IsoRay, Inc.
Form 10-K
September 28, 2012

United States Securities and Exchange Commission

Washington, d.c. 20549

FORM 10-K

x Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended June 30, 2012

or

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

Commission File No. 001-33407

**IsoRay, Inc**

(Exact name of registrant as specified in its charter)

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

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 MKT)

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 25, 2012 |
|---|---|
| Common stock, $0.001 par value | 34,584,868 |

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

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 x

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer ¨ Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act): Yes ¨ 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 – $19,348,762 as of December 31, 2011.

Documents incorporated by reference – none.

**ISORAY, INC.**

**Table of Contents**

**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 27 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. The public can also obtain copies by visiting the SEC's Public Reference Room at 100 F Street NE, Washington, DC 20549 or by calling the SEC at 1-800-SEC-0330. In addition, the Company makes copies of its annual and quarterly reports available to the public at its website at www.isoray.com. Information on this website is not a part of this Report.

**Business Operations**

**Overview**

In 2003, IsoRay obtained clearance from the FDA for treatment for all solid tumor applications using Cesium-131. Such applications include prostate cancer; ocular melanoma; head, neck and lung tumors; breast cancer; liver cancer; brain cancer; colorectal cancer; gynecological cancer; esophageal cancer; and pancreatic cancer. The brachytherapy seed form of Cesium-131 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.

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) used in the prostate, 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 to16 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.

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, however, the market for the treatment has been limited generating a minimal amount of revenue for the Company. The Company continues to make the treatment available to interested physicians and medical facilities. 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. Upon obtaining clearance in August 2009 from the FDA to permit loading Cesium-131 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. During the fiscal year ended June 30, 2010, the Company expanded the number of areas of the body in which the Proxcelan Cs-131 seeds were being utilized for treatment by adding lung cancer in August 2009, colorectal cancer in October 2009, and chest wall cancer in December 2009. During the fiscal year ended June 30, 2012, the Company

continued the expansion in the number of areas of the body in which the Proxcelan Cs-131 seeds were being utilized through the addition of the treatment of brain cancer in September 2010 and the treatment of gynecological cancer in December 2010. While the Company has the delivery systems for breast cancer, management focused in fiscal 2012 on obtaining its regulatory clearances and final research and development of its GliaSite® Radiation Therapy System and marketing its brain and lung products. The GliaSite® Radiation Therapy System is the world's only system that enables doctors to use liquid radiation in areas where the cancer is most likely to remain after brain surgery and tumor removal. While management has not identified new opportunities to expand treatment to other sites in the body, it continues to investigate opportunities with interested physicians and medical facilities. Management is now focusing primarily on the brain and lung markets while the Company is researching delivery systems other than those historically used by the Company.

In March 2011, the Company received clearance to commercially deliver Proxcelan™ Cesium-131 brachytherapy seeds that are preloaded into bioabsorbable braided strands into Europe. This clearance permits the product to be commercially distributed for treatment of lung, head and neck tumors as well as tumors in other organs in Europe.

In August 2011, IsoRay Medical received clearance from the FDA for its premarket notification (510(k)) for the GliaSite® radiation therapy system. The GliaSite® Radiation Therapy System is the only FDA-cleared balloon catheter device used in the treatment of brain cancer.

In May 2012, IsoRay Medical received a CE mark for the GliaSite® Radiation Therapy System which states that the Company conforms with the product requirements of the European Council Directive 93/42/EEC. The CE mark allows the GliaSite® Radiation Therapy System to be sold in 31 European countries and to be marketed in the European Free Trade Associate member states and the European Union.

**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. The American Cancer Society estimates there will be about 241,740 new cases of prostate cancer diagnosed and an estimated 28,170 deaths associated with the disease in the United States in 2012. 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 distant sites, such as bone).

Prostate cancer accounts for about 9% of cancer related deaths in men. Prostate cancer incidence and mortality increase with age. The 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.

*Incidence of Lung Cancer*

An estimated 226,160 new cases of lung cancer are expected in 2012, accounting for 14% 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 160,340 deaths, accounting for about 28% of all cancer deaths, are expected to occur in 2012. (American Cancer Society 2012) This exceeds the combined number of deaths from the next three leading causes of cancer (breast, prostate, and colon cancers). Lung cancer 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. Tobacco smoke causes nearly 8 out of 10 cases of lung cancer. The longer a person has been smoking and the more packs a day smoked, the greater the risk. Other risk factors include occupational or environmental exposure to secondhand smoke, radon, asbestos (particularly among smokers), certain minerals and metals (chromium, cadmium, arsenic), some organic chemicals, radiation, air pollution, family history of lung cancer, certain vitamins (beta carotene supplements), radiation treatment to the lungs to treat other cancers, 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, 2012)

The 5-year survival rate is 49% for cases detected when the disease is still localized. (American Cancer Society, 2012)

*Incidence of Brain Cancer*

An estimated 22,910 new cases of malignant tumors of the brain or spinal cord are expected in 2012. The chances of a person developing a malignant tumor of the brain or spinal cord are approximately 1%. The estimated deaths related to malignant tumors in the brain or spinal cord is 13,700 (approximately 7,720 men and 5,980 women). (American Cancer Society, 2012).

The risk factors for developing malignant brain or spinal cord tumors are radiation exposure (i.e. most commonly some form of radiation therapy to the head to treat other cancers), family history, genetic disorders, people with a history of tuberous sclerosis, and immune system disorders. (American Cancer Society, 2012)

The survival rates for brain cancer depend on the type of malignant brain or spinal cord tumor and the age of the person. The survival rates for the most common types of malignant brain and spinal cord tumors are as follows: low-grade (diffuse) astrocytoma between 40 and 59%, anaplastic astrocytoma between 8 and 49%, glioblastoma between 3 and 16%, oligodendroglioma between 65 and 85%, anaplastic oligodendroglioma between 33 and 66%, and ependymoma/anaplastic ependymoma between 84 and 91%. (American Cancer Society, 2012)

*Incidence of Head and Neck Cancers*

An estimated 52,610 new cases of head and neck cancer are expected to be diagnosed in the United States in 2012 including 26,740 cases of oral cavity cancer (i.e. tongue, mouth and other oral cavity), 12,360 cases of laryngeal cancer, and 13,510 cases of pharyngeal cancer. (American Cancer Society, 2012)

Symptoms may include a sore in the throat or mouth that bleeds easily and does not heal, a lump or thickening in the cheek, ear pain, a neck mass, coughing up blood, and a red or white patch that persists on the gums, tongue, tonsil, or lining of the mouth. Difficulties in chewing, swallowing, or moving the tongue or jaw are often late symptoms. (American Cancer Society, 2012)

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 100 times the risk of these cancers to those individuals who both smoke and drink heavily. Human Papilloma Virus (HPV) infection is associated with certain types of oropharyngeal cancer. (American Cancer Society, 2012)

*Incidence of Ocular Melanoma*

The American Cancer Society estimates that 2,610 new cases of cancers of the eye and orbit (primarily melanoma) will be diagnosed in 2012 and about 270 deaths from cancer of the eye will occur in 2012 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, 2012)

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, 2012)

*Incidence of Colorectal Cancer*

An estimated 143,460 new cases of colorectal cancer are expected in the United States in 2012 including 103,170 new cases of colon cancer and 40,290 new cases of rectal cancer. (American Cancer Society, 2012)

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.

Risk factors related to colorectal cancers are classified in two groups, those that patients cannot control and those that patients can control. The risk of developing colorectal cancer in a lifetime is about 1 in 20 or approximately 5.1%. Colorectal cancer is the second leading cancer death in the Unites States when men and women are combined and third for both men and women when they are considered separately. (American Cancer Society, 2012)

Known risk factors that patients cannot control include age (9 out of 10 people with colorectal cancer are older than 50), personal history of colorectal polyps or colorectal cancer, personal history of inflammatory bowel disease, personal history of Type 2 diabetes, family history of colorectal cancer, certain family syndromes (i.e. gene changes or inherited mutations) and racial or ethnic background. (American Cancer Society, 2012)

Known risk factors that are linked to things patients can control include certain types of diets (those high in red and processed meats can increase risk while a diet high in fruits and vegetables have been linked to a lower risk), lack of exercise, being overweight, smoking, and alcohol use.. (American Cancer Society, 2012)

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. (American Cancer Society, 2012)

*Prostate Cancer Treatment Options and Protocol*

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 treatment altogether at a higher rate 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 (Grimm, et al., British Journal of Urology International, Vol. 109 (Suppl 1), 2012; Merrick, et al., Techniques in Urology, Vol. 7, 2001; Potters, et al., Journal of Urology, May 2005; Sharkey, et al., Current Urology Reports, 2002).

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.* Radical prostatectomy is surgery that is done to cure prostate cancer. It is used most often if it looks like the cancer has not spread outside of the gland. In this operation, a surgeon will remove the entire prostate gland plus some of the tissue around it, including the seminal vesicles.

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. (American Cancer Society, 2012)

*Primary External Beam Radiation Therapy (EBRT).* 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 four to six weeks. Today, standard EBRT is used much less often than in the past. Side effects of EBRT can include bowel problems, bladder problems, incontinence, impotence, fatigue, lymphedema, and urethral stricture. (American Cancer Society, 2012)

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*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 but requires daily doses over a period of seven to nine weeks to deliver the total dose of radiation prescribed to kill the tumor. 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 is generally more expensive than other common treatment modalities. (American Cancer Society, 2012)

*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. (American Cancer Society, 2012) Management estimates that at least 25% 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. (American Cancer Society, 2012)

*Cryosurgery.* Cryosurgery is sometimes used to treat prostate cancer by freezing the cells with cold metal probes. It is used only for prostate cancer that has not spread, but may not be a good option for men with large prostate glands. The probes are placed through cuts (incisions) between the anus and the scrotum. Cold gases are then passed through the probes, which creates ice balls that destroy the prostate gland. There are benefits and drawbacks to cryosurgery. Because it is less invasive than radical surgery, there is less loss of blood, a shorter hospital stay, shorter recovery time, and less pain. But freezing can damage nerves near the prostate, which results in a high rate of impotence. For this reason, most doctors do not include cryosurgery among the first options they recommend for treating prostate cancer. (American Cancer Society, 2012)

*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 and can be given by mouth or by an injection into the vein Additionally, vaccine treatment can be used to extend the life of a patient with advanced prostate cancer that does not respond to hormone therapy 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, fatigue, weight gain, depression, osteoporosis, anemia, 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, diarrhea, mouth sores, and lowered resistance to infection, and fatigue. The vaccine treatment is milder than the hormone or chemotherapy treatments but some common side effects include fever, back and joint pain, chills, fatigue, and headaches. (American Cancer Society, 2012)

*Watchful Waiting and Active Surveillance.* Because prostate cancer often grows very slowly, some men (especially those who are older or who have other major health problems) may never need treatment for their cancer. Instead, their doctor may suggest approaches called watchful waiting (also called expectant management or active surveillance). Until recently, watchful waiting meant waiting until the cancer was causing symptoms before starting any treatment. Now, it is more common to watch the patient closely with a combination of regular PSA tests, rectal exams, and ultrasounds to see if the cancer is growing. If the cancer does seem to be growing or getting worse, the doctor may suggest starting treatment.

Not all experts agree how often testing should occur for active surveillance. There is also debate about when is the best time to start treatment. Still, some early studies have shown that among men who choose active surveillance, those who elect not to be treated do as well as those who decide to start treatment right away. Active surveillance may be a good choice if the cancer is not causing any symptoms, is likely to grow slowly, and is small and contained in one place in the prostate. If the patient is young, healthy, and has a cancer that is growing fast, active surveillance may not provide adequate protection from the cancer spreading to other parts of the body. Some men choose watchful waiting because, in their view, the side effects of strong treatment outweigh the benefits. Others are willing to accept the possible side effects of active treatments in order to try to remove or destroy the cancer. (American Cancer Society, 2012)

*Comparing Cesium-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 historically clinical studies of brachytherapy have focused primarily on results from brachytherapy with I-125 and Pd-103, management believes that these data are also relevant for brachytherapy with Cesium-131. In fact, it appears that Cesium-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 was postulated that Cesium-131, with the shortest available half-life for a low-dose rate therapy isotope, should 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).

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A Cesium-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 Cesium-131, (2) to summarize the side effect profile of Cesium-131 treatment, and (3) to track biochemical (PSA) results in patients following Cesium-131 therapy.

The investigators responsible for conducting the study concluded based on the results of the monotherapy trial that Cesium-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:

1. 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 Cesium-131 study as compared to published reports of patients who underwent I-125 brachytherapy. Especially notable is the steep drop in the Cesium-131 group scores (purple line) as opposed to the more gradual drop in the I-125 group scores (green and blue lines).

2. 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.).

3. An abstract detailing the outcomes of the 100 patient multi-institutional Cesium-131 study was prepared for the 32nd Annual Meeting of the American Brachytherapy Society (April 2011), Notably, the PSA control rate at 5 years was reported as 98%. No other study of brachytherapy utilizing the competing isotopes Iodine-125 and Palladium-103 has reported five year rates as high as 98%.

Several other series have been reported that have compared dosimetric parameters (indicators of dose) among Cesium-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).

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The prospective randomized monotherapy trial headed by Dr. Brian Moran of The Chicago Prostate Cancer Center issued four year PSA results at the 32nd Annual Meeting of the American Brachytherapy Society (April 2011). Dr. Moran's study revealed a 95% PSA control rate at four years. When considering risk grouping, the four year results were 98% for low risk, 91% for intermediate risk, and 88% for high risk patients. (Moran B, et al. Cesium-131 Prostate Brachytherapy:PSA outcome. International Journal of Radiation Oncology Biology Physics 2010, 78(2 Suppl):S375.)

As of April 2011, the 100 subject clinical study of Cesium-131 for the treatment of localized prostate cancer (originally enrolled beginning in 2005) had reached the point where a five-year result had been obtained and reported in a supplement to the official journal of the American Brachytherapy Society (*Brachytherapy*) documenting the scientific program for the Society's 2011 annual meeting. In this supplement, Drs. Bradley Prestidge, William Bice, Brian Moran and colleagues reported the five-year Freedom from Biochemical Failure (FFBF – a measure of success using prostate specific antigen) for the 100 patients as 97.9%.

Although several long-term reports exist in the literature describing outcomes for Iodine-125 and Palladium-103 as highly effective, there has been no report made at five years after the introduction of these isotopes detailing a FFBF as high as 97.9%. Management believes that these impressive results at the five-year mark should create further scientific support for Cesium-131 as an attractive treatment for localized prostate cancer, overcoming at least some of the initial resistance predicated on the lack of long-term follow-up reports.

A combined therapy study incorporating a slightly attenuated dose of Cesium-131 in concert with intensity modulated radiation therapy (IMRT) has now opened and is enrolling intermediate and high risk patients. The investigators for this study are hoping to evaluate the hypothesis that a successful combination therapy can be developed that controls locally advanced prostate cancer while providing a very low rate of urinary side effects.

During the Summer of 2011, the Company launched an online data collection system that enables standardized data collection for the Company's studies providing participating institutions and physicians with a means to share data and increase collaboration.

