

Edgar Filing: IsoRay, Inc. - Form 10-K

IsoRay, Inc.  
Form 10-K  
September 28, 2010

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, 2010

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  
(State of incorporation)

41-1458152  
(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 16, 2010
Common stock, \$0.001 par value	23,048,754

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 the 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 for 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 required to be submitted and posted pursuant to Rule 405 of Regulation S-T during

Edgar Filing: IsoRay, Inc. - Form 10-K

the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  
Yes x No o

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. o

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 o    Accelerated filer o    Non-accelerated filer o  
Smaller reporting company x

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter – \$22,025,806 as of December 31, 2009.

Documents incorporated by reference – none.

---

ISORAY, INC.

## Table of Contents

	Page
ITEM 1 – BUSINESS	1
ITEM 1A – RISK FACTORS	25
ITEM 1B – UNRESOLVED STAFF COMMENTS	34
ITEM 2 – PROPERTIES	34
ITEM 3 – LEGAL PROCEEDINGS	34
ITEM 4 – [REMOVED AND RESERVED]	34
ITEM 5 – MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	35
ITEM 6 – SELECTED FINANCIAL DATA	37
ITEM 7 – MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	37
ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	48
ITEM 8 – FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	48
ITEM 9 – CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	49
ITEM 9A – CONTROLS AND PROCEDURES	49
ITEM 9B – OTHER INFORMATION	51
ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	51
ITEM 11 – EXECUTIVE COMPENSATION	55
ITEM 12 – SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	57
ITEM 13 – CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE	58
ITEM 14 – PRINCIPAL ACCOUNTANT FEES AND SERVICES	59
ITEM 15 – EXHIBITS AND FINANCIAL STATEMENT SCHEDULES	59
SIGNATURES	63

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 25 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 these reports and other information with the Securities and Exchange Commission (SEC). These reports can be obtained by accessing the SEC's website at [www.sec.gov](http://www.sec.gov). The public can also obtain copies by visiting the SEC's Public Reference Room at 100 F Street NE, Washington, DC 20549 or by calling the SEC at 1-800-SEC-0330. In addition, the Company makes copies of its annual and quarterly reports available to the public at its website at [www.isoray.com](http://www.isoray.com). Information on this website is not a part of this Report.

## Business Operations

### Overview

In 2003, IsoRay obtained clearance from the FDA for treatment for all solid tumor applications using Cesium-131 (Cs-131). Such applications include prostate cancer; ocular melanoma; head, neck and lung tumors; and breast, liver, brain and pancreatic cancer. The seed may be used in surface, interstitial and intracavity applications for tumors with known radio sensitivity. Management believes its Cs-131 technology will allow it to become a leader in the brachytherapy market. Management believes that the IsoRay Proxcelan Cesium-131 brachytherapy seed represents the first major advancement in 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 in October 2004 for the treatment of prostate cancer after clearance of its premarket notification (510(k)) by the Food and Drug Administration (FDA). In December 2007, IsoRay began selling its Proxcelan Cs-131 seeds for the treatment of ocular melanoma. In June 2009, the Company began selling its Proxcelan Cs-131 seeds for treatment of head and neck tumors, commencing with treatment of a tumor that could not be accessed by other treatment modalities. During the fiscal year ended June 30, 2010, the Company continued to expand the number of areas of the body in which the Proxcelan Cs-131 seeds were being utilized by adding lung cancer in August 2009, colorectal cancer in October 2009, and chest wall cancer in December 2009. The Company is continuing to expand the use of the Proxcelan Cs-131 seed for other cancer treatment applications using both existing delivery systems and researching delivery systems other than 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 seeds that are preloaded into bioabsorbable braided strands. This clearance permits the product to be commercially distributed for treatment of lung, head and neck 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 510(k) 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.

Brachytherapy seeds are small devices used in an interstitial radiation procedure. The procedure has become one of the primary treatments for prostate cancer. The brachytherapy procedure places radioactive seeds as close as possible to (in or near) the cancerous tumor (the word "brachytherapy" means close therapy). The seeds deliver therapeutic radiation thereby killing the cancerous tumor cells while minimizing exposure to adjacent healthy tissue. This procedure allows doctors to administer a higher dose of radiation 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 outpatient 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), then approximately 40 to 80 seeds are used in the procedure. The isotope decays over time and

eventually the seeds become inert. The seeds may be used as a primary treatment or in conjunction with other treatment modalities, such as chemotherapy, or as treatment for residual disease after excision of primary tumors. The number of seeds for other treatment sites will vary from as few as 8 to 16 to as many as 117 to 123 depending on the type of cancer, the location of the tumor being treated and the type of therapy being utilized.

## Brachytherapy Isotope Comparison

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

### Higher Energy

Cs-131 has a higher average energy than any other commonly used prostate brachytherapy isotope on the market. Energy is a key factor in how uniformly the radiation dose can be delivered throughout the prostate. This quality of a prostate implant is known as homogeneity. Early studies demonstrate Cs-131 implants are able to deliver the required dose while maintaining homogeneity across the gland itself and potentially reducing unnecessary dose to critical structures such as the urethra and rectum. (Prestidge B.R., Bice W.S., Jurkovic I., et al. Cesium-131 Permanent Prostate Brachytherapy: An Initial Report. *Int. J. Radiation Oncology Biol. Phys.* 2005: 63 (1) 5336-5337.)

### Shorter Half-Life

Cs-131 has the shortest half-life of any commonly used prostate brachytherapy isotope at 9.7 days. Cs-131 delivers 90% of the prescribed dose in just 33 days compared to 58 days for Pd-103 and 204 days for I-125. By far the most commonly reported side effects of prostate brachytherapy are irritative and obstructive symptoms in the acute phase post-implant (Neill B, et al. The Nature and Extent of Urinary Morbidity in Relation to Prostate Brachytherapy Urethral Dosimetry. *Brachytherapy* 2007:6(3)173-9.). The short half-life of Cs-131 reduces the duration of time during 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 providing comparable prostate coverage compared to I-125 or Pd-103 seeds with comparable or fewer seeds and needles. Several studies have demonstrated 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.) (Yaparalvi 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 Physics* 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 a Phase-II, Multi-institutional Cesium-131 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 SG, et al. Is There Decreased Duration of Acute Urinary and Bowel Symptoms after Prostate Brachytherapy with Cesium 131 Radioisotope? *Int. J. Radiation Oncology Biol. Phys.* 2008:72(S1)S317.) More stringent studies are underway to more fully characterize any advantage in side effect 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 “biological 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, 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 located in front of the rectum and underneath the urinary bladder. Prostate cancer is a malignant tumor that begins most often in the periphery of the gland and, like other forms of cancer, may spread beyond the prostate to other parts of the body. According to the American Cancer Society, approximately one man in six will be diagnosed with prostate cancer during his lifetime and one man in thirty-six will die of prostate cancer. 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 in the United States. The American Cancer Society estimates there will be about 217,730 new cases of prostate cancer diagnosed and an estimated 32,050 deaths associated with the disease in the United States in 2010. 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 11% of cancer related deaths in men. Prostate cancer incidence and mortality increase with age. The American Cancer Society has reported that the incidence of prostate cancer rises rapidly after age 50. Almost 2 of 3 prostate cancers are found in men over the age of 65.

The American Cancer Society recommends that men be given an opportunity to make an informed decision with their health care provider about whether to be screened for prostate cancer. The decision should be made after getting information about the uncertainties, risks, and potential benefits of prostate cancer screening. Men should not be screened unless they receive this information. In March 2010, the American Cancer Society warned that regular testing for prostate cancer is of questionable value and can do more harm than good.

This discussion about screening should take place at age 50 for men who are at average risk of prostate cancer and are expected to live at least 10 more years.

This discussion should take place starting at age 45 for men at high risk of developing prostate cancer. This includes African American men and men who have a first-degree relative (father, brother or son) diagnosed with prostate cancer at an early age (younger than age 65).

This discussion should take place at age 40 for men at even higher risk (those with several first-degree relatives who had prostate cancer at an early age).

After this discussion, those men who want to be screened should be tested with the prostate specific antigen (PSA) blood test. The digital rectal exam (DRE) may also be done as a part of screening but is no longer recommended.

#### Incidence of Lung Cancer

An estimated 222,520 new cases of lung cancer are expected in 2010, accounting for 15% of all cancer diagnoses in the United States. Lung cancer accounts for the most cancer related deaths in both men and women in the United States. An estimated 157,300 deaths, accounting for about 28% of all cancer deaths, are expected to occur in 2010. This exceeds the combined number of deaths from the three leading causes of cancer (breast, prostate, and colon cancers). It also accounts for 6% of all deaths from any source in the United States. (Cancer Management: A Multidisciplinary Approach, 11th ed. (2008). Richard Pazdur, Lawrence R. Coia, William J. Hoskins, Lawrence D. Wagman; American Cancer Society, 2009.)

Cigarette smoking is by far the most important risk factor for lung cancer. Risk increases with quantity and duration of cigarette consumption. Cigar and pipe smoking also increase risk. Other risk factors include occupational or environmental exposure to secondhand smoke, radon, asbestos (particularly among smokers), certain metals (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, 2010)

The 1-year relative survival for lung cancer increased from 35% in 1975-1979 to 42% in 2002-2005, largely due to improvements in surgical techniques and combined therapies. However, the 5-year survival rate for all stages combined is only 16%. The 5-year survival rate is 53% for cases detected when the disease is still localized, but only 15% of lung cancers are diagnosed at this early stage. (American Cancer Society, 2010)

#### Incidence of Head and Neck Cancers

An estimated 49,260 new cases of head and neck cancer are expected in 2010, including 23,880 cases of oral cavity cancer, 12,720 cases of laryngeal cancer, and 12,660 cases of pharyngeal cancer diagnosed in the United States. (American Cancer Society, 2010.)

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 jaw are often late symptoms. (American Cancer Society, 2010)

Known risk factors include all forms of smoked and smokeless tobacco products and excessive consumption of alcohol. Many studies have reported a synergism between smoking and alcohol use, resulting in more than a 30-fold increased risk in individuals who both smoke and drink heavily. Human Papilloma Virus (HPV) infection is associated with certain types of oropharyngeal cancer. (American Cancer Society, 2010)

### Incidence of Ocular Melanoma

The American Cancer Society estimates that 2,480 new cases of cancers of the eye and orbit (primarily melanoma) will be diagnosed in 2010 and about 230 deaths from cancer of the eye will occur in 2010 in the United States. Primary eye cancer can occur at any age but most occur in people over 50 years of age. (American Cancer Society, 2010)

Many patients with eye melanoma (cancer) have no symptoms unless the cancer grows in certain parts of the eye or becomes more advanced. Signs and symptoms of eye melanomas can include problems with vision including blurry vision or sudden loss of vision, floaters or flashes of light, visual field loss, a growing dark spot on the iris, change in the size or shape of the pupil, change in position of the eyeball within its socket, bulging of the eye, and/or change in the way the eye moves within the socket. Known risk factors for ocular melanoma include sun exposure, certain occupations (e.g. welders, farmers, fishermen, chemical workers and laundry workers), race/ethnicity/eye and skin color, and certain inherited conditions such as dysplastic nevus syndrome. (American Cancer Society, 2010)

### Incidence of Colorectal Cancer

An estimated 142,570 new cases of colorectal cancer are expected in the United States in 2010, including 102,900 new cases of colon cancer and 39,670 new cases of rectal cancer. (American Cancer Society, 2010.)

Symptoms may include a change in bowel habits including diarrhea, constipation, or narrowing of the stool that lasts for more than a few days, a feeling of the need to have a bowel movement which is not relieved by doing so, rectal bleeding, dark stools or blood in the stool, cramping or abdominal pain, weakness and fatigue, and unintended weight loss.

Known risk factors include age, personal history of colorectal polyps or colorectal cancer, personal history of inflammatory bowel disease, family history of colorectal cancer, inherited syndromes and racial and ethnic background.

The 5-year relative survival rates for colon cancer are 74% in stage I, a range of 37% to 67% in stage II, a range of 28% to 73% in stage III and 6% in stage IV. The 5-year relative survival rates for rectal cancer are 74% in stage I, a range of 32% to 65% in stage II, a range of 33% to 74% in stage III and 6% in stage IV.

### Prostate Brachytherapy

The industry has experienced an overall decrease in the number of cases of prostate cancer treated with brachytherapy as physicians have elected to utilize other treatment modalities, or to defer definitive treatment to a higher degree than historically.

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 effects of RP include impotence and incontinence. According to a study published in the Journal of the American Medical Association in January 2000, approximately 60% of men who had a RP reported erectile dysfunction as a result of surgery. This same study stated that approximately 40% of the patients observed reported at least occasional incontinence. New methods such as laparoscopic 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 cancerous 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 the disease free survival rates after RP or brachytherapy treatment. Side effects of EBRT can include diarrhea, rectal leakage, irritated intestines, frequent urination, burning while urinating, and blood in the urine. Also the incidence of incontinence and impotence 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 the beam at the prostate from multiple different angles and to vary the intensity of the beam. Thus, damage to normal tissue and critical structures is minimized by distributing the unwanted radiation over a larger geometric area. This course of treatment is similar to EBRT and requires daily doses over a period of seven to eight weeks to deliver the total dose of radiation prescribed to kill the tumor. Because IMRT is a new treatment, less clinical data regarding treatment effectiveness and the incidence of side effects is available. One advantage of IMRT, and to some extent EBRT, is the ability to treat cancers that have begun to spread from the tumor site. An increasingly popular therapy for patients with more advanced prostate cancer is a combination of IMRT with seed brachytherapy, known as combination or dual therapy. IMRT in the U.S. (including dual therapy) is projected to grow 9% per year from 31,500 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 to treat extra-prostatic extensions or high risk prostate cancers that have grown outside the prostate. Combination therapy treats high risk patients with a full course of IMRT or EBRT over a period of several weeks. When this initial treatment is completed, the patient must then wait for several more weeks to months to have the prostate seed implant. Management estimates that at least 30% of all prostate implants are now dual therapy cases.

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

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

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

#### 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 when compared to other treatment options. A recent study of 2,963 prostate cancer patients who underwent brachytherapy as their sole therapeutic modality at 11 institutions across the U.S. concluded that low-risk patients (who make up the preponderance of localized cases) who underwent adequate implants experienced rates of PSA relapse survival of greater than 90% between eight and ten years (Zelefsky MJ, 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 (Buron C, et al. "Brachytherapy versus prostatectomy in localized prostate cancer: results of a French multicenter prospective medico-economic study". International Journal of Radiation Oncology, Biology, Physics, Volume 67, 2007, 812-822). 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, 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-dose 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) to 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 as an isotope for permanent seed prostate brachytherapy (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).

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 figure below depicts the symptom scores in the Cs-131 study as compared to published reports of patients who underwent I-125 brachytherapy. Especially 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 blue 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 PSAs to date from the 100 patient Cs-131 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 69, (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 View Point." International Journal of Radiation Oncology Biology Physics, Volume 69 (Supplement 3), 2007, S677-8; Sutlief S and Wallner K, "Cs-131 Prostate Brachytherapy and Treatment Plan Parameters." Medical Physics, Volume 34, 2007, 2431; Kurtzman S, "Dosimetric Evaluation of Permanent Prostate 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 PSA response and treatment related morbidities following brachytherapy for localized carcinoma of the prostate in low to intermediate risk patients. Dr. Moran concluded that prostate brachytherapy with Cs-131 is effective and well-tolerated; both PSA response and the acute morbidity profile were very encouraging. Dr. Moran will continue to track these patients in order to collect long-term outcomes.

The Cs-131 Advisory Group's (CAG) article entitled "Recommendations for permanent prostate brachytherapy with 131Cs: a consensus report from the Cesium Advisory Group" was published in Brachytherapy in the fourth quarter of calendar year 2008. The CAG is sponsored by the Company. The objective of the article was to provide consensus recommendations for Cs-131 prostate brachytherapy based on experience to date for physicians still unfamiliar with Cs-131. These recommendations are based on three clinical trials in which one of the trials has completed the patient accrual, published in the peer reviewed literature, and the 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 Company has also commissioned a dual therapy protocol. This multi-institutional trial observes the dosimetric characteristics of Cs-131 and health related quality of life (HRQOL) results following combined Cs-131 transperineal permanent prostate brachytherapy and external beam radiotherapy in patients with intermediate to high risk prostate cancer. This protocol is being conducted to confirm clinically what radiobiological data suggests regarding this treatment modality. The quantified dosimetric variables collected will be correlated to the reported HRQOL data and ultimately compared to existing data in the literature for similar investigations using I-125 and Pd-103. Patient enrollment for this study began in April 2007 and during the year ended June 30, 2010 enrollment to the study was closed.

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

#### Lung Cancer Treatment Options

Lung cancer has historically been treated utilizing surgery, radiation therapy, other local treatments, chemotherapy and targeted therapy. Surgery generally involves removing a portion of the lung (lobectomy, segmentectomy, wedge resection) or the entire lung (pneumonectomy). Chemotherapy may be used either as a primary treatment or a secondary treatment depending on the type and stage of the lung cancer. Standard 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 however this is now used less often as it is being replaced with newer EBRT techniques such as 3D-CRT, IMRT and stereotactic radiation therapy. (American Cancer Society, 2010)

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 this procedure to apply the Proxcelan Cs-131 brachytherapy seeds generally dissolves after about 45 days. Cs-131 delivers 90% of its dose in 33 days and is therefore well-suited to use with bioabsorbable mesh.

#### Head and Neck Cancer Treatment Options

Most head and neck cancers have historically been treated with some combination of surgery including tumor resection, Mohs micrographic surgery, full or partial mandible (jaw bone) resection, maxillectomy, laryngectomy, neck dissection, pedicle or free flap reconstruction, tracheostomy, gastrostomy tube or dental extraction and implants; chemotherapy and radiation therapy including external beam radiation therapy (EBRT), accelerated and hyperfractionated radiation therapy, three-dimensional conformal radiation therapy (3D-CRT) and intensity modulated radiation therapy (IMRT), and brachytherapy (both high-dose rate (HDR) and low-dose rate (LDR)).

