robotic surgeries are projected to more than replace the decrease in the RP and laparoscopic procedures (Source: iData Research Inc., 2008).

Primary External Beam Radiation Therapy. EBRT involves directing a beam of radiation from outside the body at the prostate gland to destroy cancer tissue. EBRT treatments are received on an outpatient basis five days per week usually over a period of eight or nine weeks. Some studies have shown, however, that the ten-year disease free survival rates with treatment through EBRT are less than 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 five to six years after EBRT is comparable to that for surgery. EBRT procedures are projected to increase slightly from 22,000 procedures in 2006 to 24,900 in 2012 (Source: Millennium Research Group, 2008).

Intensity Modulated Radiation Therapy. IMRT is considered a more advanced form of EBRT in which sophisticated computer control is used to aim th beam at the prostate from multiple different angles and to vary the intensity of the beam. This damage to normal tissue and critical structures is minimiz by distributing the unwanted radiation over a larger geometric area. This course of treatment is similar to EBRT and requires daily doses over a period o 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 regard 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 have begun to spread from the tumor site. An increasingly popular therapy for patients with more advanced prostate cancer is a combination of IMRT wit seed brachytherapy, known as combination or dual therapy. IMRT in the U.S. (including dual therapy) is projected to grow 9% per year from 31,5 procedures in 2007 to 48,500 procedures in 2012 (Source: Millennium Research Group, 2008). IMRT is generally more expensive than other common treatment modalities.

Dual or Combination Therapy. Dual therapy is the combination of IMRT or 3-dimensional conformal external beam radiation and seed brachytherapy treat extra-prostatic extensions or high risk prostate cancers that have grown outside the prostate. Combination therapy treats high risk patients with a fu 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 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 durations 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 t giving a series of radiation treatments through these catheters. The catheters are then removed, and no radioactive material is left in the prostate gland computer-controlled machine inserts a single highly radioactive iridium seed into the catheters one by one. This procedure is typically repeated at least thre times while the patient is hospitalized for at least 24 hours. HDR is projected to grow approximately 1.3% per year from 26,200 procedures in 2007 through 2012 (Source: Millennium Research Group, 2008).

Cryosurgery. Cryosurgery involves placing cold metal probes into the prostate and freezing the tissue in order to destroy the tumor. Cryosurgery pati typically stay in the hospital for a day or two and have had higher rates of impotence and other side effects than those who have used seed implan brachytherapy. Market research firms project that cryosurgery will grow only steadily through 2012. To date the market has remained almost flat (Source: Millennium Research Group, 2008).

Additional Treatments. Additional treatments include hormone therapy and chemotherapy. Hormone therapy is generally used to shrink the tumor or ma it grow more slowly but will not eradicate the cancer. Likewise, chemotherapy will not eradicate the cancer but can slow the tumor growth. Generally, treatment alternatives are used by doctors to extend patients' lives once cancer has reached an advanced stage or in conjunction with other treatm 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 t 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 curative 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.

Comparing Cs-131 to I-125 and Pd-103 Clinical Results

Long-term survival data is 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. In fact, it appears that Cs-131 offers 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 describing the use of I-125 and Pd-103 brachytherapy in the treatment of early-stage prostate cancer have been very positive. A recent study of 2,963 prostate cancer patients who underwent brachytherapy as their sole therapeutic modality at institutions across the U.S. concluded that low-risk patients (who make up the preponderance of localized cases) who underwent adequate implant experienced rates of PSA relapse survival of greater than 90% between eight and ten years (Zelefsky MJ, Kuban DA, et al, "Multi-institutional analysis of long-term outcome for stages T1-T2 prostate cancer treated with permanent seed implantation" International Journal of Radiation Oncology Biology Physics, Volume 67, Issue 2, 2007, 327-333).

Other recent studies have demonstrated similar, durably high rates of control following brachytherapy for localized prostate cancer out to 15 years post-treatment (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", International Journal of Radiation Oncology Biology Physics, Vol. 67, Issue 1, 2007, 57-64.). The cumulative effect of these series has been the conclusion by leaders in the field that brachytherapy offers a disease control rate as high as surgery, though with a lesser side-effect profile than surgery (Ciezki JP "Prostate brachytherapy for localized prostate cancer" Current Treatment Options in Oncology, Volume 6, 2005, 389-393).

Reduced Incidence of Side Effects. Sexual impotence and urinary incontinence are two major concerns men face when choosing among various forms of treatment for prostate cancer. Studies have shown that brachytherapy with existing sources results in lower rates of impotence and incontinence than surgery (Frank, Buron). Combined with the high disease control rates described in many studies, these findings have driven the adoption of brachytherapy as a front-line therapy for localized prostate cancer.

It has been noted, however, that a significant proportion of patients who undergo I-125 or Pd-103 brachytherapy experience acute urinary irritative symptoms following treatment – in fact more so than with surgery or external beam radiation therapy (Frank SJ, Pisters LL, et al, "An assessment of quality of life following radical prostatectomy, high dose external beam radiation therapy, and brachytherapy iodine implantation as monotherapies for localized prostate cancer" Journal of Urology, Volume 177, 2007, 2151-2156). It has been postulated that Cs-131, with the shortest available half-life for a low-rate therapy isotope, will result in a quicker resolution of these irritative symptoms based on the shorter time interval over which normal tissue receives radiation from the implanted sources.

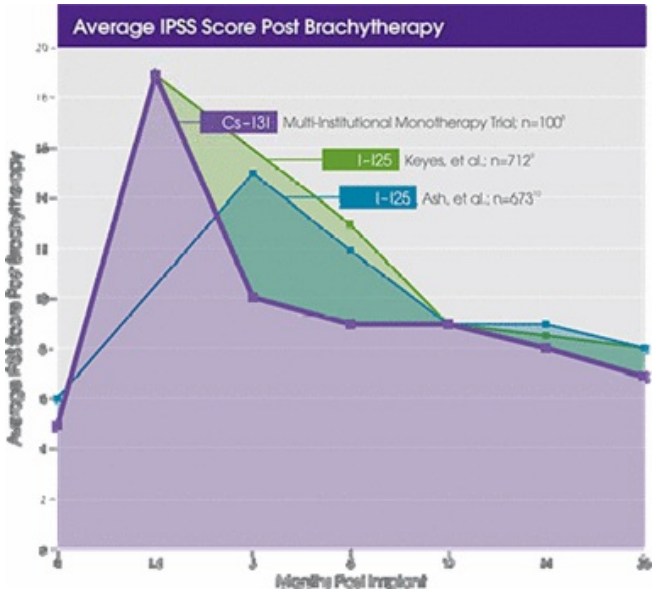
Preliminary data drawn from several clinical studies suggest that patients treated with Cs-131 do in fact experience a faster resolution of these side effects in comparison to similar studies published for other isotopes (Defoe SG, et al, "Is there a decreased duration of acute urinary and bowel symptoms after prostate brachytherapy with Cesium 131 isotope?", International Journal of Radiation Oncology Biology Physics, Volume 72 (Supplement 1), S317; Jones A, et al "IPSS Trends for Cs-131 Permanent Prostate Brachytherapy" Brachytherapy, Volume 7, Issue 2, 194; Platta CS, et al, "Early Outcomes of Prostate Seed Implants with 131Cs: Toxicity and Initial PSA Dynamics from a Single Institution" International Journal of Radiation Oncology Biology Physics, Volume 72 (Supplement 1), 2008, S323-4).

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 that sought to (1) document the dosimetric characteristics of Cs-131, (2) summarize the side effect profile of Cs-131 treatment, and (3) to track biochemical (PSA) results in patients following Cs-131 therapy.

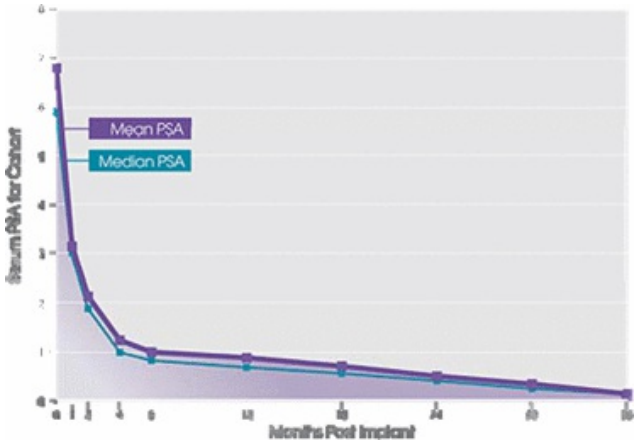
The investigators responsible for conducting the study have concluded based on the results of the monotherapy trial that Cs-131 is a viable alternative isotope for permanent seed prostate brachytherapy (Prestidge BR, Bice WS, "Clinical outcomes of a Phase II, multi-institutional Cesium-131 permanen prostate brachytherapy trial". *Brachytherapy*, *Volume 6, Issue 2*, *April-June 2007*, Page 78).

Some of the significant and specific findings were as follows:

- Patient reported irritative urinary symptoms (IPSS Scores) were mild to moderate with relatively rapid resolution within 4-6 months. The figu below depicts the symptom scores in the Cs-131 study as compared to published reports of patients who underwent I-125 brachytherapy. Especial notable is the steep drop in the Cs-131 group scores (purple line) as opposed to the more gradual drop in the I-125 group scores (green and bl lines).



- Prostate Specific Antigen, or PSA, response over 36 months has been very encouraging to date with similar tumor control rates to that of I-125. (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). The graph below depicts the median PSA to date from the 100 patient Cs-13 brachytherapy series as compared to previously published I-125 series. There have been no PSA failures in the Cs-131 monotherapy study to date. (A PSA failure is a rise in the blood level of PSA in prostate cancer patients after treatment with radiation or surgery.)



- Gland coverage was excellent and the dose delivered to critical structures outside the prostate 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.).

Several other series have been reported that have compared dosimetric parameters (indicators of dose) among Cs-131, Pd-103, and I-125. These comparative studies have shown a clear advantage to Cesium-131 from a dosimetric point-of-view, in terms of successful gland coverage obtained (typically measured by D90) while keeping unnecessary gland over-dosing (typically measured by V150 or V200) to a minimum (Musmacher JS, et al, "Dosimetric Comparison of Cesium-131 and Palladium-103 for Permanent Prostate Brachytherapy" International Journal of Radiation Oncology Biology Physics, Volume 6 (Supplement 3), 2007, S730-1; Yaparpalvi R, et al, "Is Cs-131 or I-125 or Pd-103 the Ideal Isotope for Prostate Boost Brachytherapy? A Dosimetric Vie Point." International Journal of Radiation Oncology Biology Physics, Volume 69 (Supplement 3), 2007, S677-8; Sutlief S and Wallner K, "Cs-131 Prost Brachytherapy and Treatment Plan Parameters." Medical Physics, Volume 34, 2007, 2431; Kurtzman "Dosimetric Evaluation of Permanent Prosta Brachytherapy Using Cs-131 Sources" International Journal of Radiation Oncology Biology Physics, Volume 66 (Supplement 3), S395).

The monotherapy Cs-131 trial will continue to follow patients with annual updates on symptoms and patient long-term survival data. The Company anticipates maintaining this ongoing monitoring over several years to prove the long-term effectiveness of Cs-131.

The prospective randomized monotherapy trial headed by Dr. Brian Moran of The Chicago Prostate Cancer Center directly compared Cs-131 to I-125 P response and treatment related morbidities following brachytherapy for localized carcinoma of the prostate in low to intermediate risk patients. Dr. Mo concluded that prostate brachytherapy with Cs-131 is effective and well-tolerated; both PSA response and the acute morbidity profile were v encouraging. Dr. Moran will continue to track these patients in order to collect long-term outcomes.

Recently accepted for publication was the Cs-131 Advisory Group's (CAG) article entitled "Recommendations for permanent prostate brachytherapy wit ^{131}Cs: a consensus report from the Cesium Advisory Group". The objective of the article was to provide consensus recommendations for Cs-131 prostat brachytherapy based on experience to date for physicians still unfamiliar with Cs-131. The recommendations are based on three clinical trials, one of whi has completed accrual and has been published in the peer reviewed literature, and combined CAG experience of more than 1,200 Cs-131 implants. The recommendations from the group are designed to aid practitioners in the safe and effective delivery of Cs-131 prostate brachytherapy. The Consensus Pape was published in Brachytherapy in the fourth quarter of calendar year 2008. The CAG is sponsored by the Company.

The Company has also commissioned a dual therapy protocol. This multi-institutional trial observes the dosimetric characteristics of Cs-131 heal related quality of life (HRQOL) results following combined Cs-131 transperineal permanent prostate brachytherapy and external beam radiothera 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 existing data in the literature for similar investigations using I-125 and Pd-103. Patient enrollment for this study began in April 2007 and 65 patients had been enrolled through June 30, 2009.

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

Lung Cancer Treatment Options

Lung cancer has historically been treated by surgery and chemotherapy but in recent years various forms of radiation have also been used. Surgery genera involves removing a portion of the lung or the entire lung. Chemotherapy may be used either as a primary treatment or a secondary treatment depending the type and stage of the lung cancer. External beam radiation therapy is sometimes used as the primary treatment if the tumor cannot be removed by surgery due to the tumor's location or the patient's health.

Brachytherapy is now being used in conjunction with surgery to kill small areas of cancer that might be missed during surgery. The Company believes that Cs-131, with its shorter half-life and high energy, is better suited for treating lung cancer than either I-125 or Pd-103. The bioabsorbable mesh used in th procedure generally dissolves after about 45 days. Cs-131 delivers 90% of its dose in 33 days and is therefore well-suited to use with the bioabsorbable me in this procedure.

Head and Neck Cancer Treatment Options

Most head and neck cancers are treated with some combination of surgery, chemotherapy, and radiation therapy. Surgery is the most common option an takes many different forms in an effort to remove any cancerous tissue. Chemotherapy is often used in conjunction with surgery or radiation thera depending on the type and stage of the cancer. External beam radiation therapy and brachytherapy have been used together or in combination with surge or chemotherapy.

Ocular Melanoma Treatment Options

In addition to brachytherapy to treat ocular melanoma, other treatment options include surgery, external beam radiation, and laser therapy. Surgery c include removal of part of the iris, a portion of the outer eyeball, or removal of the entire eyeball. External beam radiation (including proton beam radiation therapy and stereotactic radiosurgery) involves sending radiation from a source outside the body that is focused on the cancer but has not been widely used to date for ocular melanoma. Laser therapy burns the cancer tissue by using a highly focused, high-energy light beam and is effective fo small melanomas near the optic nerve as it causes less nerve damage. (American Cancer Society, 2009)

Brachytherapy using Cs-131, I-125, or Pd-103 is done by placing the seeds in a plaque (shaped like a small cap) that is attached to the eyeball with min stitches for 2 to 5 days. The patient generally stays in the hospital until the plaque is removed from the eye. Brachytherapy cures approximately 9 out of small tumors and can preserve the vision of some patients. (American Cancer Society, 2009)

Our Strategy

The key elements of IsoRay's strategy for fiscal year 2010 include:

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

- *Work with our distribution partner, BrachySciences, to increase prostate market penetration.* With BrachyScience's additional sales personne IsoRay expects to reach an increasing number of centers and physicians across the country that have not had access to a sales representative in th area. IsoRay received its first order from BrachySciences in August 2009. The increases from this distribution channel have been slow due to man of the same issues that IsoRay's direct sales force encounters (e.g. facility license amendments). However, management believes that distributio sales will become an important sales channel in the future.

- *Increase utilization of Cs-131 in treatment of other solid tumor applications such as head and neck and lung cancers.* IsoRay Medical has receivei clearance from the FDA for its Premarket Notification, (510(k)) for Proxcelan™ brachytherapy seeds that are preloaded into bioabsorbable braid strands. This order clears the product for commercial distribution for treatment of lung and head and neck tumors as well as tumors in other orga IsoRay has received interest from some physicians who wish to use Cs-131 for other tumor sites including lung, and head and neck, due to the sho half life that may potentially help reduce the migration of the radioactivity to other parts of the body before the treatment dose has bi delivered to the tumor. While Cs-131 brachytherapy seeds themselves have been cleared for these applications since 2003, this current 510 allows Cesium-131 seeds to be delivered in a convenient and sterile format that can be implanted without additional seed loading by the facilit The 510(k) also permits the application of the braided strands onto bioabsorbable mesh matrix to further facilitate the implant procedure. The material (mesh) used to hold the flexible suture material in place dissolves within 45 days. With the treatment dose from Cs-131 being delivered in 33 days, many physicians feel confident that the treatment dose needed to treat the tumor will be delivered prior the mesh dissolving. IsoRay will continue to explore joint ventures with other companies to develop the appropriate technologies and therapeutic delivery systems for treatment other solid tumors such as breast, liver, pancreas, and brain cancers.

- *Continue to develop an enriched barium manufacturing process.* Working with leading scientists, IsoRay is working to design and create proprietary process for manufacturing enriched barium, a key source material for Cs-13 This will ensure adequate future supply of Cs-131 an greater efficiencies in producing the isotope.

- *Continue to develop data on Cs-131 for treatment of ocular melanoma.* The Company's first sale for ocular melanoma occurred in late 2007 periodic sales have occurred since then. IsoRay is sponsoring a prospective review of the patients treated with Cs-131 to date. This clinical dat expected to be available for the American Brachytherapy Society annual meeting in the Spring of 2010. Although the ocular melanoma market is not a large one, this application of Cs-131 shows potential viability for other solid tumors.

- *Support clinical research and sustained product development.* The Company plans to structure and support clinical studies on the therapeut benefits of Cs-131 for the treatment of solid tumors and other patient benefits. We are and will continue to support clinical studies with sever leading radiation oncologists to clinically document patient outcomes, provide support for our product claims, and compare the performance of ou seeds to competing seeds. IsoRay plans to sustain long-term growth by implementing research and development programs with leading medica institutions in the U.S. and other countries to identify and develop other applications for IsoRay's core radioisotope technology.

- *Introduce Proxcelan Cesium-131 brachytherapy seeds to the Canadian and Russian markets.* Health Canada's Therapeutic Products Directorate has approved IsoRay's Class 3 Medical Device License Applications for Model CS-1 Proxcelan ™ (Cesium-131) brachytherapy seeds and th Proxcelan™ Sterile Implant Devices containing Model CS-1 Seeds. This allows IsoRay to market its brachytherapy seeds and related preload brachytherapy seeds throughout Canada. IsoRay will conduct a search to look for a viable distribution partner in Canada. Approval to mark Cesium-131 seeds in Russia was also obtained in 2009; however, the economic downturn in Russia has slowed the Company's market penetratio efforts. The Company is now focusing on the Canadian and Russian markets and is no longer pursuing sales in the European Union (EU) Management no longer believes a strategic alliance with IBt, SA, a Belgian company, will be consummated nor will management leverage IBt distribution channels in the EU.