**Non-Prostate Product Offerings**

*Lung Cancer Treatment Options*

Lung cancer has historically been treated utilizing surgery, radiation therapy, other local treatments, chemotherapy and targeted therapy. More than one kind of treatment may be used, depending on the stage of the patient's cancer and other factors. (American Cancer Society, 2012)

1. Surgery generally involves removing a portion of the lung (lobectomy, segmentectomy, and wedge resection), the entire lung (pneumonectomy) or a sleeve resection for some cancers in the large airways in the lungs. The type of operation depends on the size and place of the tumor and on how well the patient's lungs are working.

2. Chemotherapy may be used either as a primary treatment or a secondary treatment depending on the type and stage of the lung cancer. Chemotherapy ("chemo") is treatment with anti-cancer drugs that are put into a vein or taken by mouth. These drugs enter the bloodstream and go throughout the body, making this treatment useful for cancer that has spread (metastasized) to organs beyond the lung. Doctors give chemo in cycles, with each round of treatment followed by a break to allow the body time to recover. Chemo cycles generally last about 3 to 4 weeks, and the treatments may involve 4 to 6 cycles. Chemotherapy may be used as a main treatment for more advanced cancers or for some people who are not healthy enough for surgery, to try to shrink a tumor before surgery, or after surgery to try to kill any cancer cells that may have been left behind.

3. Radiation treatment is the use of high-energy rays to kill cancer cells or shrink tumors. The radiation may come from outside the body (external radiation) or from radioactive seeds placed into or next to the tumor (brachytherapy).

· External Beam Radiation Therapy (EBRT) is focused from outside the body on the cancer. This is the type of radiation most often used to treat a primary lung cancer or its spread to other organs. Most often, radiation treatments are given 5 days a week for 4 to 7 weeks. Newer types of this type of radiation are called 3D-CRT, IMRT, and stereotactic body radiation therapy.

· High Dose Rate (HDR) Brachytherapy (internal radiation therapy) is used most often to shrink tumors to relieve symptoms caused by lung cancer that is blocking an airway and is increasingly being used as part of a larger treatment plan to attempt to cure the cancer. For this type of treatment, the doctor places a small source of radioactive material (often in the form of seeds or pellets) right into the cancer or into the airway next to the cancer. This is usually done through a bronchoscope, and is increasingly done during surgery. The pellets are usually removed after a short time.

· Low Dose Rate Brachytherapy is most often used in combination with surgery in early stage (stages I and II) non-smcall cell lung cancers for patients who cannot tolerate the surgical removal of a large portion of their lung. In these cases, a smaller amount of lung tissue than usual is removed at surgery, at which time a number of permanently implanted seeds are placed into the cut tissue. The addition of brachytherapy to surgery in these patients has been shown to reduce the recurrence of cancer regrowth (Colonias A, et al. International Journal of Radiation Oncology, Biology, Physics Volume 79, p 105-9, 2011.)

The Company believes that Cesium-131, with its shorter half-life and high energy (faster rate of decay), is better suited for treating lung cancer in Stages I and II than I-125. The bioabsorbable mesh used in this procedure to apply the Proxcelan Cesium-131 brachytherapy seeds generally dissolves after about 45 days. Cesium-131 delivers 90% of its dose in 33 days and is therefore well-suited to use with bioabsorbable mesh. A report was published in November 2011 describing the more technical details applicable to Cesium-131 implants (Parashar B, et al. Cesium-131 Permanent Seed Brachytherapy: Dosimetric Evaluation and Radiation Exposure to Surgeons, Radiation Oncology, and Staff. Brachytherapy 10(6):508-513, 2011).

The Company has also initiated an anticipated 100 patient study of Cesium-131 brachytherapy in the treatment of early stage non-small cell lung cancer ("NSCLC"). In this study, patients who are poor candidates for large surgical resections undergo a limited ("sub-lobar") resection followed by Cesium-131 mesh brachytherapy. This study is based upon strong evidence collected to date suggesting that Iodine-125 mesh implants utilized in a similar way assist the limited surgical resection in achieving high rates of local cancer control. (see Colonias, et al. Mature Follow-up for High Risk Stage I Non-Small Cell Lung Carcinoma Treated with Sub-lobar Resection and Intra-operative Iodine-125 Brachytherapy. International Journal of Radiation Oncology Biology Physics 2011, 79(1), 105.) As of June 30, 2012, 19 patients were enrolled in the study and entered in the study database.

*Brain Cancer Treatment Options*

Most brain and spinal cord tumors are difficult to treat and require several specialists. The most common forms of treatment are resection at surgery (craniotomy); radiation therapy including external beam radiation therapy (EBRT), three-dimensional conformal radiation therapy (3D-CRT), intensity modulated radiation therapy (IMRT), conformal proton beam radiation therapy, stereotactic radiosurgery, and brachytherapy; chemotherapy; targeted therapy; and other types of drugs (including corticosteroids, and anti-seizure drugs). (American Cancer Society, 2012)

Treatment is determined based on an individual's specific type of tumor as well as other factors and in many cases the best course of action is a combination of the treatment options discussed above.

In June 2012, the world's first Cesium-131 brachytherapy seed sutured mesh was implanted on a patient suffering from a recurring meningioma tumor. The treatment of brain cancer now has several several delivery methods, including the implantable mesh described above, single seed applications, implantable strands, and by implantable device, including GliaSite® radiation therapy system, the world's only liquid radiation balloon catheter device used in the treatment of brain cancer. The Company recently started a program permitting hospitals to inventory limited amounts of Cesium-131 so it is available immediately when needed.

*Head and Neck Cancer Treatment Options*

Most head and neck cancers historically have 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)). (American Cancer Society, 2012)

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. (American Cancer Society, 2012)

Management believes Proxcelan Cesium-131 continues to represent an improved approach to brachytherapy treatment of specific head and neck cancers.

*Ocular Melanoma Treatment Options*

In addition to brachytherapy to treat ocular melanoma, other treatment options include surgery, external beam radiation, chemotherapy, 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, 2012)

Brachytherapy has become the most commonly used radiation treatment for most eye melanomas. Studies have shown that in many cases it is as effective as surgery (enucleation). Brachytherapy using Cesium-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 in a procedure that lasts 1 to 2 hours and are usually kept in place for 4 to 7 days. The patient generally stays in the hospital until the plaque is removed from the eye following a procedure that takes less than 1 hour. Brachytherapy cures approximately 9 out of 10 small tumors and can preserve the vision of some patients. (American Cancer Society, 2012). Management believes that while Cesium-131 provides the best treatment alternative, it is at a disadvantage to I-125 or Pd-103 as a result of Cs-131's short half life as most patients are unwilling to wait for it to be ordered when

the other products are often available immediately.

*Colorectal Treatment Options*

Colorectal cancer has historically been treated using surgery, radiation therapy, chemotherapy, immunotherapy and other targeted therapies. (American Cancer Society, 2012)

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, 2012)

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, 2012)

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.

**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

Cesium-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 Cesium-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

Cesium-131 has the shortest half-life of any commonly used prostate brachytherapy isotope at 9.7 days. Cesium-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 Cesium-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 Cesium-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 Cesium-131 over the other commonly used prostate brachytherapy isotopes. (Musmacher JS, et al. Dosimetric Comparison of

Cesium-131 and Palladium-103 for Permanent Prostate Brachytherapy. *Int. J. Radiation Oncology Biol. Phys.* 2007:69(3)S730-1.) (Yaparpalvi R, et al. Is Cs-131 or I-125 or Pd-103 the "Ideal" Isotope for Prostate Boost Brachytherapy? A Dosimetric View Point. *Int. J. Radiation Oncology Biol. Phys.* 2007:69(3)S677-8) (Sutlief S, et al. Cs-131 Prostate Brachytherapy and Treatment Plan Parameters. *Medical Physics* 2007:34(6)2431.) (Yang R, et al. Dosimetric Comparison of Permanent Prostate Brachytherapy Plans Utilizing Cs-131, I-125 and Pd-103 Seeds. *Medical 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.) Recent studies with longer follow-up periods continue to support the resolution of urinary and rectal side effects in a rapid fashion following treatment with Cesium-131. (Jacobs B, et al. Acute lower urinary tract symptoms after prostate brachytherapy with Cesium-131. *Urology.* 2010:76(5)1143.)

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Higher Biologically Effective Dose

Another benefit to the short half-life of Cesium-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 Cesium-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. Cesium-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 Cesium-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.)

Studies with longer follow-up periods report very high rates of PSA control post-treatment with Cesium-131 for prostate cancer: 95% at four years (Moran B, et al. Cesium-131 Prostate Brachytherapy: PSA Outcome. *Int. J. Radiation Oncology Biol Phys.* 2010:78(3S1) S375.) and 98% at five years. (Prestidge B. et al. Five-year biochemical control following Cesium-131 Permanent Prostate Brachytherapy in a Multi-Institutional Trial. *Brachytherapy* 10(3S1)S27.)

**Our Strategy**

The key elements of IsoRay's strategy for fiscal year 2013 include:

*Continue to introduce the Proxcelan Cesium-131 brachytherapy seed into the U.S. market for prostate cancer.* Prostate cancer treatment represents the original and core business for the Company's Proxcelan Cesium-131 product. With five year data relating to biochemical (PSA) control of prostate cancer now presented to the prostate cancer field, IsoRay intends to continue to seek to increase the number of centers using Proxcelan through its direct sales force. Because intermediate- to long-term follow-up data is required to convince clinicians and patients to consider any particular therapy for localized prostate cancer, the availability of five-year data with Proxcelan in the treatment of

prostate cancer represents a significant milestone. IsoRay hopes to capture much of the incremental market growth if and when seed implant brachytherapy recovers market share from other treatments, take market share from existing competitors, and expand the use of Cesium-131 as a dual therapy option where it has experienced success.

*Return the 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 Company received a CE Mark in May 2012 allowing distribution in 31 countries. Management believes that the European market will be receptive to this treatment option and the product faces fewer regulatory hurdles there than in the United States. The Company intends to distribute the product from Germany (the location of the first European sale in July 2012) to other European nations. The Company plans to contact previous users of the product and leverage significant existing clinical data related to the safety and effectiveness of the GliaSite system in order to restore GliaSite as a strong treatment option for patients suffering from primary and metastatic brain cancers.

*Increase utilization of Cesium-131 in treatment of other solid tumor applications such as lung, head and neck, 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 and bioabsorbable braided strands attached to bioabsorbable mesh. 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 has successfully launched an initiative to market its Proxcelan™ source in bioabsorbable carrier material as a lung cancer treatment. It has begun selling its lung cancer treatment product but has not been in the market long enough to determine long-term success of the product. 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.

*Support clinical research and sustained product development*. The publication and presentation of speculative and real-world data contribute to the acceptability of Cesium-131 in the oncologic marketplace, and discussion in the medico-scientific community of established and novel Cesium-131 applications is considered a prerequisite to expansion into untapped markets. The Company plans to structure and support clinical studies on the therapeutic benefits of Cesium-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. The Company has deployed a secure, regulatory environment compliant, online information system capable of large usable databases to participating investigators.

Over fiscal year 2012, five presentations were accepted by the joint American Brachytherapy Society / European Society for Radiotherapy and Oncology meeting describing Cesium-131 treatment of prostate, lung and head and neck cancers. Two presentations were accepted by the annual meeting of the American Society for Radiation Oncology (ASTRO), and five publications were abstracted to the MEDLINE database of citations of the medical literature that reported topics related to Cesium-131 as a cancer treatment. The Company will continue to seek to increase the number of reports made to society meetings and the peer reviewed literature in order to seek to enhance the standing of its products in the scientific community.

*Maintain ISO 13485:2003 certification.* In August 2008, the Company obtained its initial ISO 13485:2003 certification. This permitted the Company to register its products in Europe in 2008 and in Canada and Russia during fiscal year 2009. The ISO 13485:2003 certification demonstrates that the Company is in compliance with this internationally recognized quality standard and the initial certification was valid for a three year period. In June 2012, the Company received a recertification to ISO 13485:2003 for an additional three year period, which was affirmed through a surveillance audit in July 2012. This recertification was important as it allows the Company to continue to register its products in foreign markets that utilize this certification as part of their medical device approval processes.

**Products**

*Proxcelan Cesium-131*

IsoRay markets the Proxcelan Cesium-131 brachytherapy seed for the treatment of prostate cancer; lung cancer; ocular melanoma; head and neck cancers; colorectal cancer, brain cancer; and gynecological cancer. The Company intends to market Cesium-131 for the treatment of other malignant diseases as opportunities are identified in the future through the use of existing proven technologies that have received FDA-clearance. The strategy of utilizing existing FDA-cleared technologies reduces the time and cost required to develop new applications of Cesium-131 and deliver

them to market.

*Competitive Advantages of Proxcelan Cesium-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 Cesium-131 will increase industry growth and facilitate meaningful penetration into the treatment of other forms of cancer such as lung cancer.

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

**Cesium-131 Manufacturing Process and Suppliers**

*Product Overview*

Cesium-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 Cesium-131. The radioactive isotope Cesium-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 (Cesium-131).

To produce the Proxcelan seed, the purified Cesium-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 Cesium-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 Cesium-131. 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 cost effectively produce commercially viable quantities of Cesium-131 and Ba-131.

The Company has identified key reactor facilities in the U.S. and Russia that are capable of meeting these requirements. In order to maintain a stable supply and pricing of Cesium-131 from UralDial, LLC (a Russian LLC), IsoRay renewed its supply agreement with the supplier during 2011 to provide Cesium-131 isotope from Russia to the Company's facility in Richland, WA through December 31, 2012. UralDial historically has obtained Cesium-131 from two reactors but as one of the reactors has been shut down now relies on one reactor.

The Company also receives irradiated barium from the MURR reactor located in the United States. For the fiscal year ended June 30, 2012, we obtained more Cesium from our domestic source than ever before as approximately sixty

percent (60%) of our Cesium-131 was supplied by our Russian supplier and forty percent (40%) from domestic sources. The Company has demonstrated the capability to expand Cesium-131 manufacturing capability at the MURR reactor in a cost effective manner to meet the current needs of the Company, however, the Company will continue to obtain Cesium-131 from its foreign supplier to mitigate the risk of reliance on a single source.

In recent years, management believed that failure to obtain deliveries of Cesium-131 from its Russian supplier (UralDial, LLC) would have a material adverse effect on seed production. Management now believes that its existing domestic supplier can meet the Company's isotope requirements for the near future and can mitigate the periodic required shutdowns at the foreign facility. In the fiscal year 2012, the Company continued testing the production capabilities of the reactor at the MURR facility to determine whether it could produce an increased quantity of isotope in a cost effective manner. These tests focused on areas within the reactor previously thought to be impracticable. This testing process validated management's belief that the MURR facility can be utilized to offset either a short-term or long term supply issue with isotope that meets or exceeds the purity levels that are specified for use in the Company's products. The Company has also identified other reactors that could provide irradiation services but until further testing is completed management is not certain whether they are adequate to meet the needs of the Company.

*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.

In June 2012, IsoRay completed a recertification to ISO13485:2003 audit by BSI (British Standards Institution) with no nonconformities. The Company is subject to a comprehensive audit every three years with a maintenance audit occurring in the other two years of the audit cycle. The completion of an audit without nonconformities confirms the Company’s commitment and success in achieving the standards of manufacturing and quality systems which allows the Company to continue to market products in Canada and Europe.

*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 Cesium-131 (from the international supplier's reactor), separation and purification of Cesium-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 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 Cesium-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.