Surgery is the most common option. Chemotherapy is often used in conjunction with surgery or radiation therapy depending on the type and stage of the cancer. External beam radiation therapy and brachytherapy have been used together or in combination with surgery or chemotherapy

Management believes Proxcelan Cs-131 represents an improved approach to brachytherapy treatment of head and neck cancers.

#### Ocular Melanoma Treatment Options

In addition to brachytherapy to treat ocular melanoma, other treatment options include surgery, external beam radiation, and laser therapy. Surgery could include removal of part of the iris, a portion of the outer eyeball, or the removal of the entire eyeball, and is used less often than in the past as the use of radiation therapy has grown. External beam radiation (including conformal 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 as widely used to date for ocular melanoma. Laser therapy, rarely used now to treat ocular melanoma, burns the cancerous tissue by using a highly focused, high-energy light beam. Laser therapy can be effective for very small melanomas but it is more often used to treat side effects from radiation. (American Cancer Society, 2010)

Brachytherapy has become the most commonly used radiation treatment for most eye melanomas. 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 minute stitches for 4 to 5 days. The patient generally stays in the hospital until the plaque is removed from the eye. Brachytherapy cures approximately 9 out of 10 small tumors and can preserve the vision of some patients. (American Cancer Society, 2010)

#### Colorectal Treatment Options

Colorectal cancer has historically been treated using surgery, radiation therapy, chemotherapy and other targeted therapies. Depending on the stage of the cancer, two or more of these types of treatment may be combined at the same time or used after one another. (American Cancer Society, 2010)

For the treatment of early stage colon and rectal cancers, surgery is often the main treatment. Colorectal surgeries include open colectomy, laparoscopic-assisted colectomy, and polypectomy and local excision. Rectal surgeries include polypectomy and local excision, local transanal resection, transanal endoscopic microsurgery (TEM), lower anterior resection, proctectomy with coloanal anastomosis, abdominoperineal resection and pelvic exenteration. (American Cancer Society, 2010)



For the treatment of colorectal cancers beyond early stage, other surgery treatments (radiofrequency ablation, ethanol ablation, cryosurgery and hepatic artery embolization), radiation therapy (external beam radiation, endocavitary radiation, brachytherapy, yttrium-90 microsphere radioembolization), chemotherapy, and targeted therapies (Avastin, Erbitux, Vectibix) can be used. (American Cancer Society, 2010)

Low-dose rate (LDR) brachytherapy including Proxcelan Cesium-131 is typically utilized in treating individuals with rectal cancer who are not healthy enough to tolerate curative surgery. This is generally a one-time only procedure and does not require ongoing visits for several weeks as is common with other types of radiation therapy such as external-beam radiation therapy and endocavitary radiation therapy. Management believes that the advantages provided by Cesium-131 shown through the treatment of other cancers will benefit patients utilizing Proxcelan Cesium -131 brachytherapy seeds in the treatment of their colorectal cancers with low-dose rate brachytherapy.

## Our Strategy

The key elements of IsoRay's strategy for fiscal year 2011 include:

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

Management plans to continue to build on an increasing number of studies related to Cs-131 therapy in the management of cancer that were published in the medical literature and presented at relevant oncology society meetings in 2010. The publication and presentation of speculative and real-world data contribute to the acceptability of Cs-131 in the oncologic marketplace, and discussion in the medico-scientific community of established and novel Cs-131 applications is considered a prerequisite to expansion into untapped markets.

In calendar year 2010, eight presentations were made at the American Brachytherapy Society describing Cs-131 treatment of prostate, lung, and breast cancer. Five publications were abstracted to the MEDLINE database of citations of the medical literature that reported patients treated with Cs-131 for prostate cancer. Five additional publications mentioned Cs-131 as an accepted treatment for prostate cancer, and two publications specifically discussed the physics and dosimetric profile of Cs-131 for the treatment of prostate and eye cancers.

§ Continue to introduce the Proxcelan Cs-131 brachytherapy seed into the U.S. market for prostate cancer. Utilizing our direct sales organization, IsoRay intends to continue to seek to increase the number of centers making the use of Proxcelan Cs-131 seeds available to their patients in brachytherapy procedures for prostate cancer and by increasing the number of patients being treated at current centers using the Proxcelan Cs-131 seeds. IsoRay hopes to capture much of the incremental market growth if and when seed implant brachytherapy recovers market share from other treatments and to take market share from existing competitors.

§ Increase utilization of Cs-131 in treatment of other solid tumor applications such as head and neck, lung, chest wall, and colorectal cancers. IsoRay Medical has clearance from the FDA for its premarket notification, (510(k)) for Proxcelan™ brachytherapy seeds that are preloaded into bioabsorbable braided strands. This order cleared the product for commercial distribution for treatment of lung and head and neck tumors as well as tumors in other organs. IsoRay will continue to explore licenses or joint ventures with other companies to develop the appropriate technologies and therapeutic delivery systems for treatment of other solid tumors such as breast, liver, pancreas, and brain cancers.



§ Return Gliasite® radiation therapy system to market in the United States and European Union (EU). In June of 2010, the Company acquired exclusive worldwide distribution rights to the Gliasite® radiation therapy system, the only FDA-cleared balloon catheter device used in the treatment of brain cancer from Hologic, Inc. The product possesses an established reimbursement rate for both in-patient and out-patient settings. The Company intends to return the product to market in a configuration equivalent to the original FDA-cleared device. The Company is working to obtain the rights to license or acquire the Iotrex solution (Iodine -125) manufactured for use in the Gliasite® radiation therapy system. The Company has developed a liquid Cesium-131 solution for use in the Gliasite® radiation therapy system as either a substitute for the Iotrex or as an alternative treatment option for physicians to utilize in the system.

§ Continue to develop data on Cs-131 for treatment of ocular melanoma. The Company's first sale for ocular melanoma occurred in late 2007 and periodic sales have occurred since then. IsoRay is sponsoring a prospective review of the patients treated with Cs-131 to date. This clinical data will be presented at the November 2010 annual meeting of the American Society for Therapeutic Radiology and Oncology (ASTRO). Although the ocular melanoma market is not a large one, this application of Cs-131 continues to demonstrate the potential viability for other solid tumors.

- Introduce Proxcelan Cesium-131 brachytherapy seeds to the Canadian and European Union (EU) 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 the Proxcelan™ Sterile Implant Devices containing Model CS-1 Seeds. This allows IsoRay to market its brachytherapy seeds and related preloaded brachytherapy seeds throughout Canada. In November 2009, the Company entered into a distribution agreement with Inter V Medical of Montreal, Quebec, Canada for exclusive rights to sell the Proxcelan Cs-131 brachytherapy seed in Canada. Approval to market Cesium-131 seeds in Russia was also obtained in 2009; and the Company has an exclusive distribution agreement in place with a Russian distributor, UralDial LLC, to distribute Proxcelan Cs-131 brachytherapy seeds in Russia, however, the economic downturn in Russia has slowed the Company's market penetration efforts. The Company is focusing on the Canadian and European Union (EU) markets until the Russian market recovers.

§ Maintain ISO 13485 certification. In August 2008, the Company obtained its ISO 13485 certification. This was an important step to allow the Company to register and eventually sell its Proxcelan Cs-131 brachytherapy seeds in Canada, the European Union (EU) and Russia. The Company completed its registrations 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, lung cancer, ocular melanomas, head and neck cancers, and colorectal cancer. The Company intends to market Cs-131 for the treatment of other malignant disease, such as brain and gynecological cancers, in the near future through the use of existing proven technologies that have received FDA-clearance. The strategy of utilizing existing FDA-cleared technologies intends to reduce the time and cost required to develop new applications of Cs-131 and deliver them to market.

## 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	Isotope Delivery Over Time			
	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 nuclear 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 a nuclear reactor. The irradiation process converts a small fraction of this material into a radioactive form of barium (Ba-131). The Ba-131 decays by electron capture to the radioactive isotope of interest (Cs-131).

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

**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 materials from the reactor core on a routine basis for subsequent processing to produce ultra-pure Cs-131. In addition, the supplier's nuclear reactor facility must have sufficient irradiation capacity to accommodate barium targets and the nuclear reactors must have sufficient neutron flux to economically produce commercially viable quantities of Cs-131. Ideally, the irradiation facility will also have a radiochemical separation infrastructure to carry out the initial separation steps. The Company has identified key reactor facilities in the U.S. and Russia that are capable of meeting these requirements. In order to manage the Russian supply more effectively IsoRay entered into a second agreement with UralDial, LLC (a Russian LLC) on November 30, 2009 to provide Cs-131 isotope from Russia to the Company's facility in Richland, WA through December 31, 2010. 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, 2010, approximately sixty-eight percent (68%) of our Cs-131 was supplied by one of two Russian supply sources and thirty-two percent (32%) 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 to 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 will continue to rely solely on its existing suppliers in the near future, however, 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 monitors these procedures and controls to ensure that they are operating properly, thereby working to maintain a high-quality product. Also, the quality, production, and customer service departments maintain open communications to ensure that all regulatory requirements for the FDA, DOT, and applicable nuclear radiation and health authorities are fulfilled.

In July 2008, IsoRay had its baseline inspection by the FDA at its manufacturing and administrative offices in Richland, WA. This inspection was carried out 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 individual 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-life products. Time from order confirmation to completion of product manufacture is reduced to several working days, including receipt of irradiated barium (from the domestic supplier's reactor) or unpurified Cs-131 (from the international supplier's reactor), separation and purification of Cs-131, isotope labeling of the core, loading of cores into pre-welded titanium "cans" for final welding, testing, quality assurance and shipping.

It is up to each physician to determine the dosage necessary for implants and acceptable dosages vary among physicians. Many of the physicians who order our seeds order more seeds than necessary to assure themselves that they have a sufficient quantity. Upon receipt of an order, the Company either delivers the seeds from its facility directly to the physician in either loose or preloaded form or sends the order to an independent preloading service that delivers the seeds preloaded into needles or cartridges just prior to implant. If the implant is postponed or rescheduled, the short half-life of the seeds makes them unsuitable for use and therefore they must be re-ordered.

Due to the lead time for obtaining and processing the Cs-131 isotope and the short half-life, the Company relies on sales forecasts and historical knowledge to estimate the proper inventory levels of isotope 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 2010, IsoRay pursued further automation identified by management to reduce cost and increase radiation safety while allowing an expansion of product loading configurations. The Company will continue to evaluate and implement automation in the future that supports process improvement, employee safety and resource management. The Company continues to contract with a third party to outsource certain sub-processes where cost effective.

#### Manufacturing Facility

The Company maintains a production facility located at Applied Process Engineering Laboratory (APEL). The APEL facility became operational in September 2007. The production facility has over 15,000 square feet and includes space for isotope separation, seed production, order dispensing, a clean room for radiopharmacy work, and a dedicated shipping area. A description of the lease terms for the APEL facility is located in the Other Commitments and Contingencies section of Item 7 below. Management believes that the APEL facility will be utilized for manufacturing space through fiscal year 2016 which is the original lease term plus the two three-year renewal options. Management has exercised the first of two three-year renewal options to extend the APEL facility lease through April 2013 and it believes that the Company will exercise the second three-year renewal option 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-131 production. The facility's capacity is fully allocated to the Navy and management believes it would be difficult to have IsoRay's commercial operations at 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 five principal configurations provided in a sterile or non-sterile 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 fiscal year 2010, the Company delivered approximately 67% of its Proxcelan seeds to customers configured in Mick cartridges, approximately 31% of the Proxcelan seed configured in stranded forms and the remaining 2% in a loose form.

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

IsoRay currently has agreements with several independent radiopharmacies to assay, preload, and sterilize 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 services to supplement our own custom preloading operation and to meet the requests of the ordering physicians.

We currently load approximately 96% of Mick cartridges in our own facility which in fiscal year 2010 accounted for approximately 67% of seeds sold. The remaining approximately 33% of seeds sold are strand configurations including preloaded strands. Although the Company performs in-house analytical services to eliminate loss in isotope activity due to radioactive decay, the Company utilizes independent radiopharmacies to back up its own preloading operation, handle periodic increases in demand and cater to certain doctors’ preferences.

Independent radiopharmacies traditionally 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 are able to preserve the product branding opportunity and eliminate any concerns related to the handling of our product by a third party prior to receipt by the end user.

Providing custom packaging configurations enhances our product while providing an additional revenue stream and incremental margins to the Company 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 requirements on-site, eliminating the need for additional staffing to sterilize seeds and needles, and eliminating the expense of additional assaying of the seeds.

With clearance from the FDA for preloading flexible braided strands and bioabsorbable mesh, IsoRay became the second company in the industry that has 510(k) clearance to preload both the strands and the mesh. This allows IsoRay to reduce loading costs by providing them directly to our customers.

## 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 preliminary clinical studies, management believes there is no apparent clinical reason to use other isotopes when Cs-131 is available. The advantages associated with a higher energy and shorter half-life isotope are generally accepted within the clinical community and the Company intends to help educate potential patients about the clinical benefits 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-131 seeds from seeds using the other isotopes. We continue to target the competing isotope products of iodine and palladium rather than the various manufacturers and distributors of these isotopes. Using this strategy, the choice of brachytherapy isotopes should be less dependent on the name and distribution strengths of the various iodine and palladium manufacturers and distributors and more dependent on the therapeutic benefits of Cs-131.

The professional and patient market segments each play a role in the ultimate choice of cancer treatment and the specific isotope chosen for seed brachytherapy treatment. The Company has developed a customized brand message for each audience. In 2010, the Company’s website [www.isoray.com](http://www.isoray.com) was again substantially updated to deliver the message that Cs-131 is for the treatment of cancers throughout the body and includes sections that provide background information on the Company, cancer treatment utilizing brachytherapy in prostate, lung, ocular and brain, information for physicians/clinician resources, investor information, current events that representatives will attend, and contact information. IsoRay also maintains print and visual medias (including physician brochures discussing the clinical advantages of Cs-131, clinical information binders, informational DVDs, single sheet glossies with targeted clinical data, etc.), and advertisements in leading medical journals. In addition, the Company attends national professional meetings, including the 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 expects articles for professional journals such as Medical Physics, the Brachytherapy Journal, and the International Journal of Radiation Oncology, Biology, and Physics regarding the benefits of and clinical trials involving Cs-131 will continue to be submitted.

IsoRay has conducted physician training programs in the past but is no longer doing so as it no longer believes the costs of these training programs are offset by improved sales.

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 relate incidents of their patients coming for consultations armed with articles researched on the Internet and other sources describing new treatments and medications. In many cases, these patients are demanding a certain therapy or drug and the physicians are complying when medically appropriate.

Because of this consumer-driven market factor, we also promote our products directly to the general public. We target the prostate cancer patient, his spouse, family and care givers. We emphasize to these segments the specific advantages of the Proxcelan Cesium-131 brachytherapy seed through our websites (located at [www.isoray.com](http://www.isoray.com) and [www.proxcelan.com](http://www.proxcelan.com)), patient advocacy efforts, informational patient brochures and DVDs with patient testimonials,

patient focused informational website ([www.proxcelan.com](http://www.proxcelan.com)), and advertisements in specific markets supporting brachytherapy. None of our websites should be 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. The 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 physicians across the country are now independently publishing papers and 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 the United States. Not all of these facilities offer seed brachytherapy services. These institutions are staffed with radiation oncologists and medical physicists who provide expertise in radiation therapy treatments and serve as consultants for urologists and prostate cancer patients. We target the radiation oncologists and the medical physicists as well as urologists as key clinical decision-makers in the type of radiation therapy offered to prostate cancer patients.

IsoRay has a direct sales organization to introduce Proxcelan Cesium-131 brachytherapy seeds to radiation oncologists and medical physicists. Currently IsoRay has five direct sales persons and a VP of Business Development. These sales people include those experienced in the brachytherapy market and the medical device market. 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 due to changes in the sales compensation program, termination of those who failed to sell sufficient amounts of products, and the travel demands required by the position. With the assistance of an executive search firm, the Company is currently actively recruiting one to two additional sales persons with previous experience in radiation oncology and specifically with brachytherapy sales.

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 of approximately 6 sales persons and a manager, bringing the total sales personnel selling Proxcelan Cs-131 brachytherapy seeds in the U.S. to approximately 12. The BrachySciences sales force sold its first Cs-131 prostate implant in August 2009; but its results to date have been disappointing.

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 other countries. This strategy should reduce the time and expenses required to identify, train and penetrate the key implant centers and establish relationships with the key opinion leaders in these markets. Using established distributors also should reduce the time spent acquiring the proper radiation handling licenses and other regulatory requirements of these markets.

#### Reimbursement

Reimbursement by third party payers is the primary means of payment for all IsoRay products. The Centers for Medicare and Medicaid Services (CMS) is the primary payer, providing coverage for approximately 65% of all prostate brachytherapy cases. Well established brachytherapy coverage and payment policies are currently in place by CMS and other non-governmental payers. In 2003, CMS established a unique HCPCS code for Cs-131 brachytherapy seeds that permitted providers to report the use of Cs-131 directly to payers. In July 2007, CMS established two separate Cs-131 codes for providers to report loose seeds and stranded seeds due to the cost differential of these two products. Reimbursement for prostate brachytherapy services and sources is well established in the US and most providers (hospitals and physicians) are not faced with reimbursement challenges when providing this treatment option to patients.

Prostate brachytherapy is typically performed in an outpatient setting, and as such, is covered by the CMS Outpatient Prospective Payment System. Through December 31, 2009, when charges for the seeds were correctly submitted by the provider to CMS, CMS reimbursed the hospital or clinic for the cost of the seeds. On January 1, 2010, CMS changed the hospital outpatient system by implementing a fixed reimbursement per seed for stranded and loose seeds.