- *Maintain ISO 13485 certification.* In August 2008, the Company obtained its ISO 13485 certification. This was an important step to allow t Company to register and eventually sell its Proxcelan Cs-131 brachytherapy seeds in Canada and Russia. The Company completed its registration of Proxcelan Cs-131 brachytherapy seeds in Canada and Russia during fiscal year 2009.

Products

IsoRay markets the Proxcelan Cs-131 brachytherapy seed for the treatment of prostate cancer, ocular melanomas, and head and neck cancers, and intends t market Cs-131 for the treatment of other malignant disease, such as lung, in the near future. Additionally, the Company is investigating its ability to marke other radioactive isotopes.

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.

		Isotope Delivery Over Time		
Isotope	**Half-Life**	**Energy**	**90% Dose**	**Total Dose**
Cs-131	9.7 days	30.4 KeV	33 days	115 Gy
Pd-103	17 days	20.8 KeV	58 days	125 Gy
I-125	60 days	28.5 KeV	204 days	145 Gy

Cs-131 Manufacturing Process and Suppliers

Product Overview. Cs-131 is a radioactive isotope that can be produced by the neutron bombardment of Barium-130 (Ba-130). When placed into a nuclea reactor and exposed to a flux of neutrons, Ba-130 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 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 electro capture to the radioactive isotope of interest (Cs-131).

To produce the Proxcelan seed, the purified Cs-131 isotope is adsorbed onto a ceramic core containing a gold X-ray marker. This internal core assembly 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-sour providers for certain components such as the gold X-ray marker and the titanium capsule as these suppliers have been validated by our quality departme and they have been cost effective.

Barium Enrichment Device. The Company has retained an independent contractor to develop 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 cost. The Company's prototype enrichment device has experienced development delays, is now 18 months beyond its original completion date and is now expected to be tested in the Fall of 2009, but there is no assurance this testing will occur by then or whether it will be successful. The Company will owe an additional $56,610 to thi contractor upon completion of a successful demonstration of the enrichment process and will determine following the demonstration whether the prototype model will be capable of producing sufficient quantities of enriched barium. If the prototype model will not produce sufficient quantities, then the Company will need to spend $100,000 to $150,000 for a larger production model.

Isotope Suppliers. Due to the short half-life of both the Ba-131 and Cs-131 isotopes, potential suppliers must be capable of removing irradiated material 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 ha sufficient irradiation capacity to accommodate barium targets and the nuclear reactors must have sufficient neutron flux to economically produ commercially viable quantities of Cs-131. Ideally, the irradiation facility will also have radiochemical separation infrastructure to carry out the in separation steps. The Company has identified key reactor facilities in the U.S. and in Russia that are capable of meeting these requirements. In order manage the Russian supply more effectively IsoRay entered into an agreement with UralDial, LLC (a Russian LLC) to provide Cs-131 isotope from Russia the Company's facility in Richland, WA. UralDial obtains Cs-131 from two suppliers. The Company also continues to receive irradiated barium from the MURR reactor located in the United States. For the fiscal year ended June 30, 2009, approximately sixty-five percent (65%) of our Cs-131 was supplied by one of two Russian supply sources and 35% from domestic sources.

The Company plans to expand Cs-131 manufacturing capability at the MURR reactor but will continue to obtain Cs-131 from multiple suppliers. Failure obtain deliveries of Cs-131 from at least one of its Russian suppliers could have a material adverse effect on seed production. Management believes it w continue to rely solely on its existing suppliers in the near future and shutdowns from these suppliers could cause delays in deliveries and production.

Quality Controls. We have established procedures and controls to comply with the FDA's Quality System Regulation. The Company constantly monitor these procedures and controls to ensure that they are operating properly, thereby working to maintain a high-quality product. Also, the quality, productio and customer service departments maintain open communications to ensure that all regulatory requirements for the FDA, DOT, and applicable nucle radiation and health authorities are fulfilled.

In July 2008, IsoRay had its baseline inspection by the FDA at its manufacturing and administrative offices in Richland, WA. This inspection was carried ou over a five day period of time during which the investigator performed a complete inspection following Quality Systems Inspection Techniques (QSIT). At the end of the inspection no report of deviations from Good Manufacturing Practices or list of observations (form FDA 483) was issued to IsoRay.

Order Processing. The Company has implemented a just-in-time production process that is responsive to customer input and orders to ensure that individu customers receive a higher level of customer service than received from our competitors who have the luxury of longer lead times due to longer half-l products. Time from order confirmation to completion of product manufacture is reduced to several working days, including receipt of irradiated bariu (from a supplier's reactor), separation of Cs-131, isotope labeling of the core, and loading of cores into pre-welded titanium "cans" for final welding, testin 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 ordei our seeds order more seeds than necessary to assure themselves that they have a sufficient quantity. Upon receipt of an order, the Company either delivers t seeds from its facility directly to the physician or sends the order to an independent preloading service that delivers the seeds preloaded into needles 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 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 knowl to estimate the proper inventory levels of isotope needed to fulfill all customer orders. Consequently, some portion of the isotope is lost through decay and is not used in an end product. Management continues to reduce the variances between ordered isotope and isotope deliveries and is continually improving its ordering process efficiencies.

Automated Manufacturing Process

In fiscal 2009, IsoRay automated certain aspects of its manufacturing line identified by management to provide process efficiencies, cost savings and consistent manufacturing quality. The Company will continue to evaluate and implement automation in the future that supports process improvement an resource management. In addition, management plans to implement processes and automation in support of additional treatment sites such as head and ne and lung in 2009-2010. The Company also has a contract with a third party to outsource certain sub-processes.

Manufacturing Facility

The Company maintains a production facility located at Applied Process Engineering Laboratory (APEL). The APEL facility became operational September 2007. The production facility has over 15,000 square feet and includes space for isotope separation, seed production, order dispensing, a clea 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 Contingencies section of Item 7 below. Management believes that the APEL facility will be utilized for manufacturing space through fiscal year 2016 w is the original lease term plus the two three-year renewal options. Management currently anticipates exercising both three-year renewal options to extend thi APEL facility lease through April 2016.

Management no longer believes that the shuttle system at Idaho's Advanced Test Reactor (ATR) will provide the conditions necessary for Cs-13 production. The facility's capacity is fully allocated to the Navy and management believes would be difficult to have IsoRay's commercial operations the same facility as these military operations, even if the shuttle was certified for use in IsoRay operations, which has not occurred.

Repackaging Services

Most brachytherapy manufacturers offer their seed product to the end user packaged in the principal configurations provided in a sterile or non-steri package depending on the customer's preference. These include:

- *Loose seeds*
- *Pre-loaded needles* (loaded typically with three to five seeds and spacers)
- *Pre-loaded Mick cartridges* (fits the Mick applicator)
- *Strands of seeds* (consists of seeds and spacers in a biocompatible "shrink wrap")
- *Preloaded Strands* (strands loaded into the needle)

In 2008, the Millenium Research Group reported that the estimated market shares for each of the five packaging types are: loose seeds and preloaded loo seeds (8%), Mick cartridges (26%), and all strand configurations including preloaded strands (66%). Market trends indicate significant movement toward 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 usel method of providing this service is through independent radiopharmacies. Manufacturers send loose seeds along with the physician's instructions to the radiopharmacy which, in turn, loads needles and/or strands the seeds according to the doctor's instructions. These radiopharmacies then sterilize the produc 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 loose seeds. Shipping to independent pharmacies creates additional loss of our isotope through decay. While the Company pre-loads many of its current orders, we have continued to utilize loading servi to supplement our own custom preloading operation and to meet the requests of the ordering physicians.

We currently load approximately 95% of Mick cartridges in our own facility which in fiscal year 2009 accounted for approximately 60% of seeds sold. T remaining approximately 40% of seeds sold are strand configurations including preloaded strands. During fiscal year 2008, the Company began offerin 100% confirmation assay performed by in-house analytical services. Providing the assay and ultimately the preloading services in-house allows Company to eliminate approximately 25% loss in isotope activity due to radioactive decay. The cost of priority overnight shipment of each order of seeds to a third-party provider is also eliminated. However, we will continue to utilize the independent radiopharmacies to back up our own preloading operation, to handle periodic increases in demand, and to cater to certain doctors' preferences.

With a clearance from the FDA for preloading flexible braided strands and bioabsorbable mesh, IsoRay will become the second company in the industry tha has 510(k) clearance to preload both the strands and the mesh. This will allow IsoRay to keep these services in house, reduce costs and provide these service directly to our customers.

Independent radiopharmacies usually provide the final packaging of the product delivered to the end user thereby eliminating the opportunity for reinforcing the "branding" of our seed product. By providing our own repackaging service, we will preserve the product branding opportunity and eliminate any concerns related to the handling of our product by a third party prior to delivery to the end user.

Providing custom packaging configurations enhances our product while providing an additional revenue stream and incremental margins to the Compa through pricing premiums charged to our customers. 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 sterilize seeds needles, and eliminating the expense of additional assaying of the seeds.

Marketing and Sales

Marketing Strategy

The Company is marketing Proxcelan Cesium-131 brachytherapy seeds as the "seed of choice" for prostate brachytherapy. Based on current and prelimin 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 from Cs-131 for their brachytherapy seed treatment.

IsoRay has chosen to identify its proprietary Cs-131 seed with the trademarked brand of "Proxcelan." Management is using this brand to differentiate Cs-1 seeds from seeds using the other isotopes. We continue to target the competing isotope products of iodine and palladium rather than the vario manufacturers and distributors of these isotopes. Using this strategy, the choice of brachytherapy isotopes should be less dependent on the name an 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 se brachytherapy treatment. The Company has developed a customized brand message for each audience. In 2009, the Company's website www.isoray.com was substantially updated to include sections for clinicians, product information, and resources. IsoRay also maintains print and visual medias (includin physician brochures discussing the clinical advantages of Cs-131, clinical information binders, informational DVDs, single sheet glossies with target clinical data, etc.), and advertisements in the leading medical journals. In addition, the Company attends national professional meetings, including th following:

- American Brachytherapy Society (ABS);
- American Society for Therapeutic Radiation and Oncology (ASTRO);
- Association of American Physicists in Medicine (AAPM); and
- Various local chapter meetings.

The Company also continues to consult with noted contributors from the medical physics community and will have articles submitted to professiona journals such as *Medical Physics, the Brachytherapy Journal,* and the *International Journal of Radiation Oncology, Biology, and Physics* regarding th benefits of and clinical trials involving Cs-131.

Beginning in January 2008, IsoRay implemented a variety of physician Cs-131 training outreach programs including the following: a two day train course held approximately three times per year at Chicago Prostate Cancer Center (CPCC); doctoring and mentoring programs led by Steve Kurtzman, M IsoRay's Medical Director; and a training DVD for physicians who choose not to leave their practices to attend a training course. The objective of t training programs is to increase the physician's confidence in using the product.

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

Because of this consumer-driven market factor, we also promote our products directly to the general public. We target the prostate cancer patient, his spou family and care givers. We emphasize to these segments the specificadvantages of the Proxcelan Cesium-131 brachytherapy seed through our webs (located at www.isoray.com and www.proxcelan.com), patient advocacy efforts, informational patient brochures and DVDs with patient testimonials, patie focused informational website (www.proxcelan.com), and advertisements in specific markets supporting brachytherapy. None of our websites should b considered a part of this report.

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

Apart from clinical studies and papers sponsored by the Company, several physiciansacross the country are now independently publishing papers an studies extolling the benefits of Cs-131.

Sales and Distribution

According to a recent industry survey, approximately 2,000 hospitals and free standing clinics are currently offering radiation oncology services in 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 oncologis 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. Current IsoRay has four direct sales persons and a VP of Business Development. These sales people include those experienced in the brachytherapy market and t medical device market. In 2008, the Company had six direct sales persons and a National Sales Director; however, the Company has experienced so turnover in the sales force due to changes in the sales compensation program, termination of those who failed to sell sufficient amounts of products, and travel demands required by the position. The Company is currently actively recruiting one to two additional sales persons.

In 2009, IsoRay entered into an exclusive distribution agreement with BrachySciences to market Cs-131 seeds in the U.S. BrachySciences has a sales force approximately 6 sales persons and a manager bringing the total sales personnel selling Proxcelan Cs-131 brachytherapy seeds in the U.S. to approximate 12. The BrachySciences sales force sold its first Cs-131 prostate implant in August 2009; but it has taken longer than anticipated for BrachyScienc customers to obtain the license amendments required for the Cs-131 product.

The Company expects to continue to expand its customer base outside the U.S. market, through use of established distributors in the key markets of ot 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 license 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 insuranc companies. These payers reimburse the hospitals and clinics via well-established payment procedures. In 2003, the Company was approved for an initia HCPCS code for Cs-131 brachytherapy seeds. In July 2007, CMS divided the HCPCS code into two codes for all manufacturers of brachytherapy seeds. 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 fo prostate brachytherapy services, and is the payer in approximately 65% 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 proposed in July 2009 to implement a fixed price per seed reimbursement following the HCPCS methodology. Its proposal is to pay one price for loose seeds and another for stranded seeds. Iodine, palladium and cesium would each have their own pricing. In 2008, CMS previously proposed that a fixed price per seed be used for reimbursement; however, Congress (after postponing a decision on the Medical Bill which included brachytherapy seed reimbursement voted on July 15,2008 to continue the pass-through reimbursement for brachytherapy seeds through December 31, 2009. Management believes that Congress will again intervene to maintain current reimbursement practices. 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, 2009 include:

Various Northern California facilities (1)		22.6% of revenue
Chicago Prostate Cancer Center	Westmont, IL	12.4% of revenue

(1) The following facilities located in northern California are used by one doctor (the Company's Medical Director): Community Hospital of Los Gatos (8.0% of total revenue), Fremont Surgery Center (5.9%), Mills Peninsula Health Services (3.6%), El Camino Hospital (3.6%) and all other used by this doctor combined (1.5%).

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 has a registered U.S. trademark for Proxcelan.

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. In August 2008, this patent was granted by the USPTO under Patent Number 7,410,458, with an expiration date of November 12, 2023. 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 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 requir IsoRay to return the patent if IsoRay permanently abandons sales of products using the invention. During fiscal years 2009 and 2008, the Company recorded royalty expense of $20,063 and $21,219, respectively, related to this patent.

The terms of a license agreement with the Lawrence Family Trust (successor to D. Lawrence) for a patent application and related "know-how" require 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 applicati was ultimately abandoned, only a 1% "know-how" royalty remains applicable. To date, management believes that there have been no product sal incorporating the "know-how;" and therefore believes no royalty is due pursuant to the terms of the agreement. Management believes that ultimately royalties should be paid under this agreement as there is no intent to use this "know-how" in the future.

The Lawrence Family Trust has disputed management's contention that it is not using this "know-how". On September 25, 2007 and again on October 31 2007, the Company participated in nonbinding mediation regarding this matter; however, no settlement was reached with the Lawrence Family Trust. A additional settlement discussions, which ended in April 2008, the parties failed to reach settlement. The parties may demand binding arbitration at an time.

Research and Development

During the three-year period ended June 30, 2009, IsoRay and its predecessor companies incurred more than $3.7 million in costs related to research development activities. The Company expects to continue ongoing research and development activities for the foreseeable future.

Whether successful or not, the Company anticipates ending its major research and development project to develop a proprietary separation process manufacture enriched barium during fiscal year 2010. During fiscal year 2009, the Company incurred approximately $39,000 on this project. The remaining project costs are anticipated to be approximately $100,000 to $150,000 for a production model (if required) in addition to the $56,610 payment to be mad for the prototype if the demonstration is successful.

Government Regulation

The Company's present and future intended activities in the development, manufacture and sale of cancer therapy products are subject to extensive l 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 Syst Regulations, also known as the Good Manufacturing Practices, which include extensive record keeping and periodic inspections of manufacturing facilities. The Company's predecessor obtained FDA 510(k) clearance in March 2003 to market the Proxcelan Cs-131 seed for the treatment of localized solid tum and other malignant disease and IsoRay obtained FDA 510(k) clearance in November 2006 to market preloaded brachytherapy seeds.

In the United States, the FDA regulates, among other things, new product clearances and approvals to establish the safety and efficacy of these products. 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, labe storage, record keeping, approval, distribution, use, reporting, advertising and promotion of such products. Noncompliance with applicable requirements ca 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, preventing us from entering into government supply contracts, withdrawal or previously approved applications, and criminal prosecution.

In the United States, medical devices are classified into three different categories under which the FDA applies increasing levels of regulation: Class I, Class 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. Th is a shorter FDA review and clearance process for Class II medical devices, the premarket notification or 510(k) process, whereby a company can marke certain Class II medical devices that can be shown to be substantially equivalent to other legally marketed devices. Since brachytherapy seeds have be 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 Manufacturi Practices, or cGMP. These regulations require that we and any of our contract manufacturers design, manufacture and service products, and mainta documents in a prescribed manner with respect to manufacturing, testing, distribution, storage, design control, and service activities. Modifications 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.

The Medical Device Reporting regulation requires that we provide information to the FDA on deaths or serious injuries alleged to be associated with the u 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 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. Fo example, our facility is licensed as a medical product manufacturing facility in the State of Washington and is subject to periodic state regulatoi 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 Canada and Russia, we initiated the process in fiscal year 2008 to obtain the European C Mark, Canadian registration, and certification to ISO 13485, an internationally recognized quality system. European law requires that medical devices sc in any EU Member State comply with the requirements of the European Medical Device Directive (MDD) or the Active Implantable Medical Devic Directive (AIMDD). IsoRay's products are classified in Europe as an active implantable and are subject to the AIMDD. Compliance with AIMDD an 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 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. M of the recognized EU Notified Bodies are also recognized by Health Canada to conduct the ISO 13485 inspections for Canadian registration. During fisc year 2009, the Company received its certification to ISO 13485 and obtained approval from Health Canada for its Canadian registration. The Company now focusing on the Canadian and Russian markets and is no longer pursuing sales in the European Union (EU). Management no longer believes a strateg alliance with IBt, SA, a Belgian company, will be consummated nor will management leverage IBt's distribution channels in the EU.