To provide the Cesium-131 required by many patients for brain cancer, the Company recently instituted a program providing certain hospitals an inventory of Cesium-131 so that it is available when needed.

*Automated Manufacturing Process*

In fiscal 2011 and 2012, IsoRay pursued further automation identified by management to reduce cost and increase radiation safety while allowing an expansion of product loading configurations. In fiscal year 2013, the Company intends to 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.

*Pre-loading Services*

In addition to providing loose seeds to customers, most brachytherapy manufacturers offer their seed product to the end user packaged in various configurations provided in a sterile or non-sterile package depending on the customer's preference. These include:

§ *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 "carrier sleeve")
§ *Preloaded strands* (strands loaded into the needle)
§ *Pre-loaded braided strands (*seeds loaded into a flexible bioabsorbable strand)
§ *Pre-loaded braided strands attached to bioabsorbable mesh* (creates planar implants out of braided strands and bioabsorbable mesh)

In fiscal year 2012, the Company delivered approximately 50% of its Proxcelan seeds to customers configured in Mick cartridges, approximately 40% of the Proxcelan seed configured in both stranded and braided strand forms and the remaining 10% 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 93% of Mick cartridges in our own facility which in fiscal year 2012 accounted for approximately 56% of seeds sold. Approximately 33% of seeds sold are strand configurations including strands pre-loaded in needles and the remaining 11% of seeds are sold as loose seeds. 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, reduce isotope decay loss, control overall product quality and eliminate any concerns related to the handling of our product by a third party prior to receipt by the end user.

By providing custom packaging configurations that are produced by our personnel, we can enhance the overall control of the quality of our product while providing larger incremental margins to the Company through a decreased cost of loading seeds when compared to the cost of loading through third-party loading service. Using the loading services of the Company allows a larger percentage of the loading pricing premiums charged to our customers to be retained by the Company. The end users of these packaging options are willing to pay a premium for these loading services in lieu of loading seeds themselves because of the cost savings realized as the result of the risk reduction that occurs through eliminating the need for loose seed handling and loading requirements on-site by their staff, eliminating the need for additional staffing to sterilize seeds and needles after loading them, and eliminating the additional expense of assaying of the seeds.

With clearance from the FDA received in 2009 that allows 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 these seeds loaded into flexible braided strands and flexible braided strands attached to bioabsorbable mesh directly to our customers.

In fiscal year 2012, IsoRay was able to add the capability to CE mark the products which allows for shipment of seeds loaded into flexible braided strands and flexible strands attached to bioabsorbable mesh into the European Union.

**GliaSite® Radiation Therapy System**

IsoRay markets the GliaSite® Radiation Therapy System (RTS) for the treatment of brain cancer, i.e. primary and recurrent gliomas and metastic brain tumors. Specifically, the intended use of GliaSite® RTS is the management of surgically resectable brain tumors where adjuvant radiation therapy of the post-resection tissue bed is indicated.

*Product Overview*

GliaSite® RTS is the only FDA cleared balloon catheter device used in the treatment of brain cancer. The main components included in the GliaSite® RTS are the GliaSite Catheter Tray, Iotrex Radiotherapy Solution, GliaSite Access Tray and Iotrex Solidifier.

*Manufacturing Process and Key Suppliers*

The catheter tray includes a GliaSite® RTS catheter, two non-coring needles, and two right anchoring clips. On one end of the catheter subassembly is a balloon device which is later filled with Iotrex Radiotherapy Solution and on the other end is an infusion port which is attached to the skull and is punctured by a needle to get the solution to the balloon at the end of the catheter. The GliaSite catheter is available in 3 difference sizes, including 2, 3, and 4 cm. The appropriate size to be used is determined at time of implant by the physician to ensure adequate conformance of the resection cavity.

A dual balloon configuration is used to act as a primary and secondary reservoir for the Iotrex Radiotherapy solution within the resection cavity in the brain. The size of the balloon differs in accordance with the size of the catheter and with sizes ranging from 5 cc, 15 cc and 35 cc for a 2cm, 3cm and 4cm catheter, respectively. The balloon catheter is manufactured by Vesta and conforms to the applicable required IsoRay quality standards. In addition IsoRay ensures that testing is performed to ensure that the balloons are properly produced and will not leak.

The infusion port consists of a port body, reservoir base, and a self sealing septum. The infusion port is produced by Smith Medical and conforms to the applicable required IsoRay quality standards. It is attached to the catheter

subassembly and is bonded in place. It is designed to allow repeated punctures with a 20 gauge needle and the design prevents complete penetration of the reservoir with the needle.

The Iotrex Radiotherapy Solution is inserted in the balloon catheter through the infusion port using a needle. Iotrex is the radiation source with the GliaSite® catheter to deliver the intracranial radiation therapy. Iotrex is supplied in sterile unit dose vials with each containing 195 mCi at the time of calibration. The key suppliers of the Iotrex Radiotherapy Solution are Iso-Tex and Anazao. The typical treatment doses of Iotrex Radiotherapy Solution are 1 - 3 vials.

Other accessories sold and packaged with the GliaSite® catheter trays include Access Trays and Solidifier. These accessories assist in the delivery of the Iotrex and subsequent removal after completion of the radiotherapy treatment. Included in the Access tray package are infusion sets, syringe assemblies, safety lumen access supplies, gauze pads, etc. each of which assist in the surgical implant and removal of the GliaSite® device and are assembled at the IsoRay facility. The solidifier (IS 8000 Solidifier) is a product that solidifies liquid radioactive waste associated with the Iotrex. All accessories are obtained from distributors and are sterilized and tested by the Company to ensure compliance with quality standards.

From start to finish, including the creation of the GliaSite catheter subassemblies, the manufacture of the device takes approximately 4 weeks. The Company maintains on hand a number of subassemblies that reduce the manufacture time to 2 weeks, which includes sterilization of the final product. The subassemblies are maintained in a clean room facility and are not dated until the entire GliaSite medical device is Gamma sterilized. Management periodically evaluates the appropriate lot sizes in which to manufacture the GliaSite product to ensure that sterilization capacity is optimized, enough product is on hand to meet customer needs, and reduce the risk of expired product utilizing the history of prior GliaSite device manufacturers and sales forecasts.

*Quality Control*

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.

In June 2012, IsoRay completed an annual ISO13485:2003 audit from BSI (British Standards Institution) with no nonconformities. The Company is subject to an audit every three years with a maintenance audit every year. The successful audit, confirms the Company’s commitment and success in meeting the standards of manufacturing and quality systems that allows the Company to continue to market products in Canada and Europe.

*Order Processing*

IsoRay Medical requires hospitals to have 6 GliaSite catheters at time of surgical implant in the patient, which includes 2 catheters of each size. The facilities are encouraged to maintain an inventory of the 6 catheters on hand and to re-order after an implant to ensure that these levels are maintained. At the time of the surgical implant the catheter size is determined based on the size of the resection and an extra is on hand in the case of a failure with the implant of the first catheter.

The Company implements a just-in-time order process for the Iotrex radiotherapy solution. The Iodine-125 stock is ordered by the Company and drop shipped to Iso-Tex, the Company’s contracted manufacturer of Iotrex. The Iodine-125 is tested by Iso-Tex and if accepted is used to manufacture the Iotrex radiotherapy solution which has a 30 day shelf life once manufactured. Once manufacture is complete by Iso-Tex, testing is performed on the product and the test results are sent to IsoRay along with the batch record for review and acceptance. Iso-Tex then ships the vials of Iotrex to the radiopharmacies who then ship to the related facilities performing the implants.

Due to the lead time for obtaining and processing the Iodine-125 by Iotrex, the Company relies on sales forecasts and historical knowledge from prior manufacturers to estimate the proper inventory levels of catheters as well as Iotrex given the 1 year and 30 day shelf life respectably. Consequently, some portions of the product including the Iotrex or GliaSite device itself are lost through decay and are subsequently destroyed.

*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 Commitments and Contingencies note included in 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.

**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 Cesium-131 is available. The advantages associated with the higher energy and shorter half-life of the isotope are generally accepted within the scientific community and the Company intends to help educate potential patients about the clinical benefits from Cesium-131 for their brachytherapy seed treatment.

The market for treatments for localized prostate cancer treatment is very competitive and largely hinges upon the demonstration of long term follow-up data that has been presented to the prostate cancer treatment profession. Therefore, highly compelling technical arguments alone — absent published long term follow-up data – can fail to provide significant marketability, even for treatments that ultimately prove highly effective. The fact that Proxcelan Cesium-131 was introduced to the prostate cancer marketplace more than a decade after Iodine-125 and Palladium-103, and the resulting time for mature clinical data to be developed has proven an obstacle to widespread market acceptance. Management believes that the impressive results achieved for treatment with Cesium-131 at the five-year mark should create further scientific support for Cesium-131 as an attractive treatment for localized prostate cancer, overcoming at least some of the initial resistance predicated on the lack of long-term follow-up reports.

IsoRay has chosen to identify its proprietary Cesium-131 seed with the trademarked brand of "Proxcelan." Management is using this brand to differentiate Cesium-131 seeds from seeds using the other isotopes. We continue to target the competing isotope products of Iodine-125 and Palladium-103 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 Cesium-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. The Company's website www.isoray.com delivers the message that Cesium-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, physician/clinician resources, investor information, current events that representatives will attend, and contact information. IsoRay also maintains print and visual media (including physician brochures discussing the clinical advantages of Cesium-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);
- Congress of Neurological Surgeson (CNS);
- Society for Neuro-Oncology (SNO);
- American Association of Neurological Surgeons (AANS);
- American Association for Thoracic Surgery (AATS);
- 2012 Multidisciplinary Symposium on Thoracic Oncology; 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 Cesium-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 and www.proxcelan.com), patient advocacy efforts, informational patient brochures and DVDs with patient testimonials, patient focused informational website (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 on the benefits of Cesium-131.

The Company’s marketing plan with regard to non-prostate segments includes identifying and exhibiting at scientific meetings attended by specialty physicians who perform procedures related to Company’s product offerings; direct sales contact with such physicians (for example thoracic surgeons and neuro-surgeons); and the development and dissemination of training videos and other media that outline Company’s products. The Company also continues to work with its existing radiation oncology physician customers and to educate them as to additional or new Company products.

*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.

With respect to non-prostate applications, the Company targets neurosurgeons and thoracic surgeons in addition to radiation oncologists. After these decision makers determine to use the Company's radiation therapy, the Company then needs approval for the procedure from the medical physicists on staff. The sales cycle for non-prostate applications has proved a longer process than prostate and often takes nine months before the Company is licensed in a new hospital and can make its first sale.

IsoRay has a direct sales organization consisting of seven territorial sales managers to introduce Proxcelan Cesium-131 brachytherapy seeds to radiation oncologists and medical physicists for use in treating cancer throughout the body. All of the Company's sales force solicits potential specialist physicians in all areas of the body and none specialize solely in the prostate or other organs. This approach allows our sales representatives to call on a single location for the various specialties so that if a particular physician is unavailable they can contact those who are available resulting in a more efficient sales approach. Compensation paid to the sales force is uniform for sales made regardless of the organ treated.

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.

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 Cesium-131 brachytherapy seeds that permitted providers to report the use of Cesium-131 directly to payers. In July 2007, CMS established two separate Cesium-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, which since 2010 has provided 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 2013 but there is no assurance that this will occur. Private insurance companies have historically followed the CMS reimbursement policies. The Company expects that CMS will continue its annual review of payments provided as reimbursement for our various products and that CMS will continue to provide favorable reimbursement rates for our Cesium-131 brachytherapy seeds with a slight decrease in reimbursement from 2012 to 2013.

Unlike prostate brachytherapy implants, lung and brain procedures utilizing either seed brachytherapy or the GliaSite RTS are performed when the patient has been admitted to the hospital. In-patient procedures, as they are known, are covered by CMS which remits a set amount depending on the kind of surgery being performed and the status of the patient. Under this Diagnostic Related Group or “DRG” system, the hospital pays for all the items involved in the care of the patient excluding physician fees. The brachytherapy seeds or the GliaSite RTS in these in-patient cases are not paid for separately by CMS, but rather the hospital pays for the seeds out of the DRG payments from CMS. Because the Company's seeds may be more expensive than the cost incurred by a hospital for a competing treatment, this reimbursement method can sometimes result in greater difficulty convincing the hospitals to use the Company's products.

**Other Information**

*Customers*

The top five facilities or physician practices that utilize multiple surgical facilities at which procedures are performed account for approximately 48.43% of the total Company product sales for the twelve months ended June 30, 2012 include:

| | |
|---|---|
| El Camino, Los Gatos, & other facilities (Northern CA) (1) | 26.35% of revenue |
| University of Pittsburgh Medical Center | 6.73% of revenue |
| Biocompatibles, Inc | 6.12% of revenue |
| York Cancer Center | 5.01% of revenue |
| Sentara Healthcare | 4.22% of revenue |
| Total of top five facilities or physician practices | 48.43% of revenue |

(1) The single largest physician also serves as the Company's medical director. During the fiscal year ended June 30, 2012, this physician added additional physicians to his practice which is expected to reduce risk associated with seasonality.

The loss of either the single largest physician or a combination of the other significant physicians could have a material adverse effect on the Company's revenues, which would continue until the Company located new customers to replace them and there can be no assurance this would occur in a timely manner or at all.

*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 Cesium-131 developed by IsoRay employees. The Company is currently working on developing and patenting additional methods of deriving Cesium-131 and other isotopes.

There are specific conditions attached to the assignment of the Cesium-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 Cesium-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 2012 and 2011, the Company recorded royalty expense of $19,497 and $26,474, 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, 2012, IsoRay and its subsidiaries incurred approximately $1.5 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 Cesium-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 and in August 2009 for preloading flexible braided strands and bioabsorbable mesh.

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 Cesium-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 Cesium-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 its 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 13485:2003, 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 brachytherapy seeds are classified in Europe as an active implantable and are subject to the AIMDD and GliaSite RTS is an EU Class 3 device subject to the Medical Device Directive, (MDD). Compliance with the AIMDD, MDD, and obtaining a CE Mark involves being certified to ISO 13485:2003 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 13485:2003 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 13485:2003 inspections for Canadian registration. During fiscal year 2009, the Company received its certification to ISO 13485:2003 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 Cesium-131 brachytherapy seeds and the GliaSite® RTS constitute both medical devices and radioactive sealed sources and are subject to these regulations. The Company has received sealed source device approval from the State of Washington Department of Health for the GliaSite® RTS, components of which are manufactured at our Richland facility.

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.

In August 2011, IsoRay Medical received clearance from the FDA for its premarket notification (510(k)) for the GliaSite® radiation therapy system. The GliaSite® Radiation Therapy System is the only FDA-cleared balloon catheter device used in the treatment of brain cancer.

In April 2012, IsoRay Medical received a CE mark for the GliaSite® Radiation Therapy System which states that the Company conforms with the product requirements of the European Council Directive 93/42/EEC. The CE mark allows the GliaSite® Radiation Therapy System to be sold in 31 European countries and to be marketed in the European Free Trade Associate member states and the European Union.

*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 approximately forty-eight percent (48%) of the Company's business is dependent on five physicians, simultaneous vacations by these five physicians could cause significant drops in the Company's productivity during those reporting periods.