Iodine, palladium and cesium each have their own reimbursement values for stranded and loose seeds. If reported correctly when seeds are submitted for payment to CMS, providers are reimbursed at a flat rate that is equivalent to the cost of the seeds. It is expected that this reimbursement system established in January 2010 will continue as it is currently scheduled through calendar 2011 but there is no assurance that this will occur. Private insurance companies have historically followed the CMS reimbursement policies.

## Other Information

### Customers

Customers representing ten percent or more of total Company sales for the twelve months ended June 30, 2010 include:

Various Northern California facilities (1)	11.6% of revenue
El Camino Hospital (Los Gatos, CA) (1)	11.0% of revenue
University of Pittsburgh Medical Center (Pittsburgh, PA)	10.7% of revenue

(1) The following facilities located in northern California are used by one doctor (the Company's Medical Director): Fremont Surgery Center (6.1%), Mills Peninsula Health Services (2.6%), San Mateo Surgery Center (1.4%) and all others used by this doctor combined (1.5%). El Camino Hospital is a facility used by two doctors, 6.4% of the 11% (58% of the facility sales) are attributable to the Company's Medical Director for a total of approximately 18% of sales.

The loss of any of these significant customers would have a material 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 for 1% of gross profit payment from seed sales to Lane Bray and 1% of gross profit from any use of the Cs-131 process patent for non-seed products. If IsoRay reassigns the Royalty Agreement to another company, these royalties increase to 2%. The Royalty Agreement has an anti-shelving clause which requires IsoRay to return the patent if IsoRay permanently abandons sales of products using the invention. During fiscal years 2010 and 2009, the Company recorded royalty expense of \$23,041 and \$20,063, respectively, related to this patent.

The terms of a license agreement with the Lawrence Family Trust (successor to Don Lawrence) for a patent application and related “know-how” 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 remains applicable. To date, management believes that there have been no product sales incorporating the “know-how;” and therefore believes 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 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. 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.

#### Research and Development

During the three-year period ended June 30, 2010, IsoRay and its predecessor companies incurred more than \$2.7 million in costs related to research and development activities. The Company expects to continue ongoing research and development activities for the foreseeable future.

#### Government Regulation

The Company's present and future intended activities in the development, manufacture and sale of cancer therapy products are subject to extensive laws, regulations, regulatory approvals and guidelines. Within the United States, the Company's therapeutic radiological devices must comply with the U.S. Federal Food, Drug and Cosmetic Act, which is enforced by the FDA. The Company is also required to adhere to applicable FDA Quality System 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 tumors 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. We are also subject to other federal and state laws and regulations, including the Occupational Safety and Health Act and the Environmental Protection Act.

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

In the United States, medical devices are classified into three different categories over which the FDA applies increasing levels of regulation: Class I, Class II, and Class III. Most Class I devices are exempt from premarket notification (510(k)); most Class II devices require premarket notification (510(k)); and most Class III devices require premarket approval. Our Proxcelan Cs-131 seed is a Class II device and received 510(k) clearance in March 2003.

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

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

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

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

In support of IsoRay's global strategy to expand marketing to Canada, the European Union (EU) and Russia, we initiated the process in fiscal year 2008 to obtain the European CE Mark, Canadian registration, and certification to ISO 13485, an internationally recognized quality system. European law requires that medical devices sold in any EU Member State comply with the requirements of the European Medical Device Directive (MDD) or the Active Implantable Medical Device Directive (AIMDD). IsoRay's products are classified in Europe as an active implantable and are subject to the AIMDD. Compliance with AIMDD and obtaining a CE Mark involves being certified to ISO 13485 and obtaining approval of the product technical file by a notified body that is recognized by competent authorities of a Member State. Compliance with ISO 13485 is also required for registration of a company for sale of its products in Canada. Many of the recognized EU Notified Bodies are also recognized by Health Canada to conduct the ISO 13485 inspections for Canadian registration. During fiscal year 2009, the Company received its certification to ISO 13485 and obtained approval from Health Canada for its Canadian registration. The Company continues to focus on the Canadian and Russian markets while renewing its efforts to penetrate the European Union market.

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



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

#### Seasonality

The Company believes that some seed implantation procedures are deferred around physician vacations (particularly in the summer months), holidays, and medical conventions and conferences resulting in a seasonal influence on the Company's business. These factors cause a momentary decline in revenue which management believes is ultimately realized later. Because almost thirty-four percent (34%) of the Company's business is dependant on three physicians, simultaneous vacations by these three physicians could cause significant drops in the Company's productivity during those reporting periods.

#### Employees

As of September 3, 2010, IsoRay employed thirty-six 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's employees are represented by any collective bargaining unit. The Company estimates that successful implementation of its growth plan will result in up to three to five additional employees by the end of fiscal year 2011.

In fiscal year 2010, the Company employed five direct sales persons and a VP of Business Development. The Company experienced some growth in the sales group as there were three sales persons added and one sales person lost through attrition.

#### Competition

The Company competes in a market characterized by technological innovation, extensive research efforts, and significant competition. In general, the Proxcelan Cesium-131 brachytherapy seed competes with conventional methods of treating localized cancer, including, but not limited to, all forms of prostatectomy surgery and external beam radiation therapy which includes intensity modulated radiation therapy, as well as competing permanent brachytherapy devices. Surgery has historically represented the most common medical treatment for early-stage, localized prostate cancer but use of radical prostatectomy has declined in recent years. EBRT is also a well-established method of treatment and is widely accepted for patients who represent a poor surgical risk or whose prostate cancer has advanced beyond the stage for which surgical treatment is indicated. Management believes that if general conversion from these treatment options (or other established or conventional procedures) to the Proxcelan Cesium-131 brachytherapy seed does occur, such conversion will likely be the result of a combination of equivalent or better efficacy, reduced incidence 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, claimed over 59% of the Pd-103 market share (through CR Bard, other distributors, and direct distribution) in 2008. (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. However, as the Company expands the application of its Proxcelan Cesium-131 seed to other cancers (other than prostate), management believes it may improve its competitive advantages over Pd-103 and I-125 which do not have as wide of an application to other certain locations or have the potential for greater side effects. 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 core 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 a 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 sales for homeland security applications, 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, the European Union (EU) and Russia and later into other international markets through partnerships and strategic alliances with channel partners for manufacturing and distribution but other than with respect to Canada has only one distribution agreement outside the United States as of the date of this Report.

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, lung and head and neck tumors, and colorectal tumors as of the date of this Report. The Company continues to have discussions with prominent physicians and to evaluate 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 throughout the body. Our new liquid form of Cs-131 may be advantageous to use in other FDA cleared devices as an alternative to our titanium-encapsulated seed to deliver radiation to these other body sites.

Consistent with the strategy of identifying alternative methods of delivering our isotopes to new locations, the Company has obtained exclusive worldwide distribution rights to the GliSite® radiation therapy system, the world's only FDA-cleared balloon catheter device used in the treatment of brain cancer. This technology was previously used to treat approximately 500 cases annually in some 40 hospitals worldwide however this technology has not been available for sale since 2007. This exclusive worldwide distribution agreement with Hologic, Inc aligns with the Company strategy to locate existing FDA-cleared technologies to provide new ways to treat other organs with Cesium-131. The Company is in negotiations with a previous distributor of the GliSite® radiation therapy system in the European Union for distribution rights to the system in Germany, Austria, Switzerland and Italy but there is no assurance an agreement will be reached. The Company intends to return the product to market in a configuration equivalent to the original FDA-cleared device. The Company is working to obtain the rights to license or acquire the

Iotrex solution (Iodine-125) manufactured for use in the GliaSite® radiation therapy system. The Company has developed a liquid Cesium-131 solution for use in the GliaSite® radiation therapy system as either a substitute for the Iotrex solution if an intellectual property agreement can not be reached or as a future alternative treatment option for physicians to utilize in the system. Use of liquid Cesium-131 will require clearance of a 510(k) application with the FDA.

## ITEM 1A – RISK FACTORS

### Risks Related to Our Industry and Operations

**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, the European Union (EU) 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; the ability of physicians to properly utilize the device and avoid excessive levels of radiation to patients, and the ability to use this product to treat multiple types of cancers in various organs. Because of our reliance on this product as the sole source of our revenue, any material adverse developments with respect to the commercialization of this product may cause us to continue to incur losses rather than profits in the future.

**Although Cleared To Treat Any Malignant Tissue, Our Sole Product Is Currently Used To Treat Primarily One Type Of Cancer.** Currently, the Proxcelan Cs-131 seed is used almost exclusively for the treatment of prostate cancer (over ninety-six percent of our sales). We are just beginning to treat other types of cancer including lung cancer (approximately 3% of our sales) and ocular melanoma, head and neck, colorectal and chest wall that together constitute less than one percent of our sales. Management believes the Proxcelan Cs-131 seed will continue to be used to treat other types of cancers as the Company identifies existing delivery systems that it can be utilized or develops new delivery methods for the product, however these delivery systems may not prove as effective as anticipated. Management believes that clinical data gathered by select groups of physicians under treatment protocols specific to other organs will be needed prior to widespread acceptance of our product for treating other cancer sites. If our current and future products do not become accepted in treating cancers of other sites, our sales will depend solely on treatment of prostate cancer, a market with increasing competition and ongoing loss of market share by all brachytherapy products.

**We Have Ongoing 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, 2010 will be sufficient to meet our anticipated cash requirements for operations, debt service, and capital expenditure requirements through at least the next seven months or until approximately January 31, 2011. The Company has an active S-3 filing to issue additional shares of up to \$4.0 million in at the market transactions and has a sales agreement with C. K. Cooper & Company, Inc (CKCC) through December 31, 2010 to sell common stock to investors. Management now estimates that operational cashflow breakeven will be achieved at approximately \$700,000 in monthly revenue. However, there is no assurance as to when break-even will occur. If we are unable to generate profits and unable to obtain additional financing to meet our working capital requirements, we may have to curtail our business.

**We Rely Heavily On A Limited Number Of Suppliers.** Some materials used in our products are currently available only from a limited number of suppliers. In fiscal 2010, approximately sixty-eight percent (68%) of our Cs-131 was supplied through UralDial from reactors located in Russia. Unless the Company substantially increases its purchase requirements resulting from significant increases in demand for its product, the cost of Cs-131 in Russia could increase from current pricing. Our current contract with UralDial terminates on December 31, 2010 and will have to be renegotiated. Management will seek to negotiate 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 in the United States. Reliance on any single supplier increases the risks associated with concentrating isotope production at a single reactor facility which can be subject to unanticipated shutdowns. Failure to obtain deliveries of Cs-131 from multiple sources could have a material adverse effect on seed production 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 require. Additional factors that could cause interruptions or delays in our source of materials include limitations on the availability of raw materials or manufacturing performance experienced by our suppliers and a breakdown in our commercial relations with one or more suppliers. Some of these factors may be completely out of our and our suppliers' control.

Virtually all titanium tubing used in brachytherapy seed manufacture comes from a single source, Accellent Corporation. We currently obtain a key component of our seed core from 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 substitute equivalent materials in a cost-effective and timely manner. To mitigate any potential interruptions, the Company continually evaluates its inventory levels and management believes that the Company maintains a sufficient quantity on hand to alleviate any potential disruptions.

Unfavorable Industry Trends in the Prostate Market. Several factors occurred in fiscal 2009 that caused our revenues to significantly decline and these factors continued into fiscal 2010 contributing to our failure to improve sales in the prostate market. Beginning in the fall of 2008, U.S. consumers significantly curtailed all spending (even for life saving medical procedures) which impacted the brachytherapy industry as a whole. In February of 2009 noted urologists announced at a medical conference that prostate specific antigen (PSA) testing was not as necessary as previously believed. Their statements were widely publicized. Management continues to believe that many people have been influenced by these statements to cut back on PSA testing thereby decreasing in the short term the number of prostate procedures performed.

In 2010, the American Cancer Society revised their advice regarding PSA testing. In March 2010, the American Cancer Society warned that regular testing for prostate cancer is of questionable value and can do men more harm than good. The ACS suggested that an initial discussion about screening should take place at age 50 for men who are at average risk of prostate cancer and are expected to live at least 10 more years. For men at high risk of developing prostate cancer, the discussion should take place starting at age 45 for men at high risk of developing prostate cancer, this includes African American men and men who have a first-degree relative (father, brother or son) diagnosed with prostate cancer at an early age (younger than age 65). For men at even higher risk such as those with several first-degree relatives who had prostate cancer at an early age, this discussion should take place at age 40. After this discussion, those men who want to be screened should be tested with the prostate specific antigen (PSA) blood test. The digital rectal exam (DRE) may also be done as a part of screening but is no longer recommended.

Also the emergence of IMRT as the preferred treatment alternative as a result of a much higher reimbursement rate to physicians compared to brachytherapy treatments has resulted in declining market share for brachytherapy treatment. In fiscal 2010, each of these factors continues to impact the performance of the Company in the prostate market and the industry as a whole and there is no assurance that they will not continue to impact sales of the Company in the prostate market through fiscal 2011.

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 barium targets. The amount of Cs-131 that can be produced from a given reactor source is limited by the power level and volume available within the reactor for irradiating targets. This limitation can be overcome by utilizing barium feedstock that is enriched in the stable isotope Ba-130. However, the number of suppliers of enriched barium is limited and they may be unable to produce this material in sufficient quantities and at a reasonable price.

IsoRay entered into an exclusive agreement (through December 31, 2010) with UralDial in Russia to provide Cs-131 in quantities sufficient to supply a significant percentage of future demand for this isotope. Due to the purchase of enriched barium in June 2007, IsoRay has access to sufficient 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 we 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. In December 2009, the Company entered into a new agreement with UralDial to purchase Cs-131 directly from UralDial through December 31, 2010 instead of directly from Institute of Nuclear Materials (INM) and Research Institute of Atomic Reactors (RIAR) as the Company had done prior to the original agreement with UralDial in December 2008. As a result, the Company continues to rely on UralDial to obtain Cs-131 from Russian sources. UralDial has agreed to maintain at least two Russian sources of its Cs-131 and through the UralDial agreement we have obtained set pricing for our Russian Cs-131 through the end of 2010. There can be no guarantee that UralDial will always be able to supply us with sufficient Cs-131 or will renew our existing contract on favorable terms in December 2010, which could be due in part to risks associated with foreign operations and beyond our and UralDial's control. 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 our products if they cannot be assured of receiving favorable reimbursement for treatments using our products from third-party payers, such as Medicare and private health insurance plans. Currently, Medicare reimburses hospitals at fixed rates that cover the cost of stranded and loose seeds. Clinics and physicians performing procedures in a free standing center are reimbursed at the actual cost of the seeds. It is expected that CMS will continue to reimburse providers using this same methodology in 2011.

In 2003, IsoRay applied to the CMS and received a reimbursement code for our Cs-131 seed. On July 1, 2007, CMS revised the coding system for brachytherapy seeds and separated the single code into two codes – one code for loose seeds and a second code for stranded seeds. This methodology was applied to all companies manufacturing brachytherapy seeds. Reimbursement amounts are reviewed and revised annually based upon information submitted to CMS on claims by providers. Although no changes are anticipated for 2011, adjustments can be made to reimbursement amounts or coverage policies, which could result in changes to reimbursement for brachytherapy services. These changes can positively or negatively affect market demand for our products. We monitor these changes and provide comments, as permitted, when changes are proposed, prior to implementation.

In July 2010, CMS published proposed changes for both reimbursement programs for government fiscal year 2011. No changes in reimbursement have been proposed by CMS for 2011. If the proposed changes are finalized, as expected in November 2010, there will be no changes in CMS reimbursement for 2011 but there is no assurance this will occur and is subject to revision annually.



Historically, private insurers have followed Medicare guidelines in establishing reimbursement rates. However, third-party payers are increasingly challenging the pricing of certain medical services or devices, and we cannot be sure that they will reimburse our customers at levels sufficient for us to maintain favorable sales and price levels for our products. There is no uniform policy on reimbursement among third-party payers, and we can provide no assurance that our products will continue to qualify for reimbursement from all third-party payers or that reimbursement rates will not be reduced. A reduction in or elimination of third-party reimbursement for treatments using our products would likely have a material adverse effect on our revenues.

Furthermore, any federal and state efforts to reform government and private healthcare insurance programs, such as those passed by the federal government in 2010, could significantly affect the purchase of 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 be enacted, whether other healthcare legislation or regulations affecting the business may be proposed or enacted in the future or what effect any such legislation or regulations would have on our business, financial condition or results of operations.

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

- § our achievement of product development objectives and milestones;
- § demand and pricing for the Company’s products;
- § effects of aggressive competitors;
- § hospital, clinic and physician purchasing decisions;
- § research and development and manufacturing expenses;
- § patient outcomes from our therapy;
- § physician acceptance of our products;
- § government or private healthcare reimbursement policies;
- § healthcare reform:
- § 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 June 30, 2010, the Proxcelan Cs-131 seed has been implanted in over 5,000 patients and research papers are being published on the use of the Proxcelan seed. While there is less historical statistical data for the Proxcelan seed than is available for I-125 and Pd-103 seeds during the fiscal year ended June 30, 2010, the Company reached a key milestone by collecting the first 5 year outcome data for patients that received treatment with the Proxcelan seed. In addition, during 2010 there were nine reports of the Proxcelan seed being used in the treatment of prostate and ocular melanoma published in peer-reviewed literature. There were eight presentations made at the 2010 meeting of the American Brachytherapy Society covering the application of the Proxcelan seed in prostate, lung and breast cancers. While this limited data may prevent us from drawing statistically significant conclusions, the side effects experienced by these patients were less severe than side effects observed in seed brachytherapy with I-125 and Pd-103 and in other forms of treatment such as radical prostatectomy. These early results indicate that the onset of side effects generally occurs between one and three weeks post-implant, and the side effects are resolved between five and eight weeks post-implant, more quickly than the resolution of side effects that occur with competing seeds or with other forms of treatment. These limited findings

support management's belief that the Cs-131 seed will result in less severe side effects than competing treatments, but we may have to gather data on outcomes from additional patients before we can establish statistically valid conclusions regarding the incidence of side effects from our seeds.