In the United States, as a manufacturer of medical devices and devices utilizing radioactive byproduct material, we are subject to extensive regulation by only federal governmental authorities, such as the FDA, but also by state and local governmental authorities, such as the Washington State Department Health, to ensure such devices are safe and effective. In Washington State, the Department of Health, by agreement with the federal Nuclear Regula Commission (NRC), regulates the possession, use, and disposal of radioactive byproduct material as well as the manufacture of radioactive sealed source ensure compliance with state and federal laws and regulations. Our Cs-131 brachytherapy seeds constitute both medical devices and radioactive seal 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 age 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.

Seasonality

The Company believes that some seed implantation procedures are deferred around physician vacations (particularly in the summer months), holidays, ani medical conventions and conferences resulting in a seasonal influence on the Company's business. These factors cause a momentary decline in revenu which management believes is ultimately realized later. Because almost thirty percent (30%) of the Company's business relies on three physicians simultaneous vacations by these three physicians could cause significant drops in the Company's productivity during those periods.

Employees

As of September 14, 2009, IsoRay employed 37 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 sales, 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 administrative organizations. None of the Company employees are represented by any collective bargaining unit. The Company estimates that successful implementation of its growth plan will result in u three to five additional employees by the end of fiscal year 2010.

In 2008, the Company had six direct sales persons and a National Sales Director; however, the Company has experienced some turnover in the sales force du to changes in the sales compensation program, termination of those who failed to sell sufficient quantities of product, and the travel demands required by position. The Company currently has four direct sales persons and a VP, Business Development and is actively recruiting one to two additional sales persons.

Competition

The Company competes in a market characterized by technological innovation, extensive research efforts, and significant competition. In general, Proxcelan Cesium-131 brachytherapy seed competes with conventional methods of treating localized cancer, including, but not limited to, all form prostatectomy surgery and external beam radiation therapy which includes intensity modulated radiation therapy, as well as competing permane brachytherapy devices. Surgery has historically represented the most common medical treatment for early-stage, localized prostate cancer but ra prostatectomies have declined in recent years. EBRT is also well-established method of treatment and is widely accepted for patients who represent a poo surgical risk or whose prostate cancer has advanced beyond the stage for which surgical treatment is indicated. Management believes that general conversion from these treatment options (or other established 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 and duration 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, Theragenics Corp., which introduced the original Pd-103 seed, currently claims over 59% of the Pd-103 market share (through CR Bard, other distributors, and direct distribution). (Source: Millennium Research Corp, 2008). Although factors other than being first to market contribute to becoming a market leader, the Company believes it has the opportunity to 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 a sustainable competitive advantage. 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. It is possible that three or four of the current I-125 or Pd-103 seed manufacturers (e.g., CR Bard, Oncura, Theragenics, etc.) are capable of producing and marketing a Cs-131 seed, but none have reported efforts to do so. Best Medical obtained a seed content patent in 1992 that named ten 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. In addition to the FDA and the NRC, Best Medical would be required to submit its Cs-131 seed to the TG-43 task group of the American Association of Physicists in Medicine to determine the seed's characteristics such as anisotropy, dose rate constant, etc. To date there has been no submission to the TG-43 task group for a competing Cs-131 seed.

Additional Growth Opportunities

Management of the Company sees growth opportunities through expansion into international markets and additional treatment applicability to cancers other than prostate. The Company plans to introduce Cs-131 for prostate brachytherapy initially into Canada and Russia and later into other international markets through partnerships and strategic alliances with channel partners for manufacturing and distribution.

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, head and neck, and other cancers. The Company has already begun treating ocular melanoma and is just beginning to treat lung and head and neck tumors. The Company has had discussions with prominent physicians and is looking at treatments for other cancer sites.

There is also an opportunity to develop and market other radioactive isotopes to the United States market, and to market 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 where it may be advantageous to use delivery methods other than a titanium-encapsulated seed to deliver radiation to certain organs.

ITEM 1A – 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, Canada, 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 (now coming from Russia) 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 development 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 Two Types Of Cancer. Currently, the Proxcelan Cs-131 se is used exclusively for the treatment of prostate cancer (over ninety-nine percent of sales) and ocular melanoma (less than one percent of sales). We believe the Proxcelan Cs-131 seed will be used to treat other types of cancers (and have treated a single head and neck tumor and a single lung tumor to date), 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 a 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 i 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 significant net operating losses. Due to previous capital investments and substantial cost reductions, management believes cash and cash equivalents on hand at June 30 2009 will be sufficient to meet our anticipated cash requirements for operations, debt service, and capital expenditure requirements through at least the n twelve months. If operating costs expand proportionately with revenue increases, other applications are pursued for seed usage outside the prostate mark protocols are expanded to support the integrity of our product, and marketing expenses increase, management believes approximately $1.0 million in monthly revenue will be needed to reach break-even. This is a decrease from the previous estimate of $1.5 million in monthly revenue due to recen improvements in the Company's production operating efficiencies and its cost structure implemented by new management. However, there is no assurance a 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, 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. fiscal 2009, approximately sixty-five percent (65%) of our Cs-131 was supplied through UralDial from reactors located in Russia. Unless the Comp substantially increases its purchase requirements resulting from significant increases in demand for its product, the cost of Cs-131 in Russia could increa from current pricing. Our current contract with UralDial terminates in December 2009 and will have to be renegotiated. Management will seek to negotiat favorable pricing but there is no assurance as to the outcome of these negotiations.

If the development of barium enrichment capabilities is successful, the Company plans to expand Cs-131 manufacturing capability at the MURR reactor the United States. Reliance on any single supplier increases the risks associated with concentrating isotope production at a single reactor facility which be subject to unanticipated shutdowns. Failure to obtain deliveries of Cs-131 from multiple sources could have a material adverse effect on seed product and there may be a delay before we could locate alternative suppliers beyond the three currently used.

We may not be able to locate additional suppliers outside of Russia capable of producing the level of output of cesium at the quality standards we requ 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 l component of our seed core from another single supplier. We do not have formal written agreements 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 substitu equivalent materials in a cost-effective and timely manner. To mitigate any potential interruptions, the Company continually evaluates its inventory level and management believes that the Company maintains a sufficient quantity on hand to alleviate any potential disruptions.

Industry Trends. Several factors which occurred in fiscal 2009 caused our revenues to significantly decline and these factors are still contributing to failure to improve sales in the prostate market. Beginning in the Fall of 2008, U.S. consumers significantly curtailed all spending (even for life savi medical procedures) which impacted the brachytherapy industry as a whole. In February 2009 noted urologists announced at a medical conference t PSA testing was not as necessary as previously believed. Their statements were widely publicized. Management believes that many people have been influenced by these statements to cut back on PSA testing thereby decreasing in the short term the number of procedures performed. The final factor whi occurred was the emergence of IMRT as the preferred treatment alternative as a result of a much higher reimbursement rate to physicians compared t brachytherapy treatments. Each of these factors is continuing to impact the performance of the Company in the prostate market and the industry as whole during fiscal 2010 and there is no assurance that they will not continue to impact sales of the Company.

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 UralDial and through reactor irradiation of natural barium and subsequent separation of Cs-131 from the irradiated bari 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 fo irradiating targets. This limitation can be overcome by utilizing barium feedstock that is enriched in the stable isotope Ba-130. However, the number o suppliers of enriched barium is limited and they may be unable to produce this material in sufficient quantities at a reasonable price.

IsoRay has entered into an exclusive agreement (effective through December 31, 2009) with UralDial in Russia to provide Cs-131 in quantities sufficient supply a significant percentage of future demand for this isotope. Due to the purchase of enriched barium in June 2007, IsoRay has access to sufficien quantities of enriched barium that may be recycled to increase the production of Cs-131. Although the UralDial agreement provides 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. If wi were unable to obtain supplies of isotopes from Russia in the future, our overall supply of Cs-131 would be reduced significantly unless the Company has a source of enriched barium for utilization in domestic reactors.

We Have Entered Into An Agreement With A Single Distributor For Our Cesium-131 From Russia. We previously obtained the majority of our Cs-131 fro either the Institute of Nuclear Materials (INM) or the Russian Research Institute of Atomic Reactors (RIAR), both of which are located in Russia. In December 2008, we entered into an agreement with UralDial to purchase Cs-131 directly from UralDial instead of from INM and RIAR. As a result, we now rely UralDial to obtain Cs-131 from Russian sources. UralDial has agreed to maintain at least two Russian sources of its Cs-131, and our agreement with UralDial has lower minimum purchase requirements than our prior agreements with INM and RIAR, and these lower minimum purchase requirements are being met a this time. Through the UralDial agreement, we have obtained set pricing for our Russian Cs-131 through the end of 2009. There can be no guarantee tha UralDial will always be able to supply us with sufficient Cs-131, which could be due in part to risks associated with foreign operations and beyond our and UralDial's control, and if we were unable to obtain supplies of isotopes from Russia in the future, our overall supply of Cs-131 would be reduced significantly unless we have 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 ou products if they cannot be assured of receiving favorable reimbursement for treatments using our products from third-party payers, such as Medicare an private health insurance plans. Currently, Medicare reimburses hospitals, clinics and physicians for the cost of seeds used in brachytherapy procedures on pass through basis, and will continue this method of reimbursement through December 31, 2009. Historically, private insurers have followed Medica guidelines in establishing reimbursement rates. However, third-party payers are increasingly challenging the pricing of certain medical services o 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 reimbursemen from all third-party payers or that reimbursement rates will not be reduced. A reduction in or elimination of third-party reimbursement for treatments usi 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 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 f 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 health insurance programs could significantly affect the purchase healthcare services and products in general and demand for our products in particular. Medicare is the payer in approximately 70% of all U.S. prostate brachytherapy cases and management anticipates this percentage to increase annually. We are unable to predict whether potential healthcare reforms will enacted, whether other healthcare legislation or regulations affecting the business may be proposed or enacted in the future or what effect any suc 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 fluctu significantly in the future. Fluctuation may result from a variety of factors, which are discussed in detail throughout this "RISK FACTORS" sectio 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 July 31, 2009, the Proxcelan Cs-131 seed has been implanted in over 4,000 patients and research papers are being published on the use of the Proxcelan seed. However, we have less statistical data than is available for I-125 and Pd- 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 earl 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 a eight weeks post-implant, more quickly than the resolution of side effects that occur with competing seeds or other forms of treatment. These limit 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 o outcomes from additional patients before we can establish statistically valid conclusions regarding the incidence of side effects from our seeds.

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 c Proxcelan Cs-131 seed, and on other third parties, including various radiopharmacies, to package our Proxcelan Cs-131 seed in certain specialized packaginc forms requested by customers. We are subject to the risk that these third parties may mishandle our product, which could result in adverse effects, particula 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 th advances in the pharmaceutical, biomedical, or gene therapy fields could render some or all radiation therapies, whether conventional or brachythera 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 in existence 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 see manufacturing technology, we cannot be certain that one or more of our competitors will not attempt to obtain patent protection that blocks or advers affects our product development efforts. To minimize this potential, we have entered into exclusive agreements with key suppliers of isotopes and isotopi precursors, which are subject to becoming non-exclusive as we have failed to meet minimum purchase requirements.

We May Be Unable To Adequately Protect Or Enforce Our Intellectual Property Rights Or Secure Rights To Third-Party Patents. Our ability and th 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 h 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 ou products in all countries or afford to litigate every potential violation worldwide.

Because of the large number of patent filings in the medical device and biotechnology field, our competitors may have filed applications or been issuec patents and may obtain additional patents and proprietary rights relating to products or processes competitive with or similar to ours. We cannot be certa 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 Patents, and Our Patents Pending, Is Uncertain. Although our management strongly believes that our patent on the process f producing Cs-131, our patents on additional methods for producing Cs-131 and other isotopes, our pr tent pending on the manufacture of the brachythera seed, and anticipated future patent applications, which have not yet been filed, have significan value, we cannot be certain that other like-kind proces 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 t extensive, complex, costly, and evolving governmental rules, regulations and restrictions administered by FDA, by other federal and state agencies, a by governmental authorities in other countries. Compliance with these laws and regulations is expensive and time-consuming, and changes to or failure t 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 federal, state, and local governmental authorities, such as the FDA and Washington State Department of Health, to ensure such devices are safe an 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 possession, use, and disposal of radioactive by-product material as well as the manufacture of radioactive sealed sources to ensure compliance with state and federal laws an 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, on 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-marke notification process. 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 Qual System Regulation, or QSR, which addresses requirements for a company's quality program such as management responsibility, good manufacturin practices, product and process design controls, and quality controls used in manufacturing. Compliance with applicable regulatory requirements 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 clearance for new products o existing products, and criminal prosecution. There can be no assurance that we will not incur significant costs to comply with these regulations in the futu 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 regulat 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, o foreign distributors to assist us in complying with foreign regulatory requirements. We may not be able to obtain these approvals without incurrin 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 exposure to product liability claims and related adverse publicity. Insurance coverage is expensive and difficult to obtain, and, although we currently hav 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 radioactiv 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 materia may only be disposed of at state-approved facilities. At our leased facility we use commercial disposal contractors. We may incur substantial costs related t 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, sales staff and key scientific personnel. If we lose the services of several officers, sales personnel, or key scientific personnel, our business could be harmed. Ou success also will depend upon our ability to attract and retain other highly qualified scientific, managerial, sales, and manufacturing personnel and th 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 Canada and Russia. 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 ou products in foreign markets; the burden of complying with complex and changing foreign regulatory requirements; speedy delivery requirements due to th short half-life of our product; language barriers and other difficulties in providing long-range customer service; potentially longer accounts receivae 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 some foreign countries; and the possibility that contractual provisions governed by foreign laws would be interpreted differently than intended in the ev of a contract dispute. Any future foreign sales of our products could also be adversely affected by export license requirements, the imposition governmental controls, political and economic instability, trade restrictions, changes in tariffs, and difficulties in staffing and managing foreig operations. Many of these factors may also affect our ability to import Cs-131 from Russia under our contract with UralDial.

Our Ability To Expand Operations And Manage Growth Is Uncertain. Our efforts to expand our operations will result in new and increased responsibiliti for management personnel and will place a strain upon the entire company. To compete effectively and to accommodate growth, if any, we may be requir to continue to implement and to improve our management, manufacturing, sales and marketing, operating and financial systems, procedures and controls 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 mee 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. As a smaller reporting company, the Company needs to implement additional provisions of the Sarbanes Oxley Act during fiscal year 2010. 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 of or 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; swings in seasonal demands of purchasers; investors' general perception of us; and general economic, industry and market conditions. If any of these events occur, it could cause our stock price to fall.

Our Reduced Stock Price May Adversely Affect Our Liquidity. Our common stock has been trading at less than $1.00 per share periodically in recent months. Many market makers are reluctant to make a market in stock with a trading price of less than $1.00 per share. To the extent that we have fewer market makers for our common stock, our volume and liquidity will likely decline, which could further depress our stock price.

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 common stock 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 shares. As of June 30, 2009, we had 22,942,088 outstanding shares of common stock, and the following additional shares were reserved for issuance: 2,708,166 shares upon exercise of outstanding options, 3,216,644 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 common stock 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 approximately an additional 6,000,000 shares of common stock outstanding as a result. The issuance of these shares will have the effect of further diluting 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 laws 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 of 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 of Directors 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 1B – UNRESOLVED STAFF COMMENTS

As a smaller reporting company, the Company is not required to provide Item 1B disclosure in this Annual Report.

ITEM 2 – PROPERTIES

The Company's executive offices are located at 350 Hills Street, Suite 106, Richland, WA 99354, (509) 375-1202, where IsoRay currently leases approximately 16,400 square feet of office and laboratory space for approximately $23,500 per month plus monthly janitorial expenses of approximately $460 from EnergyNorthwest, the owner of the Applied Process Engineering Laboratory (the APEL facility). The Company is not affiliated with the 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.

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 as of the date of this Report.

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 REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

The Company's Articles of Incorporation provide that the Company has the authority to issue 200,000,000 shares of capital stock, which are curren 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 $0.001 per share. As of September 14, 2009, we had 22,942,088 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 (now the NYSE Amex) under the symbol "ISR." Even though we have obtained our NYSE Amex listing, 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 NYSE Amex.

Year ended June 30, 2009	**High**	**Low**
First quarter	$ 0.90	$ 0.35
Second quarter	0.70	0.20
Third quarter	0.32	0.15
Fourth quarter	0.39	0.19

Year ended June 30, 2008	**High**	**Low**
First quarter	$ 5.20	$ 3.44
Second quarter	3.51	1.85
Third quarter	2.27	1.00
Fourth quarter	1.00	0.55

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 all outstanding and cumulative dividends through December 3 2006. There is no Series A Preferred Stock outstanding. The total Series B accrued dividends of $38,458 were paid on February 15, 2007. At June 30, 2009, there were 59,065 Series B preferred shares outstanding and cumulative dividends in arrears were $26,565. There is no Series A Preferred Stock outstanding.

As of September 14, 2009, we had approximately 320 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 (th Director Plan) pursuant to which it may grant equity awards to eligible persons. Each of the Plans has subsequently been amended. The Option Plan allow 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 t 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 ke 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 t 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 NYSE Amex) on the date of the grant, and with varying vesting periods as determined by t Board.

As of June 30, 2009, the following options had been granted under the option plans.

Plan Category	Number of securities to be issued on exercise of outstanding options, warrants, and rights #	Weighted-average exercise price of outstanding options, warrants, and rights $	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by shareholders	N/A	N/A	N/A
Equity compensation plans not approved by shareholders	2,708,166	$ 2.08	1,225,051
Total	2,708,166	$ 2.08	1,225,051

Issuer Purchases of Equity Securities

In June 2008, the Board of Directors of IsoRay authorized the repurchase of up to 1,000,000 shares of the Company's common stock (FY2009 Plan). The FY2009 Plan expired on June 30, 2009. The table below shows the activity in the FY2009 Plan from inception to June 30, 2009. There were no shares purchased during fiscal year 2008 other than in June 2008 and no shares purchased during fiscal year 2009 other than in July 2009.

FY 2009 PLAN

Period		Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plan	Maximum Number of Shares that May Yet be Purchased Under the Plan [1]
Beginning	Ending				
June 1, 2008	June 30, 2008	5,000	$ 0.731	5,000	995,000
July 1, 2008	July 31, 2008	8,200	$ 0.577	13,200	986,800
Total		13,200	$ 0.636	13,200	986,800

(1) In June 2008, the Company announced a new stock repurchase plan to purchase up to 1,000,000 shares of the Company's common stock. The Plan expired on June 30, 2009.

Sales of Unregistered Securities

All sales of unregistered securities were previously reported.