*Employees*

As of September 28, 2012, 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, accounting and administrative organizations. None of the Company's employees are represented by any collective bargaining unit. At June 30, 2012, the Company employed six direct sales people, which has increased to seven as of the date of this Report.

*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 Cesium-131 seed.

The Company's patented Cesium-131 separation process is likely to provide a sustainable competitive advantage. Production of Cesium-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 Cesium-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 Cesium-131, for use in their seeds. Best Medical received FDA 510(k) clearance to market a Cesium-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 Cesium-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 Cesium-131 seed.

The GliaSite RTS and the Company’s brachytherapy products used in non-prostate applications typically compete with external beam radiation therapy (EBRT), which can be provided as conventional or intensity modulated radiation therapy, or as stereotactic radiosurgery, a technique that delivers high doses of radiation to a target in a much fewer number of sessions than other forms of EBRT.

Manufacturers of EBRT equipment include Varian Medical Systems, Siemens Healthcare, Elekta AB, and Accuray Incorporated, among others. In the cases of lung and brain tumors (and other solid tumors), a surgeon will remove the tumor if it is medically prudent and this offers the patient some benefit in terms of controlling the growth of the cancer or its symptoms. In many cases, radiation therapy is added following the surgery; this is known as “adjuvant” radiation therapy. The Company believes that its form of adjuvant radiation therapy deployable in such cases offers advantages over external beam methods. However, external beam holds the vast majority of the market for adjuvant radiation therapy.

There are also various vaccines that are available for brain cancer but have not proven effective to date.

*Additional Growth Opportunities*

Management of the Company sees growth opportunities through sales from expansion into international markets and additional treatment for cancers other than prostate. The Company plans to continue to introduce Cesium-131 brachytherapy seed therapy for the treatment of prostate, lung and brain cancers 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/or distribution but has no distribution agreements or partnerships in place for brachytherapy seeds as of September 28, 2012. The Company does have a distribution agreement with a German distributor for its GliaSite® RTS.

Cesium-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 supplied Proxcelan™ Cesium-131 brachytherapy seeds for use in treating lung cancer; ocular melanoma; head and neck cancer; colorectal cancer; brain cancer; and gynecological cancer as of the date of this Report. Although it has clearance for breast cancer, management has determined not to focus on this application until it obtains greater market acceptance for its lung and brain applications. 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 Cesium-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 Cesium-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 , but it has not been approved by the FDA for use and there is no assurance that it will be approved.

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 GliaSite® RTS, 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 license agreement with Hologic Inc. aligns with the Company strategy to locate existing FDA-cleared technologies to provide new ways to treat other organs. The Company has obtained the intellectual property rights to manufacture the Iotrex solution (Iodine-125) for use in the GliaSite® radiation therapy system and has contracted with a company for the production of Iotrex and a radiopharmacy to handle the patient dosing of the solution for use in procedures. The Company negotiated a contract with a previous distributor of the GliaSite® RTS in the European Union for distribution rights to the system in Germany, Austria, Switzerland and Italy. The Company has modified the original FDA-cleared device and has received clearance from the FDA to market the product, with the modifications, which are designed to improve its performance and manufacturability, in the United States. The Company has obtained the intellectual property rights to manufacture the Iotrex solution (Iodine-125) for use in the GliaSite® RTS, and it has contracted with a company for the production of Iotrex and a radiopharmacy to handle the patient dosing of the solution for use in procedures. With receipt of a CE Mark for the GliaSite® RTS, the product may be sold in 31 European countries.

The Company developed a liquid Cesium-131 solution for use as an alternative brachytherapy radiation source in FDA cleared devices including for use in the GliaSite® radiation therapy system as either a substitute for the Iotrex solution or as a future alternative treatment option for physicians to utilize independently. Research and development was conducted during the year ended June 30, 2012 in preparation to seek regulatory approval of liquid Cesium-131 for use in combination with the GliaSite® RTS but there is no assurance approval will be obtained.

**ITEM 1A – RISK FACTORS**

*Risks Related to Our Industry and Operations*

*Our Revenues Depend Upon One Product.* With the exception of the GliaSite® radiation therapy system which the Company began selling in the 2012 fiscal year, our revenues depend solely upon the successful production, marketing, and sales of the Proxcelan Cesium-131 brachytherapy seed. The rate and level of market acceptance of this product varies 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 barium for Cesium-131 seed production; ability to produce sufficient quantities of Cesium-131; the ability of physicians to apply the correct dosage of seeds 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 primary 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 Dominant Product Is Primarily Used To Treat A Single Type Of Cancer.* Currently, the Proxcelan Cesium-131 seed is used almost exclusively for the treatment of prostate cancer (approximately eighty-six percent of our sales). We have been treating lung cancer which amounts to approximately 8% of our product sales and other cancers including head and neck; colorectal; gynecological and brain that combined constitute approximately 3% of our product sales. During the fiscal year 2012, the Company introduced the GliaSite Radiation Therapy System which contributed 3% of our product sales. Management believes the Proxcelan Cesium-131 seed will continue to be used to treat other types of cancers as the Company identifies existing delivery systems that 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*. The Company has generated material operating losses since inception. We expect to continue to experience significant net operating losses. Due to our recent successful capital raise, previous capital investments and substantial cost reductions, management believes cash and cash equivalents on hand at June 30, 2012 will be sufficient to meet our anticipated cash requirements for operations, debt service, and capital expenditure requirements through at least the next fiscal year. Management now estimates that operational cashflow breakeven will be achieved at approximately $750,000 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 significantly reduce or 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 2012, approximately sixty percent (60%) of our Cesium-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 Cesium-131 in Russia could increase from current pricing. Our current contract with UralDial terminates on December 31, 2012 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. Management is evaluating other reactors that meet current specifications to yield Cesium-131 of the purity that the Company requires for use in its products but thus far has only confirmed such availability from MURR.

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 Cesium-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, other than MURR, 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.

Virtually all of the components used in the production of the GliaSite RTS are from single sources. We do not have formal written agreements with those suppliers. Any interruption or delay in the supply of these components could harm our business as the cost and / or time required to meet the regulatory requirements of the Food and Drug Administration for the United States and our notified body for our CE mark British Standards Institute in the European Union may be prohibitive.

*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 year 2012 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 the number of prostate procedures performed.

In 2010, the American Cancer Society revised their advice regarding PSA testing warning that regular testing for prostate cancer is of questionable value and can do men more harm than good.

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 2012, each of these factors continued 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 2013.

*Future Production Increases Will Depend on Our Ability to Acquire Larger Quantities of Cesium-131 and Hire More Employees.* IsoRay currently obtains Cesium-131 through its contract with UralDial and through reactor irradiation of natural barium and subsequent separation of Cesium-131 from the irradiated barium targets. The amount of Cesium-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, 2012) with UralDial in Russia to provide Cesium-131 in quantities sufficient to supply a significant percentage of future demand for this isotope. As the result of 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 Cesium-131 and which will increase the production yield per irradiated target. Although the UralDial agreement provides for supplying Cesium-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 Cesium-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 2010, the Company entered into a new agreement which has been renewed twice through December 31, 2012, with UralDial to purchase Cesium-131 directly from UralDial 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 Cesium-131 from Russian sources. Although UralDial agreed to maintain at least two Russian sources of its Cesium-131, it now only has one reactor, through which it is able to obtain Cesium-131. Through the UralDial agreement we have obtained set pricing for our Russian Cesium-131 through the end of 2012. There can be no guarantee that UralDial will always be able to supply us with sufficient Cesium-131 or will renew our existing contract on favorable terms in December 2012, which could be due in part to risks associated with foreign operations and beyond either our or UralDial's control. If we were unable to obtain supplies of isotopes from Russia in the future, our overall supply of Cesium-131 could be reduced significantly unless we have a source of enriched barium for utilization in domestic reactors beyond the quantity that we already own. The Company has tested the utilization of other reflector regions within the reactor at MURR and found that Cesium-131 can be produced in economically viable quantities at a viable price. These reflector regions that were tested are areas located in the reactor pool, however, outside of the flux trap. The flux trap is the primary location of irradiation utilized for the production of isotope used in our product and is located in the reactor pool at the center of the fuel array. The test results provide validation of alternative irradiation locations within the MURR reactor that typically are available for use to supplement or replace existing sources of our supply of Cesium – 131.

*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 2013.

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 IsoRay anticipates a slight decrease in reimbursement, we do not believe it will have a material impact for 2013 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 2011, IsoRay introduced the GliaSite RTS that had an existing reimbursement code. As an in-patient procedure covered by CMS, hospitals are paid based on the type of surgery and the status of the patient. These procedures are done as part of a Diagnostic Related Group or “DRG” system under which the hospital pays for all items involved in the care of the patient exclusive of the physician fees.

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 65% of all U.S. prostate brachytherapy cases and management anticipates this percentage to increase annually. We are unable to predict the impact of the healthcare reform passed in 2010, those reforms that may be enacted in the future, 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;
§ the successful introduction or market penetration of alternative therapies; and
§ the outcome of the FDA's evaluation of the clearance process for class II devices.

*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 Cesium-131 seed, and on other third parties, including various radiopharmacies, to package our Proxcelan Cesium-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 Cesium-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. As physicians migrate to medical devices such as external beam radiation that have a much higher capital cost to repay and higher profit margins, this puts increasing pressure on all brachytherapy products to compete regardless of their superior treatment results. The market share for brachytherapy continues to decline as a result of this pressure from increasing usage by oncologists of external beam radiation. In addition, centers that wish to offer the Proxcelan Cesium-131 seed must comply with licensing requirements specific to the state, province, and/or country in which they do business and these licensing requirements may take a considerable amount of time to comply with. Certain centers may choose not to offer our Proxcelan Cesium-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 Cesium-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. The Company’s Gliasite RTS brachytherapy products typically compete with external beam radiation therapy (EBRT), which can be provided as conventional or intensity modulated radiation therapy, or as stereotactic radiosurgery, a technique that delivers high doses of radiation to a target in a much fewer number of sessions than other forms of EBRT. Manufacturers of EBRT equipment include Varian Medical Systems, Siemens Healthcare, Elekta AB, and Accuray Incorporated, among others. In the case of brain tumors, a surgeon will remove the tumor and radiation therapy is added following the surgery; this is known as “adjuvant” radiation therapy. The Company believes that its form of adjuvant radiation therapy deployable in such cases offers advantages over external beam methods. However,

external beam holds the vast majority of the market for adjuvant radiation therapy.

*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 Cesium-131, our patents on additional methods for producing Cesium-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 Cesium-131 brachytherapy seeds and the GliaSite® radiation therapy system 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 Cesium-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 Cesium-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 Cesium-131 seed were to rapidly become the "seed of choice," it is unlikely that we could immediately meet demand. We could experience significant cash flow difficulties and may have difficulty obtaining the working capital required to manufacture our products at those levels. This could cause customer discontent and invite competition. There can be no assurance that our personnel, systems, procedures, and controls will be adequate to immediately react to that growth.

*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, 2012, the Company determined that there were deficiencies that together constituted a material weakness. Specifically, the Company did not maintain adequate segregation of finance and accounting duties, did not have a Chief Financial Officer, and did not have a human resources manager with appropriate training and experience. The Company continues the implementation of the 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 2012, the Company hired a Senior Accountant with supervisory experience from a big four public accounting firm to address the issues with segregation of duties and the Company is assessing additional steps that may be taken in fiscal year 2013 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. Section 404(b) reporting obligations were permanently exempted through legislation passed in July 2010.

*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.* We cannot predict the size of future issuances or sales of our common stock or other equity securities 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. The issuance and sale of substantial amounts of common stock or other equity securities 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, 2012, we had 30,950,108 outstanding shares of common stock, and the following additional shares were reserved for issuance: 2,371,306 shares upon exercise of outstanding options, 1,959,799 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 4,400,000 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 MKT Listing Standards And Any Resulting Delisting Could Adversely Affect The Market For Our Common Stock*. Our common stock is presently listed on the NYSE MKT. The NYSE MKT 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 MKT, 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 MKT indefinitely. We fell below the minimum stockholders equity requirement for the quarter ended June 30, 2012, but raised additional capital in July 2012 with net proceeds of approximately $3.3 million. In the event that our common stock is delisted from the NYSE MKT, 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, 2012 if required to comply with the Form S-3 eligibility requirements. 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 that 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 – MINE SAFETY DISCLOSURES**

Not applicable

**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: 193,000,000 shares of common stock, par value of $0.001 per share; and 7,000,000 shares of preferred stock, par value of $0.001 per share. As of September 25, 2012, we had 34,584,868 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 MKT) under the symbol "ISR." Even though we have obtained our NYSE MKT 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 MKT.

| Year ended June 30, 2012 | High | Low |
|---|---|---|
| First quarter | $1.29 | $0.90 |
| Second quarter | 0.99 | 0.65 |
| Third quarter | 0.73 | 0.48 |
| Fourth quarter | 1.28 | 0.39 |

| Year ended June 30, 2011 | High | Low |
|---|---|---|
| First quarter | $1.48 | $1.00 |
| Second quarter | 1.55 | 1.07 |
| Third quarter | 1.52 | 1.02 |
| Fourth quarter | 1.23 | 0.88 |

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 16, 2011, the Board of Directors declared a dividend on the Series B Preferred Stock of all outstanding and cumulative dividends through December 31, 2011. The total Series B accrued dividends of $10,632 were paid as of December 31, 2011. At June 30, 2012, there were 59,065 Series B preferred shares outstanding and cumulative dividends in arrears were $5,316. There is no Series A or Series C Preferred Stock outstanding.

As of September 25, 2012, we had approximately 291 shareholders of record, exclusive of shares held in street name. The closing price of our common stock was $0.84 on September 25, 2012.

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 MKT) on the date of the grant, and with varying vesting periods as determined by the Board.

As of June 30, 2012, the following options had been granted under the option plans.

| Plan Category | Number of securities to be issued on exercise of outstanding options, warrants, and rights # | Weighted-average exercise price of outstanding options, warrants, and rights $ | Number of securities remaining available for future issuance under equity compensation plans |
|---|---|---|---|
| Equity compensation plans approved by shareholders | N/A | N/A | N/A |
| Equity compensation plans not approved by shareholders | 2,381,306 | $ 1.82 | 1,350,512 |

| | | | |
|---|---|---|---|
| Total | 2,381,306 | $ 1.82 | 1,350,512 |

Sales of Unregistered Securities

All sales of unregistered securities during the 2012 fiscal year were previously reported, except as follows:

On June 27, 2012, the Company issued warrants to purchase 2,500 shares of common stock to an information technology consultant, Chuck Downs, with an exercise price equal to $0.98. The warrants were issued pursuant to the exemption from registration provided by §4(2) of the Securities Act of 1933, as amended.

Use of Proceeds from Registered Securities

On October 27, 2009, 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, 2009, and the commission file number assigned to the registration statement is 333-162694.

On November 22, 2010, a securities purchase agreement was executed between an institutional investor and the Company for 2,250,000 shares of common stock with Aurora Capital acting as the placement agent for the transaction. As part of the transaction, the investor received four series of warrants (collectively, the "Warrants"). The Series A and Series C Warrants were amended and restated via an Amendment Agreement dated December 27, 2010, and the Series C Warrants were further amended and restated via an Amendment Agreement dated March 31, 2011.