**We Are Subject To The Risk That Certain Third Parties May Mishandle Our Product.** We rely on third parties, such as Federal Express, to deliver our Proxcelan Cs-131 seed, and on other third parties, including various radiopharmacies, to package our Proxcelan Cs-131 seed in certain specialized packaging forms requested by customers. We are subject to the risk that these third parties may mishandle our product, which could result in adverse effects, particularly given the radioactive nature of our product.

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

**Our Industry Is Intensely Competitive.** The medical device industry is intensely competitive. We compete with both public and private medical device, biotechnology and pharmaceutical companies that have been 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 seed manufacturing technology, we cannot be certain that one or more of our competitors will not attempt to obtain patent protection that blocks or adversely affects our product development efforts. To minimize this potential, we have entered into exclusive agreements with key suppliers of isotopes and isotope precursors, 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 the abilities of our partners to obtain and maintain patent and other protection for our products will affect our success. We are assigned, have rights to, or have exclusive licenses to patents and patents pending in the U.S. and numerous foreign countries. The patent positions of medical device companies can be highly uncertain and involve complex legal and factual questions. Our patent rights may not be upheld in a court of law if challenged. Our patent rights may not provide competitive advantages for our products and may be challenged, infringed upon or circumvented by our competitors. We cannot patent our products in all countries or afford to litigate every potential violation worldwide.

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

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

result in issued patents.



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

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

Under the FDC Act, medical devices are classified into three different categories, over which the FDA applies increasing levels of regulation: Class I, Class II, and Class III. Our Proxcelan Cs-131 seed has been classified as a Class II device and has received clearance from the FDA through the 510(k) pre-market notification process. Any modifications to the device that would significantly affect safety or effectiveness, or constitute a major change in intended use, would require a new 510(k) submission. As with any submittal to the FDA, there is no assurance that a 510(k) clearance would be granted to the Company.

In addition to FDA-required market clearances and approvals for our products, our manufacturing operations are required to comply with the FDA's Quality System Regulation, or QSR, which addresses requirements for a company's quality program such as management responsibility, good manufacturing practices, product and process design controls, and quality controls used in manufacturing. Compliance with applicable regulatory requirements is monitored through periodic inspections by the FDA Office of Regulatory Affairs (ORA). We anticipate both announced and unannounced inspections by the FDA. Such inspections could result in non-compliance reports (Form 483) which, if not adequately responded to, could lead to enforcement actions. The FDA can institute a wide variety of enforcement actions ranging from public warning letters to more severe sanctions such as fines; injunctions; civil penalties; recall of our products; operating restrictions; suspension of production; non-approval or withdrawal of pre-market clearances for new products or existing products and criminal prosecution. There can be no assurance that we will not incur significant costs to comply with these regulations in the future or that the regulations will not have a material adverse effect on our business, financial condition and results of operations.

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

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

**Our Business Involves Environmental Risks.** Our business involves the controlled use of hazardous materials, chemicals, biologics, and radioactive compounds. Manufacturing is extremely susceptible to product loss due to radioactive, microbial, or viral contamination; material or equipment failure; vendor or operator error; or due to the very nature of the product's short half-life. Although we believe that our safety procedures for handling and disposing of such materials comply with state and federal standards there will always be the risk of accidental contamination or injury. In addition, radioactive, microbial, or viral contamination may cause the closure of the respective manufacturing facility for an extended period of time. By law, radioactive materials may only be disposed of at state-approved facilities. At our leased facility we use commercial disposal contractors. We may incur substantial costs related to the disposal of these materials. If we were to become liable for an accident, or if we were to suffer an extended facility shutdown, we could incur significant costs, damages, and penalties that could harm our business.

**We Rely Upon Key Personnel.** Our success will depend, to a great extent, upon the experience, abilities and continued services of our executive officers, 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. Our success also will depend upon our ability to attract and retain other highly qualified scientific, managerial, sales, and manufacturing personnel and their ability to develop and maintain relationships with key individuals in the industry. Competition for these personnel and relationships is intense and we compete with numerous pharmaceutical and biotechnology companies as well as with universities and non-profit research organizations. We may not be able to continue to attract and retain qualified personnel.

**Our Ability To Operate In Foreign Markets Is Uncertain.** Our future growth will depend in part on our ability to establish, grow and maintain product sales in foreign markets, particularly in Canada, the European Union (EU) 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 our products in foreign markets; the burden of complying with complex and changing foreign regulatory requirements; time-sensitive delivery requirements due to the short half-life of our product; language barriers and other difficulties in providing long-distance customer service; potentially increase time to collect accounts receivable; significant currency fluctuations, which could cause third-party distributors to reduce the number of products they purchase from us because the cost of our products to them could fluctuate relative to the price they can charge their customers; reduced protection of intellectual property rights in some foreign countries; and the possibility that contractual provisions governed by foreign laws would be interpreted differently than intended in the event of a contract dispute. Any future foreign sales of our products could also be adversely affected by export license requirements, the imposition of governmental controls, political and economic instability, trade restrictions, changes in tariffs, and difficulties in staffing and managing foreign operations. Many of these factors may also affect our ability to import Cs-131 from Russia under our 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 responsibilities for management personnel and will place a strain upon the entire company. To compete effectively and to accommodate growth, if any, we may be required to continue to implement and to improve our management, manufacturing, sales and marketing, operating and financial systems, procedures and controls on a timely basis and to expand, train, motivate and manage our employees. There can be no assurance that our personnel, systems, procedures, and controls will be adequate to support our future operations. If the Proxcelan Cs-131 seed

were to rapidly become the “seed of choice,” it is unlikely that we could meet demand. We could experience significant cash flow difficulties and may have difficulty obtaining the working capital required to manufacture our products and meet demand. This would cause customer discontent and invite competition.

## Risks Related to Our Stock and Reporting Requirements

**If We Are Unable To Successfully Address The Material Weakness In Our Internal Controls, Our Ability To Report Our Financial Results On A Timely And Accurate Basis May Be Adversely Affected.** Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our reputation and operating results could be harmed. We have in the past discovered, and may in the future discover, areas of our internal controls that need improvement. In its assessment of the effectiveness in internal control over financial reporting as of June 30, 2010, the Company determined that there were deficiencies that constituted a material weakness. Specifically, the Company did not maintain a sufficient complement of personnel with the appropriate level of knowledge, experience and training to analyze, review and monitor the accounting of complex financial transactions. As a result, the Company did not prepare adequate contemporaneous documentation that would provide a sufficient basis for an effective evaluation and review of the accounting for complex transactions that are significant or non-routine. This material weakness resulted in errors in the preliminary June 30, 2010 consolidated financial statements and more than a remote likelihood that a material misstatement of the Company's annual or interim financial statements would not be prevented or detected. The Company is in the process of developing and implementing a remediation plan to address the material weakness described above, along with the deficiencies also identified in the assessment, which are described under Item 9A below. Specifically, in April 2010, an additional accounting position at the Company's operating subsidiary was filled with a Certified Public Accountant to address issues with segregation of duties, and the Company is assessing additional steps that may be taken in fiscal year 2011 to improve internal controls. We cannot be certain that these measures will ensure that we implement and maintain adequate controls over our financial processes and reporting in the future. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

**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 have continued to increase as provisions of the Sarbanes Oxley Act of 2002 have been implemented. As a smaller reporting company, the Company incurred costs to implement additional provisions of the Sarbanes Oxley Act during fiscal year 2010 in particular related to the implementation of Section 404(b). These Section 404(b) reporting obligations were permanently exempted through legislation passed in July 2010 and this exemption retrospectively applied to the year ended June 30, 2010 for companies classified as smaller reporting companies.

**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.

The Price Of Our Common Stock May Be Adversely Affected By The Future Issuance And Sale Of Shares Of Our Common Stock Or Other Equity Securities, Including Pursuant To The Sales Agreement, Or By Our Announcement That Such Issuances And Sales May Occur. We cannot predict the size of future issuances or sales of our common stock or other equity securities, including those made pursuant to the Company's sales agreement with CKCC, future acquisitions or capital raising activities, or the effect, if any, that such issuances or sales may have on the market price of our common stock. In addition, CKCC, as agent for sales under the sales agreement, will not engage in any transactions that stabilize the price of our common stock. The issuance and sale of substantial amounts of common stock or other equity securities, including the issuances and sales pursuant to the sales agreement, or announcement that such issuances and sales may occur, could adversely affect the market price of our common stock.

Our Reduced Stock Price May Adversely Affect Our Liquidity. Our common stock has been trading at less than \$1.00 per share periodically in the last year. 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 our shares. As of June 30, 2010, we had 23,048,754 outstanding shares of common stock, and the following additional shares were reserved for issuance: 2,274,706 shares upon exercise of outstanding options, 3,165,768 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 5,500,000 shares of common stock outstanding as a result. The issuance of these shares will have the effect of further diluting the proportionate equity interest and voting power of holders of our common stock.

Failure to Comply with NYSE Amex Listing Standards And Any Resulting Delisting Could Adversely Affect The Market For Our Common Stock. Our common stock is presently listed on the NYSE Amex. The NYSE Amex will consider delisting a company's securities if, among other things, the company fails to maintain minimum stockholder's equity or the company has sustained losses which are so substantial in relation to its overall operations or its existing financial resources, or its financial condition has become so impaired that it appears questionable, in the opinion of the NYSE Amex, as to whether such issuer will be able to continue operations and/or meet its obligations as they mature. There can be no assurance that we will be able to maintain our listing on the NYSE Amex indefinitely. In the event that our common stock is delisted from the NYSE Amex, trading, if any, in the common stock would be conducted in the over-the-counter market. As a result, our shareholders would likely find it more difficult to dispose of, or to obtain accurate quotations as to the market value 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 except for dividends on the Series B Preferred Stock which we intend to pay on or before December 31, 2010 if required to comply with the Form S-3 eligibility requirements. 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 in control. Further, as a Minnesota corporation, we are subject to provisions of the Minnesota Business Corporation Act, or MBCA, regarding “business combinations,” which can deter attempted takeovers in certain situations. Pursuant to the terms of a shareholder rights plan adopted in February 2007, each outstanding share of common stock has one attached right. The rights will cause substantial dilution of the ownership of a person or group that attempts to acquire the Company on terms not approved by the Board of Directors and may have the effect of deterring hostile takeover attempts. The effect of these anti-takeover provisions may be to deter business combination transactions not approved by our Board of Directors, including acquisitions that may offer a premium over the market price to some or all shareholders. We may, in the future, consider adopting additional anti-takeover measures. The authority of our Board to issue undesignated preferred or other capital stock and the anti-takeover provisions of the MBCA, as well as other current and any future anti-takeover measures adopted by us, may, in certain circumstances, delay, deter or prevent takeover attempts and other changes in control of the Company not approved by our Board of Directors.

#### ITEM 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 15,900 square feet of office and laboratory space for approximately \$23,100 per month plus monthly janitorial expenses of approximately \$430 from Energy Northwest, the owner of the Applied Process Engineering Laboratory (the APEL facility). The Company is not affiliated with this lessor. The monthly rent is subject to annual increases based on the Consumer Price Index. The current lease was entered into in May 2010, expires on April 30, 2013, and has one additional three-year renewal option remaining.

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 – [REMOVED AND RESERVED]

## 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 currently divided into two classes as follows: 194,000,000 shares of common stock, par value of \$0.001 per share; and 6,000,000 shares of preferred stock, par value of \$0.001 per share. As of September 7, 2010, we had 23,048,754 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, 2010	High	Low
First quarter	\$ 1.65	\$ 0.23
Second quarter	1.21	0.72
Third quarter	1.58	0.82
Fourth quarter	1.58	1.02
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

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 December 11, 2009, the Board of Directors declared a dividend on the Series B Preferred Stock of all outstanding and cumulative dividends through December 31, 2009. There is no Series A Preferred Stock outstanding. The total Series B accrued dividends of \$36,679 were paid as of December 31, 2009. At June 30, 2010, there were 59,065 Series B preferred shares outstanding and cumulative dividends in arrears were \$5,316. There is no Series A Preferred Stock outstanding.

As of September 3, 2010, we had approximately 259 shareholders of record, exclusive of shares held in street name.

## Equity Compensation Plans

On May 27, 2005, the Company adopted the 2005 Stock Option Plan (the Option Plan) and the 2005 Employee Stock Option Plan (the Employee Plan), pursuant to which it may grant equity awards to eligible persons. On August 15, 2006, the Company adopted the 2006 Director Stock Option Plan (the Director Plan) pursuant to which it may grant equity awards to eligible persons. Each of the Plans has subsequently been amended. The Option Plan allows the Board of Directors to grant options to purchase up to 1,800,000 shares of common stock to directors, officers, key employees and service providers of the Company, and the Employee Plan allows the Board of Directors to grant options to purchase up to 2,000,000 shares of common stock to officers and key employees of the Company. The Director Plan allows the Board of Directors to grant options to purchase up to 1,000,000 shares of common stock to directors of the Company. Options granted under all of the Plans have a ten year maximum term, an exercise price



equal to at least the fair market value of the Company's common stock (based on the trading price on the NYSE Amex) on the date of the grant, and with varying vesting periods as determined by the Board.

As of June 30, 2010, 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 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	2,274,706	\$ 1.96	1,551,845
Total	2,274,706	\$ 1.96	1,551,845

#### Sales of Unregistered Securities

All sales of unregistered securities were previously reported.

#### Use of Proceeds from Registered Securities

On October 27, 2010, we filed a registration statement on Form S-3 to register securities up to \$15 million in value for future issuance in our capital raising activities. The registration statement became effective on November 13, 2010, and we filed a prospectus supplement relating to the Sales Agreement described below on April 23, 2010. The Commission file number assigned to the registration statement is 333-162694.

On April 22, 2010, we entered into a Sales Agreement (the "Agreement") with C. K. Cooper & Company, Inc. ("CKCC"). Pursuant to the terms of the Agreement, the Company may offer and sell (the "Offering") from time to time through CKCC, as the Company's sales agent, up to \$4 million of shares of the Company's common stock, par value \$0.001 per share (the "Shares"). CKCC is not required to sell any specific number or dollar amount of Shares but will use its commercially reasonable efforts, as the Company's agent and subject to the terms of the Agreement, to sell the Shares offered, as instructed by the Company. Sales of the Shares, if any, may be made by means of ordinary brokers' transactions on the NYSE AMEX at market prices and such other sales as agreed to by the Company and CKCC. CKCC will receive from us a commission of 2.0% based on the gross sales price per share for any Shares sold through it as agent under the Agreement. Net proceeds from the sale of the Shares will be used for general corporate purposes. The Company has also agreed to reimburse CKCC for certain expenses incurred in connection with entering into the Agreement and has provided CKCC with customary indemnification rights.

On July 29, 2010, we entered into an amendment (the "Amendment") to the Agreement. The purpose of the Amendment is to extend the term of the offering of Shares by CKCC as the Company's sales agent pursuant to the Agreement. The offering of Shares pursuant to the Agreement, as amended by the Amendment, will terminate upon the earliest of (i) December 31, 2010, (ii) the sale of all Shares subject to the Agreement or (iii) the termination of the Agreement by the Company or CKCC. The other terms of the Agreement remain in effect and have not been changed by the Amendment.

CKCC has not yet commenced the Offering as it has not yet been instructed to do so by the Company.



## 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. Any declines in fair value that are considered other than temporary are recorded in the Consolidated Statements of Operations.

### Fair Value of Financial Instruments

The Accounting Standards Codification (ASC) 820, Fair Value Measurements and Disclosures, of the Financial Accounting Standards Board (FASB), permits, but does not require, entities to measure many financial instruments and certain other items not specifically identified in other topics of the ASC, such as available-for-sale investments, at fair value. We have not elected to measure additional assets and liabilities at fair value.

Fair value is defined as the price that would be received in the sale of an asset, or paid to transfer a liability, in an orderly transaction between market participants at the measurement date. A three-level valuation hierarchy is used to qualify fair value measurements based upon the transparency of inputs to the valuation of an asset or liability as of the measurement date:

Level 1. Inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets. Level 1 assets and liabilities include debt and equity securities and derivative financial instruments actively traded on exchanges, as well as U.S. Treasury securities and U.S. Government and agency mortgage-backed securities that are actively traded in highly liquid over-the-counter markets.



Level 2. Model inputs are observable inputs, other than Level 1 prices, such as quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, and inputs that are observable or can be corroborated, either directly or indirectly, for substantially the full term of the financial instrument. Level 2 assets and liabilities include debt instruments that are traded less frequently than exchange traded securities and derivative instruments, for which the model inputs are observable in the market or can be corroborated by market observable data. Examples in this category are less frequently traded mortgage-backed securities, corporate debt securities and derivative contracts.

Level 3. Inputs to the valuation methodology are unobservable but significant to the fair value measurement. Examples in this category include interests in loans held for sale, certain securitized financial assets or certain private equity investments.

Fair value is applied to eligible assets based on quoted market prices, where available. For financial instruments for which quotes from recent exchange transactions are not available, fair value is based on discounted cash flow analysis and comparisons to similar instruments. Discounted cash flow analysis is dependent upon estimated future cash flows and the level of interest rates.

The methods used for current fair value calculations of Level 2 and Level 3 assets and liabilities may not be indicative of net realizable value or reflective of future fair values. If readily determined market values became available, or if actual performance were to vary appreciably from assumptions used, assumptions may need to be adjusted, which could result in material differences from the recorded carrying amounts. We believe our methods of determining fair value are appropriate and consistent with other market participants. However, the use of different methodologies or application of different assumptions to value certain financial instruments could result in a different estimate of fair value.