ITEM 6 – SELECTED FINANCIAL DATA

As a smaller reporting company, the Company is not required to provide Item 6 disclosure in this Annual Report.

ITEM 7 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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 disclosures 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, certificates of deposit 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 temporary unrealized losses included in other comprehensive income/loss within shareholders' equity, if material. Declines in fair values that are considered other than temporary are recorded in the Consolidated Statements of Operations.

Fair Value of Financial Instruments

Effective July 1, 2008, the Company implemented Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements*. 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. The Company elected to implement this Statement with the one-year deferral permitted by FASB Staff Position (FSP) 157-2 for nonfinancial assets and nonfinancial liabilities measured at fair value, except those that are recognized or disclosed on a recurring basis. This deferral applies to fixed assets and intangible asset impairment testing and initial recognition of asset retirement obligations for which fair value is used. The Company does not expect any significant impact to our consolidated financial statements when we implement SFAS 157 for these assets and liabilities.

SFAS 157 requires disclosures that categorize assets and liabilities measured at fair value into one of three different levels depending on the observability of the inputs employed in the measurement. Level 1 inputs are quoted prices in active markets for identical assets or liabilities. Level 2 inputs are observable inputs other than quoted prices included within Level 1 for the asset or liability, either directly or indirectly through market-corroborated inputs. Level 3 inputs are unobservable inputs for the asset or liability reflecting significant modifications to observable related market data or our assumptions about pricing by market participants.

At June 30, 2009, all of the Company's financial assets and liabilities are accounted and reported at fair value using Level 1 inputs.

Also effective July 1, 2008, the Company adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115*. The statement allows entities to value many financial instruments and certain other items at fair value. SFAS 1 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. I the fair value option is elected then unrealized gains and losses are reported in earnings at each subsequent reporting date. The Company elected not t measure any additional financial instruments or other items at fair value as of July 1, 2008 in accordance with SFAS 159. Accordingly, the adoption of SFAS 159 did not impact our consolidated financial statements. The Company did elect to fair value its ARS rights that were received in October 2008 a exercised in January 2009 in accordance with SFAS 159.

Accounts Receivable

Accounts receivable are stated at the amount that management of the Company expects to collect from outstanding balances. Management provides 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.

Fixed Assets

Fixed assets are capitalized and carried at the lower of cost or net realizable value. 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 useful life of the asset.

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 ne realizable value of each asset 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 th changes could occur which could adversely affect management's estimate of net cash flows expected to be generated from its assets, and necessitate as 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 the guarantee of certain Company debt in accordance wit Accounting Principles Board (APB) Opinion No. 21, *Interest on Receivables and Payables* and Emerging Issues Task Force (EITF) Issue No. 95-13, *Classification of Debt Issue Costs in the Statement of Cash Flows*. The value of the shares issued was the estimated market price of the shares as of the d of issuance. Amortization of deferred financing costs, totaling $37,035 and $30,504 for the years ended June 30, 2009 and 2008, respectively, is included in financing expense on the statements of operations.

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 Compan entered into an agreement with IBt, SA, a Belgian company (IBt) to use IBt's proprietary "Ink Jet" production process and its proprietary polymer see technology for use in brachytherapy procedures using Cesium-131 (Cs-131). The Company paid license fees of $225,000 and $275,000 during fiscal year 2008 and 2006, respectively. During fiscal year 2009, the Company determined that the entire remaining value of the IBt license was impaired and recorded an impairment charge of $425,434.

Amortization of licenses was $30,067 and $43,452 for the years ended June 30, 2009 and 2008, respectively. Based on the licenses recorded at June 3 2009, and assuming no subsequent impairment of the underlying assets, the annual amortization expense for each fiscal year ending June 30 is expected t be as follows: $11,867 for 2010, $0 for all years 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, 2009, 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: $16,861 for 2010, $15,139 for 2011, $15,139 for 201 $15,139 for 2013, $15,139 for 2014, and $157,768 thereafter.

Asset Retirement Obligation

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 equivalent amount is capitalized to property and equipment. The initial recorded obligation is discounted using the Company's credit-adjusted risk free-ra and is reviewed periodically for 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 lea assets.

In fiscal year 2006, the Company established an initial asset retirement obligation of $63,040 which represented the discounted cost of cleanup that t Company anticipated it would have to incur at the end of its equipment and property leases in its old production facility. This amount was determine 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 additiona $56,120. During the second quarter of fiscal year 2008, the Company removed all radioactive residuals and tenant improvements from its old production facility and returned the facility to the lessor. The Company had an asset retirement obligation of $135,120 accrued for this facility but total costs incurred to decommission the facility were $274,163 resulting in an additional expense of $139,043 that is included in cost of products sold. The additional expens was mainly due to unanticipated construction costs to return the facility to its previous state. The Company originally believed that the lessor would ret many of the leasehold improvements in the building, but the lessor instead required their removal.

In September 2007, another asset retirement obligation of $473,096 was established representing the discounted cost of the Company's estimate of th obligations to remove any residual radioactive materials and all leasehold improvements at the end of the lease term at its new production facility. Th estimate was developed by qualified production personnel and the general contractor of the new facility. The Company has reviewed the estimate agai based on its experience with decommissioning its old facility and believes that the original estimate continues to be applicable.

During the years ended June 30, 2009 and 2008, the asset retirement obligations changed as follows:

	2009	2008
Beginning balance	$ 506,005	$ 131,142
New obligation	–	473,096
Settlement of existing obligation	–	(135,120)
Accretion of discount	47,466	36,887
Ending balance	$ 553,471	$ 506,005

Because the Company does not expect to incur any expenses related to its asset retirement obligations in fiscal year 2010, the entire balance as of June 2009 is classified as a noncurrent liability.

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 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 curr 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, not payable, and capital lease obligations, approximated their fair values at June 30, 2009 and 2008.

Revenue Recognition

The Company applies the provisions of SEC Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition*. SAB No. 104 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 reven 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, 2009 and 2008 was derived solely from sales of the Proxcelan Cs-131 brachytherapy seed, which is used in th treatment of cancer. The Company recognizes revenue once the product has been shipped to the customer. Prepayments, if any, received from customer 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 deferred revenue is then 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

The Company measures and recognizes expense for all share-based payments at fair value. The Company uses the Black-Scholes option valuation model t estimate fair value for all stock options on the date of grant. For stock options that vest over time, the Company recognizes compensation cost on a straight-line basis over the requisite service period for the entire award.

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 recognized.

Legal Contingencies

In the ordinary course of business, the Company is involved in legal proceedings involving contractual and employment relationships, product liabil claims, patent rights, environmental matters, and a variety of other matters. The Company is also subject to various local, state, and federal environmenta 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 th Company is in compliance with these laws and regulations. While there have been no reportable incidents or compliance issues, the Company believes that if it relocates its current production facilities then certain decommissioning expenses will be incurred and has recorded an asset retirement obligation 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 a the amount of the loss is reasonably estimable. Estimating probable losses requires analysis of multiple factors, in some cases including judgments about thi potential actions of third-party claimants and courts. Therefore, actual losses in any future period are inherently uncertain. Currently, the Company does no believe any probable legal proceedings or claims will have a material adverse effect on its financial position or results of operations. However, if actual estimated probable future losses exceed the Company's recorded liability for such claims, it would record additional charges as other expense during 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 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 recognized in operations in the period that includes the enactment of the change.

On July 1, 2007, the Company adopted Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN No. 48). FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in accordance with SFAS No. 109 *Accounting for Income Taxes*, prescribing a recognition threshold and measurement attribute for the recognition and measurement of a tax position taken or expected to be taken in a tax return. In the course of its assessment, management has determined that the Company, its subsidiary, and its predecessors are subject to examination of the income tax filings in the United States and state jurisdictions for the 2005 through 2008 tax years. In the event that the Company is assessed penalties and interest, penalties will be charged to other operating expense and interest will be charged to interest expense.

The Company adopted FIN No. 48 using the modified prospective transition method, which requires the application of the accounting standard as of July 2007. There was no impact on the financial statements as of and for the year ended June 30, 2008 as a result of the adoption of FIN No. 48. In accordance with the modified prospective transition method, the financial statements for prior periods have not been restated to reflect, and do not include, the impact of FIN No. 48.

Income (Loss) Per Common 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 and options to purchase the Company's common stock, are excluded from the calculations when their effect is antidilutive. At June 30, 2009 and 2008, the calculation of diluted weighted average shares does not include preferred stock, common stock warrants or options 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, 2009 and 2008 are as follows:

	2009	2008
Preferred stock	59,065	59,065
Common stock warrants	3,216,644	3,245,082
Common stock options	2,708,166	2,803,393
Total potential dilutive securities	5,983,875	6,107,540

Subsequent Events

Effective April 1, 2009, the Company adopted SFAS No. 165, *Subsequent Events*. This Statement establishes the accounting for, and disclosure of, material events that occur after the balance sheet date, but before the financial statements are issued. In general, these events will be recognized if the condition existed at the date of the balance sheet, and will not be recognized if the condition did not exist at the balance sheet date. Disclosure is required for nonrecognized events if required to keep the financial statements from being misleading. The guidance in this Statement is very similar to current guidance provided in accounting literature and, therefore, will not result in significant changes in practice. Subsequent events have been evaluated through the date our financial statements were issued—the filing time and date of our 2009 Annual Report on Form 10-K.

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.

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, 2009 and 2008. This discussion and analysis should be read in conjunction with our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. 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 1A — Risk Factors," beginning on page 24 of this Annual Report on Form 10-K.

Year ended June 30, 2009 compared to year ended June 30, 2008

Product sales. Sales for the year ended June 30, 2009 were $5,417,815 compared to sales of $7,158,690 for the year ended June 30, 2008. The decrease of $1,740,875 or 24% was mainly due to decreased sales volume of the Company's Proxcelan Cs-131 brachytherapy seeds along with a increased percentage of loose seed sales as compared to stranded and a lower average price due to physicians using less seeds. Loose seeds (including seeds loaded in Mick cartridges) sell at a lower price than stranded due to the additional processing time and expense required for stranded seeds. About 3% of the decrease is due to physicians ordering less seeds per implant as they have become more efficient with use of the isotope and its characteristics. The Company will need to increase the number of total implants to increase sales. Management believes that other treatment options with higher reimbursement rates, such as IMRT, put pressure on Proxcelan Cs-131 seed sales as well as other brachytherapy sales. During the year ended June 30, 2009 the Company sold its Cs-131 seeds to 72 different medical centers as compared to 99 centers during the fiscal year ended June 30, 2008.

Cost of product sales. Cost of product sales were $5,771,147 for the year ended June 30, 2009 which represents a decrease of $1,538,977 or 21% compared to cost of product sales of $7,310,124 for the year ended June 30, 2008. Materials expense decreased approximately $631,000 mainly due to ordering and using less isotope in the year ended June 30, 2009 compared to the year ended June 30, 2008. Personnel expenses, including payroll, benefits, and related taxes, decreased approximately $603,000 due to a reduction in the average production headcount levels. Prelo expenses decreased approximately $378,000 due to lower sales volumes and due to increased in-house loading. Small tools expenses decreased approximately $90,000 mainly due to expensing items in the prior year that were part of equipping the new facility that became operational in September 2007. Share-based compensation decreased approximately $92,000 mainly due to the forfeiture of unvested options by the Company former EVP-Operations.

These decreases were offset by an impairment of the Company's IBt license for $425,434 that was recorded in December 2008. Management completed its review of the license and associated technology related to this alternative encapsulation process in December 2008 and determined that the adoption of this process would entail an overhaul of the Company's existing manufacturing procedures. In addition, there is no assurance that physicians would accept this new technology without extensive education and marketing. As there are no anticipated future revenues from the license and the Company cannot sell or transfer the license, its entire value was written off in the accompanying financial statements.

During the year ended June 30, 2008, the Company removed all radioactive residuals and tenant improvements from its old production facility and returned the facility to the lessor. The Company had an asset retirement obligation of $135,120 accrued for this facility but total costs incurred to decommission the facility were $274,163 resulting in an additional expense of $139,043 that is included in cost of products sold for the year ended June 30, 2008. This additional expense incurred in the year ended June 30, 2008 was mainly due to unanticipated construction costs to return the facility to its previous state. The Company originally believed that the lessor would retain many of the leasehold improvements in the building, but instead required their removal.

Gross loss. Gross loss was $353,332 for the year ended June 30, 2009. This represents an increase of $201,898 or 133% over the prior year's gross loss of $151,434. Included in the gross loss for the year ended June 30, 2009 is the one-time IBt license impairment loss of $425,434. Without this one-time expense, the Company would have recognized a gross margin of $72,102 for the year ended June 30, 2009. Included in the gross loss the year ended June 30, 2008 is the one-time decommissioning expense of $139,043. Without this one-time expense, the Company would have recognized a gross loss of $12,391 for the year ended June 30, 2008.

Research and development expenses. Research and development expenses for the year ended June 30, 2009 were $958,665 which represents a decrease of $399,410 or 29% less than the research and development expenses of $1,358,075 for the year ended June 30, 2008. The major components of the decrease were personnel, consulting, and travel expenses. Personnel expenses, including payroll, benefits, and related taxes decreased approximately $172,000 due to lower headcount. Consulting expenses decreased approximately $455,000 as the Company's project to improve the efficiency of isotope production is currently progressing slowly and the Company has discontinued most funding until the final prototype testing trial. Travel expenses decreased approximately $44,000 due to less international travel than occurred in the prior year. These decreases were partially offset by an increase in protocol expenses of approximately $217,000 mainly due to the Company's dual-therapy study and its continued monitoring and updating of the mono-therapy study. Also in the year ended June 30, 2009, the Company finalized its on-going strategy regarding foreign patents and trademarks and wrote off $85,818 of previously capitalized costs. The Company had pursued prosecution of these patents and trademarks in various foreign countries including Australia, Japan, and China; however, the Company no longer believes that pursuing patents and trademarks in these foreign countries is fundamental to its business strategy.

Sales and marketing expenses. Sales and marketing expenses were $2,365,973 for the year ended June 30, 2009. This represents a decrease of $1,359,191 or 36% compared to the year ended June 30, 2008 when sales and marketing expenses were $3,725,164. Personnel expenses, including payroll, benefits, and related taxes, decreased approximately $603,000 due to a lower sales headcount and lower commissions due to lower revenue and a revised sales compensation plan that was originally introduced in April 2008 and subsequently amended in October 2008. Travel expenses also decreased approximately $148,000 due to the decrease in average headcount. Consulting expenses decreased approximately $214,000, mainly due to reduced reliance on third-parties as part of the Company's expense reduction initiatives. Marketing and advertising decreased approximately $179,000 as during the prior year the Company updated its marketing literature to incorporate new data published from the protocols, developed additional websites for patients and doctors, and updated its sales booth. Share-based compensation decreased approximately $90,000 due to the forfeiture of unvested options.

General and administrative expenses. General and administrative expenses for the year ended June 30, 2009 were $2,792,611 compared to general and administrative expenses of $3,568,048 for the year ended June 30, 2008. The decrease of $775,437 or 22% is primarily due to decreases in personnel costs, public company expenses, share-based compensation, legal expenses, and travel expenses partially offset by increases in consulting and bad debt allowance. Personnel costs decreased approximately $452,000 mainly due to the resignation of the Company's CEO in February 2009 and lower headcounts. The Company's new CEO was a consultant from March 2008 through February 2009 and became an employee in March 2009. Public company expenses decreased approximately $124,000 due to lower investor relations costs partially offset by increased board compensation. Legal expenses decreased by approximately $211,000 as in the year ended June 30, 2008 the Company incurred legal fees for contract drafting and review of the Company's interest in UralDial, the IBt strategic global alliance agreements, settlement agreements with former officers and directors, and for mediation costs. These decreased legal costs were partially offset by legal fees incurred in settling a lawsuit with a former employee. Travel expenses also decreased approximately $65,000. These decreases were partially offset by increased expense related to bad debt allowance of approximately $54,000 and increased consulting expenses of approximately $100,000 mainly due to compensation paid to the Company's interim CEO and the costs of the Company's ISO 13458 and CE mark audit that was conducted in July 2008.

Operating loss. The Company continues to focus its resources on improving sales while retaining the necessary administrative infrastructure increase the level of demand for the Company's product. These objectives and resulting costs have resulted in operating losses since the Company's inception. For the year ended June 30, 2009, the Company had an operating loss of $6,470,581 which is a decrease of $2,332,140 or 26% below th operating loss of $8,802,721 for the year ended June 30, 2008.

Interest income. Interest income was $111,047 for the year ended June 30, 2009 compared to interest income of $612,077 for the year ended Jun 30, 2008. Interest and investment income is mainly derived from excess funds held in money market and investment accounts. The decrease $501,030 or 82% was due to the lower average cash and short-term investment balances during the year ended June 30, 2009 and decreased inter rates.

Gain (loss) on the fair value of short-term investments. The gain of $274,000 for the year ended June 30, 2009 is due to the receipt of t Company's rights related to its auction rate securities (ARS) issued by its broker in October 2008. The gain is calculated as the fair value amount the put rights as estimated on the date of receipt plus the changes in their fair value offset by additional realized losses on the Company's ARS.

Financing and interest expense. Financing and interest expense for the year ended June 30, 2009 was $75,307 or a decrease of $17,556 or 19 compared to financing expense of $92,863 for the year ended June 30, 2008. Included in financing expense is interest expense of approximately $38,000 and $62,000 for the years ended June 30, 2009 and 2008, respectively. The decrease is due to the lower average debt balances in the y ended June 30, 2009. The remaining balance of financing expense represents the amortization of deferred financing costs.

Liquidity and capital resources. We have historically financed our operations through the sale of common stock and related warrants. During fiscal year 2009, the Company primarily used existing cash reserves to fund its operations and capital expenditures.

Cash flows from operating activities

Cash used in operating activities was approximately $3.9 million in fiscal year 2009 compared to approximately $7.7 million in fiscal year 2008, a decreas of approximately $3.8 million. Cash used by operating activities is net loss adjusted for non-cash items and changes in operating assets and liabilities.

Cash flows from investing activities

Cash provided by investing activities was approximately $2.2 million and $2.5 million for the years ended June 30, 2009 and 2008, respectively. Ca expenditures for fixed assets were approximately $58,000 in fiscal year 2009 and approximately $3.1 million in fiscal year 2008 (due to completing ou current production facility). The Company sold its remaining auction rate securities in January 2009 which generated $4.0 million of cash proceeds. The Company reinvested most of these proceeds in money market funds and certificates of deposit with maturities of less than 3 months which are classified a cash equivalents on the balance sheet.