The Shares and Warrants were issued pursuant to the Company's shelf registration statement (the "Registration Statement") on Form S-3 (File No. 333-162694), which became effective on November 13, 2009, and prospectus supplements filed on November 24, 2010 and on December 29, 2010.

By letter agreement dated October 27, 2010, LifeTech Capital, a division of Aurora Capital, LLC, acted as placement agent in connection with the placement of the securities in the November 2010 offering. LifeTech received a cash fee of 5% of the gross proceeds received under the offering (excluding proceeds received on the exercise of C or D Warrants), and also received warrants to purchase 3% of the common stock sold in the offering and 3% of the Series A, B and C Warrants exercised at any time, which warrants issued to LifeTech shall not be exercisable for six months following the closing, shall have a five year term, and an exercise price of $1.56 per share.

The November 2010 offering yielded net cash of $2,026,255 which was net of offering costs of $223,745 ($112,500 of commission expense, $108,927 of legal and accounting expense and $2,318 of other costs). Warrant liabilities that total $1,724,000 was established related to Series A, B, and C warrants. Deferred financing costs of $193,051 were established related to the warrant liabilities for Series A, B, and C warrants.

The Series A warrants were exercised on March 24, 2011 for 538,660 shares of common stock in exchange for $475,000 net of commission expense.

The Company recorded fair value adjustments to the Series A warrant liability through the exercise of the warrants on March 24, 2011. The Company expensed the unamortized deferred financing cost of $16,044 as financing expense in the Consolidated Statement of Operations. The Series A warrant liability was reclassified to equity at the fair value reported on March 24, 2011 of $119,000 during the three months ended March 31, 2011 as the warrant holder exercised the warrants during this period.

The Series B Warrants expired without being exercised and the fair value of the warrant liability for Series B was reclassified to equity was $152,000.

The Series C warrant liability was recharacterized from a warrant liability to equity at the fair value reported using the Black-Scholes Option Valuation Model on March 31, 2011 as the warrant holder and the Company amended the agreement on that date to allow for the equity treatment of the Series C warrants. The fair value of the warrant liability for Series C that was reclassified to equity was $1,119,000. The Company expensed the unamortized deferred financing cost of $142,809 as financing expense in the Consolidated Statement of Operations.

On October 13, 2011, the Company entered into an Underwriting Agreement with WestPark Capital, Inc. as managing underwriter for a best efforts all or nothing underwritten registered offering of 2,500,000 shares of the Company's common stock, par value $0.001 per share, at an offering price to the public of $0.92 per share. With every five shares of common stock purchased, the purchaser received a warrant to purchase one share of common stock with an exercise price of $1.058 with a five year term for a total of 500,003 warrants issued in the initial transaction. Under the terms of the Underwriting Agreement, the Company also granted the underwriters a 45 day option to sell up to an additional 1,027,173 shares of Common Stock (with warrants to purchase up to an additional 205,435 shares of common stock) to cover over-allotments, if any, at the offering price. There were 317,988 shares of common stock sold from the over-allotment and 63,598 warrants issued as part of the sale of the over-allotment shares. None of the warrants from either the initial sale of shares of common stock or from those sold as part of the over-allotment sale of shares of common stock have been exercised. The gross proceeds to the Company from the sale of the initial 2.5 million shares of common stock were $2,300,000 and there were net proceeds to the Company of $2,013,363. Gross proceeds from the over-allotment sale of 317,988 shares of common stock were $292,549 and net proceeds were $261,123. These shares and warrants were issued pursuant to the Registration Statement and a prospectus supplement filed on October 13, 2011.

There was no material change in the use of proceeds from our public offerings as described in our final prospectuses for these offerings filed with the SEC pursuant to Rule 424 (b). Through June 30, 2012 we had begun to use the net proceeds consistent with the use of proceeds from our public offerings as described in our final prospectuses for these offerings filed with the SEC pursuant to Rule 424 (b) and as further described in the table below, and invested the remaining net proceeds in cash and cash equivalents.

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

| | |
|---|---|
| The net cash received from the public offerings is: | |
| Proceeds from sales of common stock, pursuant to registered public offering, net | $2,219,306 |
| Proceeds from sales of common stock, pursuant to at the market offering, net | 250,632 |
| Proceeds from sales of common stock, pursuant to exercise of Series A warrants, net | 475,000 |
| Proceeds from sales of common stock, pursuant to registered public offering, net | 2,274,486 |
| Proceeds from sales of common stock, pursuant to exercise of Series C warrants, net | 834,797 |
| Total proceeds from public offerings through June 30, 2012 | $6,054,221 |
| | |
| Proceeds used in the year ended June 30, 2012: | |
| Purchase and installation of machinery and equipment | $55,057 |
| Indirect payment to directors and officers for database development | 31,350 |
| Direct payments of salaries to directors and officers | 708,864 |
| Working capital | 1,754,094 |
| Total proceeds used in the year ended June 30, 2012 | $2,549,365 |

**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.

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, 2012, 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 none and $13,277 for the years ended June 30, 2012 and 2011, respectively, is included in financing expense on the statements of operations.

Deferred financing costs related the creation of warrant liabilities as the result of the issuance of shares of common stock are deferred and amortized over the term of the related warrant on a straight-line basis. Deferred financing cost related to the creation of the warrant liability was recorded on a proportionate basis with the aggregate amount of the total offering. Amortization of deferred financing costs, totaling $61,511 and $193,052 for the years ended June 30, 2012 and 2011, respectively, is included in financing and interest expense on the consolidated statements of operations. Deferred financing costs were fully amortized at the year ended June 30, 2012 and June 30, 2011.

Licenses

Amortization of licenses is computed using the straight-line method over the estimated economic useful lives of the assets.

Amortization of licenses was $11,721 and $11,721 for the years ended June 30, 2012 and 2011, respectively. Based on the licenses recorded at June 30, 2012, 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 2013, $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 $15,731 and $15,129 for the years ended June 30, 2012 and 2011 respectively. Based on the patents and other intangible assets recorded in other assets at June 30, 2012, and assuming no subsequent impairment of the underlying assets, the annual amortization expense for each fiscal year ending June 30 is expected to be as follows: $16,597 for each year 2013 through 2016, $14,109 for 2017 and $122,758 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, 2012 and 2011, the asset retirement obligations changed as follows:

| | 2012 | 2011 |
|---|---|---|
| Beginning balance | $662,181 | $605,391 |
| Accretion of discount | 62,117 | 56,790 |
| Ending balance | $724,298 | $662,181 |

Because the Company does not expect to incur any expenses related to its asset retirement obligations in fiscal year 2013, the entire balance as of June 30, 2012 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, and notes payable, approximated their fair values at June 30, 2012 and 2011.

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, 2012 and 2011 was derived primarily from sales of the Proxcelan Cs-131 brachytherapy seed, which is used in the treatment of cancer. The Company began shipping its Gliasite Radiation Therapy System in the fiscal year ended June 30, 2012 which is used in the treatment of brain 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.

Product Returns and Allowances

The Company as part of normal operations allows for customers to receive credit for patient procedures cancelled after shipping to the customer for a variety of criteria. These criteria include but are not limited to a physical symptom on the date of procedure that interferes with the patient's ability to go forward with the procedure, discovery that a patient's condition is beyond treatment during surgery and other criteria as determined acceptable by management.

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.

Research and Development Reimbursement

Research and development reimbursement recorded during the year ended June 30, 2012 is a reimbursement from the German distributor of the GliaSite Radiation Therapy System in support of the product development. Research and development reimbursement recorded during the year ended June 30, 2011is the amount of cost recoverable as part of the grants related to the Qualified Therapeutic Discovery Project received by the Company in October 2010. The grants allowed for "Qualified Investments" to be recovered at 50% of the amounts expended up to the specified limits by tax year.

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 2010 through 2012 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 anti-dilutive due to the Company's net loss position.

Securities that could be dilutive in the future as of June 30, 2012 and 2011 are as follows:

| | 2012 | 2011 |
|---|---|---|
| Preferred stock | 59,065 | 59,065 |
| Common stock warrants | 1,959,799 | 3,819,185 |
| Common stock options | 2,381,306 | 2,423,806 |
| Total potential dilutive securities | 4,400,170 | 6,302,056 |

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 2012 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, 2012 and 2011. 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 27 of this Annual Report on Form 10-K.

Year ended June 30, 2012 compared to year ended June 30, 2011

**Product sales.** The Company generated revenue of $5,071,088 for the year ended June 30, 2012 compared to revenue of $5,238,973 for the year ended June 30, 2011, a decrease of $167,885 or 3.20%.

While total revenue decreased 3.20% or approximately $168,000 in the year ended June 30, 2012 compared to the year ended June 30, 2011, the Company experienced growth of approximately 36% or approximately $150,000 in the the use of brachytherapy seeds in the treatment of non-prostate cancers.. These non-prostate treatments using brachytherapy seeds include lung, colorectal, head and neck, chest wall, vaginal cuff and brain which increased from 8% of total revenue during the year ended June 30, 2011 to 11% of total revenue during the year ended June 30, 2012. The Company began selling its GliaSite Radiation Therapy System in the year ended June 30, 2012 which contributed approximately $163,000 of new revenue. This new revenue represents approximately 3% of the total revenue for the fiscal year ended June 30, 2012. The Company continued to experience a reduction in revenue contributed by prostate treatments using brachytherapy seeds of approximately $480,000 or 10%.

The Company experienced a decrease of 5.02% in the total number of seed brachytherapy cases for the year ended June 30, 2012 as compared to the year ended June 30, 2011. Seed brachytherapy cases treating non-prostate cancers increased by 37.18% in the year ended June 30, 2012 compared to June 30, 2011 while seed brachytherapy cases treating prostate cancer decreased by 8.46% in the year ended June 30, 2012 compared to June 30, 2011.

There were eight cases treated with the GliaSite RTS product line in the year ended June 30, 2012 and none in the prior year as the product was introduced in the year ended June 30, 2012.

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) as revenue generated from treating this modality decreased from 92% of total revenue in the fiscal year ended June 30, 2011 to 86% of total revenue in the fiscal year ended June 30, 2012.

Management has continued its focus on the new treatment modalities as they are expected to become a larger portion of the total revenue in the future. Revenues from treating these new modalities grew from 8% of total revenue in the year ended June 30, 2011 to 11% of revenue in the year ended June 30, 2012.

**Cost of product sales.** The total cost of product sales for both seed production and GliaSite RTS production was $4,367,884 for the year ended June 30, 2012.

Cost of product sales related to seed production was $4,234,542 for the year ended June 30, 2012 compared to cost of product sales related to seed production of $4,081,556 for the year ended June 30, 2011. In the year ended June 30, 2012, the Company incurred $133,342 of cost of product sales related to the production of the GliaSite Radiation Therapy System. This was the initial fiscal year of producing and selling the GliaSite Radiation Therapy System.

The Company experienced an increase in the cost of product sales of $286,328 or 7% for the year ended June 30, 2012 as compared to the year ended June 30, 2011. The fiscal year over fiscal year cost increase of $286,328 was impacted primarily by the reduction in research and development projects undertaken by management and the addition of production costs related to the GliaSite Radiation Therapy System in the year ended June 30, 2012 when compared to the year ended June 30, 2011. In the year ended June 30, 2011, these research and development efforts utilized personnel and materials of the Company whose related cost were transferred to the research and development operating expense. These cost reductions did not continue in fiscal 2012 as the research and development projects were substantially complete at June 30, 2011.

These cost increases in the year ended June 30, 2012 included the addition of $133,342 in production costs related to the GliaSite Radiation Therapy System and the addition of seed production costs of $152,986. The increase in seed production costs of $152,986 was created by an increase of approximately $27,000 in third party pre-loading expense; an increase in payroll and benefits expense of approximately $91,000 as the result of decreased use of production staff on research and development efforts; an increase in other production expenses of approximately $31,000 as the result of property tax, calibration expense and training expense; and an increase in internal pre-loading expense of approximately $36,000 that resulted from the increased use of labor, benefits and material as the result of the increased use of the Company in-house loading service by customers that previously selected the third-party loading expense.

**Gross margin.** Gross margin was $703,204 for the year ended June 30, 2012 compared to a gross margin of $1,157,417 for the year ended June 30, 2011. The decrease of $454,213 or 39% was primarily due to the decreased utilization of production personnel on the research and development projects described above, the addition of production costs related to the Gliasite Radiation Therapy System and the reduction in product sales in the year ended June 30, 2012.

**Research and development expenses.** Research and development expenses for the year ended June 30, 2012 were $780,579 which represents a decrease of $200,607 or approximately 20% less than the research and development expenses of $981,186 for the year ended June 30, 2011.

The cost decrease of approximately $201,000 in the fiscal year ended June 30, 2012 was primarily due to a decrease in other organ research expense of approximately $381,000 and an increase in protocol expense of $170,000 as the Company undertook some new protocols and the prior year contained non-recurring reversals of accrued protocol expense.

**Research and development reimbursement.** Research and development reimbursement for the year ended June 30, 2012 was $50,000 as the result of a reimbursement of developmental expenses from the distributor of the GliaSite Radiation Therapy System received from the German based distributor compared to the $515,853 received from grants during October 2010 as part of the Qualified Therapeutic Discovery Project administered by the Internal Revenue Service under the Patient Protection and Affordable Care Act (Public Law 111-148) that was recorded in the year ended June 30, 2011.

**Sales and marketing expenses.** Sales and marketing expenses were $1,215,580 for the year ended June 30, 2012 compared to sales and marketing expenses of $1,232,188 for the year ended June 30, 2011, which represents a decrease of $16,608 or 1%.

The decrease of approximately $17,000 is primarily the net result of a reduction of $32,000 in marketing and advertising expenses which resulted from the reversal of a $20,000 accrued expense that management deemed to no longer be required, a reduction in trade publication activity of approximately $12,000, an increase in travel expense of approximately $64,000 as lodging, meals, auto rentals and miscellaneous expenses increased as the result of increased headcounts; and a decrease in other expenses of $49,000.

**General and administrative expenses.** General and administrative expenses for the year ended June 30, 2012 were $2,355,015 compared to general and administrative expenses of $2,422,884 for the year ended June 30, 2011.

The decrease of approximately $68,000 is primarily the net result of decreased bad debt expense of $22,000 as the result of improved bad debt collection; decreased legal expense of $25,000 as the result of the non-recurring cost of a financing; increased wages, benefits, and related taxes of $116,000 as the result of a decreased use of staff, a return to a normal headcount in certain departments and increased insurance costs; decreased share-based compensation primarily attributable to the valuation of the options granted and immediately vested to the CEO of approximately $90,000, and a decrease in other expense of approximately $46,000 that is partially the withdrawal of a business and occupation tax credit from a prior year.

**Operating loss.** In the year ended June 30, 2012, the Company had an operating loss of $3,597,970 compared to $2,962,988 for the year ended June 30, 2011, an increase of $634,982 or 21%. The Company's operating loss increase of $635,000 was the result of a decrease in product sales of $168,000; increase in the cost of product sales of $286,000; decrease in research and development expense of $201,000; decrease in research and development expense reimbursement of $466,000; decrease in sales and marketing expense of $17,000; and decrease in general and administrative of $68,000.

**Interest income.** Interest income was $747 for the year ended June 30, 2012 compared to interest income of $3,381 for the year ended June 30, 2011. The decrease of $2,634 or 78% is the result of lower average cash balances during the year ended June 30, 2012 in combination with decreased interest rates.