Effective July 1, 2008, the Company implemented ASC 820, Fair Value Measurements and Disclosures, of the Financial Accounting Standards Board (FASB), ASC 820 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 Standard with the one-year deferral permitted for nonfinancial assets and nonfinancial liabilities measured at fair value, except those that are recognized or disclosed on a recurring basis. This deferral applied 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 ASC 820 for these assets and liabilities.

ASC 820 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, 2010, 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 ASC Topic 825, Financial Instruments. The statement allows entities to value many financial instruments and certain other items at fair value. ASC 825 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 ASC 825. Accordingly, the adoption of ASC 825 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 ASC 825.

#### 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 net realizable value of each asset to determine whether an impairment of value has occurred, and if there is a need for any asset impairment write-down.

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

#### Deferred Financing Costs

Financing costs related to the acquisition of debt are deferred and amortized over the term of the related debt using the effective interest method. Deferred financing costs include the fair value of common shares issued to certain shareholders for their guarantee of certain Company debt in accordance with (ASC) 820 Capitalization of Interest and (ASC) 230 Statement of Cash Flows. The value of the shares issued was the estimated market price of the shares as of the date of issuance. Amortization of deferred financing costs, totaling \$14,909 and \$37,035 for the years ended June 30, 2010 and 2009, 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. 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 that is included in cost of product sales for the year ended June 30, 2009. (see Footnote 7 to the audited consolidated financial statements)

Amortization of licenses was \$11,867 and \$30,067 for the years ended June 30, 2010 and 2009, respectively. Based on the licenses recorded at June 30, 2010, 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: \$11,721 for 2011, \$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 other assets. Impairments are recognized when the expected future operating cash flows to be derived from such assets are less than their carrying value.

Amortization of other assets was \$16,861 and \$11,315 for the years ended June 30, 2010 and 2009 respectively. Based on the patents and other intangible assets recorded in other assets at June 30, 2010, 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: \$15,139 for each year 2011 through 2015 and \$142,629 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 an equivalent amount is capitalized to property and equipment. The initial recorded obligation is discounted using the Company's credit-adjusted risk free-rate 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 leased assets.

In September 2007, an asset retirement obligation of \$473,096 was established representing the discounted cost of the Company's estimate of the obligations to remove any residual radioactive materials and all leasehold improvements at the end of the lease term at its new production facility. The estimate was developed by qualified production personnel and the general contractor of 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, 2010 and 2009, the asset retirement obligations changed as follows:

	2010	2009
Beginning balance	\$ 553,471	\$ 506,005
Accretion of discount	51,920	47,466
Ending balance	\$ 605,391	\$ 553,471

Because the Company does not expect to incur any expenses related to its asset retirement obligations in fiscal year 2011, the entire balance as of June 30, 2010 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, 2010 and 2009.

## Revenue Recognition

The Company applies the provisions of ASC Topic 605, Revenue Recognition. ASC 605 provides guidance on the recognition, presentation and disclosure of revenue in financial statements. ASC 605 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, 2010 and 2009 was derived primarily from sales of the Proxcelan Cs-131 brachytherapy seed, which is used in the treatment of cancer. The Company recognizes revenue once the product has been shipped to the customer. Prepayments, if any, received from customers prior to the time that products are shipped are recorded as deferred revenue. In these cases, when the related products are shipped, the amount recorded as deferred revenue is 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 to 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 liability claims, patent rights, environmental matters, and a variety of other matters. The Company is also subject to various local, state, and federal environmental regulations and laws due to the isotopes used to produce the Company's product. As part of normal operations, amounts are expended to ensure

that the Company is in compliance with these laws and regulations. While there have been no reportable incidents or compliance issues, the Company believes that if it relocates its current production facilities then certain decommissioning expenses will be incurred and has recorded an asset retirement obligation for these expenses.

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

#### Income Taxes

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

#### 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, including 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, 2010 and 2009 are as follows:

	2010	2009
Preferred stock	59,065	59,065
Common stock warrants	3,165,768	3,216,644
Common stock options	2,274,706	2,708,166
<b>Total potential dilutive securities</b>	<b>5,499,539</b>	<b>5,983,875</b>

#### Subsequent Events

Effective April 1, 2009, the Company adopted ASC 855 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 non-recognized 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 2010 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, 2010 and 2009. 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 25 of this Annual Report on Form 10-K.

### Year ended June 30, 2010 compared to year ended June 30, 2009

**Product sales.** The Company generated revenue of \$5,286,084 for the year ended June 30, 2010 compared to revenue of \$5,417,815 for the year ended June 30, 2009, a decrease of \$131,731 or 2.4%. The total number of cases for the year ended June 30, 2010 as compared to the year ended June 30, 2009 declined 5.7%. Revenue generated from prostate cancer related therapy amounted to approximately 97% of revenue in the year ended June 30, 2010 while the remaining approximately 3% is from new treatment modalities including lung, colorectal, head and neck and chest wall cancers. In the year ended June 30, 2009 nearly 100% of revenue was generated by prostate cancer therapy. Management believes that the overall market for prostate brachytherapy has received increased pressure from other treatment options with higher reimbursement rates such as intensity-modulated radiation therapy (IMRT) and management is focused on new treatment modalities to become a larger portion of the total revenue in the future.

**Cost of product sales.** Cost of product sales was \$4,560,287 for the year ended June 30, 2010 compared to cost of product sales of \$5,771,147 for the year ended June 30, 2009. While the Company continues to streamline manufacturing processes, the reduction of cost of product sales of \$1,210,860 or 21% for the year ended June 30, 2010 as compared to the year ended June 30, 2009, was substantially impacted by a one-time impairment charge of \$425,434. The remaining year to year cost reduction of \$785,426 was composed of decreases in depreciation and amortization expense of \$219,000, occupancy expense of \$66,000, payroll and benefits expense of \$172,000 and pre-loading expense of 207,000. The Company achieved a \$785,000 reduction in production costs as a result of a continued focus on analyzing and improving all aspects of production operations. These continued efforts during fiscal year 2010 have resulted in improved production processes, better utilization of labor, ability to utilize Company personnel in lieu of consultants and the continued increased use of internal seed loading capabilities by customers instead of external third-party seed loading services.

**Gross margin (loss).** Gross margin was \$725,797 for the year ended June 30, 2010 compared to a gross loss of \$353,332 for the year ended June 30, 2009. The improvement of \$1,079,129 or 305% was due to the one-time impairment charge in the year ended June 30, 2009 as well as continued reductions in production costs and more efficient use of manufacturing resources in the year ended June 30, 2010.





Research and development expenses. Research and development expenses for the year ended June 30, 2010 were \$340,959 which represents a decrease of \$617,706 or approximately 64% less than the research and development expenses of \$958,665 for the year ended June 30, 2009.

The cost savings of approximately \$618,000 were primarily due to a \$305,000 reduction in protocol expense as the major cost for the monotherapy protocol has been completed, consulting costs of \$74,000 as several production projects were completed, legal costs were reduced by \$127,000 and savings of \$60,000 in payroll and benefits, related taxes and share-based compensation.

Sales and marketing expenses. Sales and marketing expenses were \$1,953,598 for the year ended June 30, 2010 compared to sales and marketing expenses of \$2,365,973 for the year ended June 30, 2009, which represents a decrease of \$412,375 or 17%.

The decrease of approximately \$412,000 is primarily the net result of a reduction in wages, benefits, related taxes and share-based compensation of \$242,000 that is related to both temporary and permanent attrition as well as forfeiture of related equity stock options; a decrease of \$88,000 in travel that is a result of both the temporary attrition and improved trip planning; and a reduction of \$76,000 in marketing and advertising expense through reducing the number of trade journals that were used for advertising.

General and administrative expenses. General and administrative expenses for the year ended June 30, 2010 were \$2,440,140 compared to general and administrative expenses of \$2,792,611 for the year ended June 30, 2009. The decrease of approximately \$352,000 is primarily the net result of reductions in wages, benefits, related taxes and share-based compensation of \$137,000; reduction in legal expense of \$157,000; and a decrease in consulting expenses of \$92,000 that was partially offset by an increase in audit, Sarbanes-Oxley Act related compliance and tax expense of \$50,000.

Operating loss. In the year ended June 30, 2010, the Company had an operating loss of \$4,008,900 compared to \$6,470,581 for the year ended June 30, 2009, a decrease of \$2,461,681 or 38%. The Company's operating loss reduction of approximately \$2.5 million was achieved through savings in cost of product sales of \$1.2 million (including a one-time impairment charge of \$425,000), research and development of \$618,000, sales and marketing of \$412,000, and general and administrative of \$352,000.

Interest income. Interest income was \$11,433 for the year ended June 30, 2010 compared to interest income of \$111,047 for the year ended June 30, 2009. The decrease of \$99,614 or 90% is the result of lower average cash and short-term investment balances during the year ended June 30, 2010 and decreased interest rates.

Gain on the fair value of short-term investments. There was no gain on short-term investments for the year ended June 30, 2010 as compared to a gain of \$274,000 for the year ended June 30, 2009. The gain of \$274,000 for the year ended June 30, 2009 was due to the receipt of the Company's rights related to its auction rate securities (ARS) issued by its broker in October 2008. The gain was calculated as the fair value amount of 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, 2010 was \$36,389 compared to \$75,307 for the year ended June 30, 2009, a decrease of \$39,000 or 52%. Financing expense included interest expense of approximately \$19,000 and \$38,000 for the years ended June 30, 2010 and 2009, respectively. The decrease is due to the lower than average debt balances in the year ended June 30, 2010. 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 2010, 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 \$2.7 million in fiscal year 2010 compared to approximately \$3.9 million in fiscal year 2009, a decrease of approximately \$1.3 million. Cash used by operating activities is net loss adjusted for non-cash items and changes in operating assets and liabilities.

The reduction of net cash used by operating activities of \$1.3 million is attributable to the reduction of the Company's net loss of \$2.1 million with an offsetting reduction in non cash charges of \$600,000 in fiscal year 2010 compared to fiscal year 2009 and a reduction of \$260,000 in operating assets and liabilities in the fiscal year 2010 compared to the fiscal year 2009.

#### Cash flows from investing activities

Cash provided by investing activities was approximately \$1.6 million for the year ended June 30, 2010 and \$2.2 million for the year ended June 30, 2009. Cash expenditures for fixed assets were approximately \$22,000 in fiscal year 2010 and approximately \$58,000 in fiscal year 2009. The short-term investments of the Company matured in the year ended June 30, 2010 and provided \$1.7 million of cash proceeds. The Company sold its remaining auction rate securities in January 2009 which generated \$4.0 million of cash proceeds.

#### Cash flows from financing activities

Cash used in financing activities was approximately \$270,000 for the year ended June 30, 2010 and \$102,000 for the year ended June 30, 2009 and was used mainly for payments of debt, capital leases and the cash payment of stock offering costs.

#### Projected 2011 Liquidity and Capital Resources

At June 30, 2010, cash and cash equivalents amounted to \$1,678,869 with no short-term investments compared to \$2,990,744 of cash and cash equivalents and \$1,679,820 of short-term investments at June 30, 2009.

The Company had approximately \$1.2 million of cash as of September 21, 2010. As of that date management believed that the Company's monthly required cash operating expenditures were approximately \$223,000 which represents a significant decrease of approximately \$100,000 from average monthly cash operating expenditures in fiscal year 2009. Management believes that less than \$100,000 will be spent on capital expenditures for the entire fiscal year 2011, but there is no assurance that unanticipated needs for capital equipment may not arise.

The Company's loan with the Benton-Franklin Economic Development District matured and was paid during the fiscal year ended June 30, 2010. The Company has only one remaining loan facility outstanding with the Hanford Area Economic Investment Fund Committee (HAEIFC), with a principal balance of approximately \$179,995 as of June 30, 2010.

During fiscal year 2011, 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 \$100,000 in fiscal year 2011 for protocol expenses relating to lung cancer as well as continued work on the dual therapy and mono therapy prostate protocols.



Based on the foregoing assumptions, management believes cash and cash equivalents on hand at June 30, 2010 should be sufficient to meet our anticipated cash requirements for operations, debt service, and capital expenditure requirements through January 31, 2011.

Management plans to attain breakeven and generate additional cash flows by 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 implants, colorectal and lung implants while maintaining the Company's focus on cost control. Management believes the Company will reach breakeven with revenues of approximately \$750,000 per month with cashflow breakeven from operations being reached at approximately \$700,000. However, there can be no assurance that the Company will attain profitability or that the Company will be able to attain its revenue targets. Sales in the prostate market have not shown the increases necessary to breakeven during the past two fiscal years and did not improve during the year ended June 30, 2010. As management is now focused on expanding into head and neck, colorectal, lung and brain applications, management believes the Company will need to raise additional capital for protocols, marketing staff, production staff and production equipment as it attempts to gain market share. Initially, management plans to seek to sell common stock pursuant to either an "at the market" offering or through a direct registered offering at a discount to the market price of not more than 15% and has an effective Form S-3 shelf offering registration statement available for this purpose.

Management executed a sales agreement with C.K. Cooper & Company, Inc. (CKCC) on April 22, 2010 to sell shares as the Company's sales agent at market prices, which was amended on July 29, 2010. As amended, the sales agreement expires on December 31, 2010. If the shares are sold, the shares will be issued pursuant to the Form S-3 (File No. 333-162694) which became effective on November 13, 2009 and the prospectus supplement dated April 23, 2010. Sales cannot exceed \$4 million under the prospectus supplement and must be sold "at the market" price of the common stock as of the day the sales are made.

The Company may also finance its future cash needs through solicitation of warrant holders to exercise their warrants at potentially reduced exercise prices, possible strategic collaborations, debt financing or through other sources that may be dilutive to existing shareholders but as the Company now has insufficient capital to fund operations through the end of the current fiscal year, it may need to offer more substantial discounts. Management anticipates that if it raises financing that it will be at a discount to the market price of common stock of not more than 15% and dilutive to shareholders. Of course, funding may not be available to it on acceptable terms, or at all. If the Company is unable to raise additional funds, it will have to discontinue or significantly curtail operations.

#### Long-Term Debt

The Company has a single loan facility in place as of June 30, 2010. The loan facility is from 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, 2010 was \$179,995. This loan is secured by receivables, equipment, materials and inventory, and certain life insurance policies and also required personal guarantees. The final payment on the HAEIFC loan will be due in September 2013.

HAEIFC has granted the Company a waiver from enforcing several loan covenants in the loan agreement. The waiver is effective through June 30, 2011.

#### Other Commitments and Contingencies

In May 2010, Medical exercised the first of two options to renew the original lease that was entered into on May 2, 2007 with Energy Northwest, the owner of the Applied Process Engineering Laboratory (the APEL lease), for an

additional 3 years with a new lease expiration date of April 30, 2013. Due to a reduction in some lab and office space at APEL, the rent has been reduced to approximately \$23,100 per month.

Future minimum lease payments under operating leases, including the one remaining three-year renewal of the APEL lease, are as follows:

Year ending June 30,		
2011	\$	296,157
2012		284,915
2013		282,390
2014		282,390
2015		282,390
Thereafter		235,324
	\$	1,663,566

In February 2006, the Company signed a license agreement with International Brachytherapy SA (IBt), a Belgian company, covering North America and providing the Company with access to IBt's Ink Jet production process and its proprietary polymer seed technology for use in brachytherapy procedures using Cs-131. 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 eliminated 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. In 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 was postponed due to an electrical problem that damaged equipment and due to economic difficulties in the Ukraine that have protracted the contractor's efforts with a planned demonstration originally expected in Fall 2009. The contractor has not delivered a successful demonstration as required by the contract despite on-going commitments to the Company to do so. There is no assurance this demonstration will occur or whether it will be successful. If a successful demonstration occurs, the Company will then need 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 cost estimated to be \$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 had a significant impact on the operations of the Company. If current levels of inflation hold steady, management does not believe future operations will be negatively impacted.

#### New Accounting Standards

On July 1, 2009, the Company adopted ASC 105, Generally Accepted Accounting Principles, new accounting provisions which establishes the FASB Accounting Standards Codification™ (the Codification) as the single official source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with generally accepted accounting principles (GAAP) other than rules and interpretive releases issued by the Securities and Exchange Commission. The Codification reorganized the literature and changed the naming mechanism by which topics are referenced. The Codification became effective for interim and annual periods ending after September 15, 2009. The Company's accounting policies and amounts presented in the financial statements were not impacted by this change.

On July 1, 2009, the Company adopted new accounting provisions which were delayed from the effective date of fair value accounting for one year for certain nonfinancial assets and nonfinancial liabilities, excluding those that are recognized or disclosed in financial statements at fair value on a recurring basis (that is, at least annually). For purposes of applying the new provisions, nonfinancial assets and nonfinancial liabilities include all assets and liabilities other than those meeting the definition of a financial asset or a financial liability. The Company had previously adopted new standards for fair value accounting on July 1, 2008. The adoption of these new provisions did not have a material effect on the Company but will affect future calculations of asset retirement obligations and long-lived asset impairment.

On July 1, 2009, the Company adopted ASC 805, Business Combinations, this new accounting standard applies to business combinations and for non-controlling interests. The new business combination provisions require an acquirer to measure the identifiable assets acquired, the liabilities assumed and any non-controlling interest in the acquiree at their fair values on the acquisition date, with goodwill being the excess value over the net identifiable assets acquired. In addition, the new provisions require that a non-controlling interest in a subsidiary be reported as equity in the consolidated financial statements. The calculation of earnings per share will continue to be based on income amounts attributable to the parent. The adoption of these statements did not have a material effect on the Company's financial statements.

#### 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, 2010. 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. 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(f) 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.