Cash flows from financing activities

Cash used in financing activities was approximately $102,000 for the year ended June 30, 2009 and was used mainly for payments of debt and capital leases.

Projected 2010 Liquidity and Capital Resources

At June 30, 2009, cash and cash equivalents amounted to $2,990,744 and short-term investments amounted to $1,679,820 compared to $4,820,033 of cash and cash equivalents and $3,726,000 of short-term investments at June 30, 2008.

The Company had approximately $3.3 million of cash and $960,000 of short-term investments as of September 14, 2009. As of that date management believed that the Company's monthly required cash operating expenditures were approximately $350,000 which represents a significant decrease of approximately $150,000 to $200,000 from average monthly expenses in fiscal year 2008. Management believes that less than $100,000 will be spent on capital expenditures for the entire fiscal year 2010, but there is no assurance that unanticipated needs for capital equipment may not arise.

The Company's loan with BFEDD matures in fiscal year 2010 and will be paid in full by the end of the second quarter. The balance of the loan at June 2009 was $115,898 and is included in current liabilities.

If the Company is able to complete its major research and development project to develop a proprietary separation process to manufacture enriched barium this process should improve isotope production efficiency during fiscal year 2010. The Company will owe an additional $56,610 to the contractor upon completion of a successful demonstration of the enrichment process. Once a successful demonstration of the enrichment process has occurred, the Company will have to decide if the smaller test model will produce sufficient quantities of enriched barium or if an additional investment of $100,000 to $150,000 will be required to build a larger production model.

During fiscal year 2010, the Company intends to continue its existing protocol studies and begin new protocol studies on lung cancer treatment using Cs-131. Currently, the Company has budgeted approximately $220,000 in fiscal year 2010 for protocol expenses relating to lung cancer as well as continued work on the dual therapy and mono therapy prostate protocols.

Assuming operating costs expand proportionately with revenue increases, we continue pursuing other applications for seed usage outside the prostate market, protocols are continued supporting the integrity of our product and sales and marketing expenses remain steady, management believes the Company will reach breakeven with revenues of approximately $1.0 million per month.

Based on the foregoing assumptions, management believes cash, cash equivalents, and short-term investments on hand at June 30, 2009 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 (through our direct sales channels and through our distributors), expanding into other market applications which initially will include head and neck and lung, 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 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 solicitation of warrant holders to exercise their warrants, the sale of equity securities 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 warrant exercises or equity sales, these sales may be dilutive to existing investors.

Long-Term Debt and Capital Lease Agreements

The Company has two loan facilities in place as of June 30, 2009. The first loan is from the Benton-Franklin Economic Development District (BFEDD) an original principal amount of $230,000 and was funded in December 2004. It bears interest at eight percent and has a final balloon payment due in October 2009, which the Company intends to pay in full at that time. As of June 30, 2009, the principal balance owed was $115,898. 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 common stock. The second loan is from the Hanford Area Economic Investment Fund Committee (HAEIFC) and was originated in June 2006. The loan originally had a total facility of $1,400,000 which was reduced in September 2007 to the amount of the Company's initial draw of $418,670. The principal balance owed on the loan as of June 30, 2009 was $221,562. This loan is secured by receivables, equipment, materials and inventory, and certain lif insurance policies and also required personal guarantees. The final payment on the HAEIFC loan will be due in September 2013.

The Company is in violation of certain covenants of the BFEDD loan as of June 30, 2009. The Company has not requested a waiver as the loan is due in less than six months and is classified as current on the Company's balance sheet. The Company is currently in violation of the covenants regarding paying officers in excess of $100,000 per year, paying rent in excess of $45,000 per year at its current location, and repurchasing any of its outstanding stock. Unde the terms of the loan agreement, BFEDD can raise the interest rate to 13 percent or request repayment of the entire amount outstanding after giving th Company 15 days notice. If BFEDD were to take these measures, the Company would immediately repay the remaining balance of the loan.

HAEIFC has granted the Company a waiver from enforcing a fixed charge coverage ratio. The waiver is effective through June 30, 2010.

The Company no longer has any capital leases as of June 30, 2009.

Other Commitments and Contingencies

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, original monthly rent of approximately $26,700, subject to annual increases based on the Consumer Price Index, plus monthly janitorial expenses o approximately $700. This new facility became operational in September 2007. Due to a reduction in some lab and office space at APEL, the rent has been reduced to approximately $23,500 per month plus monthly janitorial expenses of approximately $460.

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

Year ending June 30,	
2010	$ 305,908
2011	302,235
2012	290,993
2013	288,467
2014	288,467
Thereafter	528,857
	$2,004,927

In February 2006, the Company signed a license agreement with International Brachytherapy SA (IBt), a Belgian company, covering North America an providing the Company with access to IBt's Ink Jet production process and its proprietary polymer seed technology for use in brachytherapy procedur using Cs-131. Under the original agreement royalty payments were to be paid on net sales revenue incorporating the technology.

On October 12, 2007, the Company entered into Amendment No. 1 (the Amendment) to its License Agreement dated February 2, 2006 with IBt. The Company paid license fees of $275,000 (under the original agreement) and $225,000 (under the Amendment) during fiscal years 2006 and 2008 respectively. The Amendment eliminates the previously required royalty payments based on net sales revenue, and the parties originally intended to negotiate terms for future payments by the Company for polymer seed components to be purchased at IBt's cost plus a to-be-determined profit percentage. Management no longer believes that introducing Cs-131 polymer seeds is a viable strategy due to concerns regarding physician acceptance and the costs to revamp the Company's existing manufacturing procedures to incorporate this technology. During December 2008, the Company recorded an impairment charge to write down this license based on its current intentions to not utilize this technology.

In November 2008, a subsidiary of the Company entered into a written contract with a contractor based in the Ukraine to formalize a research and development project originally begun over three years ago to develop a proprietary separation process to manufacture enriched barium. There is no assurance that this process can be developed. The contract called for an initial payment of $17,800 and a payment of $56,610 upon completion of a successful demonstration. The Company's initial demonstration has been postponed due to an electrical problem that damaged equipment and due to economic difficulties in the Ukraine that have protracted the contractor's efforts. The Company anticipates that the device will be tested in the Fall of 2009 but there is no assurance this testing will occur by then or whether it will be successful. After a successful demonstration, the Company will decide if the prototype model will produce sufficient quantities of enriched barium or if a larger production model will need to be built for an additional $100,000 to $150,000.

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 if it relocates its current production facilities then certain decommissioning expenses will be incurred. An asset retirement obligation was established in the first quarter of fiscal year 2008 for the Company's obligations at its new production facility. This asset retirement obligation will be for obligations to remove any residual radioactive materials and to remove all 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.

Inflation

Management does not believe that the current levels of inflation in the United States have 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 December 2007, the FASB issued statement No. 160, *Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB No. 51* (SFAS 160). The statement requires noncontrolling interests or minority interests to be treated as a separate component of equity, not as a liability or other item outside of permanent equity. Upon a loss of control, the interest sold, as well as any interest retained, is required to be measured at fair value, with any gain or loss recognized in earnings. Based on SFAS 160, assets and liabilities will not change for subsequent purchase or sales transactions with noncontrolling interests as long as control is maintained. Differences between the fair value of consideration paid or received and the carrying value of noncontrolling interests are to be recognized as an adjustment to the parent interest's equity. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008 and earlier adoption is prohibited. The adoption of this statement is not expected to have a material effect on the Company's financial statements.

In May 2008, FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*. SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the United States. It was effective November 15, 2008, following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. The adoption of this statement did not have a material effect on the Company's financial statements.

The FASB issued SFAS No. 168, *The FASB Standards Codification and the Hierarchy of Generally Accepted Accounting Principles—a replacement of FASB Statement 162*, in late June 2009. The FASB Accounting Standards Codification will become the source of authoritative U.S. generally accepted accounting principles (GAAP) and will supersede all then-existing non-SEC accounting and reporting standards on the effective date, September 15, 2009. The Codification will not change GAAP, but consolidates it into a logical and consistent structure. The Company will be required to revise our references to GAAP in our financial statements beginning with the first quarter of fiscal year 2010.

ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, the Company is not required to provide Item 7A disclosure in this Annual Report.

ITEM 8 – FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

ITEM 9 – CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

There were no disagreements or reportable events with DeCoria, Maichel & Teague, P.S.

ITEM 9A – CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

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, 2009. 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 procedures is designed to provide a reasonable level of assurance that the objectives of the system will be met.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15 of the Exchange Act. 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 effectiveness of our internal control over financial reporting based on the framework in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control – Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of June 30, 2009.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

Changes in Internal Control over Financial Reporting

There have not been any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

Our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls and internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management or board override of the control.

The design of any system of controls also 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; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

ITEM 9B – 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, 2009 that have not been already disclosed on a Form 8-K filed with the SEC.

PART III

ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Each member of the Board of Directors serves a one-year term and is subject to reelection at the Company's Annual Meeting of Shareholders held each year.

Board Committees

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

Audit Committee

The Audit Committee was established on December 8, 2006, the date on which its Charter was adopted. 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 "audit committee financial expert" as defined in Item 407(d)(5) of Regulation S-K 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, 2009 were as follows:

Name	Age	Position Held	Term*
Dwight Babcock	61	Chairman, Chief Executive Officer	Annual
Jonathan Hunt	42	Chief Financial Officer, Treasurer	
Lori Woods	47	Chief Operating Officer	
Robert Kauffman	68	Vice-Chairman	Annual
Thomas LaVoy	49	Director	Annual
Albert Smith	65	Director	Annual

* For directors only

Dwight Babcock – Mr. Babcock was appointed CEO of the Company on February 18, 2009. He was previously appointed Chairman and Interim CEO of the Company on February 26, 2008 and has served as a Director of the Company since 2006. 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.

Jonathan Hunt – Mr. Hunt has over 15 years of finance and accounting experience, including financial reporting, SEC knowledge, and operation analysis. Before joining IsoRay in 2006, he was employed by Hypercom Corporation, a global provider of electronic payment solutions and manufactur of credit card terminals, serving as its Assistant Corporate Controller from 2005 to 2006. His finance background also includes serving as both Manager and Director of Financial Reporting and a Director of Operation 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.

Lori Woods – Ms. Woods joined the Company in July 2006, was appointed Acting Chief Operating Officer on February 26, 2008, and was appointed Chief Operating Officer on February 18, 2009. Ms. Woods 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 AMI 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.

Robert Kauffman – Mr. Kauffman has been a Director of the Company since 2005 and was appointed Vice-Chairman of the Company on February 26, 2008. 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 so electric power systems with annual revenues in excess of $35 million. Prior to Photocomm, Mr. Kauffman was a senior executive of the Atlantic Richfie Company (ARCO) whose varied responsibilities included Senior Vice President of ARCO Solar, Inc., President of ARCO Plastics Company and Vic President of ARCO Chemical Company. Mr. Kauffman earned an M.B.A. in Finance at the Wharton School of the University of Pennsylvania, and hold B.S. in Chemical Engineering from Lafayette College, Easton, Pennsylvania.

Thomas LaVoy – Mr. LaVoy has been a Director of the Company since 2005. Mr. LaVoy has served as Chief Financial Officer of SuperShuttle Internatio 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 has been a Director of the Company since 2006. 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 Solutions, LLC, a private video conferencing company with headquarters in Scottsdale, Arizona in December 2005. In January 2008, he formed Face to Face Live, Inc. (successor to Extreme Video Solutions) where he presently serves as CEO. Mr. Smith presently serves as Chairman of the Board for Doulos Ministries, Inc. 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 elec 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 curre directors to the Company's board. There are also no arrangements, agreements or understandings between non-management shareholders that may directly o 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 a 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 t 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	61	VP, Regulatory Affairs and Quality Assurance
Lane Bray	81	Chemist
Anthony Pasqualone	54	VP, Business Development

Fredric Swindler – Mr. Swindler joined the Company in October 2006 and has over 30 years experience in manufacturing and regulatory compliance. M Swindler served as VP, Quality Assurance and Regulatory Affairs for Medisystems Corporation, a manufacturer and distributor of medical devices, from 19 until joining the Company. During his tenure at Medisystems Corporation, Mr. Swindler developed a quality system to accommodate vertically integra 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 P 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 note authority in the use of cesium and strontium ion exchange for Department of Energy's West Valley and Hanford nuclear waste cleanup efforts. In 2 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 nine 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 invented and patented the proprietary isotope separation and purification process that is assigned to IsoRay. Mr. Bray was elected 'Tri-Citian of the Year' in 1988, nominated for 'Engineer of the Year' by the America Nuclear Society in 1995, and was elected 'Chemist of the Year for 1997' by the American Chemical Society Eastern Washington Section. Mr. Bray retir from the Pacific Northwest National Laboratory in 1998. Since retiring in 1998, Mr. Bray worked part time for PNNL on special projects until devoting al 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.

Anthony Pasqualone – Mr. Pasqualone joined the Company in November 2008 and has been involved in marketing brachytherapy extensively since 198 when brachytherapy started to gain attention as a viable treatment option for prostate cancer. Prior to joining IsoRay, Mr. Pasqualone served as the National Oncology Development Manager at Calypso Medical from April 2007 to November 2008. Prior to that Mr. Pasqualone was a consultant w BrachySciences from December 2005 to April 2007. He also served as VP of Strategic Markets from May 2003 to December 2005 in the Urology Divisi of CR Bard. From April 1997 to May 2003 he was a principal and Vice President of Sales at SourceTech Medical, which developed and introduced SeedLink to the brachytherapy market in 2003. He started his career managing brachytherapy sales as the National Sales Manager at Theragenics Corporation, where he helped develop market acceptance of Pd-103. In 1995 he brought the first stranded product to market while working with the team at Oncura (Amersham Corporation). Mr. Pasqualone is an alumnus of Fordham University with a BS in Science.

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 wh 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 Sectio 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 3 2009 except as follows: Dwight Babcock (two Form 4s), Jonathan Hunt (one Form 4), A. Smith (one Form 4), and Lori Woods (one Form 4). We believe all o 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 Executi 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 ou website at http://www.isoray.com/ethicsForCeo.htm. Each of these policies comprises written standards that are reasonably designed to deter wrongd and to promote the behavior described in Item 406 of Regulation S-K 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 11 – EXECUTIVE COMPENSATION

The following summary compensation table sets forth information concerning compensation for services rendered in all capacities during our past two fisc years awarded to, earned by or paid to each of the following individuals. Salary and other compensation for these officers, employees and former officers ar set by the Compensation Committee of the Board of Directors, except for employee compensation which is set by officers of the Company.

Summary Compensation Table

Name and principal position	Year	Salary ($)	Bonus ($)	Stock awards ($)	Option awards ($) [1]	Nonequity incentive plan compensation ($)	Nonqualified deferred compensation earnings ($)	All other compensation ($)	Total ($)
Dwight Babcock, Chairman and CEO [2]	2009	140,308	-	-	50,000	-	-	-	190,308
	2008	22,000	-	-	70,000	-	-	-	92,000
Jonathan Hunt, Chief Financial Officer	2009	144,119	-	-	21,900	-	-	-	166,019
	2008	139,616	-	-	-	-	-	-	139,616
Lori Woods, Chief Operating Officer	2009	185,296	-	-	21,900	-	-	-	207,196
	2008	179,615	-	-	-	-	-	-	179,615
Robert Bilella, Territory Sales Manager	2009	86,722	106,550	-	2,448	-	-	-	195,720
	2008	117,283	121,150	-	-	-	-	-	238,433

(1) Amounts represent the FAS 123R valuation for the fiscal years ended June 30, 2009 and 2008, respectively. All such options were awarded under on of the Company's stock option plans. All options awarded (with the exception of Mr. Babcock's 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 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. Babcock became the Chairman and Interim CEO on February 26, 2008 and was appointed CEO on February 18, 2009. He was serving as Interim CEO on a contract basis. Mr. Babcock also received compensation as a Director of the Company until his appointment as CEO on February 18, 2009 which is disclosed in the Non-Employee Director Compensation table.

Ms. Woods has an employment contract with the Company dated February 14, 2007. The agreement was for an initial term of two years, was extended for an additional year, and 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 1 months, whichever is shorter. Good reason is defined in the agreement to mean a reduction in salary or benefits, a change in Ms. Woods' title, positio 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 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 additi 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 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 opti 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.

Mr. Hunt has an employment contract with the Company dated May 19, 2009. The agreement is for an initial term of one year and will extend automatic for additional one-year terms on each anniversary of the effective date of the agreement unless terminated by either party with 90 days prior notice. In the event that Mr. Hunt is terminated without cause, becomes disabled, or terminates his employment for good reason, he will be entitled to his salary a benefits for 12 months. Good reason is defined in the agreement to mean a reduction of salary or benefits, a change in Mr. Hunt's title, position, authority, responsibilities, causing Mr. Hunt to relocate, or any breach by the Company of this agreement. If Mr. Hunt is terminated within one year of a change control then he shall be entitled to his salary and benefits for 18 months. In the event of Mr. Hunt's termination without cause or termination within one ye of a change of control, all of his unvested stock options shall immediately vest in full and shall be exercisable as provided in the applicable stock optio plan. The agreement also includes certain restrictive covenants that prohibit Mr. Hunt from providing services to a competing business for the period of this agreement plus one year.

Outstanding Equity Awards at Fiscal Year-End

	Option awards				
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date
Dwight Babcock, Chairman and CEO	50,000	-	-	6.30	3/31/2016
	50,000	-	-	3.80	6/23/2016
	50,000	-	-	3.11	8/15/2016
	100,000	-	-	0.75	5/13/2018
	200,000	-	-	0.26	6/1/2019
Jonathan Hunt, Chief Financial Officer	30,000	-	-	5.50	5/1/2016
	33,333	16,667(2)	-	3.10	10/17/2016
	10,000	5,000(3)	-	4.40	3/2/2017
	13,333	6,667(4)	-	4.14	6/1/2017
	-	10,000(5)	-	0.65	7/1/2018
	-	100,000(6)	-	0.26	6/1/2019
Lori Woods, Chief Operating Officer	33,333	16,667(1)	-	3.50	7/5/2016
	33,333	16,667(2)	-	3.10	10/17/2016
	10,000	5,000(3)	-	4.40	3/2/2017
	13,333	6,667(4)	-	4.14	6/1/2017
	-	10,000(5)	-	0.65	7/1/2018
	-	100,000(6)	-	0.26	6/1/2019
Robert Bilella, Territory Sales Manager	84,236	-	-	4.15	6/23/2015
	-	18,000(6)	-	0.26	6/1/2019

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

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

(3) Representsthe March 2, 2007 grant, one-third of which became exercisable on March 2, 2008, one-third of which became exercisable on March 2, 2009, and the final third will become exercisable on March 2, 2010.