**Change in fair value of warrant liability.** There was a gain on the warrant liability for the year ended June 30, 2012 in the amount of $170,000 as compared to $334,000 for the year ended June 30, 2011. The gain of $170,000 for the year ended June 30, 2012 was the result of the recording of warrant liabilities related to warrants issued in combination with a stock issuance that occurred in October and December 2011 compared to the warrants issued in

combination with the stock issuance that occurred in October 2010. This gain represents the net fair value adjustments to the warrant liability during the years ended June 30, 2012 and June 30, 2011. The warrant liability for the warrants issued in October 2010 was fully extinguished during the year ended June 30, 2011.

**Financing and interest expense.** Financing and interest expense for the year ended June 30, 2012 was $61,682 compared to $216,606 for the year ended June 30, 2011, a decrease of $154,924 or 72%.

Financing expense included interest expense of approximately $171 and $9,388 for the years ended June 30, 2012 and 2011, respectively, a decrease of $9,217. The decrease is due to the decreased debt balances in the year ended June 30, 2012.

The remaining balance of financing expense represents the amortization of deferred debt financing costs of approximately $0 and $13,300 for the years ended June 30, 2012 and 2011, respectively, and the amortization of deferred equity financing costs of approximately $61,500 and $193,000 for the years ended June 30, 2012 and 2011, respectively.

**Liquidity and capital resources.** The Company has historically financed its operations through the sale of common stock and the issuance of related common stock warrants. During fiscal year 2012, the Company used existing cash reserves and cash received through sales of common stock to fund its operations and capital expenditures.

*Cash flows from operating activities*

Cash used in operating activities was approximately $2.45 million in fiscal year 2012 compared to approximately $2.42 million in fiscal year 2011, an increase of approximately $29,000 or 1.2%. Cash used by operating activities is net loss adjusted for non-cash items and changes in operating assets and liabilities.

The increase of net cash used by operating activities of $29,000 is attributable to the increase in the Company's net loss of $647,000 with an increase in non cash charges of $131,000 in fiscal year 2012 compared to fiscal year 2011 and a reduction of $749,000 in operating assets and liabilities in the fiscal year 2012 compared to the fiscal year 2011.

*Cash flows from investing activities*

Cash used by investing activities was approximately $96,000 for the year ended June 30, 2012 and provided by investing activities was approximately $160,000 for the year ended June 30, 2011. Cash expenditures for fixed assets were approximately $55,000 in the year ended June 30, 2012 and approximately $137,000 in the year ended June 30, 2011. Cash expenditures for licenses and other assets were approximately $40,000 in the year ended June 30, 2012 and were approximately $20,000 in the year ended June 30, 2011.

*Cash flows from financing activities*

Cash provided in financing activities was approximately $3.1 million for the year ended June 30, 2012 and cash used in financing activities was approximately $3.0 million for the year ended June 30, 2011. Cash provided in financing activities was provided primarily through sales of common stock reduced by the payment of debt and preferred dividends in the year ended June 30, 2012 and the year ended June 30, 2011. Cash used in financing activities was used mainly for payments of debt, preferred dividends and the cash payment of stock offering costs during the year ended June 30, 2012 and the year ended June 30, 2011.

*Projected 2013 Liquidity and Capital Resources*

At June 30, 2012, cash and cash equivalents amounted to $2,672,711 compared to $2,112,254 of cash and cash equivalents at June 30, 2011.

The Company had approximately $5.34 million of cash on hand as of September 12, 2012. The increase from June 30, 2012 was the result of the sale of common stock in July 2012. As of that date, management believed that the Company's monthly required cash operating expenditures were approximately $200,000 which remains materially unchanged from average monthly cash operating expenditures in fiscal year 2011. Management believes that less than $300,000 will be spent on capital expenditures for the entire fiscal year 2013, but there is no assurance that unanticipated needs for capital equipment may not arise.

During fiscal year 2013, the Company intends to continue its existing protocol studies and begin new protocol studies for several of its non-prostate applications. The Company has budgeted approximately $150,000 in fiscal year 2013 for protocol expenses relating to lung cancer as well as continued work on the dual therapy prostate protocols. These expenditures may include maintenance costs for the online data collection system developed during the fiscal years 2011 and 2012.

Based on the foregoing assumptions, management believes cash and cash equivalents on hand at June 30, 2012 should be sufficient to meet our anticipated cash requirements for operations and capital expenditure requirements through at least the next twelve months.

Management plans to attain breakeven and generate additional cash flows by increasing revenues from the Company's existing treatment applications of the Cs-131 brachytherapy seed to both new and existing customers (through our direct sales channels and through our distributors), while expanding into new market applications for Cs-131 and continuing to maintain the Company's focus on cost control.

Additionally, management plans to increase revenue through expanding the sale of the FDA cleared and ISO 13845:2003 certified GliaSite® radiation therapy system to current customers, adding new customers through the Company’s direct sales force, through the existing distribution agreement which covers Germany, Austria, Switzerland, Italy and Luxembourg and the addition of other distribution channels to European Union countries covered by the ISO certifications. This product will be utilized in the treatment of Glioblastoma multiforme which is the most common and aggressive primary brain cancer in humans.

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 continued to shrink, which has not allowed breakeven to be reached during the past two fiscal years and these sales continued to decline during the year ended June 30, 2012.

As management has focused on expanding into head and neck, colorectal, lung and brain applications and experienced growth in sales for non-prostate seed applications in excess of 36% comparing fiscal year 2012 to fiscal year 2011, management believes the Company may need to continue to raise additional capital after fiscal year 2013 is complete to meet NYSE MKT listing standards as this entry into new markets may take longer to generate revenues.

In fiscal year 2011, management sold common stock pursuant to both an "at the market" offering and through a direct registered offering as described below. Management sold additional common stock through an underwritten offering in fiscal 2012 and a direct offering in July 2012 under its Form S-3 shelf offering registration statement.

On April 22, 2010 we entered into a Sales Agreement (the "Agreement") with C.K. Cooper & Company, Inc. ("CKCC"), which was amended on July 29, 2010. On October 1, 2010 the Company instructed CKCC to commence sales via placement notice permitting "at the market" sales of common stock through October 31, 2010. CKCC sold 304,227 shares of common stock on behalf of the Company receiving $250,632 in equity net of offering costs of $118,149 ($7,301 in commissions, $110,276 in legal and accounting expenses, and $571 in other costs). The offering of shares pursuant to the Agreement, as amended, terminated on December 31, 2010.

These shares were issued pursuant to the Company's shelf registration statement (the "Registration Statement") on Form S-3 (File No. 333-162694), which became effective on November 13, 2009, and a prospectus supplement filed

on April 23, 2010.

There was no material change in the use of proceeds from our public offering as described in our final prospectus filed with the SEC pursuant to Rule 424 (b). All proceeds from this offering had been used as of June 30, 2011.

On November 22, 2010, a securities purchase agreement was executed between an institutional investor and the Company for 2,250,000 shares of common stock with Aurora Capital acting as the placement agent for the transaction. As part of the transaction, the investor received four series of warrants (collectively, the "Warrants"). The Series A and Series C Warrants were amended and restated via an Amendment Agreement dated December 27, 2010, and the Series C Warrants were further amended and restated via an Amendment Agreement dated March 31, 2011.

The shares and Warrants were issued pursuant to the Registration Statement, and prospectus supplements filed on November 24, 2010 and on December 29, 2010.

By letter agreement dated October 27, 2010, LifeTech Capital, a division of Aurora Capital, LLC, acted as placement agent in connection with the placement of the securities in the November 2010 offering. LifeTech received a cash fee of 5% of the gross proceeds received under the offering (excluding proceeds received on the exercise of C or D Warrants), and also received warrants to purchase 3% of the common stock sold in the offering and 3% of the Series A, B and C Warrants exercised at any time, which warrants issued to LifeTech were not exercisable for six months following the closing, have a five year term, and an exercise price of $1.56 per share.

The November 2010 offering yielded net cash of $2,026,255 which was net of offering costs of $223,745 ($112,500 of commission expense, $108,927 of legal and accounting expense and $2,318 of other costs). Warrant liabilities in the amount of $1,724,000 were established related to Series A, B, and C Warrants. Deferred financing costs of $193,051 were established related to the warrant liabilities for Series A, B, and C Warrants.

The Series A Warrants were exercised on March 24, 2011 for 538,660 shares of common stock in exchange for $475,000 net of commission expense.

The Company recorded fair value adjustments to the Series A Warrants liability through the exercise of these warrants on March 24, 2011. The Company expensed the unamortized deferred financing cost of $16,044 as financing expense in the Consolidated Statement of Operations. The Series A Warrants liability was reclassified to equity at the fair value reported on March 24, 2011 of $119,000 during the three months ended March 31, 2011 as the warrant holder exercised the warrants during this period.

The Series B Warrants expired without being exercised and the fair value of the warrant liability for Series B was reclassified to equity was $152,000.

The Series C Warrant liability was recharacterized from a warrant liability to equity at the fair value reported using the Black-Scholes Option Valuation Model on March 31, 2011 as the warrant holder and the Company amended the agreement on that date to allow for the equity treatment of the Series C Warrant. The fair value of the warrant liability for Series C that was reclassified to equity was $1,119,000. The Company expensed the unamortized deferred financing cost of $142,809 as financing expense in the Consolidated Statement of Operations. All but 100 Series C Warrants to purchase shares of common stock have now been exercised. Series D Warrants to exercise 1,140,432 shares at $1.56 per share remain outstanding as well.

On October 13, 2011, the Company entered into an Underwriting Agreement with WestPark Capital, Inc. as managing underwriter for a best efforts all or nothing underwritten registered offering of 2,500,000 shares of the Company’s common stock, par value $0.001 per share, at an offering price to the public of $0.92 per share. With every five shares of common stock purchased, the purchaser received a warrant to purchase one share of common stock with an exercise price of $1.058 with a five year term for a total of 500,003 warrants issued in the initial transaction. Under the terms of the Underwriting Agreement, the Company also granted the underwriters a 45 day option to sell up to an additional 1,027,173 shares of Common Stock (with warrants to purchase up to an additional 205,435 shares of common stock) to cover over-allotments, if any, at the offering price. There were 317,988 shares of common stock sold from the over-allotment and 63,598 warrants issued as part of the sale of the over-allotment shares. None of the warrants from either the initial sale of shares of common stock or from those sold as part of the over-allotment sale of shares of common stock have been exercised. The gross proceeds to the Company from the sale of the initial 2.5 million shares of common stock were $2,300,000 and there were net proceeds to the Company of $2,013,363. Gross proceeds from the over-allotment sale of 317,988 shares of common stock were $292,549 and net proceeds were

$261,123. These shares and warrants were issued pursuant to the Registration Statement and a prospectus supplement filed on October 13, 2011.

There was no material change in the use of proceeds from our public offerings as described in our final prospectuses for these offerings filed with the SEC pursuant to Rule 424 (b). Through June 30, 2012 we had begun to use the net proceeds from our public offerings as described in our final prospectuses for these offerings filed with the SEC pursuant to Rule 424 (b) and as further described in the table below, and invested the remaining net proceeds in cash and cash equivalents.

No offering expenses in either offering were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

| | |
|---|---|
| The net cash received from the public offerings is: | |
| Proceeds from sales of common stock, pursuant to registered public offering, net | $2,219,306 |
| Proceeds from sales of common stock, pursuant to at the market offering, net | 250,632 |
| Proceeds from sales of common stock, pursuant to exercise of Series A warrants, net | 475,000 |
| Proceed from sales of common stock, pursuant to registered public offering, net | 2,274,486 |
| Proceeds from sales of common stock, pursuant to exercise of Series C warrants, net | 834,797 |
| Total proceeds from public offerings through June 30, 2012 | $6,054,221 |
| | |
| Proceeds used in the year ended June 30, 2012: | |
| Purchase and installation of machinery and equipment | $55,057 |
| Indirect payments to directors and officers for database development | 31,350 |
| Direct payments of salaries to directors and officers | 708,864 |
| Working capital | 1,754,094 |
| Total proceeds used in the year ended June 30, 2012 | $2,549,365 |

On July 16, 2012, the Company entered into a Securities Purchase Agreement with Ladenberg Thalmann & Co., Inc. as placement agent for the sale of $3.5 million of shares of common stock at a per share price of $0.965. On July 19, 2012, the Company received net proceeds of $3.296 million after offering costs of $204,000. These shares were issued pursuant to the Registration Statement and a prospectus supplement filed on July 17, 2012.

No offering expenses in either offering were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

Management does not anticipate needing to raise financing during fiscal 2013. If financing is obtained it may be dilutive to shareholders. Of course, funding may not be available to us on acceptable terms, or at all. If the Company is unable to raise additional funds, it will have to discontinue or significantly curtail operations.

*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, | |
|---|---|
| 2013 | 286,212 |
| 2014 | 286,212 |
| 2015 | 286,212 |
| 2016 | 238,510 |
| | $1,097,146 |

The Company is subject to various local, state, and federal environmental regulations and laws due to the isotopes used to produce the Company's products. 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 products. The Company also carries product liability insurance to help protect it from this risk.

The Company received a Qualify Therapeutic Discovery Project (QTDP) grant in lieu of a QTDP credit for the Company tax years 2010 and 2011. The costs of the Company associated with these grants are subject to examination as are the tax returns of the Company. While there is no indication that the Internal Revenue Service intends to examine these returns or the costs utilized as the underlying basis for the receipt of the grant funds, these grant funds are subject to recapture if the associated costs are determined by the Service to not meet the definition of a "Qualified Investment" during an examination.

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**

Effective July 2011, the Company adopted ASU 2011-02 "Receivables (Topic 310): A Creditor’s Determination of Whether a Restructuring Is a Troubled Debt Restructuring". This Accounting Standards Update clarifies presentation requirements for financial statements as part of the SEC Form 10-Q which have not impacted filings to date, however, this clarification update may impact future filings. The Company's accounting policies and amounts presented in the financial statements were not impacted by this change.

Effective January 2012, the Company adopted ASU 2011-03 "Transfers and Servicing (Topic 860): Reconsideration of Effective Control for Repurchase Agreements". This Accounting Standards Update clarifies presentation requirements for financial statements as part of the SEC Form 10-Q which have not impacted filings to date, however, this clarification update may impact future filings. The Company's accounting policies and amounts presented in the financial statements were not impacted by this change.

Effective January 2012, the Company adopted ASU 2011-04 "Fair Value Measurement (Topic 820): Amendements to Achieve Common Fair Value Measurement and Disclosure Requirements for U.S. GAAP and IFRSs". This Accounting Standards Update clarifies presentation requirements for financial statements as part of the SEC Form 10-Q which have not impacted filings to date, however, this clarification update may impact future filings. The Company's accounting policies and amounts presented in the financial statements were not impacted by this change.

Effective January 2012, the Company adopted ASU 2011-09 "Compensation – Retirement Benefits – Multiemployer Plans (Subtopic 715-80): Disclosures about an Employer's Participation in a Multiemployer Plan (September 2011)". This Accounting Standards Update clarifies presentation requirements for financial statements as part of the SEC Form 10-Q which have not impacted filings to date, however, this clarification update may impact future filings. The Company's accounting policies and amounts presented in the financial statements were not impacted by this change.