A material weakness is a significant deficiency, or combination of significant deficiencies, that result in more than a remote likelihood that a material misstatement of the annual or interim financial statements will occur and not be detected by management before the financial statements are published. In its assessment of the effectiveness in internal control over financial reporting as of June 30, 2010, the Company determined that there was a material weakness and a significant deficiency, as described below.

- **Material weakness** - The Company did not maintain a sufficient complement of personnel with the appropriate level of knowledge, experience and training to analyze, review and monitor the accounting of complex financial transactions. As a result, the Company did not prepare adequate contemporaneous documentation that would provide a sufficient basis for an effective evaluation and review of the accounting for complex transactions that are significant or non-routine. This material weakness resulted in errors in the preliminary June 30, 2010 consolidated financial statements and more than a remote likelihood that a material misstatement of the Company's annual or interim financial statements would not be prevented or detected.
- **Significant deficiency** - There is a lack of segregation of duties in preparation of the financial statements and other key financial transactions. The Controller is responsible for almost every key financial duty and has access to all of the Company's financial information. Such a lack of segregation of duties is typical in a company with limited resources. Although the Company's CEO and Board of Directors review the financial statements and would most likely discover any misappropriation of funds, this cannot be assured by the existing system.

Due to the above significant deficiency and the resulting material weakness, management concluded that our internal control over financial reporting was not effective as of June 30, 2010.

The Company is in the process of developing and implementing a remediation plan to address the material weakness and significant deficiency as described above.

The Company has taken the following actions to improve internal control over financial reporting:

- In April 2010, the Company filled an additional accounting position with an individual who is a Certified Public Accountant to address issues with segregation of duties.
- The Company plans to continue to enhance staff knowledge through continued training and periodic reviews.

In light of the aforementioned material weakness, management conducted a thorough review of all significant or non-routine transactions and adjustments for the year ended June 30, 2010. As a result of this review, management believes that there are no material inaccuracies or omissions of material fact and to the best of its knowledge, believes that the consolidated financial statements for the year ended June 30, 2010 fairly present in all material respects the financial condition and results of operations for the Company in conformity with U.S. generally accepted accounting principles.

This annual report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting due to a permanent exemption for smaller reporting companies from the internal control audit requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002.

#### 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, 2010 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 an “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 under applicable NYSE Amex standards. 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, 2010 were as follows:

Name	Age	Position Held	Term*
Dwight Babcock	62	Chairman, Chief Executive Officer	Annual
Brien Ragle	41	Controller, Principal Financial and Accounting Officer	
Robert Kauffman	70	Vice-Chairman	Annual
Thomas LaVoy	50	Director	Annual
Albert Smith	66	Director	Annual

\* For directors only

51

---

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. Mr. Babcock brings over 35 years of CEO-level experience to his service on the Company's Board.

Brien Ragle – Mr. Ragle has over 14 years of finance and accounting experience, including financial reporting, and cost, project, and management accounting in addition to performing operational analysis. Mr. Ragle became IsoRay's Controller in October 2009. Before joining IsoRay in January 2007 as Cost Accounting Manager, Mr. Ragle was employed by BNG America, LLC, a wholly-owned subsidiary of Energy Solutions, LLC (ES) from 2005 to 2006 as a Project Accounting Manager and from 2000 to 2004 as a Business Unit Controller by SCM Consultants, Inc, a wholly-owned subsidiary of Tetra Tech, Inc (TTEK). Mr. Ragle holds Bachelor of Arts degrees in Business Administration, accounting emphasis, and Hospitality Management from Washington State University and is a Certified Public Accountant in the State of Washington.

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 solar electric power systems with annual revenues in excess of \$35 million. Prior to Photocomm, Mr. Kauffman was a senior executive of the Atlantic Richfield Company (ARCO) whose varied responsibilities included Senior Vice President of ARCO Solar, Inc., President of ARCO Plastics Company and Vice President of ARCO Chemical Company. Mr. Kauffman earned an M.B.A. in Finance at the Wharton School of the University of Pennsylvania, and holds a B.S. in Chemical Engineering from Lafayette College, Easton, Pennsylvania. Mr. Kauffman has substantial experience in serving as CEO for public companies, and brings these skills to his service on the Company's Board.

Thomas LaVoy – Mr. LaVoy has been a Director of the Company since 2005. Mr. LaVoy has served as Chief Financial Officer of SuperShuttle International, Inc., since July 1997 and as Secretary since March 1998. SuperShuttle is one of the largest providers of shuttle services in major cities throughout the West and Southwest regions of the United States. He has also served as a director of Alanco Technologies, Inc. (NASDAQ: ALAN) since 1998 and presently serves on its audit committee. 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. Mr. LaVoy brings over 25 years of CFO experience for progressively growing companies in multiple industries to his service on the Company's Board.

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 privately held 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. Mr. Smith brings his entrepreneurial skills in founding and growing multiple private companies, together with a strong sales and marketing background, to his service on the Company's Board.

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

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

### Significant Employees

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

Name	Age	Position Held & Tenure
Lane Bray	82	Chief Chemist
Fredric Swindler	62	Vice-President, Regulatory Affairs and Quality Assurance
Anthony Pasqualone	55	Vice-President, Business Development
William Cavanagh, III	44	Vice-President, Research and Development

Lane Bray – Mr. Bray is known nationally and internationally as a technical expert in separations, recovery, and purification of isotopes and is a noted authority in the use of cesium and strontium ion exchange for Department of Energy’s West Valley and Hanford nuclear waste cleanup efforts. In 2000, Mr. Bray received the ‘Radiation Science and Technology’ award from the American Nuclear Society. Mr. Bray has authored or co-authored over 110 research publications, 12 articles for nine technical books, and holds 28 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-Citizen of the Year’ in 1988, nominated for ‘Engineer of the Year’ by the American Nuclear Society in 1995, and was elected ‘Chemist of the Year for 1997’ by the American Chemical Society, Eastern Washington Section. Mr. Bray retired from the Pacific Northwest National Laboratory in 1998. Since retiring in 1998, Mr. Bray worked part time for PNNL on special projects until devoting all of his efforts to IsoRay in 2004. Mr. Bray has been a Washington State Legislator, a Richland City Councilman, and a Mayor of Richland. Mr. Bray has a B.A. in Chemistry from Lake Forest College.

Fredric Swindler – Mr. Swindler joined IsoRay Medical in October 2006 and has over 40 years experience in manufacturing and regulatory compliance. Mr. Swindler also serves as Secretary for IsoRay, Inc., a position he has held since June 11, 2008. Mr. Swindler served as VP, Quality Assurance and Regulatory Affairs for Medisystems Corporation, a manufacturer and distributor of medical devices, from 1994 until joining the Company. During his tenure at Medisystems Corporation, Mr. Swindler developed a quality system to accommodate vertically integrated manufacturing, developed regulatory strategies, policies and procedures, and submitted nine pre-market notifications (510(k)) to the FDA. Prior to this, Mr. Swindler held various positions with Marquest Medical Products from 1989 to 1994, Sherwood Medical Products from 1978 to 1989, Oak Park Pharmaceuticals in 1978, and Mead Johnson & Company from 1969 to 1978. Mr. Swindler holds a Bachelor of Science degree in Biomedical Engineering from Rose-Hulman Institute of Technology and a Masters of Business Administration from the University of Evansville.



Anthony Pasqualone – Mr. Pasqualone joined IsoRay Medical in November 2008 and has been involved in marketing brachytherapy extensively since 1989 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 with BrachySciences from December 2005 to April 2007. He also served as a VP of Strategic Markets from May 2003 to December 2005 in the Urology Division 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.

William Cavanagh III – Mr. Cavanagh joined IsoRay Medical in January 2010. Mr. Cavanagh has most recently been engaged in the research and development of dendritic cell therapies for cancer and infectious diseases. He served as Chief Scientific Officer for Sangretech Biomedical, LLC for the six years prior to joining IsoRay Medical. At Sangretech, he oversaw the design and implementation of a novel cancer therapy. Mr. Cavanagh began his extensive career in cancer treatment technologies in the early 1990s, when he helped lead research and development of a therapy involving the insertion of radioactive sources directly into the prostate for the treatment of prostate cancer (prostate brachytherapy). He has designed several cancer treatment-related studies, is listed as an author on 34 peer-reviewed publications, and is the listed inventor on a U.S. patent application detailing a novel treatment for cancer. Mr. Cavanagh has also served as Director of the Haakon Ragde Foundation for Advanced Cancer Studies in Seattle, Washington, where he led the research foundation in the selection of viable research projects directed at treating advanced cancers. Mr. Cavanagh holds a B.S. in Biology from the University of Portland (Oregon) and completed two years of medical school before beginning his career in research management.

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

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

We believe that IsoRay's executive officers, directors and 10% shareholders timely complied with their filing requirements during the year ended June 30, 2010 except for a single Form 3, which was filed late by Brien Ragle.

#### Code of Ethics

We have adopted a Code of Conduct and Ethics that applies to all of our officers, directors and employees and a separate Code of Ethics for Chief Executive Officer and Senior Financial Officers that supplements our Code of Conduct and Ethics. The Code of Conduct and Ethics was previously filed as Exhibit 14.1 to our Form 10-KSB for the period ended June 30, 2006, and the Code of Ethics for Chief Executive Officer and Senior Financial Officers was previously filed as Exhibit 14.2 to this same report. The Code of Ethics for Chief Executive Officer and Senior Financial Officers is also available to the public on our website at [http://www.isoray.com/corporate\\_governance..](http://www.isoray.com/corporate_governance..) Each of these policies comprises written standards that are reasonably designed to deter wrongdoing and to promote the behavior described in Item 406 of Regulation S-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 fiscal years awarded to, earned by or paid to each of the following individuals. Salary and other compensation for these officers, employees and former officers are 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)	Nonqualified Nonequity deferred incentive plan compensation		All other compensation (\$)	Total (\$)
						earnings			
Dwight Babcock Chairman and CEO (2)	2010	237,539	25,000	-	136,000	-	-	-	398,539
Brien Ragle Controller, PFO / PAO	2010	92,771	-	-	24,480	-	-	-	117,251
Robert Bilella Territory Sales Manager	2009	83,109	-	-	5,202	-	-	-	88,311
Frederic Swindler	2010	97,200	100,650	-	5,610	-	-	-	203,460
VP – QA / RA	2009	86,722	106,550	-	2,448	-	-	-	195,720
	2010	160,000	-	-	24,480	-	-	-	184,480
	2009	160,000	-	-	9,450	-	-	-	169,450

(1) Amounts represent the ASC 718, Compensation – Stock Compensation valuation for the fiscal years ended June 30, 2010 and 2009, respectively. All such options were awarded under one 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 of grant. All options were granted at the fair market value of the Company's stock on the date of grant and the Company used a Black-Scholes methodology as discussed in the footnotes to the financial statements to value the options.

(2) Mr. 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 table above.

## Outstanding Equity Awards at Fiscal Year-End

Option awards

Equity

Edgar Filing: IsoRay, Inc. - Form 10-K

Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Incentive plan awards:		Option exercise price (\$)	Option expiration date
			Number of securities underlying unexercised options (#)	Number of securities underlying unexercised options (#)		
Dwight Babcock, Chairman and CEO	50,000	-	-	-	6.30	03/31/2016
	50,000	-	-	-	3.80	06/23/2016
	50,000	-	-	-	3.11	08/15/2016
	50,000	-	-	-	4.14	06/01/2007
	100,000	-	-	-	0.75	05/13/2018
	200,000	-	-	-	0.26	06/01/2019
	100,000	-	-	-	1.43	06/30/2020
Brien Ragle Controller, Principal Finance and Accounting Officer	5,000(2)	-	-	-	4.40	03/02/2017
	2,000(3)	-	-	-	4.14	06/01/2017
	34,000(5)	-	-	-	0.26	06/01/2019
	20,000(6)	-	-	-	1.43	06/30/2020
Fred Swindler Vice-President, Quality Assurance and Regulatory Affairs	10,000(2)	-	-	-	4.40	03/02/2017
	10,000(3)	-	-	-	4.14	06/01/2017
	10,000(4)	-	-	-	0.65	07/01/2018
	50,000(5)	-	-	-	0.26	06/01/2019
	20,000(6)	-	-	-	1.43	06/30/2020
Robert Bilella Territory Sales Manager	84,236(1)	-	-	-	4.15	06/23/2015
	18,000(5)	-	-	-	0.26	06/01/2019
	5,000(6)	-	-	-	1.43	06/30/2020

- (1) Represents the June 23, 2005 grant, all of which were exercisable as of June 23, 2008.
- (2) Represents the March 2, 2007 grant, all of which were exercisable as of March 2, 2010.
- (3) Represents the June 1, 2007 grant, all of which were exercisable as of June 1, 2010.
- (4) 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.
- (5) Represents a June 1, 2009 grant, one-third of which became 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.
- (6) Represents a June 30, 2010 grant, one-third of which will become exercisable on June 30, 2011, one-third of which will become exercisable on June 30, 2012, and the final third will become exercisable on June 30, 2013.

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 plans for its executives or employees.

#### Non-Employee Director Compensation

Name	Fees earned or	Stock awards	Option awards	Non-qualified	All other	Total	
	paid in cash			Non-equity incentive			deferred
	(\$)	(\$)	(\$)	plan compensation	earnings	(\$)	
Robert Kauffman	61,500	-	-	-	-	-	61,500
Thomas LaVoy	49,500	-	-	-	-	-	49,500
Albert Smith	37,500	-	-	-	-	-	37,500

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. 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 non-employee director had stock options to purchase 150,000 shares of the Company's common stock outstanding as of June 30, 2010.



## 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 21, 2010 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 21, 2010, the Company had 23,048,754 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.

Name of Beneficial Owner	Common Stock Share Ownership			
	Common Shares Owned	Common Stock Options Exercisable Within 60 Days	Common Warrants	Percent of Class (1)
Dwight Babcock (2)	130,856	550,000	12,500	2.94%
Brien Ragle	-	18,333	-	—%
Robert Kauffman	63,802	150,000	-	—%
Thomas LaVoy	40,423	150,000	-	—%
Albert Smith	198,101	150,000	-	1.50%
Directors and Executive Officers as a group	433,182	1,018,333	12,500	6.08%

(1) Percentage ownership is based on 23,048,754 shares of Common Stock outstanding on September 21, 2010. Shares of Common Stock subject to stock options or warrants which are currently exercisable or will become exercisable within 60 days after September 21, 2010 are deemed outstanding for computing the percentage ownership of the person or group holding such options or warrants, but are not deemed outstanding for 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%

Edgar Filing: IsoRay, Inc. - Form 10-K

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 21, 2010.

(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 in the royalty agreement, 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 \$23,041 and \$20,063 for the years ended June 30, 2010 and 2009, respectively, related to these payments.

##### Patent and Know-How Royalty License Agreement

Effective August 1, 1998, Pacific Management Associates Corporation (PMAC) transferred its entire right, title and interest in an exclusive license agreement with Donald Lawrence to IsoRay, LLC (a predecessor company) in exchange for a membership interest. The terms of the license agreement require the payment of a royalty based on the Net Factory Sales Price, as defined in the agreement, of licensed product sales. Because the licensor's patent application was ultimately abandoned, only a 1% "know-how" royalty based on Net Factory Sales Price, as defined, remains applicable. To date, management believes that there have been no product sales incorporating the "know-how" and that therefore no royalty is due pursuant to the terms of the agreement. Management believes that ultimately no royalties should be paid under this agreement as there is no intent to use this "know-how" in the future.

The licensor of the Lawrence "know-how" has disputed management's contention that it is not using this "know-how". On September 25, 2007 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, 2010	Year ended June 30, 2009
1.	Audit fees	\$ 65,861	\$ 31,047
2.	Audit-related fees	–	–
3.	Tax fees	10,350	7,900
4.	All other fees	22,750	–
	Totals	\$ 98,961	\$ 39,947

Audit fees include fees for the audit of our annual financial statements, reviews of our quarterly financial statements, and related consents for documents filed with the SEC. Tax fees include fees for the preparation of our federal and state income tax returns. All other fees are related to deferred offering costs for the active S-3 filing.

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

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

## 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 on August 3, 2005.
3.1	Articles of Incorporation and By-Laws are incorporated by reference to the Exhibits to the Company's Registration Statement of September 15,

Edgar Filing: IsoRay, Inc. - Form 10-K

- 1983.
- 3.2 Certificate of Designation of Rights, Preferences and Privileges of Series A and B Convertible Preferred Stock, filed with the Minnesota Secretary of State on June 29, 2005 incorporated by reference to the Form 8-K filed on August 3, 2005.
- 3.3 Restated and Amended Articles of Incorporation incorporated by reference to the Form 10-KSB filed on October 11, 2005.
- 3.4 Text of Amendments to the Amended and Restated By-Laws of the Company, incorporated by reference to the Form 8-K filed on February 7, 2007.
- 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 January 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 August 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 by 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 Management Associates Corporation, incorporated by reference to the Form SB-2 filed on November 10, 2005.
- 10.3 Royalty Agreement of Invention and Patent Application, dated July 12, 1999 between Lane A. Bray and IsoRay LLC, incorporated by reference to the Form SB-2 filed on November 10, 2005.
- 10.4 Intentionally Omitted.
- 10.5 Section 510(k) Clearance from the Food and Drug Administration to market Lawrence CSERION Model CS-1, dated March 28, 2003, incorporated by reference to the Form SB-2 filed on November 10, 2005.
- 10.6 Intentionally Omitted.
- 10.7 Intentionally Omitted.
- 10.8 Intentionally Omitted.
- 10.9 Intentionally Omitted.
- 10.10 Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Sealed Source, dated September 17, 2004, incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.
- 10.11 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.