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

(5) Represents a July 1, 2008 grant, one-third of which became exercisable on July 1, 2009, one-third of which will become exercisable on July 1, 2010, and the final third will become exercisable on July 1, 2011.

(6) Represents a June 1, 2009 grant, one-third of which will become exercisable on June 1, 2010, one-third of which will become exercisable on June 1, 2011, and the final third will become exercisable on June 1, 2012.

The Company has a 401(k) plan that 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 plan for its executives or employees.

Non-Employee Director Compensation

Name	Fees earned or paid in cash ($)	Stock awards ($)	Option awards ($)	Non-equity incentive plan compensation ($)	Non-qualified deferred compensation earnings ($)	All other compensation ($)	Total ($)
Dwight Babcock	50,500	-	-	-	-	-	50,500
Robert Kauffman	64,500	-	-	-	-	-	64,500
Thomas LaVoy	52,500	-	-	-	-	-	52,500
Albert Smith	38,500	-	-	-	-	-	38,500

Beginning in fiscal year 2008, each non-employee director received cash compensation of $3,000 per month. In addition, each non-employee director received $1,000 per Board meeting attended in person or $500 per Board meeting attended via telephone and $500 per committee meeting attended. Beginning in March 2008, Mr. Babcock (until his appointment as CEO on February 18, 2009) began receiving an additional $3,000 per month for serving as Chairman, Mr. Kauffman began receiving an additional $2,000 per month for serving as Vice-Chairman, and Mr. LaVoy began receiving an additional $1,000 per month for serving as Audit Committee Chairman.

Each director had stock options to purchase 150,000 shares of the Company's common stock outstanding as of June 30, 2009, except for Mr. Babcock who was granted options to purchase an additional 100,000 shares of the Company's common stock on May 13, 2008 for serving as Interim CEO and an additional 200,000 shares of the Company's common stock on June 1, 2009 for serving as CEO. These grants of 100,000 and 200,000 shares are noted in the executives' Outstanding Equity Awards at Fiscal Year-End table above.

Compensation Committee Interlocks and Insider Participation

As a smaller reporting company, the Company is not required to provide this disclosure.

Compensation Committee Report

As a smaller reporting company, the Company is not required to provide this disclosure.

ITEM 12 – 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 14, 2009 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 14, 2009, the Company had 22,942,088 shares of common stock and 59,065 shares of preferred stock outstanding. Except as otherwise indicated below, the address for each listed beneficial owner is c/o IsoRay, Inc., 350 Hills Street, Suite 106, Richland, Washington 99354.

Common Stock Share Ownership

Name of Beneficial Owner	Common Shares Owned	Common Stock Options Exercisable Within 60 Days	Common Warrants	Percent of Class (1)
Dwight Babcock (2)	130,856	450,000	12,500	2.54%
Lori Woods	8,000	126,665	-	—%
Jonathan Hunt	-	106,665	-	—%
Robert Kauffman	63,802	150,000	-	—%
Thomas LaVoy	40,423	150,000	-	—%
Albert Smith	198,101	150,000	-	1.51%
Directors and Executive Officers as a group	441,182	1,133,330	12,500	6.59%

(1) Percentage ownership is based on 22,942,088 shares of Common Stock outstanding on September 14, 2009. Shares of Common Stock subject to stock options or warrants which are currently exercisable or will become exercisable within 60 days after September 14, 2009 are deemed outstanding for computing the percentage ownership of the person or group holding such options or warrants, but are not deemed outstanding computing the percentage ownership of any other person or group.
(2) Mr. Babcock's common shares owned include 2,695 shares owned by his spouse.

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 14, 2009.
(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 13 – 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. The Company recorded royalty expense of $20,063 and $21,219 for the years ended June 30, 2009 and 2008, respectively, related to these payments.

Roger Girard, the Company's former Chairman and CEO, had personally guaranteed $20,000 of the BFEDD loan, which was funded in December 2004. In exchange for his personal guaranty, Mr. Girard received 5,728 shares of common stock. As a condition of his resignation in February 2008, the Company prepaid $20,000 on the BFEDD loan and obtained Mr. Girard's release and Mr. Girard in turn surrendered the 5,728 shares to the Company. As part of his settlement, Mr. Girard also surrendered 30,072 shares of common stock he had received in 2004 for personally guaranteeing a portion of a line of credit for the Company.

Mr. Girard and David Swanberg, the Company's former Executive VP – Operations, personally guaranteed a portion of the HAEIFC loan. As part of their resignations, the Company obtained their releases from these personal guarantees by prepaying $60,000 and $40,000, respectively.

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 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 and again on October 31, 2007, the Company participated in nonbinding mediation regarding this matter; however, no settlement was reached with the Lawrence Family Trust. After additional settlement discussions which ended in April 2008, the parties still failed to reach a settlement. The parties may demand binding arbitration at any time.

Director Independence

Using the standards of the NYSE Amex, the Company's Board has determined that Mr. Kauffman, Mr. LaVoy, and Mr. Smith each qualify under such standards as an independent director. Mr. Kauffman, Mr. LaVoy and Mr. Smith each meet the NYSE Amex listing standards for independence both as a director and as a member of the Audit Committee, and Mr. Kauffman and Mr. Smith each meet the NYSE Amex 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 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.:

	Year ended June 30, 2009	Year ended June 30, 2008
1. Audit fees	$ 32,047	$ 42,107
2. Audit-related fees	–	–
3. Tax fees	7,900	7,750
4. All other fees	–	–
Totals	$ 39,947	$ 49,857

Audit fees include fees for the audit of our annual financial statements, review of our quarterly financial statements, and related consents for documents with the SEC. Tax fees include fees for the preparation of our federal and state income tax returns.

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 accountants' full-time, permanent employees.

ITEM 15 – EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(Except as otherwise indicated, all exhibits were previously filed)

Exhibit #	Description
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 August 3, 2005.
3.1	Articles of Incorporation and By-Laws are incorporated by reference to the Exhibits to the Company's Registration Statement September 15, 1983.
3.2	Certificate of Designation of Rights, Preferences and Privileges of Series A and B Convertible Preferred Stock, filed with the Minnes 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 February 7, 2007.
3.5	Amended and Restated By-Laws of the Company dated as of January 8, 2008, incorporated by reference to the Form 8-K filed on Janua 14, 2008.
4.2	Intentionally Omitted.
4.3	Intentionally Omitted.
4.4	Intentionally Omitted.
4.5	Intentionally Omitted.
4.6	Intentionally Omitted.
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	Intentionally Omitted.
4.10	Intentionally Omitted.
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	Intentionally Omitted.
4.14	Form of IsoRay, Inc. Common Stock Purchase Warrant, dated August 9, 2006, incorporated by reference to the Form 8-K filed on Augu 18, 2006.
4.15	Intentionally Omitted.
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 b reference to Exhibit 1 to the Company's Registration Statement on Form 8-A filed February 7, 2007.
4.21	2008 Employee Stock Option Plan, incorporated by reference to the Form S-8 filed on January 14, 2008.
10.2	Universal License Agreement, dated November 26, 1997 between Donald C. Lawrence and William J. Stokes of Pacific Managemen 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 b reference to the Form SB-2 filed on November 10, 2005.
10.4	Intentionally Omitted.
10.5	Section 510(k) Clearance from the Food and Drug Administration to market Lawrence SERION Model CS-1, dated March 28, 200 incorporated by reference to the Form SB-2 filed on November 10, 2005.
10.6	Intentionally Omitted.
10.7	Intentionally Omitted.
10.8	Intentionally Omitted.
10.9	Development Loan Agreement for $230,000, dated September 15, 2004 between Benton-Franklin Economic Development District an IsoRay Medical, Inc., incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.
10.10	Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Seal Source, dated September 17, 2004, incorporated b reference to the Form SB-2/A2 filed on April 27, 2006.
10.11	Intentionally Omitted.
10.12	Intentionally Omitted.
10.13	Intentionally Omitted.
10.14	Intentionally Omitted.
10.15	Intentionally Omitted.
10.16	Intentionally Omitted.
10.17	Intentionally Omitted.
10.18	State of Washington Radioactive Materials License dated October 6, 2005, incorporated by reference to the Form SB-2 filed November 10, 2005.
10.19	Express Pricing Agreement Number 219889, dated October 5, 2005 between FedEx and IsoRay Medical, Inc., incorporated by referenc to the Form 10-QSB filed on November 21, 2005.
10.20	Intentionally Omitted.
10.21	Intentionally Omitted.
10.22	Agreement dated August 9, 2005 between the Curators of the University of Missouri and IsoRay Medical, Inc., incorporated by referenc to the Form SB-2/A2 filed on April 27, 2006 (confidential treatment requested).

10.23	Intentionally Omitted.
10.24	Intentionally Omitted.
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 filed on March 24, 2006 (confidential treatment requested).
10.27	Intentionally Omitted.
10.28	Service Agreement between IsoRay, Inc. and Advanced Care Medical, Inc., dated March 1, 2006, incorporated by reference to the Fo SB-2/A2 filed on April 27, 2006.
10.29	Intentionally Omitted.
10.30	Intentionally Omitted.
10.31	Loan Agreement, dated June 15, 2006, by and between IsoRay Medical, Inc. and the Hanford Area Economic Investment Fun 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 Investmen 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, 200 incorporated by reference to the Form 8-K filed on August 18, 2006.
10.34	Intentionally Omitted.
10.35	Form of Officer and Director Indemnification Agreement, incorporated by reference to the Form SB-2 Post Effective Amendment No. filed on October 13, 2006.
10.36	Intentionally Omitted.
10.37	Intentionally Omitted.
10.38	Form of Securities Purchase Agreement by and among IsoRay, Inc. and the Buyers dated March 22, 2007, incorporated by reference 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	Intentionally Omitted.
10.41	Intentionally Omitted.
10.42	Intentionally Omitted.
10.43	Intentionally Omitted.
10.44	Intentionally Omitted.
10.45	Intentionally Omitted.
10.46	Amendment No. 1 to License Agreement, dated October 12, 2007, by and between IsoRay Medical, Inc. and IBt, SA, incorporated b reference to the Form 8-K filed on October 17, 2007.
10.47	Intentionally Omitted.
10.48	Intentionally Omitted.
10.49	Contract, dated December 10, 2008, by and between IsoRay Medical, Inc. and UralDial LLC, incorporated by reference to the Form 8- filed on December 12, 2008 (confidential treatment requested for redacted portions).
10.50	Distribution Agreement, dated February 18, 2009, by and between IsoRay Medical, Inc. and Biocompatibles, Inc., incorporated by reference to the Form 8-K filed on February 24, 2009 (confidential treatment requested for redacted portions).
10.51	Amendment No. 1 to Service Agreement, dated February 18, 2009, by and between IsoRay Medical, Inc. and Biocompatibles, Inc., incorporated by reference to the Form 8-K filed on February 24, 2009 (confidential treatment requested for redacted portions).
10.52	Executive Employment Agreement between IsoRay, Inc. and Jonathan Hunt, dated May 19, 2009, incorporated by reference to the For 8-K filed on May 26, 2009.
10.53	Loan Covenant Waiver Letter dated August 24, 2009 from the Hanford Area Economic Investment Fund Committee, filed herewith.

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

Reports on Form 8-K

On May 18, 2009, the Company filed a Current Report on Form 8-K announcing its financial results for the third quarter of fiscal year 2009.

On May 26, 2009, the Company filed a Current Report on Form 8-K announcing an employment agreement entered into with Mr. Hunt.

IsoRay, Inc.
Index to Financial Statements

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 Subsidiaries ("the Company") (see Note 1) as of June 30, 2009 and 2008, 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 Subsidiaries as of June 30, 2009 and 2008, 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 22, 2009

IsoRay, Inc. and Subsidiaries
Consolidated Balance Sheets

	June 30, 2009	June 30, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,990,744	$ 4,820,033
Short-term investments	1,679,820	3,726,000
Accounts receivable, net of allowance for doubtful accounts of $86,931 and $33,031, respectively	746,568	1,016,495
Inventory	789,246	899,964
Prepaid expenses and other current assets	151,077	267,001
Total current assets	6,357,455	10,729,493
Fixed assets, net of accumulated depreciation and amortization	4,891,484	6,040,641
Deferred financing costs, net of accumulated amortization	28,186	65,221
Licenses, net of accumulated amortization	11,867	455,646
Restricted cash	178,615	175,852
Other assets, net of accumulated amortization	273,959	345,040
Total assets	$ 11,741,566	$ 17,811,893
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 698,882	$ 751,402
Accrued payroll and related taxes	188,703	344,612
Notes payable, due within one year	161,437	64,486
Capital lease obligations, due within one year	-	25,560
Total current liabilities	1,049,022	1,186,060
Notes payable, due after one year	176,023	344,898
Asset retirement obligation, noncurrent	553,471	506,005
Total liabilities	1,778,516	2,036,963
Commitments and contingencies (Note 18)		
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 shares issued and outstanding	59	59
Common stock, $.001 par value; 194,000,000 shares authorized; 22,942,088 shares issued and outstanding	22,942	22,942
Treasury stock, at cost, 13,200 and 5,000 shares	(8,390)	(3,655)
Additional paid-in capital	47,818,203	47,464,507
Accumulated deficit	(37,869,764)	(31,708,923)
Total shareholders' equity	9,963,050	15,774,930
Total liabilities and shareholders' equity	$ 11,741,566	$ 17,811,893

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

IsoRay, Inc. and Subsidiaries
Consolidated Statements of Operations

	June 30, 2009	June 30, 2008
Product sales	$ 5,417,815	$ 7,158,690
Cost of product sales	5,771,147	7,310,124
Gross loss	(353,332)	(151,434)
Operating expenses:		
Research and development expenses	958,665	1,358,075
Sales and marketing expenses	2,365,973	3,725,164
General and administrative expenses	2,792,611	3,568,048
Total operating expenses	6,117,249	8,651,287
Operating loss	(6,470,581)	(8,802,721)
Non-operating income (expense):		
Interest income	111,047	612,077
Gain (loss) on fair value of short-term investments	274,000	(274,000)
Financing and interest expense	(75,307)	(92,863)
Non-operating income, net	309,740	245,214
Net loss	$ (6,160,841)	$ (8,557,507)
Basic and diluted loss per share	$ (0.27)	$ (0.37)
Weighted average shares used in computing net loss per share:		
Basic and diluted	22,942,088	23,028,075

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

IsoRay, Inc. and Subsidiaries
Consolidated Statement of Changes in Shareholders' Equity

	Series B Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
Balances at June 30, 2007	59,065	$ 59	22,789,324	$ 22,789	-	$ -	$ 45,844,793	$ (23,151,416)	$ 22,716,225
Issuance of common stock pursuant to exercise of warrants			290,876	291			1,010,622		1,010,913
Issuance of common stock pursuant to exercise of options			10,000	10			11,890		11,900
Repurchase of Company common stock (see Note 13)					5,000	(3,655)			(3,655)
Cancellation of shares (see Note 12)			(148,112)	(148)			148		-
Share-based compensation							597,054		597,054
Net loss								(8,557,507)	(8,557,507)
Balances at June 30, 2008	59,065	$ 59	22,942,088	$ 22,942	5,000	$ (3,655)	$ 47,464,507	$ (31,708,923)	$ 15,774,930
Repurchase of Company common stock (see Note 13)					8,200	(4,735)			(4,735)
Share-based compensation							353,696		353,696
Net loss								(6,160,841)	(6,160,841)
Balances at June 30, 2009	59,065	$ 59	22,942,088	$ 22,942	13,200	$ (8,390)	$ 47,818,203	$ (37,869,764)	$ 9,963,050

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

IsoRay, Inc. and Subsidiaries
Consolidated Statements of Cash Flows

	Year ended June 30,	
	2009	**2008**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (6,160,841)	$ (8,557,507)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization of fixed assets	1,206,935	1,103,940
Impairment of IBt license	425,434	-
Write-off of certain foreign patents and trademarks	85,818	-
Impairment of fixed assets	-	85,000
Amortization of deferred financing costs and other assets	79,563	107,555
Amortization of discount on short-term investments	-	(150,621)
(Gain) loss on fair value of short-term investments	(274,000)	274,000
Settlement of asset retirement obligation	-	(135,120)
Accretion of asset retirement obligation	47,466	36,887
Share-based compensation	353,696	597,054
Changes in operating assets and liabilities:		
Accounts receivable, net	269,927	76,430
Inventory	110,718	(19,130)
Prepaid expenses and other current assets	114,777	191,122
Accounts payable and accrued expenses	(52,520)	(1,196,578)
Accrued payroll and related taxes	(155,909)	(114,456)
Deferred revenue	-	(23,874)
Net cash used by operating activities	(3,948,936)	(7,725,298)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of fixed assets	(57,778)	(3,090,934)
Additions to licenses and other assets	(37,773)	(293,303)
Change in restricted cash	(2,763)	(175,852)
Purchase of short-term investments	(1,679,820)	(13,273,653)
Proceeds from the sale or maturity of short-term investments	4,000,000	19,367,114
Net cash provided by investing activities	2,221,866	2,533,372
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal payments on notes payable	(71,924)	(168,074)
Principal payments on capital lease obligations	(25,560)	(194,855)
Proceeds from cash sales of common stock, pursuant to exercise of warrants	-	1,010,913
Proceeds from cash sales of common stock, pursuant to exercise of options	-	11,900
Repurchase of Company common stock	(4,735)	(3,655)
Net cash (used) provided by financing activities	(102,219)	656,229
Net decrease in cash and cash equivalents	(1,829,289)	(4,535,697)
Cash and cash equivalents, beginning of year	4,820,033	9,355,730
CASH AND CASH EQUIVALENTS, END OF YEAR	$ 2,990,744	$ 4,820,033
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 38,752	$ 63,818
Non-cash investing and financing activities:		
Increase in fixed assets related to asset retirement obligation	$ -	$ 473,096

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

IsoRay, Inc.
Notes to Consolidated Financial Statements
For the years ended June 30, 2008 and 2007

1. Organization

Century Park Pictures Corporation (Century) was organized under Minnesota law in 1983. Century had no operations during the period from 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.