**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, 2012. 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.

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, 2012, the Company determined that there were three deficiencies that in combination constituted a material weakness.

- *Segregation of Duties* - The Company did not employ a sufficient complement of finance and accounting personnel during the last two quarters of 2012 to ensure that there was a proper segregation of incompatible duties related to cash management and financial reporting. In these two quarters, the Company had a single accounting professional as an employee with the appropriate combination of education and experience to perform the finance and accounting functions that resulted in the creation of inadequate secondary level of review of key accounting estimates, filings, reports and other documentation to ensure financial information was free of material misstatement or error. Such a lack of segregation of duties is typical in a Company this size and with limited resources. Although the Company's CEO and Board of Directors review the financial statements and would more likely than not discover a misappropriation of funds, this cannot be assured by the existing system.

- *Lack of Qualified Management* - The Company has not employed a Chief Financial Officer, with appropriate employment terms providing for independence from the influence of executive management and direct access to the Audit Committee, since September 2009. The lack of a CFO reduces the likelihood of necessary oversight by executive management and the proper function of entity-level controls necessary to mitigate other deficiencies that may exist.

- *Lack of a Dedicated Human Resource Function* – The Company lacks an appropriately trained and experienced human resources function exposing the Company to additional risk relating to employment laws and practices, additional risk related to the timely replacement of key personnel that could impact the Company's ability to continue operations or to timely meet financial reporting filing obligations.

As a result of these three deficiencies and the material weakness resulting from the combination of these deficiencies, management concluded that our internal control over financial reporting was not effective as of June 30, 2012.

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

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

- In April 2012, the Company hired a senior accountant with supervisory experience from a big four accounting firm to address the 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, 2012. 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, 2012 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, 2012 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 MKT 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, 2012 were as follows:

| Name | Age | Position Held | Term* |
|---|---|---|---|
| Dwight Babcock | 64 | Chairman, Chief Executive Officer | Annual |
| Brien Ragle | 43 | Controller, Principal Financial and Accounting Officer | |
| Robert Kauffman | 72 | Vice-Chairman | Annual |
| Thomas LaVoy | 52 | Director | Annual |
| Albert Smith | 68 | Director | Annual |
| Fredric Swindler | 65 | Vice-President, Regulatory and Quality Affairs | |
| William Cavanagh III | 46 | Vice President, Research and Development | |

* For directors only

Dwight Babcock – Mr. Babcock was appointed CEO of the Company on February 18, 2009. He was previously appointed Chairman and Interim CEO of the Company on February 26, 2008 and has served as a Director of the Company since 2006. Mr. Babcock has served as Chairman and Chief Executive Officer of Apex Data Systems, Inc., an information technology company, since 1975. Apex Data Systems automates the administration and claims adjudication needs of insurance companies both nationally and internationally. Mr. Babcock was formerly President and CEO of Babcock Insurance Corporation (BIC) from 1974 until 1985. BIC was a nationally recognized third party administrator operating within 35 states. Mr. Babcock has knowledge and experience in the equity arena and has participated in various activities within the venture capital, private and institutional capital markets. Mr. Babcock studied marketing and economics at the University of Arizona where he currently serves on the University of Arizona Astronomy Board. Mr. Babcock brings over 35 years of CEO-level experience to his service on the Company's Board.

Brien Ragle – Mr. Ragle has over 15 years of finance and accounting experience, including SEC reporting, financial reporting, cost, project, and management accounting in addition to performing operational analysis. Mr. Ragle became IsoRay's Controller – Principal Financial and Accounting Officer in October 2009. Mr. Ragle was IsoRay's Cost Accounting Manager from January 2007 until 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 Project Accounting Manager for all projects located in the Western United States 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 with an emphasis in accounting, and Hospitality Management from Washington State University. Mr. Ragle is a Certified Public Accountant in the State of Washington. Mr. Ragle filed for personal bankruptcy under Chapter 13 of the U.S. Bankruptcy Code on January 26, 2011.

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. (OTCBB: 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. (OTCBB: 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.

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.

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.

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 is 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*

A significant employee of our subsidiary, IsoRay Medical, Inc., and his age as of the date of this report are set forth in the table below. Also provided is a brief description of the experience of our significant employee during the past five years.

| Name | Age | Position Held & Tenure |
|---|---|---|
| Lane Bray | 84 | Chief Chemist |

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-Citian 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.

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, 2012, except as follows – Dwight Babcock (three Form 4s); William Cavanagh (one Form 4); and Fredric Swindler (one Form 4). Each of these Form 4s was filed late.

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. 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 ($) | Option awards ($) | Non-equity incentive plan compensation (1) | Nonqualified deferred compensation earnings ($) | All other compensation ($) | Total ($) |
|---|---|---|---|---|---|---|---|---|---|
| Dwight Babcock | 2012 | 276,212 | - | - | 42,078 | - | - | - | 318,290 |
| Chairman and CEO | 2011 | 271,000 | - | - | 84,576 | - | - | - | 355,576 |
| Frederic Swindler | 2012 | 163,077 | - | - | 5,680 | - | - | - | 168,757 |
| VP–QA / RA | 2011 | 160,000 | - | - | 15,224 | - | - | - | 175,224 |
| William Cavanagh | 2012 | 154,039 | - | - | 15,148 | - | - | - | 169,187 |
| VP – R&D | 2011 | 124,808 | 11,500 | - | 26,641 | - | - | - | 162,949 |
| Robert Bilella | 2012 | 97,200 | 85,270 | - | - | - | - | - | 182,470 |
| NE Area Sales Director | 2011 | 97,200 | 102,775 | - | 3,526 | - | - | - | 203,501 |

§ Amounts represent the ASC 718*, Compensation – Stock Compensation* valuation for the fiscal years ended June 30, 2012 and 2011, 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.

Outstanding Equity Awards at Fiscal Year-End

| | Option awards | | | | |
|---|---|---|---|---|---|
| Name | Number of securities underlying unexercised Option (#) exercisable | Number of securities underlying unexercised options (#) unexercisable | Equity Incentive plan awards: Number of securities underlying unexercised unearned options (#) | options exercise price ($) | option expiration date |
| Dwight Babcock, Chairman and CEO | 50,000 (1) | - | - | 6.30 | 03/31/2016 |
| | 50,000 (1) | - | - | 3.80 | 06/23/2016 |
| | 50,000 (1) | - | - | 3.11 | 08/15/2016 |
| | 100,000 (1) | - | - | 0.75 | 05/13/2018 |
| | 200,000 (1) | - | - | 0.26 | 06/01/2019 |
| | 100,000 (1) | - | - | 1.43 | 06/30/2020 |
| | 100,000 (1) | - | - | 0.99 | 06/07/2021 |
| | 50,000 (1) | - | - | 0.98 | 06/27/2022 |
| Fred Swindler Vice-President, Quality Assurance and Regulatory Affairs | 10,000 (3) | - | - | 4.40 | 03/02/2017 |
| | 10,000 (4) | - | - | 4.14 | 06/01/2017 |
| | 10,000 (5) | - | - | 0.65 | 07/01/2018 |
| | 50,000 (6) | - | - | 0.26 | 06/01/2019 |
| | 20,000 (7) | - | - | 1.43 | 06/30/2020 |
| | 20,000 (8) | - | - | 0.99 | 06/07/2021 |
| | 7,500 (10) | - | - | 0.98 | 06/27/2022 |
| William Cavanagh Vice-President of Research and Development | 30,000 (9) | - | - | 0.84 | 01/08/2020 |
| | 35,000 (7) | - | - | 1.43 | 06/30/2020 |
| | 35,000 (8) | - | - | 0.99 | 06/07/2021 |
| | 20,000 (10) | - | - | 0.98 | 06/27/2022 |
| Robert Bilella NE Area Sales Director | 84,236 (2) | - | - | 4.15 | 06/23/2015 |
| | 18,000 (6) | - | - | 0.26 | 06/01/2019 |
| | 5,000 (7) | - | - | 1.43 | 06/30/2020 |
| | 5,000 (8) | - | - | 0.99 | 06/07/2021 |

1)

Represents options issued to Mr. Babcock which were all immediately vested and exercisable. The grant dates are 10 years prior to the expiration date in the table above.

2) Represents the June 23, 2005 grant, all of which were exercisable as of June 23, 2008.

3) Represents the March 2, 2007 grant, all of which were exercisable as of March 2, 2010.

4) Represents the June 1, 2007 grant, all of which were exercisable as of June 1, 2010.

5) Represents a July 1, 2008 grant, all of which were exercisable as of July 1, 2011.

6) Represents a June 1, 2009 grant, all of which were exercisable as of June 1, 2012.

7) Represents a June 30, 2010 grant, one-third of which became exercisable on June 30, 2011, one-third of which became exercisable on June 30, 2012, and the final third will become exercisable on June 30, 2013.

8) Represents a June 7, 2011 grant, one-third of which became exercisable on June 30, 2012, one-third of which will become exercisable on June 30, 2013, and the final third will become exercisable on June 30, 2014.

9) Represents a January 8, 2010 grant, one-third of which became exercisable on January 8, 2011, one-third of which became exercisable on January 8, 2012, and the final third will become exercisable on January 8, 2013.

10) Represents a June 27, 2012 grant, one-third of which will exercisable on June 27, 2013, one-third of which will become exercisable on June 27, 2014, and the final third will become exercisable on June 27, 2015.

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.

Director Compensation

| Name | Fees earned or paid in cash ($) | Stock awards ($) | Option awards ($) | Non-equity incentive plan compensation ($) | Non-qualified deferred compensation ($) | All other compensation ($) | ($) | Total ($) |
|---|---|---|---|---|---|---|---|---|
| Robert Kauffman | 61,000 | - | - | - | - | - | | 61,000 |
| Thomas LaVoy | 49,000 | - | - | - | - | - | | 49,000 |
| Albert Smith | 25,000 | - | - | - | - | - | | 25,000 |

During fiscal year 2012, each non-employee director received cash compensation of $2,000 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. Mr. Kauffman receiving an additional $3,000 per month for serving as Vice-Chairman, and Mr. LaVoy received an additional $2,000 per month for serving as Audit Committee Chairman. Each non-employee director had stock options to purchase shares of the Company's common stock outstanding as of June 30, 2012 as follows - Mr. Kauffman and Mr. LaVoy each had stock options to purchase 150,000 shares of common stock and Mr. Smith had stock options to purchase 175,000 shares of common stock.

*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 10, 2012 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 10, 2012, the Company had 34,582,202 shares of common stock and 59,065 shares of preferred stock outstanding. Except as otherwise indicated below, the address for each listed beneficial owner is c/o IsoRay, Inc., 350 Hills Street, Suite 106, Richland, Washington 99354.

**Common Stock Share Ownership**

| Name of Beneficial Owner | Common Shares Owned | Common Stock Options | Common Stock Warrants | Percent of Class (1) | |
|---|---|---|---|---|---|
| Dwight Babcock (2) | 209,068 | 700,000 | 12,500 | 2.63 | % |
| Brien Ragle | - | 26,999 | - | 0.08 | % |
| Robert Kauffman | 88,802 | 150,000 | - | 0.69 | % |
| Thomas LaVoy | 65,423 | 150,000 | - | 0.62 | % |
| Albert Smith | 198,101 | 175,000 | - | 1.08 | % |
| Directors and Executive Officers as a group | 561,394 | 1,201,999 | 12,500 | 5.10 | % |

1) Percentage ownership is based on 34,582,202 shares of Common Stock outstanding on September 10, 2012. Shares of Common Stock subject to stock options or warrants which are currently exercisable or will become exercisable within 60 days after September 10, 2012 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 % |
| 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 10, 2012.
(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 $19,497 and $26,474 for the years ended June 30, 2012 and 2011, 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 MKT, 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 MKT 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 MKT 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, 2012 | Year ended June 30, 2011 |
|---|---|---|
| 1. Audit fees | $ 61,750 | $ 56,250 |
| 2. Audit-related fees | 14,528 | 13,684 |
| 3. Tax fees | 11,500 | 10,350 |
| 4. All other fees | 2,275 | 17,732 |
| Totals | $ 90,053 | $ 98,016 |

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. Audit-related fees include consulting fees to meet the compliance requirements of the Sarbanes-Oxley Act. Tax fees include fees for the preparation of our federal and state income tax returns. All other fees are related to consulting costs related to the accounting and recording of complex accounting transactions that occurred in the year ended June 30, 2012.

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 |
|---|---|
| 1.1 | Common Stock Underwriting Agreement, dated October 13, 2011, by and between IsoRay, Inc. and WestPark Capital, Inc., incorporated by reference to the Form 8-K filed on October 13, 2011. |
| 2.1 | Merger Agreement dated as of May 27, 2005, by and among Century Park Pictures Corporation, Century Park Transitory Subsidiary, Inc., certain shareholders and IsoRay Medical, Inc. incorporated by reference to the Form 8-K filed on August 3, 2005. |
| 2.2 | Certificate of Merger, filed with the Delaware Secretary of State on July 28, 2005 incorporated by reference to the Form 8-K filed on August 3, 2005. |
| 3.1 | Articles of Incorporation and By-Laws are incorporated by reference to the Exhibits to the Company's Registration Statement of September 15, 1983. |

| | |
|---|---|
| 3.2 | Certificate of Designation of Rights, Preferences and Privileges of Series A and B Convertible Preferred Stock, filed with the Minnesota Secretary of State on June 29, 2005 incorporated by reference to the Form 8-K filed on August 3, 2005. |
| 3.3 | Restated and Amended Articles of Incorporation incorporated by reference to the Form 10-KSB filed on October 11, 2005. |
| 3.4 | Text of Amendments to the Amended and Restated By-Laws of the Company, incorporated by reference to the Form 8-K filed on February 7, 2007. |
| 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. |
| 4.22 | Form of Series [A] [B] [C] Warrant to Purchase Common Stock, incorporated by reference to the Form 8-K filed on November 22, 2010. |
| 4.23 | Form of Series D Warrant to Purchase Common Stock, incorporated by reference to the Form 8-K filed on November 22, 2010. |
| 4.24 | Form of Amended and Restated Series A Warrant, incorporated by reference to the Form 8-K filed on December 28. 2010. |
| 4.25 | Form of Amended and Restated Series C Warrant, incorporated by reference to the Form 8-K filed on December 28. 2010. |
| 4.26 | |

| | |
|---|---|
| | Form of Common Stock Purchase Warrant, incorporated by reference to the Form 8-K filed on October 13, 2011. |
| 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. |
| 10.18 | State of Washington Radioactive Materials License dated October 6, 2005, incorporated by reference to the Form SB-2 filed on November 10, 2005. |
| 10.19 | Express Pricing Agreement Number 219889, dated October 5, 2005 between FedEx and IsoRay Medical, Inc., incorporated by reference to the Form 10-QSB filed on November 21, 2005. |
| 10.20 | 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 | Intentionally Omitted. |
| 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 | Intentionally Omitted. |
| 10.32 | Intentionally Omitted. |
| 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 | Intentionally Omitted. |
| 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 | Intentionally Omitted. |
| 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 | Intentionally Omitted. |
| 10.51 | Intentionally Omitted. |
| 10.52 | Intentionally Omitted. |
| 10.53 | Intentionally Omitted. |
| 10.62 | Letter Agreement between IsoRay, Inc. and LifeTech Capital, a division of Aurora Capital, LLC dated October 27, 2010, incorporated by reference to the Form 8-K filed on November 22, 2010. |
| 10.63 | Form of Securities Purchase Agreement, dated as of November 22, 2010, by and between IsoRay, Inc. and the signatories thereto, incorporated by reference to the Form 8-K filed on November 22, 2010. |
| 10.64 | Form of Lock-Up Agreement, dated as of November 22, 2010, by and between IsoRay, Inc. and the signatories thereto, incorporated by reference to the Form 8-K filed on November 22, 2010. |
| 10.65 | Amendment Agreement dated as of December 27, 2010, by and among IsoRay, Inc. and the investor that is a signatory thereto, incorporated by reference to the Form 8-K filed on December 28, 2010. |
| 10.66 | License Agreement dated as of June 1, 2011, by and between Dr. Reddy's Laboratories (EU) Ltd. and IsoRay Medical, Inc., incorporated by reference to the Form 8-K filed on June 7, 2011 (confidential treatment requested for redacted portions). |
| 10.67 | Financial Consulting Agreement, dated August 1, 2011, by and between Shareholder Relations and IsoRay Medical, Inc., incorporated by reference to the Form 8-K filed on August 5, 2011. |
| 10.68 | International Distribution Agreement, dated October 31, 2011, by and between IsoRay Medical, Inc. and Karlheinz Goehl-Medizintechnik Gohl, incorporated by reference to the Form 8-K filed on November 3, 2011. |
| 10.69 | Contract No. 77/2011, dated November 24, 2011, by and between IsoRay, Inc. and UralDial LLC, incorporated by reference to the Form 8-K filed on December 8, 2011. |
| 10.70 | Securities Purchase Agreement, dated July 13, 2012, by and between IsoRay, Inc. and certain Purchasers, incorporated by reference to the 8-K filed on July 16, 2012. |
| 10.71 | Placement Agency Agreement, dated July 13, 2012, from IsoRay, Inc. to Ladenburg Thalmann & Co. Inc., incorporated herein by reference to the 8-K filed on July 16, 2012. |
| 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. |
| 99.1 | State of Washington Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Device dated November 21, 2011, filed herewith. |