Edgar Filing: IsoRay, Inc. - Form 10-K

- 10.18 State of Washington Radioactive Materials License dated October 6, 2005, incorporated by reference to the Form SB-2 filed on November 10, 2005.
- 10.19 Express Pricing Agreement Number 219889, dated October 5, 2005 between FedEx and IsoRay Medical, Inc., incorporated by reference to the Form 10-QSB filed on November 21, 2005.

Edgar Filing: IsoRay, Inc. - Form 10-K

- 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 reference to the Form SB-2/A2 filed on April 27, 2006 (confidential treatment requested for redacted portions).
- 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-K filed on March 24, 2006 (confidential treatment requested for redacted portions).
- 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 Form 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 Fund Committee, incorporated by reference to the Form 8-K filed on June 21, 2006.
- 10.32 Commercial Security Agreement, dated June 15, 2006, by and between IsoRay Medical, Inc. and the Hanford Area Economic Investment Fund Committee, incorporated by reference to the Form 8-K filed on June 21, 2006.
- 10.33 Common Stock and Warrant Purchase Agreement among IsoRay, Inc. and the other signatories thereto, dated August 9, 2006, incorporated by reference to the Form 8-K filed on August 18, 2006.
- 10.34 Intentionally Omitted.
- 10.35 Form of Officer and Director Indemnification Agreement, incorporated by reference to the Form SB-2 Post Effective Amendment No. 2 filed on October 13, 2006.
- 10.36 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 to the Form 8-K filed on March 23, 2007.
- 10.39 Form of Common Stock Purchase Warrant dated March 21, 2007, incorporated by reference to the Form 8-K filed on March 23, 2007.
- 10.40 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 by 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-K filed on December 12, 2008 (confidential treatment requested for redacted portions).
- 10.50



Edgar Filing: IsoRay, Inc. - Form 10-K

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).

## Edgar Filing: IsoRay, Inc. - Form 10-K

- 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 Intentionally Omitted.
- 10.53 Intentionally Omitted.
- 10.54 Distributor Agreement, dated effective November 10, 2009, by and between IsoRay Medical, Inc. and Inter V Medical, Inc., incorporated by reference to the Form 8-K filed on November 18, 2009 (confidential treatment requested for redacted portions).
- 10.55 Distribution Agreement, dated effective November 15, 2009, by and between IsoRay Medical, Inc. and Oncura, Inc., incorporated by reference to the Form 8-K filed on December 3, 2009 (confidential treatment requested for redacted portions).
- 10.56 Contract, dated December 1, 2009, by and between IsoRay Medical, Inc. and UralDial LLC, incorporated by reference to the Form 8-K filed on December 7, 2009 (confidential treatment requested for redacted portions).
- 10.57 Sales Agreement between IsoRay, Inc. and C. K. Cooper & Company, Inc., dated April 22, 2010, incorporated by reference to the Form 8-K filed on April 23, 2010.
- 10.58 Consulting and Severance Agreement dated January 12, 2010 between IsoRay, Inc. and Lori Woods, incorporated by reference to the Form 10-Q filed on May 12, 2010.
- 10.59 License Agreement, dated effective June 14, 2010, by and between IsoRay Medical, Inc. and Hologic Inc., incorporated by reference to the Form 8-K filed on June 23, 2010 (confidential treatment requested for redacted portions).
- 10.60 Amendment, dated July 29, 2010, of the Sales Agreement between IsoRay, Inc. and C. K. Cooper & Company, Inc., dated April 22, 2010, incorporated by reference to the Form 8-K filed on July 30, 2010.
- 10.61 Loan Covenant Waiver Letter dated September 23, 2010 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 April 23, 2010, the Company filed a Current Report on Form 8-K announcing its entry into a Sales Agreement with C.K Cooper and Company, Inc to offer and sell from time to time as the Company's agent, up to \$4 million of shares of the Company's common stock, par value \$0.001 per share.

On May 12, 2010, the Company filed a Current Report on Form 8-K announcing its financial results for the quarter ended March 31, 2010.

On June 23, 2010, the Company filed a Current Report on Form 8-K announcing that its wholly owned subsidiary IsoRay Medical, Inc. entered into a License Agreement with Hologic Inc.

On July 30, 2010, the Company filed a Current Report on Form 8-K announcing that the Company entered into an amendment to the Sales Agreement between the Company and C.K. Cooper & Company, Inc. dated April 22, 2010. The purpose of the Amendment is to extend the term of the offering of shares pursuant to the Sales Agreement

until December 31, 2010.

62

---

IsoRay, Inc.  
Index to Financial Statements

	Page
Report of Independent Registered Public Accounting Firm	F-2
Financial Statements:	
Consolidated Balance Sheets as of June 30, 2010 and 2009	F-3
Consolidated Statements of Operations for the years ended June 30, 2010 and 2009	F-4
Consolidated Statement of Changes in Shareholders' Equity for the years ended June 30, 2010 and 2009	F-5
Consolidated Statements of Cash Flows for the years ended June 30, 2010 and 2009	F-6
Notes to Consolidated Financial Statements	F-7

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, 2010 and 2009, 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, 2010 and 2009, 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 23, 2010

IsoRay, Inc and Subsidiaries  
Consolidated Balance Sheets

	June 30, 2010	June 30, 2009
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 1,678,869	\$ 2,990,744
Short-term investments	-	1,679,820
Accounts receivable, net of allowance for doubtful accounts of \$36,390 and \$86,931, respectively	896,266	746,568
Inventory	681,677	789,246
Prepaid expenses and other current assets	259,975	151,077
<b>Total current assets</b>	<b>3,516,787</b>	<b>6,357,455</b>
Fixed assets, net of depreciation and amortization	3,959,983	4,891,484
Deferred financing costs, net of accumulated amortization	13,277	28,186
Restricted cash	180,154	178,615
Other assets, net of accumulated amortization	272,594	285,826
<b>Total assets</b>	<b>\$ 7,942,795</b>	<b>\$ 11,741,566</b>
<b>Liabilities and shareholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 404,401	\$ 416,993
Accrued protocol expense	242,029	221,888
Accrued radioactive waste disposal	60,060	60,000
Accrued payroll and related taxes	186,513	103,887
Accrued vacation	68,525	84,817
Notes payable, due within one year	49,445	161,437
<b>Total current liabilities</b>	<b>1,010,973</b>	<b>1,049,022</b>
Notes payable, due after one year	130,550	176,023
Asset retirement obligation, non-current	605,391	553,471
<b>Total liabilities</b>	<b>1,746,914</b>	<b>1,778,516</b>
Commitments and contingencies (Note 18)		
<b>Shareholders' equity:</b>		
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
	23,049	22,942

Edgar Filing: IsoRay, Inc. - Form 10-K

Common stock, \$.001 par value; 194,000,000 shares authorized; 23,048,754 and 22,942,088 shares issued and outstanding

Treasury stock, at cost 13,200 shares	(8,390)	(8,390)
Additional paid-in capital	48,084,783	47,818,203
Accumulated deficit	(41,903,620)	(37,869,764)
<b>Total shareholders' equity</b>	<b>6,195,881</b>	<b>9,963,050</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 7,942,795</b>	<b>\$ 11,741,566</b>

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

F-3

---

IsoRay, Inc and Subsidiaries  
Consolidated Statements of Operations

	June 30, 2010	June 30, 2009
Product sales	\$ 5,286,084	\$ 5,417,815
Cost of product sales	4,560,287	5,771,147
Gross income / (loss)	725,797	(353,332)
Operating expenses:		
Research and development	340,959	958,665
Sales and marketing	1,953,598	2,365,973
General and administrative	2,440,140	2,792,611
Total operating expenses	4,734,697	6,117,249
Operating loss	(4,008,900)	(6,470,581)
Non-operating income (expense):		
Interest income	11,433	111,047
Gain on fair value of short-term investments	-	274,000
Financing and interest expense	(36,389)	(75,307)
Non-operating income / (expense), net	(24,956)	309,740
Net loss	(4,033,856)	(6,160,841)
Preferred stock dividends	(10,632)	(10,632)
Net loss applicable to common shareholders	\$ (4,044,488)	\$ (6,171,473)
Basic and diluted loss per share	\$ (0.18)	\$ (0.27)
Weighted average shares used in computing net loss per share:		
Basic and diluted	22,960,421	22,942,088

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



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

	Series B Preferred		Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Preferred Stock Shares	Amount	Shares	Amount	Shares	Amount			
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 (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
Issuance of common stock pursuant to exercise of options			106,666	107			30,226		30,333
Payment of dividend to Preferred shareholders							(36,679)		(36,679)
Share-based compensation							273,033		273,033
Net loss								(4,033,856)	(4,033,856)
Balances at June 30, 2010	59,065	\$ 59	23,048,754	\$ 23,049	13,200	\$ (8,390)	\$ 48,084,783	\$ (41,903,620)	\$ 6,195,881

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

IsoRay, Inc and Subsidiaries  
Consolidated Statements of Cash Flows

	June 30, 2010	June 30, 2009
<b>Cash flows from operating activities:</b>		
Net loss	\$ (4,033,856)	\$ (6,160,841)
<b>Adjustments to reconcile net loss to net cash used by operating activities:</b>		
Depreciation and amortization of fixed assets	953,243	1,206,935
Impairment of IBt license	-	425,434
Write-off of certain foreign patents and trademarks	-	85,818
Amortization of deferred financing and other assets	43,637	79,563
(Gain) loss on fair value of short-term investments	-	(274,000)
Accretion of asset retirement obligation	51,920	47,466
Share-based compensation	273,033	353,696
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable, net	(149,698)	269,927
Inventory	107,569	110,718
Prepaid expenses, other current assets and other assets	(6,194)	114,777
Accounts payable and accrued expenses	(12,593)	(258,408)
Accrued protocol expense	20,141	161,888
Accrued radioactive waste disposal	60	44,000
Accrued payroll and related taxes	82,627	(118,145)
Accrued vacation	(16,292)	(37,764)
<b>Net cash used by operating activities</b>	<b>(2,686,403)</b>	<b>(3,948,936)</b>
<b>Cash flows from investing activities:</b>		
Purchases of fixed assets	(21,742)	(57,778)
Additions to licenses and other assets	(11,721)	(37,773)
Change in restricted cash	(1,539)	(2,763)
Purchase of short-term investments	-	(1,679,820)
Proceeds from the sale or maturity of short-term investments	1,679,820	4,000,000
<b>Net cash provided by investing activities</b>	<b>1,644,818</b>	<b>2,221,866</b>
<b>Cash flows from financing activities:</b>		
Principal payments on notes payable	(157,465)	(71,924)
Principal payments on capital lease obligations	-	(25,560)
Preferred dividends paid	(36,679)	-
Proceeds from cash sales of common stock, pursuant to exercise of options	30,333	-
Cash payment on stock offering costs	(106,479)	-
Repurchase of Company common stock	-	(4,735)
<b>Net cash used by financing activities</b>	<b>(270,290)</b>	<b>(102,219)</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(1,311,875)</b>	<b>(1,829,289)</b>
<b>Cash and cash equivalents, beginning of year</b>	<b>2,990,744</b>	<b>4,820,033</b>

Cash and cash equivalents, end of year	\$ 1,678,869	\$ 2,990,744
Supplemental disclosures of cash flow information:		
Cash paid for interest	\$ 18,698	\$ 38,752

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

F-6

---

IsoRay, Inc.  
Notes to Consolidated Financial Statements  
For the years ended June 30, 2010 and 2009

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 planned to 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 to be other than temporary are recorded in the Consolidated Statements of Operations.

Fair Value of Financial Instruments

Effective July 1, 2008, the Company implemented ASC Topic 820, Fair Value Measurements and Disclosures. ASC Topic 820 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 permitted one-year deferral permitted 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, intangible asset impairment testing and initial recognition of asset retirement obligations for which fair value is used. The Company did not experience any significant impact to our consolidated financial statements when we implemented ASC Topic 820 for these assets and liabilities.

F-7

---

ASC Topic 820 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.

There were no financial assets or liabilities at June 30, 2010.

Also effective July 1, 2008, the Company utilized the guidance contained in ASC Topic 820 regarding 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. Accordingly, the adoption of this 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.

#### 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 experience 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 treated as 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 net realizable value of each asset to determine whether there is an impairment in value which has occurred, and there is a need for any asset impairment write-down.



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

#### Deferred Financing Costs

Financing costs related to the acquisition of debt are deferred and amortized over the term of the related debt using the effective interest method. Deferred financing costs include the fair value of common shares issued to certain shareholders for their guarantee of certain Company debt (see Note 10). The value of the shares issued was the estimated market price of the shares as of the date of issuance. Amortization of deferred financing costs, totaling \$14,909 and \$37,035 for the years ended June 30, 2010 and 2009, respectively, is included in financing and interest expense on the consolidated statements of operations.

#### Licenses

Amortization of licenses is computed using the straight-line method over the estimated economic useful lives of the assets. Amortization of licenses was \$11,867 and \$30,067 for the years ended June 30, 2010 and 2009, respectively. Based on the licenses recorded at June 30, 2010, 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: \$11,721 for 2011, \$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 related impairments are recognized when the expected future operating cash flows to be derived from such assets are less than their carrying value.

Amortization of other assets was \$16,861 and \$11,315 for the years ended June 30, 2010 and 2009, respectively. Based on the patents and other intangible assets recorded in other assets at June 30, 2010, 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: \$15,139 for 2011 through 2015, and \$142,629 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 an equivalent amount is capitalized to property and equipment. The initial recorded obligation is discounted using the Company's credit-adjusted risk-free rate 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 leased assets.

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





During the years ended June 30, 2010 and 2009, the asset retirement obligations changed as follows:

	2010	2009
Beginning balance	\$ 553,471	\$ 506,005
Accretion of discount	51,920	47,466
Ending balance	\$ 605,391	\$ 553,471

Because the Company does not expect to incur any expenses related to its asset retirement obligations in fiscal year 2011, the entire balance as of June 30, 2010 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.

At June 30, 2009, the Company's financial assets, composed of short-term investments, were reported at fair value using Level 1 inputs. There were no financial assets or liabilities at June 30, 2010.

#### Revenue Recognition

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, 2010 and 2009 was derived primarily from sales of the Proxcelan Cs-131 brachytherapy seed, which is used in the treatment of cancer. The Company recognizes revenue once the product has been shipped to the customer. Prepayments, if any, received from customers prior to the time that products are shipped are recorded as deferred revenue. In these cases, when the related products are shipped, the amount recorded as deferred revenue is 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.

#### 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 product 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 to 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.

F-10

---

### Advertising and Marketing Costs

Advertising costs are expensed as incurred except for the cost of tradeshow and related marketing materials which are deferred until the tradeshow occurs. Advertising and marketing costs expensed (including tradeshow) were \$292,727 and \$376,319 for the years ended June 30, 2010 and 2009, respectively. Marketing costs of \$8,900 and \$5,800 were included in prepaid expenses at June 30, 2010 and 2009 respectively.

### Legal Contingencies

In the ordinary course of business, the Company is involved in legal proceedings involving contractual and employment relationships, product liability claims, patent rights, environmental matters, and a variety of other matters. The Company is also subject to various local, state, and federal environmental regulations and laws due to the isotopes used to produce the Company's product. As part of normal operations, amounts are expended to ensure that the Company is in compliance with these laws and regulations. While there have been no reportable incidents or compliance issues, the Company believes that if it relocates its current production facilities then certain decommissioning expenses will be incurred and has recorded an asset retirement obligation for these expenses.

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

### Income Taxes

Income taxes are accounted for under the liability method. Under this method, the Company provides deferred income taxes for temporary differences that will result in taxable or deductible amounts in future years based on the reporting of certain costs in different periods for financial statement and income tax purposes. This method also requires the recognition of future tax benefits such as net operating loss carry-forwards, 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. Management has determined that the Company, its subsidiary, and its predecessors are subject to examination of their 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 or interest, penalties will be charged to other operating expense and interest will be charged to interest expense.

### 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, including 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, 2010 and 2009 are as follows:

Edgar Filing: IsoRay, Inc. - Form 10-K

	2010	2009
Preferred stock	59,065	59,065
Common stock warrants	3,165,768	3,216,644
Common stock options	2,274,706	2,708,166
Total potential dilutive securities	5,499,539	5,983,875

F-11

---

### Subsequent Events

Effective April 1, 2009, the Company adopted ASC 855, 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 non-recognized 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 2010 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 including the allowance for doubtful accounts receivable; net realizable value of the enriched barium inventory; the estimated useful lives used in calculating depreciation and amortization on the Company's fixed assets, patents, trademarks and other assets; estimated amount and fair value of the asset retirement obligation related to the Company's production facilities; and inputs used in the calculation of expense related to share-based compensation including volatility, estimated lives and forfeiture rates of options granted.. Accordingly, actual results could differ from those estimates and affect the amounts reported in the financial statements.

### Impact of Recently Issued Accounting Pronouncements

On July 1, 2009, the Company adopted new accounting provisions which establishes the FASB Accounting Standards Codification™ (ASC or the Codification) as the single official source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with generally accepted accounting principles (GAAP) other than rules and interpretive releases issued by the Securities and Exchange Commission. The Codification reorganized the literature and changed the naming mechanism by which topics are referenced. The Codification became effective for interim and annual periods ending after September 15, 2009. The Company's accounting policies and amounts presented in the financial statements were not impacted by this change.

On July 1, 2009, the Company adopted new accounting provisions which were delayed from the effective date of fair value accounting for one year for certain nonfinancial assets and nonfinancial liabilities, excluding those that are recognized or disclosed in financial statements at fair value on a recurring basis (that is, at least annually). For purposes of applying the new provisions, nonfinancial assets and nonfinancial liabilities include all assets and liabilities other than those meeting the definition of a financial asset or a financial liability. The Company had previously adopted new standards for fair value accounting on July 1, 2008. The adoption of these new provisions did not have a material effect on the Company but will affect future calculations of asset retirement obligations and long-lived asset impairment.