IsoRay International LLC, a Washington limited liability company, was formed on November 27, 2007 to serve as an owner in a Russian LLC that will distribute the Company's products to the Russian market and also license the Company's technology for use in manufacturing Cs-131 brachytherapy seeds in Russia. During fiscal year 2009, the Company divested its ownership in the Russian LLC.

2. Summary of Significant Accounting Policies

Consolidation

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

Cash Equivalents

The Company considers all highly liquid investments with original 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, certificates of deposit 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 temporary unrealized losses included in other comprehensive income/loss within shareholders' equity, if material. Declines in fair values that are considered other than temporary are recorded in the Consolidated Statements of Operations.

Fair Value of Financial Instruments

Effective July 1, 2008, the Company implemented Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements*. 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. The Company elected to implement this Statement with the one-year deferral permitted by FASB Staff Position (FSP) 157-2 for nonfinancial assets and nonfinancial liabilities measured at fair value, except those that are recognized or disclosed on a recurring basis. This deferral applies to fixed assets and intangible assets, impairment testing and initial recognition of asset retirement obligations for which fair value is used. The Company does not expect any significant impact to our consolidated financial statements when we implement SFAS 157 for these assets and liabilities.

SFAS 157 requires disclosures that categorize assets and liabilities measured at fair value into one of three different levels depending on the observability of the inputs employed in the measurement. Level 1 inputs are quoted prices in active markets for identical assets or liabilities. Level 2 inputs are observable inputs other than quoted prices included within Level 1 for the asset or liability, either directly or indirectly through market-corroborated means. Level 3 inputs are unobservable inputs for the asset or liability reflecting significant modifications to observable related market data or our assumptions about pricing by market participants.

At June 30, 2009, all of the Company's financial assets and liabilities are accounted and reported at fair value using Level 1 inputs.

Also effective July 1, 2008, the Company adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115*. The statement allows entities to value many financial instruments and certain other items at fair value. SFAS 159 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. If the fair value option is elected then unrealized gains and losses are reported in earnings at each subsequent reporting date. The Company elected not to measure any additional financial instruments or other items at fair value as of July 1, 2008 in accordance with SFAS 159. Accordingly, the adoption of SFAS 159 did not impact our consolidated financial statements. The Company did elect to fair value its ARS rights that were received in October 2008 and exercised in January 2009 in accordance with SFAS 159 (see Note 3).

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.

Fixed Assets

Fixed assets are capitalized and carried at the lower of cost or net realizable value. 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 useful life of the asset.

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 ne realizable value of each asset 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 th changes could occur which could adversely affect management's estimate of net cash flows expected to be generated from its assets, and necessitate as 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 Note 10) i accordance with Accounting Principles Board (APB) Opinion No. 21, *Interest on Receivables and Payables* and Emerging Issues Task Force (EITF) Issue No 95-13, *Classification of Debt Issue Costs in the Statement of Cash Flows*. The value of the shares issued was the estimated market price of the shares as of t date of issuance. Amortization of deferred financing costs, totaling $37,035 and $30,504 for the years ended June 30, 2009 and 2008, respectively, included in financing expense on the statements of operations.

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 Compan entered into an agreement with IBt, SA, a Belgian company (IBt) to use IBt's proprietary "Ink Jet" production process and its proprietary polymer see technology for use in brachytherapy procedures using Cesium-131 (Cs-131). The Company paid license fees of $225,000 and $275,000 during fiscal year 2008 and 2006, respectively. During fiscal year 2009, the Company determined that the entire remaining value of the IBt license was impaired and recorded an impairment charge of $425,434 (see Note 7).

Amortization of licenses was $30,067 and $43,452 for the years ended June 30, 2009 and 2008, respectively. Based on the licenses recorded at June 3 2009, and assuming no subsequent impairment of the underlying assets, the annual amortization expense for each fiscal year ending June 30 is expected t be as follows: $11,867 for 2010, $0 for all years 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, 2009, 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: $16,861 for 2010, $15,139 for 2011, $15,139 for 201 $15,139 for 2013, $15,139 for 2014, and $157,768 thereafter.

Asset Retirement Obligation

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 equivalent amount is capitalized to property and equipment. The initial recorded obligation is discounted using the Company's credit-adjusted risk free-ra and is reviewed periodically for 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 lea assets.

In fiscal year 2006, the Company established an initial asset retirement obligation of $63,040 which represented the discounted cost of cleanup that t Company anticipated it would have to incur at the end of its equipment and property leases in its old production facility. 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. During the second quarter of fiscal year 2008, the Company removed all radioactive residuals and tenant improvements from its old production facility and returned the facility to the lessor. The Company had an asset retirement obligation of $135,120 accrued for this facility but total costs incurred to decommission the facility were $274,163 resulting in an additional expense of $139,043 that is included in cost of products sold. The additional expense was mainly due to unanticipated construction costs to return the facility to its previous state. The Company originally believed that the lessor would retain many of the leasehold improvements in the building, but the lessor instead required their removal.

In September 2007, another asset retirement obligation of $473,096 was established representing the discounted cost of the Company's estimate of its obligations to remove any residual radioactive materials and all leasehold improvements at the end of the lease term at its new production facility. This estimate was developed by qualified production personnel and the general contractor for the new facility. The Company has reviewed the estimate again based on its experience with decommissioning its old facility and believes that the original estimate continues to be applicable.

During the years ended June 30, 2009 and 2008, the asset retirement obligations changed as follows:

	2009	2008
Beginning balance	$ 506,005	$ 131,142
New obligation	–	473,096
Settlement of existing obligation	–	(135,120)
Accretion of discount	47,466	36,887
Ending balance	$ 553,471	$ 506,005

Because the Company does not expect to incur any expenses related to its asset retirement obligations in fiscal year 2010, the entire balance as of June 2009 is classified as a noncurrent liability.

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, and capital lease obligations, approximated their fair values at June 30, 2009 and 2008.

Revenue Recognition

The Company applies the provisions of SEC Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition*. SAB No. 104 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, 2009 and 2008 was derived solely from sales of the Proxcelan Cs-131 brachytherapy seed, which is used in t treatment of cancer. The Company recognizes revenue once the product has been shipped to the customer. Prepayments, if any, received from customer 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 deferred revenue is then 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, particularl those with extensive industry experience and knowledge, to develop a proper methodology.

Shipping and Handling Costs

Shipping costs include charges associated with delivery of goods from the Company's facilities to its customers and are reflected in cost of prod sales. Shipping costs paid to the Company by our customers are classified as product sales.

Stock-Based Compensation

The Company measures and recognizes expense for all share-based payments at fair value. The Company uses the Black-Scholes option valuation model t estimate fair value for all stock options on the date of grant. For stock options that vest over time, the Company recognizes compensation cost on a straight-line basis over the requisite service period for the entire award.

Research and Development Costs

Research and development costs, including salaries, research materials, administrative expenses and contractor fees, are charged to operations 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 a an expense in the period acquired. Depreciation of capitalized equipment used to perform research and development is classified as research an development expense in the year recognized.

Advertising and Marketing Costs

Advertising costs are expensed as incurred except for the cost of tradeshows and related marketing materials which are deferred until the trades occurs. Advertising and marketing costs expensed (including tradeshows) were $376,319 and $598,663 for the years ended June 30, 2009 and 2008, respectively. Marketing costs of $5,800 were included in prepaid expenses at June 30, 2009.

Legal Contingencies

In the ordinary course of business, the Company is involved in legal proceedings involving contractual and employment relationships, product liabil claims, patent rights, environmental matters, and a variety of other matters. The Company is also subject to various local, state, and federal environmenta 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 th Company is in compliance with these laws and regulations. While there have been no reportable incidents or compliance issues, the Company believes that if it relocates its current production facilities then certain decommissioning expenses will be incurred and has recorded an asset retirement obligation 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 a the amount of the loss is reasonably estimable. Estimating probable losses requires analysis of multiple factors, in some cases including judgments about thi potential actions of third-party claimants and courts. Therefore, actual losses in any future period are inherently uncertain. Currently, the Company does no believe any probable legal proceedings or claims will have a material adverse effect on its financial position or results of operations. However, if actual estimated probable future losses exceed the Company's recorded liability for such claims, it would record additional charges as other expense during 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.

On July 1, 2007, the Company adopted Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN No. 48). FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in accordance with SFAS No. 109 *Accounting for Income Taxes*, prescribing a recognition threshold and measurement attribute for the recognition and measurement of a tax position taken or expected to be taken in a tax return. In the course of its assessment, management has determined that the Company, its subsidiary, and its predecessors are subject to examination of the income tax filings in the United States and state jurisdictions for the 2005 through 2008 tax years. In the event that the Company is assessed penalties and interest, penalties will be charged to other operating expense and interest will be charged to interest expense.

The Company adopted FIN No. 48 using the modified prospective transition method, which requires the application of the accounting standard as of July 1, 2007. There was no impact on the financial statements as of and for the year ended June 30, 2008 as a result of the adoption of FIN No. 48. In accordance with the modified prospective transition method, the financial statements for prior periods have not been restated to reflect, and do not include, the impact of FIN No. 48.

Income (Loss) Per Common 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 and options to purchase the Company's common stock, are excluded from the calculations when their effect is antidilutive. At June 30, 2009 and 2008, the calculation of diluted weighted average shares does not include preferred stock, common stock warrants or options 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, 2009 and 2008 are as follows:

	2009	2008
Preferred stock	59,065	59,065
Common stock warrants	3,216,644	3,245,082
Common stock options	2,708,166	2,803,393
Total potential dilutive securities	5,983,875	6,107,540

Subsequent Events

Effective April 1, 2009, the Company adopted SFAS No. 165, *Subsequent Events*. This Statement establishes the accounting for, and disclosure of, materia events that occur after the balance sheet date, before the financial statements are issued. In general, these events will be recognized if the conditio existed at the date of the balance sheet and will not be recognized if the condition did not exist at the balance sheet date. Disclosure is required fo nonrecognized events if required to keep the financial statements from being misleading. The guidance in this Statement is very similar to current guidan provided in accounting literature and, therefore, will not result in significant changes in practice. Subsequent events have been evaluated through the d our financial statements were issued—the filing time and date of our 2009 Annual Report on Form 10-K.

Use of Estimates

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

Impact of Recently Issued Accounting Pronouncements

In December 2007, the FASB issued statement No. 160, *Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB No. 51* (SFAS 160). The statement requires noncontrolling interests or minority interests to be treated as a separate component of equity, not as a liability or other item outside of permanent equity. Upon a loss of control, the interest sold, as well as any interest retained, is required to be measured at fair value, with an gain or loss recognized in earnings. Based on SFAS 160, assets and liabilities will not change for subsequent purchase or sales transactions wi noncontrolling interests as long as control is maintained. Differences between the fair value of consideration paid or received and the carrying value noncontrolling interests are to be recognized as an adjustment to the parent interest's equity. SFAS 160 is effective for fiscal years beginning on or af December 15, 2008 and earlier adoption is prohibited. The adoption of this statement is not expected to have a material effect on the Company's financi statements.

In May 2008, FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*. SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the United States. It was effective November 15, 2008, following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. The adoption of this statement did not have a material effect on the Company's financial statements.

The FASB issued SFAS No. 168, *The FASB Standards Codification and the Hierarchy of Generally Accepted Accounting Principles—a replacement of FASB Statement 162*, in late June 2009. The FASB Accounting Standards Codification will become the source of authoritative U.S. generally accept accounting principles (GAAP) and will supersede all then-existing non-SEC accounting and reporting standards on the effective date, September 1 2009. The Codification will not change GAAP, but consolidates it into a logical and consistent structure. The Company will be required to revise our references to GAAP in our financial statements beginning with the first quarter of fiscal year 2010.

3. Short-Term Investments

The Company's short-term investments consisted of the following at June 30, 2009 and 2008:

	2009	2008
Certificates of deposit	$ 1,679,820	$ –
Municipal debt securities	–	3,726,000
	$ 1,679,820	$ 3,726,000

Beginning in February 2008, the uncertainties in the credit markets prevented the Company from liquidating its ARS (consisting of various student loan portfolios). The securities continued to pay interest according to their stated terms and were all AAA/Aaa rated investments. Through September 2008, the Company classified these securities as available-for-sale and recorded them at fair market value. The Company recognized a decline in the fair value of these securities (which was caused by the market uncertainties) as other than temporary and recorded the loss in the statement of operations.

In October 2008, the Company accepted an offer from UBS to provide the Company with certain Rights pertaining to our ARS. The Rights were a put option allowing the Company to sell its ARS to UBS at par value at any time from January 2, 2009 to January 4, 2011. The Rights did not meet the definition of a derivative under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, as there is no net settlement method. The Rights also did not meet the definition of a security under SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. The Company elected to measure the Rights under the fair value option of SFAS 159 on the date they were received (see Note 2) and classified them as short-term investments.

Also in October 2008, the Company reclassified its ARS from available-for-sale to trading and recorded all changes in fair value to these securities in the statement of operations. The Company felt this reclassification was appropriate given that it accepted the offer of the Rights, it did not intend to hold these investments to maturity, and there was no longer an active market to permit their sale in the normal course of business.

On January 2, 2009, the Company exercised its put option with UBS to redeem its ARS at par value. The entire $4 million of cash was deposited into the Company's account on January 5, 2009.

4. Inventory

Inventory consisted of the following at June 30, 2009 and 2008:

	2009	2008
Raw materials	$ 609,932	$ 696,958
Work in process	155,827	191,684
Finished goods	23,487	11,322
	$ 789,246	$ 899,964

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 at an off-site storage location in Richland, Washington and is included in raw materials at June 30, 2009 and 2008.

5. Prepaid Expenses

Prepaid expenses consisted of the following at June 30, 2009 and 2008:

	2009	2008
Prepaid contract work	$ –	$ 60,107
Prepaid insurance	30,625	38,059
Prepaid rent	24,402	24,199
Other prepaid expenses	61,900	106,960
Other current assets	34,150	37,676
	$ 151,077	$ 267,001

6. Fixed Assets

Fixed assets consisted of the following at June 30, 2009 and 2008:

	2009	2008
Production equipment	$ 3,089,793	$ 2,786,748
Office equipment	169,890	153,215
Furniture and fixtures	148,265	148,265
Leasehold improvements (a)	4,643,965	4,622,136
Capital lease assets (b)	–	222,911
Construction in progress	3,359	64,219
	8,055,272	7,997,494
Less accumulated depreciation	(3,163,788)	(1,956,853)
	$ 4,891,484	$ 6,040,641

(a) Balance includes asset retirement addition of $473,096 as of June 30, 2009 and 2008.

(b) The Company's capital leases were properly terminated during fiscal year 2009. The Company now has ownership of these assets and continues to use them in its facilities. Therefore, the Company reclassified these assets to production equipment during fiscal ye 2009. Accumulated amortization of capital lease assets totaled $0 and $166,328 at June 30, 2009 and 2008, respectively.

Depreciation and amortization expense related to fixed assets totaled $1,206,935 and $1,103,940 for 2009 and 2008, respectively.

The Company recorded an impairment charge of $85,000 in fiscal year 2008 for a hot cell that is not currently in use. This impairment charge is included in cost of product sales on the Consolidated Statement of Operations. The Company estimated its fair market value based on values for similar assets.

7. Impairment of IBt License

In December 2008, the Company reevaluated its license agreement with International Brachytherapy SA (IBt) in connection with an overall review of present coststructure and projected market and manufacturing strategies (see Note 18 for further details on the IBt license agreement). Managem determined through this review that it does not currently intend to utilize the IBt license as part of its market strategy due to the cost of revamping manufacturing process to incorporate the technology and as there can be no assurance that physicians would accept this new technology without extensiv education and marketing costs. However, the Company does not intend to cancel the license agreement at this time; therefore, the license was reviewed terms of an "abandoned asset" for purposes of SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. As there are no anticipated future revenues from the license and the Company cannot sell or transfer the license, it was determined that the entire value was impaired. Therefore, the Company recorded an impairment charge of $425,434 in December 2008 that is included in cost of product sales for the year ended June 30, 2009.

8. Restricted Cash

The Washington Department of Health, effective October 2007, has required the Company to provide collateral for the decommissioning of its facility. To satisfy this requirement, the Company funded two certificates of deposits (CDs) totaling $172,500 in separate banks. The CDs both have original maturities of three months but are classified as long-term as the Company does not anticipate decommissioning the facility until the end of the current lease plus the lease option periods. Interest earned on the CDs is rolled-over at the maturity of each CD and becomes part of the restricted cash balance. Interest earned and added to restricted cash during the fiscal year ended June 30, 2009 and 2008 was $2,763 and $3,352, respectively. These funds will be used to settle a portion of the Company's remaining asset retirement obligations (Note 2).

9. Other Assets

Other assets, net of accumulated amortization, consisted of the following at June 30, 2009 and 2008:

	2009	2008
Deferred charges	$ 40,496	$ 322,319
Patents and trademarks, net of accumulated amortization of $25,244 and $19,094	233,463	22,721
	$ 273,959	$ 345,040

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 $6,150 and $2,631 for the years ended June 30, 2009 and 2008, respectively.

During fiscal year 2009, the Company performed a review of its prepaid legal fees for patents and trademarks that have not been obtained and are classified within other assets on the consolidated balance sheet. The focus of the review was patent and trademark applications that the Company had been pursuing in foreign countries. The Company decided to limit its foreign applications to Canada, Europe, and Russia, as well as the continued protection of the US patents and trademarks. This resulted in the write-off of $85,818 of other patent and trademark application fees relating to other countries during fiscal year 2009 that is included in research and development expenses.

10. Notes Payable

Notes payable consisted of the following at June 30, 2009 and 2008:

	2009	2008
Benton-Franklin Economic Development District (BFEDD) note payable [(a)]	$ 115,898	$ 145,745
Hanford Area Economic Investment Fund Committee (HAEIFC) note payable [(b)]	221,562	263,639
	337,460	409,384
Less amounts due within one year	(161,437)	(64,486)
Amounts due after one year	$ 176,023	$ 344,898

(a) The note payable to BFEDD, which is collateralized by substantially all of the Company's assets, and guaranteed by certain shareholders, w executed pursuant to a Development Loan Agreement. The note contains certain restrictive covenants relating to: working capital; level long-term debt to equity; incurrence of additional indebtedness; payment of compensation to officers and directors; and payment o 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, 2009, the Company was not in compliance with certain of the covenants and the entire balance has been classified as a current liability.

(b) In June 2006, the Company entered into a note payable with HAEIFC, which is collateralized by receivables, inventory, equipment, and certa life insurance policies. The loan originally had a total facility of $1,400,000 which was reduced in September 2007 to the amount of th Company's initial draw of $418,670. 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 fin installment due in July 2016. At June 30, 2009, 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, 2010.