On July 1, 2009, the Company adopted new accounting provisions for business combinations and for non-controlling interests. The new business combination provisions require an acquirer to measure the identifiable assets acquired, the liabilities assumed and any non-controlling interest in the acquiree at their fair values on the acquisition date, with goodwill being the excess value over the net identifiable assets acquired. In addition, the new provisions require that a non-controlling interest in a subsidiary be reported as equity in the consolidated financial statements. The calculation of earnings per share will continue to be based on income amounts attributable to the parent. The adoption of these

statements did not have a material effect on the Company's financial statements.

F-12

---

In January 2010, the Company adopted ASU No. 2010-06, “Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements,” which amends ASC 820. This new accounting guidance requires expanded fair value measurement disclosures in quarterly and annual financial statements. The new guidance clarifies existing disclosure requirements for the Level 2 and Level 3 fair value measurement. Additionally, the new guidance also requires details of significant transfers of assets between Level 1 and Level 2 fair value measurement categories, including the reasons for such transfers, as well as gross presentation of activity within the Level 3 fair value measurement category. ASU No. 2010-06 is effective for the Company on January 1, 2010, except for the gross presentation of Level 3 activity, which is effective January 1, 2011. Adoption of ASU No. 2010-06 did not impact the results of operations, financial position or cash flows of the Company.

On February 24, 2010, the Company adopted ASU No. 2010-09, “Subsequent Events (Topic 855): Amendments to Certain Recognition and Disclosure Requirements” which amends FASB ASC 855, “Subsequent Events.” According to this standard, SEC filers are no longer required to disclose the date through which subsequent events have been evaluated in originally issued and revised financial statements. ASU No. 2010-09 was effective immediately and the Company adopted these new requirements on February 24, 2010.

In April 2010, the Company adopted ASU 2010-12, “Income Taxes (Topic 740): Accounting for Certain Tax Effects of the 2010 Health Care Reform Acts.” After consultation with the FASB, the SEC stated that it “would not object to a registrant incorporating the effects of the Health Care and Education Reconciliation Act of 2010 when accounting for the Patient Protection and Affordable Care Act.” The Company does not expect the provisions of ASU 2010-12 to have a material impact on the financial position, results of operations or cash flows of the Company.

### 3. Short-Term Investments

The Company’s short-term investments consisted of the following at June 30, 2010 and 2009:

	2010	2009
Certificates of deposit	\$ —	\$ 1,679,820
Municipal debt securities	—	—
	\$ —	\$ 1,679,820

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, 2010 and 2009:

	2010	2009
Raw materials	\$ 546,080	\$ 609,932
Work in process	130,840	155,827
Finished goods	4,757	23,487
	\$ 681,677	\$ 789,246

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, 2010 and 2009.

F-13

---

## 5. Prepaid Expenses

Prepaid expenses consisted of the following at June 30, 2010 and 2009:

	2010	2009
Prepaid insurance	6,757	30,625
Prepaid rent	–	24,402
Other prepaid expenses	222,527	61,900
Other current assets	30,691	34,150
	\$ 259,975	\$ 151,077

## 6. Fixed Assets

Fixed assets consisted of the following at June 30, 2010 and 2009:

	2010	2009
Production equipment	\$ 3,114,894	\$ 3,089,793
Office equipment	169,890	169,890
Furniture and fixtures	148,265	148,265
Leasehold improvements (a)	4,643,965	4,643,965
Construction in progress	–	3,359
	8,077,014	8,055,272
Less accumulated depreciation	(4,117,031)	(3,163,788)
	\$ 3,959,983	\$ 4,891,484

(a) Balance includes asset retirement addition of \$473,096 as of June 30, 2010 and 2009.

Depreciation and amortization expense related to fixed assets totaled \$953,243 and \$1,206,935 for 2010 and 2009, respectively.

## 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 its present cost structure and projected market and manufacturing strategies (see Note 18 for further details on the IBt license agreement). Management 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 its manufacturing process to incorporate the technology and as there can be no assurance that physicians would accept this new technology without extensive education and marketing costs. However, the Company does not intend to cancel the license agreement at this time; therefore, the license was reviewed in terms of an “abandoned asset” for purposes of ASC Topic 360, Property, Plant and Equipment. 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 one remaining three-year lease option period. The end date of the current lease including the one three-year renewal option is April 2016. 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, 2010 and 2009 was \$1,539 and \$2,763, respectively. These funds will be used to settle a portion of the Company's remaining asset retirement obligations (Note 2).

F-14

---

## 9. Other Assets

Other assets, net of accumulated amortization, consisted of the following at June 30, 2010 and 2009:

	2010	2009
Deferred charges	\$ 54,270	\$ 52,363
Patents and trademarks, net of accumulated amortization of \$40,383 and \$25,244	218,324	233,463
	\$ 272,594	\$ 285,826

Deferred charges consist of prepaid legal fees for patents and trademarks which have not yet been obtained, and prepayments and deposits on fixed assets and contracts. Amortization of patents and trademarks was \$15,139 and \$6,150 for the years ended June 30, 2010 and 2009, respectively.

During fiscal year 2009, the Company performed a review of its prepaid legal fees for patents and trademarks that had not been obtained and were classified within other assets on the consolidated balance sheet. The focus of the review was on 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 decision resulted in the write-off of \$85,818 of other patent and trademark application fees relating to other countries during fiscal year 2009 that was included in research and development expenses.

## 10. Notes Payable

Notes payable consisted of the following at June 30, 2010 and 2009:

	2010	2009
Benton-Franklin Economic Development District (BFEDD) note payable (a)	\$ –	\$ 115,898
Hanford Area Economic Investment Fund Committee (HAEIFC) note payable (b)	179,995	221,562
	179,995	337,460
Less amounts due within one year	(49,445)	(161,437)
Amounts due after one year	\$ 130,550	\$ 176,023

(a) The note payable to BFEDD, which was collateralized by substantially all of the Company's assets, and guaranteed by certain shareholders, was executed pursuant to a Development Loan Agreement. The note contained certain restrictive covenants relating to: working capital; levels of long-term debt to equity; incurrence of additional indebtedness; payment of compensation to officers and directors; and payment of dividends. The note was payable in monthly installments including interest at 8.0% per annum with a final balloon payment made in November 2009.

(b) In June 2006, the Company entered into a note payable with HAEIFC, which is collateralized by receivables, inventory, equipment, and certain life insurance policies. The 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 note contains certain restrictive covenants relating to: financial ratios; payment of compensation to officers and

directors; and payment of dividends and employee bonuses. The note accrues interest at 9% and is payable in monthly installments with the final installment due in September 2013. At June 30, 2010, 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, 2011.

Principal maturities on notes payable as of June 30, 2010 are as follows:

Year ending June 30,	
2011	\$ 49,445
2012	54,059
2013	54,154
2014	17,337
2015	—
Thereafter	—
	\$ 179,995

#### 11. Share-Based Compensation

The following table presents the share-based compensation expense recognized in accordance with ASC Topic 718, Stock Compensation, during the years ended June 30, 2010 and 2009:

	Year ended June 30,	
	2010	2009
Cost of product sales	\$ 22,615	\$ 17,619
Research and development	5,206	23,450
Sales and marketing expenses	74,745	148,407
General and administrative expenses	170,467	164,220
Total share-based compensation	\$ 273,033	\$ 353,696

The total value of the stock options awards is expensed ratably over the vesting period of the employees receiving the awards. As of June 30, 2010, total unrecognized compensation cost related to stock-based options and awards was \$248,492 and the related weighted-average period over which it is expected to be recognized is approximately 1.36 years.

The Company currently provides share-based compensation under three equity incentive plans approved by the Board of Directors: the Amended and Restated 2005 Stock Option Plan (the Option Plan), the Amended and Restated 2005 Employee Stock Option Plan (the Employee Plan), and the 2006 Director Stock Option Plan (the Director Plan). The Option Plan allows the Board of Directors to grant options to purchase up to 1,800,000 shares of common stock to directors, officers, key employees and service providers of the Company. The Employee Plan allows the Board of Directors to grant options to purchase up to 2,000,000 shares of common stock to officers and key employees of the Company. The Director Plan allows the Board of Directors to grant options to purchase up to 1,000,000 shares of common stock to directors of the Company. Options granted under all of the plans have a ten year maximum term, an exercise price equal to at least the fair market value of the Company's common stock on the date of the grant, and varying vesting periods as determined by the Board. For stock options with graded vesting terms, the Company recognizes compensation cost on a straight-line basis over the requisite service period for the entire award.

A summary of stock option information within the Company's share-based compensation plans for the year ended June 30, 2010 is as follows:

	Shares	Price (a)	Life (b)	Value (c)
Outstanding at June 30, 2010	2,274,706	\$ 1.96	7.21	\$ 924,174
Vested and expected to vest at June 30, 2010	2,180,616	\$ 2.02	7.14	\$ 843,714

Vested and exercisable at June 30, 2010            1,730,961    \$            2.36            6.75    \$            512,760

F-16

---

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

The aggregate intrinsic value of options exercised during the years ended June 30, 2010 and 2009 was \$109,700 and \$0, respectively. The Company's current policy is to issue new shares to satisfy option exercises.

The weighted average fair value of stock option awards granted and the key assumptions used in the Black-Scholes valuation model to calculate the fair value are as follows for the year ended June 30, 2010 and 2009:

	Years ended June 30,	
	2010	2009
Weighted average fair value of options granted	\$ 1.26	\$ 0.21
Key assumptions used in determining fair value:		
Weighted average risk-free interest rate	1.90%	2.55%
Weighted average life of the option (in years)	4.78	4.66
Weighted average historical stock price volatility	168.79%	128.23%
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 \$.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, 2010 and 2009, there were no Series A preferred shares outstanding.

F-17

---

## 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 December 11, 2009, the Board of Directors declared a dividend on the Series B Preferred Stock of all outstanding and cumulative dividends through December 31, 2009. The total dividends of \$36,679 were paid as of December 31, 2009. The Company anticipates paying any cash dividends on the Series B Preferred Stock on or before December 31, 2010 if required to comply with the Form S-3 eligibility requirements. At June 30, 2010, there were 59,065 Series B preferred shares outstanding and cumulative dividends in arrears were \$5,316.

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, 2010 and 2009.

## 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:

	2010		2009	
	Warrants	Price (a)	Warrants	Price (a)
Beginning balance outstanding	3,216,644	\$ 5.55	3,245,082	\$ 5.50
Cancelled/expired	(56,876)	0.70	(28,438)	0.70
Granted	6,000	1.18	—	—
Ending balance outstanding	3,165,768	\$ 5.62	3,216,644	\$ 5.55

(a) Weighted average exercise price per share.

On January 13, 2010, 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 warrants on January 8, 2008 for a one-year period beyond their initial expiration dates of October 2007 to February 2008 and again extended the these warrants on January 13, 2010 for an additional one-year period beyond their extended expiration dates of October 2009 to February 2010. Based on these extensions, the warrants will now expire between October 2010 and February 2011. No other terms or conditions of the warrants were changed. The change in expiration dates affected 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 1,286,219 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 similar 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 ASC Topic 815, Derivatives and Hedging, these warrants were equity instruments rather than derivatives.

On June 8, 2010, the Board of Directors issued 6,000 warrants to Schultz Public Relations at an exercise price of \$1.18 and a five year term. These warrants were issued for services rendered by Schultz Public Relations at an exercise price equal to the closing price of the Company's common stock on the grant date.

The following table summarizes additional information about the Company's common warrants outstanding as of June 30, 2010:

Number of Warrants	Range of Exercise Prices	Expiration Date
53,000	\$6.00	October 2010
162,500	\$6.00	November 2010
909,469	\$6.00	December 2010
700,250	\$6.00	January 2011
276,923	\$6.00 to \$6.50	February 2011
826,100	\$5.00	March 2011
206,526	\$4.40	March 2012
6,000	\$1.18	June 2015
25,000	\$2.00	July 2015
<b>3,165,768</b>		

#### Common Stock Options

A summary of the Company's stock option activity and related information for the years ended June 30, 2010 and 2009 is as follows:

	2010		2009	
	Shares	Price (a)	Shares	Price (a)
Beginning balance outstanding	2,708,166	\$ 2.08	2,803,393	\$ 2.62
Granted (b)	290,000	1.34	993,900	0.31
Cancelled	(616,794)	2.48	(1,089,127)	1.86
Exercised	106,666	0.28	—	—
Ending balance outstanding	2,274,706	\$ 1.96	2,708,166	\$ 2.08
Exercisable at end of year	1,730,961	\$ 2.36	1,837,018	\$ 2.74

(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, 2010:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Shares	Price (a)	Life (b)	Shares	Price (a)
\$0.26	670,600	\$ 0.26	8.91 yrs	356,856	\$ 0.26
\$0.65 to \$0.84	150,000	0.76	7.87 yrs	103,333	0.75
\$1.00 to \$1.43	372,802	1.33	7.76 yrs	189,486	1.30
\$1.96 to \$2.00	300,000	2.00	5.08 yrs	300,000	2.00
\$3.10 to \$3.11	349,534	3.11	6.16 yrs	349,534	3.11
\$3.50 to \$3.85	150,000	3.70	6.00 yrs	150,000	3.70
\$4.14 to \$4.15	128,270	4.15	5.65 yrs	128,270	4.15
\$4.40	33,500	4.40	6.68 yrs	33,500	4.40
\$5.50 to \$6.50	120,000	6.29	5.71 yrs	120,000	6.29
<b>Total options</b>	<b>2,274,706</b>			<b>1,730,961</b>	

(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 no shares of its common stock during the year ended June 30, 2010 and 8,200 shares of its common stock for \$4,735 during the year ended June 30, 2009.

#### 14. Income Taxes

The Company recorded no income tax provision or benefit for the years ended June 30, 2010 and 2009.

The Company had a net deferred tax asset of approximately \$12.6 and \$11.3 million as of June 30, 2010 and 2009, respectively. The deferred tax asset has arisen principally from net operating loss carry-forwards, share-based compensation, depreciation and amortization, and accrued compensation. The deferred tax asset was calculated based on the currently enacted 34% statutory income tax rate. Since management of the Company cannot determine if it is more likely than not that the Company will realize the benefit of its net deferred tax asset, a valuation allowance equal to the full amount of the net deferred tax asset at June 30, 2010 and 2009 has been established.

At June 30, 2010, the Company had tax basis net operating loss carry-forwards of approximately \$32.4 million available to offset future regular taxable income. These net operating loss carry-forwards expire through 2030.

#### 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.

F-20

---

In December 2008 and December 2009, the Company negotiated contracts to purchase Cs-131 from UralDial. Under the contracts, the Company will purchase Cs-131 from UralDial rather than purchasing Cs-131 directly from the two suppliers in Russia that the Company had purchased from previously. UralDial will provide Cs-131 from at least two Russian facilities subject to scheduled maintenance shutdowns of the facilities from time to time. The recent contract entered into in December 2009 continues to stabilize the supply arrangements for the 12 months beginning in December 2009 and ending in December 2010.

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 approval to sell Cs-131 seeds in Russia. However, the economic downturn in Russia has slowed the Company's market penetration efforts. There was no revenue from this agreement in the years ended June 30, 2009 or June 30, 2010.

#### 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. In fiscal year 2010, this agreement generated approximately \$22,000 in sales.

#### 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 2010 and 2009, the Company recorded royalty expenses of \$23,041 and \$20,063, 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.

F-21

---



## Operating Lease Agreements

The Company leases office and laboratory space and production and office equipment under non-cancelable 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 was renewed in May 2010 for occupancy of 15,932 square feet of manufacturing and office space with a three year term expiring on April 30, 2013, plus an option to renew for one additional three-year term, and monthly rent of approximately \$23,100, subject to annual increases based on the Consumer Price Index, plus monthly janitorial expenses of approximately \$400. Due to the severe economic penalty associated with not exercising the one lease renewal option remaining, the Company currently intends to exercise the one remaining three-year renewal option at the appropriate time in the lease. The amount of space returned to the landlord during the lease renewal process in fiscal year 2010 was sufficient to offset the annual cost of living increase prescribed in the lease agreement.

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

Year ending June 30,	
2011	\$ 296,157
2012	284,915
2013	282,390
2014	282,390
2015	282,390
Thereafter	235,324
	\$ 1,663,566

Rental expense amounted to \$306,212 and \$325,496 for the years ended June 30, 2010 and 2009, 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 and providing the Company with access to IBt's Ink Jet production process and its proprietary polymer seed technology for use in brachytherapy procedures using Cs-131. 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 eliminated 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. No agreement has been reached on these terms and there is no assurance that the parties will consummate an agreement pursuant to such terms. The Company does not 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 investments, and accounts receivable.

The Company's cash and cash equivalents are maintained with high-quality financial institutions. The accounts are guaranteed by the Federal Deposit Insurance Corporation (FDIC) up to \$250,000. At June 30, 2010, cash balances uninsured by the FDIC totaled approximately \$1.4 million.

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

The Company's accounts receivable result from credit sales to customers. The Company had three customers whose sales were greater than 10% for the year ended June 30, 2010 and two customers whose sales were greater than 10% for the year ended 2009. These customers represented a combined 33.1% and 35.0% of the Company's total revenues for the years ended June 30, 2010 and 2009, respectively. These same customers accounted for a combined 42.3% and 39.6% of the Company's net accounts receivable balance at June 30, 2010 and 2009, 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 28, 2010

ISORAY, INC., a Minnesota corporation

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

By /s/ Brien L. Ragle  
Brien L. Ragle, Controller, Principal Financial and  
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 28, 2010

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

/s/ Brien L. Ragle  
Brien L. Ragle, Controller,  
Principal Financial and  
Accounting Officer

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

/s/ Thomas LaVoy  
Thomas LaVoy, Director

/s/ Albert Smith  
Albert Smith, Director