Principal maturities on notes payable as of June 30, 2009 are as follows:

Year ending June 30,	
2010	$ 161,437
2011	49,445
2012	54,059
2013	59,154
2014	13,365
Thereafter	–
	$ 337,460

11. Share-Based Compensation

THE FOLLOWING TABLE PRESENTS THE SHARE-BASED COMPENSATION EXPENSE RECOGNIZED IN ACCORDANCE WITH SFAS 123R DURING THE YEARS ENDED JUNE 30, 2009 AN 2008:

	Year ended June 30,	
	2009	2008
Cost of product sales	$ 17,619	$ 109,578
Research and development	23,450	43,885
Sales and marketing expenses	148,407	238,230
General and administrative expenses	164,220	205,361
Total share-based compensation	$ 353,696	$ 597,054

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, 2009, TOTA UNRECOGNIZED COMPENSATION COST RELATED TO STOCK-BASED OPTIONS AND AWARDS WAS $223,295 AND THE RELATED WEIGHTED-AVERAGE PERIOD OVER WHICH IT IS EXPECT to be recognized is approximately 0.96 years.

THE COMPANY CURRENTLY PROVIDES SHARE-BASED COMPENSATION UNDER THREE EQUITY INCENTIVE PLANS APPROVED BY THE BOARD OF DIRECTORS: THE AMENDED AN RESTATED 2005 STOCK OPTION PLAN (THE OPTION PLAN), THE AMENDED AND RESTATED 2005 EMPLOYEE STOCK OPTION PLAN (THE EMPLOYEE PLAN), AND THE 200 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 COMMO STOCK TO DIRECTORS, OFFICERS, KEY EMPLOYEES AND SERVICE PROVIDERS OF THE COMPANY. THE EMPLOYEE PLAN ALLOWS THE BOARD OF DIRECTORS TO GRANT OPTION 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 G 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 A 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 ON THE GRANT DATE. THE OPTIONS ISSUED TO THE EMPLOYEES VEST OVER THREE YEARS WHILE THE OPTIONS GRANTED TO THE NON-EMPLOYEE directors were immediately vested.

The COMPANY'S FORMER CEO, WHO ALSO SERVED AS CHAIRMAN OF THE BOARD, WAS GRANTED 150,000 OPTIONS, AND THE FORMER EXECUTIVE VICE PRESIDENT OPERATION (EVP–Operations), who also served 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 THE OPTIONS FROM THE JUNE 1, 2007 GRANT. AFTER THE CANCELLATION, THE FORMER CEO AND FORMER 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 FORMER CEO AND FORMER EVP–OPERATIONS WER 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. ADDITIONAL COMPENSATION COST ASSOCIATED WITH THE FORMER CEO'S AND EVP–OPERATIONS' 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 RECOMPENSATION cost was recognized in fiscal year 2007.

All of these subsequently cancelled options are included in the options outstanding as OF JULY 1, 2007 AND ARE INCLUDED IN THE OPTIONS CANCELLED IN FISCAL YE 2008 (see Note 12).

A summary of stock option activity within the Company's share-based compensation plans for the year ended June 30, 2009 is as follows:

	Shares	Price (a)	Life (b)	Value (c)
Outstanding at June 30, 2009	2,708,166	$ 2.08	7.92	$ –
Vested and expected to vest at June 30, 2009	2,615,395	$ 2.14	7.85	$ –
Vested and exercisable at June 30, 2009	1,837,018	$ 2.74	7.12	$ –

(a) Weighted average exercise price per share.
(b) Weighted average remaining contractual life.
(c) Aggregate intrinsic value. As of June 30, 2009, all options outstanding have an exercise price greater than the closing market price of $0.25.

The aggregate intrinsic value of options exercised during the years ended June 30, 2009 and 2008 was $0 and $25,300, 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 value are as follows for the year ended June 30, 2009 and 2008:

	Years ended June 30, 2009	2008
Weighted average fair value of options granted	$ 0.21	$ 0.70
Key assumptions used in determining fair value:		
Weighted average risk-free interest rate	2.55%	3.17%
Weighted average life of the option (in years)	4.66	6.00
Weighted average historical stock price volatility	128.23%	141.67%
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. Although the Company is using the Black-Scholes option valuation model, management believes that because changes in the subjective input assumptions can materially affect the fair value estimate, this valuation model does not necessarily provide a reliable single measure of the fair value of its stock options. The risk-free interest rate is based on the U.S. treasury security rate with an equivalent term in effect as of the date of grant. The expected option lives, volatility, and forfeiture assumptions are based on historical data of the Company.

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 Articles of Incorporation authorize 6,000,000 shares of $0.001 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 Articles 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, 2009, 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 Articles 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, 2009, there were 59,065 Series B preferred shares outstanding and cumulative dividends in arrears were $26,565.

In addition to the previously outstanding shares of common stock and Series B preferred stock, the Company had the following transactions that affected shareholders' equity during the years ended June 30, 2009 and 2008.

Cancellation of Common Shares

In March 2008, the Company cancelled 148,112 shares of common stock held by Roger Girard, the Company's former CEO, due to the release of Mr. Girard from certain personal guarantees of Company debt and due to Mr. Girard's resignation as Chairman, President, and CEO. The shares were originally issued in connection with Mr. Girard's personal guarantee of Company debt or were contingent on his employment through August 2008.

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:

	2009		2008	
	Warrants	Price (a)	Warrants	Price (a)
Beginning balance outstanding	3,245,082	$ 5.50	3,627,764	$ 5.31
Cancelled/expired	(28,438)	0.70	(91,806)	4.18
Exercised	–	–	(290,876)	3.48
Ending balance outstanding	3,216,644	$ 5.55	3,245,082	$ 5.50

(a) Weighted average exercise price per share.

On August 20, 2008, the Board of Directors extended the expiration dates of warrants issued pursuant to the Company's private placement memorandums dated October 17, 2005 and February 1, 2006 for an additional one-year period. The Board of Directors had previously retroactively extended these warr on January 8, 2008 for a one-year period beyond their initial expiration dates of October 2007 to February 2008. Based on these extensions, the warrants wil now expire between October 2009 and February 2010. No other terms or conditions of the warrants were changed. The change in expiration dates affecte outstanding warrants to purchase 2,102,142 shares of common stock. Of these outstanding warrants, there were warrants to purchase 12,500 common shares held by the Chairman and CEO of the Company. Prior to the original extension, warrants to purchase 1,186,219 shares of common stock had passed their original expiration dates.

The change in expiration date was a modification of the original warrant based on market conditions and was accounted for as a financing transaction simi to an extension of time in the offering 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 following table summarizes additional information about the Company's common warrants outstanding as of June 30, 2009:

Number of Warrants	Range of Exercise Prices	Expiration Date
53,000	$ 6.00	October 2009
162,500	$ 6.00	November 2009
909,469	$ 6.00	December 2009
700,250	$ 6.00	January 2010
276,923	$ 6.00 to $6.50	February 2010
56,876	$ 0.70	March 2010
826,100	$ 5.00	March 2011
206,526	$ 4.40	March 2012
25,000	$ 2.00	July 2015
3,216,644		

Common Stock Options

A summary of the Company's stock option activity and related information for the years ended June 30, 2009 and 2008 is as follows:

	2009		2008	
	Shares	Price (a)	Shares	Price (a)
Beginning balance outstanding	2,803,393	$ 2.62	3,683,439	$ 2.86
Granted (b)	993,900	0.31	100,000	0.75
Cancelled	(1,089,127)	1.86	(970,046)	3.35
Exercised	–	–	(10,000)	1.19
Ending balance outstanding	2,708,166	$ 2.08	2,803,393	$ 2.62
Exercisable at end of year	1,837,018	$ 2.74	2,442,001	$ 2.42

(a) Weighted average exercise price per share.
(b) All options granted had exercise prices equal to or greater than the ending market price of the Company's common stock on the grant date.

The following table summarizes additional information about the Company's stock options outstanding as of June 30, 2009:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Shares	Price (a)	Life (b)	Shares	Price (a)
$ 0.26	898,900	$ 0.26	9.93	200,000	$ 0.26
$ 0.65 to $0.75	130,000	0.73	8.90 yrs	100,000	0.75
$ 1.00 to $1.19	272,802	1.05	6.57 yrs	222,802	1.06
$ 1.96 to $2.00	342,118	2.00	5.35 yrs	342,118	2.00
$ 3.10 to $3.11	440,400	3.11	6.86 yrs	407,066	3.11
$ 3.50 to $3.85	150,000	3.70	7.00 yrs	133,333	3.73
$ 4.14 to $4.15	189,431	4.14	6.82 yrs	165,187	4.15
$ 4.40	63,265	4.40	7.37 yrs	45,262	4.40
$ 5.50 to $6.50	221,250	6.06	5.48 yrs	221,250	6.06
Total options	2,708,166			1,837,018	

(a) Weighted average exercise price.
(b) Weighted average remaining contractual life.

13. Treasury Stock

In June 2008, the Board of Directors of IsoRay authorized the repurchase of up to 1,000,000 shares of the Company's common stock. The Company repurchased 8,200 shares of its common stock for $4,735 during the year ended June 30, 2009 and 5,000 shares of its common stock for $3,655 during the year ended June 30, 2008.

14. Income Taxes

The Company recorded no income tax provision or benefit for the years ended June 30, 2009 and 2008.

1. The Company had a net deferred tax asset of approximately $11.3 and $9.3 million as of June 30, 2009 and 2008, 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 asset at June 30, 2009 and 2008 has been established.

At June 30, 2009, the Company had tax basis net operating loss carryforwards of approximately $26.9 million available to offset future regular tax income. These net operating loss carryforwards expire through 2029.

15. 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.

16. UralDial, LLC

On January 23, 2008, the Company, through its subsidiary IsoRay International LLC, became a thirty percent (30%) owner in a Russian limited liability company, UralDial, LLC (UralDial), a new company based in Yekaterinburg, Russia. In December 2008, the Company entered into an agreement to sell its thirty percent (30%) interest in UralDial for a nominal amount. UralDial did not have any material assets or liabilities at the time of the Company's disposition of its ownership interest.

Also in December 2008, the Company finalized a contract to purchase Cs-131 from UralDial. Under the contract, the Company will purchase Cs-131 from UralDial rather than purchasing Cs-131 directly from its two existing suppliers in Russia. UralDial will provide Cs-131 from at least two Russian facilities subject to scheduled maintenance shutdowns of the facilities from time to time. The contract stabilizes supply arrangements for the 12 months beginning on December 15, 2008 and ending on December 31, 2009.

The Company has an existing distribution agreement with UralDial that allows UralDial to distribute Proxcelan Cs-131 brachytherapy seeds in Russia. The Company, through UralDial, has regulatory approvals to sell Cs-131 seeds in Russia. However, the economic downturn in Russia has slowed the Company's market penetration efforts.

17. Distribution Agreement

On February 18, 2009, the Company entered into an exclusive distribution agreement with BrachySciences, a division of Biocompatibles International plc. The agreement allows BrachySciences to sell the Company's Proxcelan Cs-131 brachytherapy seeds throughout the United States. The Company did not have any sales under this agreement in fiscal year 2009.

18. 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 transaction.

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 2009 and 2008, the Company recorded royalty expenses of $20,063 and $21,219, respectively.

Patent and Know-How Royalty License Agreement

The Company is the holder of an exclusive license to use certain "know-how" developed by one of the founders of a predecessor to the Company and licensed to the Company by the Lawrence Family Trust, a Company shareholder. The terms of this 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 in the agreement, remains applicable. To date, management believes that there have been no product sales incorporating the "know-how" and 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 "know-how" has disputed management's contention that it is not using this "know-how". On September 25, 2007 and again on October 31, 2007, the Company participated in nonbinding mediation regarding this matter; however, no settlement was reached with the Lawrence Family Trust. After additional settlement discussions, which ended in April 2008, the parties failed to reach a settlement. The parties may demand binding arbitration at any time.

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 April 2016 (including renewal dates). The Company's significant lease is 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 originally provided 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 vacated its leased space at the PEcoS-IsoRay Radioisotope Laboratory (PIRL). The APEL lease has a three year term expiring on April 30, 2010, plus options 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. Subsequent to the initial signing of this lease, the Company reconfigured its space requirements and returned some lab space to Energy Northwest. This has reduced the Company's rent to approximately $23,500 per month plus janitorial expenses of approximately $460 per month.

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,	
2010	$ 305,908
2011	302,235
2012	290,993
2013	288,467
2014	288,467
Thereafter	528,857
	$ 2,004,927

Rental expense amounted to $325,496 and $354,202 for the years ended June 30, 2009 and 2008, respectively.

License Agreement with IBt

In February 2006, the Company signed a license agreement with International Brachytherapy SA (IBt), a Belgian company, covering North America an providing the Company with access to IBt's Ink Jet production process and its proprietary polymer seed technology for use in brachytherapy procedur using Cs-131. Under the original agreement royalty payments were to be paid on net sales revenue incorporating the technology.

On October 12, 2007, the Company entered into Amendment No. 1 (the Amendment) to its License Agreement dated February 2, 2006 with IBt. Th Company paid license fees of $275,000 (under the original agreement) and $225,000 (under the Amendment) during fiscal years 2006 and 2008 respectively. The Amendment eliminates the previously required royalty payments based on net sales revenue, and the parties intend to negotiate terms f future payments by the Company for polymer seed components to be purchased at IBt's cost plus a to-be-determined profit percentage. No agreement ha been reached on these terms and there is no assurance that the parties will consummate an agreement pursuant to such terms. The Company does no currently intend to use this technology and recorded an impairment charge on the remaining book value of the license in fiscal year 2009.

19. 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 investmen and accounts receivable.

The Company's cash and cash equivalents are maintained with high-quality financial institutions. The accounts are guaranteed by the Federal Dep Insurance Corporation (FDIC) up to $250,000. At June 30, 2009, cash balances uninsured by the FDIC totaled approximately $2.5 million. A portion of this amount (approximately $2.3 million) is held in a money market account that is protected by the US Treasury Department's Temporary Guara Program for Money Market Funds.

Short-term investments are held by a major, high-quality financial institution. Generally, these securities are traded in a high 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 realized losses on its investments.

The Company's accounts receivable result from credit sales to customers. The Company had two customers whose sales were greater than 10% for each of th years ended June 30, 2009 and 2008, respectively. These customers represented a combined 35.0% and 34.3% of the Company's total revenues for the yea ended June 30, 2009 and 2008, respectively. These same customers accounted for a combined 39.6% and 38.4% of the Company's net accounts receivabl balance at June 30, 2009 and 2008, 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 or a supplier of Cs-131 or irradiated barium 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.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: September 23, 2009

ISORAY, INC., a Minnesota corporation

By /s/ Dwight Babcock
Dwight Babcock, Chief Executive Officer and Chairman

By /s/ Jonathan R. Hunt
Jonathan R. Hunt, Chief Financial Officer and Principal Accounting Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Dated: September 23, 2009

/s/ Dwight Babcock
Dwight Babcock, Chief Executive Officer and Chairman

/s/ Jonathan R. Hunt
Jonathan R. Hunt, Chief Financial Officer and Principal Accounting Officer

/s/ Robert Kauffman
Robert Kauffman, Director and Vice-Chairman

/s/ Thomas LaVoy
Thomas LaVoy, Director

/s/ Albert Smith
Albert Smith, Director

HAEIFC

Hanford Area Economic Investment Fund Committee

P.O. Box 6335
Kennewick, Washington 99336-0335
www.haeifc.com

August 24, 2009

IsoRay, Inc.
350 Hills St.
Suite 106
Richland, WA 99354
Attention: Jonathan Hunt

Ref: Loan Covenant Waiver

Mr. Hunt;

This letter is to advise you that at its regularly scheduled Board meeting on August 24, 2009, by unanimous vote the Hanford Area Economic Investment Fund Committee approved the waiver of the loan covenant Fixed Charge Coverage, until June 30, 2010.

All other terms, conditions and covenants of IsoRay, Inc. loan to remain in full force and affect.

If you have any questions please contact Stephen P. Sensney, Loan Consultant, at 1-509-832-0080.

Sincerely;

Stephen P. Sensney
Loan Consultant

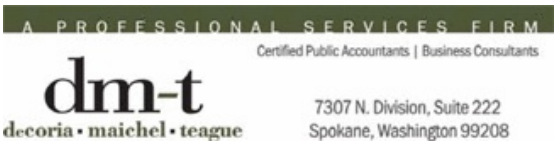
ORAL AGREEMENTS OR ORAL COMMITMENTS TO LOAN MONEY, EXTEND CREDIT, OR TO FORBEAR FROM ENFORCING REPAYMENT OF A DEBT ARE NOT ENFORCEABLE UNDER WASHINGTON LAW.

EXHIBIT 21

SUBSIDIARIES OF THE REGISTRANT

IsoRay Medical, Inc., a Delaware corporation

IsoRay International LLC, a Washington limited liability company



CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the registration statements Nos. 333-127717 and 333-136728 on Form S-8 and Nos. 333-140246 and 333-141934 on Form S-3 of our report dated September 22, 2009, with respect to the consolidated balance sheets of IsoRay, Inc. and Subsidiaries as of June 30, 2009 and 2008, and the related consolidated statements of operations, changes in shareholders' equity and cash flows for the years then ended, which report appears in the Form 10-K filing for IsoRay, Inc. to be filed on or about September 25, 2009.

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

DeCoria, Maichel & Teague, P.S.
Spokane, Washington
September 22, 2009

Exhibit 31.1

CERTIFICATION

I, Dwight Babcock, Chief Executive Officer, certify that:

1. I have reviewed this annual report on Form 10-K of IsoRay, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a 15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting

Date: September 23, 2009

/s/ Dwight Babcock
Dwight Babcock
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Jonathan R. Hunt, Chief Financial Officer, certify that:

1. I have reviewed this annual report on Form 10-K of IsoRay, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a 15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 23, 2009

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

Exhibit 32

Section 1350 Certifications

Pursuant to 18 U.S.C. § 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of IsoRay, Inc., a Minnesota corporation (the Company), hereby certify that:

To my knowledge, the Annual Report on Form 10-K of the Company for the annual period ended June 30, 2009 (the Report) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: September 23, 2009

/s/ Dwight Babcock

Dwight Babcock
Chief Executive Officer

Dated: September 23, 2009

/s/ Jonathan R. Hunt

Jonathan R. Hunt
Chief Financial Officer