Reports on Form 8-K

On May 15, 2012, the Company filed a Current Report on Form 8-K announcing its financial results for the quarter ended March 31, 2012.

On July 16, 2012, the Company filed a Current Report on Form 8-K announcing its entry into a Securities Purchase Agreement providing for the sale of up to 3,626,943 shares to certain investors with Ladenberg, Thalmann & Co. Inc. acting as placement agent.

On July 17, 2012, the Company filed an amended Current Report on Form 8-K/A, amending its Current Report on Form 8-K filed on July 16, 2012, to file the legal opinion for the offering as an exhibit to the Report.

**IsoRay, Inc.**

**Index to Financial Statements**

**Report of Independent Registered Public Accounting Firm**

Board of Directors and Shareholders

IsoRay, Inc.

Richland, Washington

We have audited the accompanying consolidated balance sheets of IsoRay, Inc. and Subsidiaries ("the Company") (see Note 1) as of June 30, 2012 and 2011, 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, 2012 and 2011, 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 26, 2012

IsoRay, Inc and Subsidiaries

Consolidated Balance Sheets

| | June 30, 2012 | 2011 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $2,672,711 | $2,112,254 |
| Accounts receivable, net of allowance for doubtful accounts of $57,604 and $63,867, respectively | 865,056 | 792,835 |
| Inventory | 444,345 | 749,849 |
| Other receivables | 9,925 | 425,901 |
| Prepaid expenses and other current assets | 144,116 | 141,154 |
| Total current assets | 4,136,153 | 4,221,993 |
| Fixed assets, net of accumulated depreciation and amortization | 2,416,853 | 3,208,911 |
| Restricted cash | 181,027 | 180,809 |
| Inventory, non-current | 469,758 | - |
| Other assets, net of accumulated amortization | 301,691 | 277,182 |
| Total assets | $7,505,482 | $7,888,895 |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $389,105 | $372,259 |
| Accrued protocol expense | - | 98,159 |
| Accrued radioactive waste disposal | 52,000 | 108,060 |
| Accrued payroll and related taxes | 119,881 | 125,014 |
| Accrued vacation | 88,006 | 70,706 |
| Total current liabilities | 648,992 | 774,198 |
| Warrant derivative liability | 314,000 | - |
| Asset retirement obligation | 724,298 | 662,181 |
| Total liabilities | 1,687,290 | 1,436,379 |
| Commitments and contingencies (Note 16, 17, 18) | | |
| Shareholders' equity: | | |
| Preferred stock, $.001 par value; 7,000,000 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 |
| Series C: 1,000,000 shares allocated; no shares issued and outstanding | - | - |
| Common stock, $.001 par value; 193,000,000 shares authorized; 30,950,108 and 26,443,118 shares issued and outstanding | 30,950 | 26,443 |
| Treasury stock, at cost 13,200 shares | (8,390) | (8,390) |
| Additional paid-in capital | 54,030,311 | 51,180,237 |
| Accumulated deficit | (48,234,738) | (44,745,833) |
| Total shareholders' equity | 5,818,192 | 6,452,516 |
| Total liabilities and shareholders' equity | $7,505,482 | $7,888,895 |

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

IsoRay, Inc and Subsidiaries

Consolidated Statements of Operations

| | For the year ended June 30, 2012 | 2011 |
|---|---|---|
| Product sales | $5,071,088 | $5,238,973 |
| Cost of product sales | 4,367,884 | 4,081,556 |
| Gross income | 703,204 | 1,157,417 |
| Operating expenses: | | |
| Research and development expenses | 780,579 | 981,186 |
| Research and development reimbursement | (50,000) | (515,853) |
| Sales and marketing expenses | 1,215,580 | 1,232,188 |
| General and administrative expenses | 2,355,015 | 2,422,884 |
| Total operating expenses | 4,301,174 | 4,120,405 |
| Operating loss | (3,597,970) | (2,962,988) |
| Non-operating income (expense): | | |
| Interest income | 747 | 3,381 |
| Change in fair value of warrant liability | 170,000 | 334,000 |
| Financing and interest expense | (61,682) | (216,606) |
| Non-operating income (loss) , net | 109,065 | 120,775 |
| Net loss | (3,488,905) | (2,842,213) |
| Preferred stock dividends | (10,632) | (10,632) |
| Net loss applicable to common shareholders | $(3,499,537) | $(2,852,845) |
| Basic and diluted loss per share | $(0.12) | $(0.11) |
| Weighted average shares used in computing net loss per share: | | |
| Basic and diluted | 28,621,831 | 25,131,563 |

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 Stock | | Common Stock | | Treasury Stock | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Shares | Amount | Additional Paid-in Capital | Accumulated Deficit | Total |
| 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 |
| Issuance of common stock and stock purchase warrants pursuant to registered pubic offering, net | | | 2,250,000 | 2,250 | | | 2,217,056 | | 2,219,306 |
| Initial fair value of derivative warrant liablity | | | | | | | (1,724,000 ) | | (1,724,000) |
| Exercise of derivative warrant liability | | | | | | | 119,000 | | 119,000 |
| Reclassification of derivative warrant liability | | | | | | | 1,119,000 | | 1,119,000 |
| Expiration of derivative warrant liability | | | | | | | 152,000 | | 152,000 |
| Issuance of common stock pursuant to at the market, net | | | 304,227 | 304 | | | 250,328 | | 250,632 |
| Issuance of common stock pursuant to exercise of | | | 765,004 | 765 | | | 674,054 | | 674,819 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| warrants, net | | | | | | | | | |
| Issuance of common stock pursuant to exercise of options | | | 75,133 | 75 | | | 55,959 | | 56,034 |
| Payment of dividend to preferred shareholders | | | | | | | (10,632) | | (10,632) |
| Share-based compensation | | | | | | | 242,689 | | 242,689 |
| Net loss | | | | | | | | (2,842,213) | (2,842,213) |
| Balances at June 30, 2011 | 59,065 | $59 | 26,443,118 | $26,443 | 13,200 | $(8,390) | $51,180,237 | $(44,745,833) | $6,452,516 |
| Issuance of common stock and stock purchase warrants pursuant to registered pubic offering, net | | | 2,817,988 | 2,818 | | | 2,271,668 | | $2,274,486 |
| Initial deferral of financing costs | | | | | | | 61,511 | | $61,511 |
| Initial fair value of derivative liablity | | | | | | | (484,000) | | $(484,000) |
| Issuance of common stock pursuant to exercise of warrants, net | | | 1,669,402 | 1,669 | | | 833,128 | | 834,797 |
| Issuance of common stock pursuant to exercise of options | | | 19,600 | 20 | | | 5,076 | | 5,096 |
| Payment of dividend to preferred shareholders | | | | | | | (10,632) | | (10,632) |
| Share-based compensation | | | | | | | 173,323 | | 173,323 |
| Net loss | | | | | | | | (3,488,905) | (3,488,905) |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Balances at June 30, 2012 | 59,065 | $59 | 30,950,108 | $30,950 | 13,200 | $(8,390) | $54,030,311 | $(48,234,738) | $5,818,192 |

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

**IsoRay, Inc and Subsidiaries**

**Consolidated Statements of Cash Flows**

| | For the Year Ended | |
|---|---|---|
| | June 30, 2012 | June 30, 2011 |
| Cash flows from operating activities: | | |
| Net loss | $(3,488,905) | $(2,842,213) |
| Adjustments to reconcile net loss to net cash used by operating activities: | | |
| Allowance for doubtful accounts | (6,263) | 27,477 |
| Depreciation and amortization of fixed assets | 847,115 | 888,568 |
| Amortization of deferred financing costs and other assets | 77,242 | 233,180 |
| Gain on fair value of warrant liabilities | (170,000) | (334,000) |
| Accretion of asset retirement obligation | 62,117 | 56,790 |
| Share-based compensation | 173,323 | 242,689 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | (65,958) | 75,954 |
| Inventory | (164,254) | (68,172) |
| Other receivables | 415,976 | (421,902) |
| Prepaid expenses, other current assets and other assets | (2,962) | (89,951) |
| Accounts payable and accrued expenses | 16,846 | (32,142) |
| Accrued protocol expense | (98,159) | (143,870) |
| Accrued radioactive waste disposal | (56,060) | 48,000 |
| Accrued payroll and related taxes | (5,133) | (61,499) |
| Accrued vacation | 17,300 | 2,181 |
| Net cash used by operating activities | (2,447,775) | (2,418,910) |
| | | |
| Cash flows from investing activities: | | |
| Purchases of fixed assets | (55,057) | (137,496) |
| Additions to licenses and other assets | (40,240) | (19,718) |
| Change in restricted cash | (218) | (655) |
| Net cash used by investing activities | (95,515) | (157,869) |
| | | |
| Cash flows from financing activities: | | |
| Principal payments on notes payable | - | (179,995) |
| Preferred dividends paid | (10,632) | (10,632) |
| Proceeds from sales of common stock, pursuant to registered public offering, net | 2,274,486 | 2,219,306 |
| Proceeds from sales of common stock, pursuant to at the market, net | - | 250,632 |
| Proceeds from sales of common stock, pursuant to exercise of warrants, net | 834,797 | 674,819 |
| Proceeds from cash sales of common stock, pursuant to exercise of options | 5,096 | 56,034 |
| | | |
| Net cash provided by financing activities | 3,103,747 | 3,010,164 |
| | | |
| Net increase decrease in cash and cash equivalents | 560,457 | 433,385 |

| | | |
|---|---|---|
| Cash and cash equivalents, beginning of year | 2,112,254 | 1,678,869 |
| Cash and cash equivalents, end of year | $2,672,711 | $2,112,254 |
| Supplemental disclosures of cash flow information: | | |
| Cash paid for interest | $171 | $10,720 |
| Non-cash investing and financing activities: | | |
| Initial deferral of financing expense | $61,511 | $- |
| Initial fair value of warrant liabilities | 484,000 | 1,724,000 |
| Total non-cash investing and financing activities | $545,511 | $1,724,000 |
| Reclassification of derivative warrant liability to equity upon exercise | $- | $(119,000.00) |
| Reclassification of derivative warrant liability to equity | - | (1,119,000 ) |
| Reclassification of derivative warrant liability to equity upon expiration | - | (152,000 ) |
| Total Reclassification of derivative warrant liability | $- | $(1,390,000 ) |

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

**IsoRay, Inc.**

**Notes to Consolidated Financial Statements**

**For the years ended June 30, 2012 and 2011**

## 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.

## 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.

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.

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 no longer useable.

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.

Other Assets

Other assets, which include deferred charges, patents and licenses, 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. Licenses include costs related to licenses related to the use of technology or operational licenses. These licenses are recorded at stated cost, less accumulated amortization. Amortization of licenses is computed using the straight-line method over the estimated economic useful lives of the assets. The Company periodically reviews the carrying values of licenses and evaluates the recorded basis for any impairments. Any impairments are recognized when the expected future operating cash flows to be derived from the licenses are less than their carrying value. 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.

Asset Retirement Obligation

The estimated 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 fixed assets. 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.

Financial Instruments

At June 30, 2012 and 2011, the carrying value of financial instruments such as accounts receivable, other receivables, accounts payable and accrued liabilities, approximated fair value based on the short-term maturities of these 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.

Fair Value Measurement

ASC Topic 820, *Fair Value Measurements and Disclosures,* establishes a fair value hierarchy for those assets and liabilities measured at fair value which distinguishes between assumptions based on market data (observable inputs). The hierarchy consists of: Level 1 – quoted market prices in active markets for identical instruments; Level 2 – inputs other than Level 1inputs that are observable; and Level 3 – unobservable inputs developed using estimates and assumptions determined by the Company.

At June 30, 2012 and 2011, there were no assets or liabilities measured at fair-value on a recurring basis which were measured using Level 1 inputs. The Company had one liability, the warrant derivative liability that was measured at fair value on a recurring basis using Level 2 inputs during the years ended June 30, 2012 and 2011. Certain assets and liabilities are measured at fair value on a non-recurring basis; that is, the instruments are not measured at fair-value on an ongoing basis, but are subject to fair value adjustments only in certain circumstances (for example, when there is evidence of impairment). The Company had no assets measured at fair value on a nonrecurring basis during the years ended June 30, 2012 or 2011.

Warrant Derivative Liabilities

For the warrant derivative liabilities which are measured at fair value on a recurring basis, the Company uses the Black-Scholes valuation model.

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, 2012 and 2011 was derived primarily from sales of the Proxcelan Cs-131 brachytherapy seed, which is used in the treatment of cancer. The Company began shipping its GliaSite Radiation Therapy System in the fiscal year ended June 30, 2012 which is used in the treatment of brain 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 its 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.

Research and Development Reimbursement

Research and development reimbursement includes allowable costs that have been incurred for related grants and other cost sharing arrangements for product research and development. These amounts have been recorded in prepaid expenses and other current assets. An accrual in prepaid expenses and other current assets for these cost reimbursements is recorded in the year in which it is earned and the accrual is relieved when the reimbursement is received. Research and development reimbursements were $50,000 and $515,853 for the year ended June 30, 2012 and 2011 respectively. As of June 30, 2012 and 2011, none and $406,537 were receivable from the Internal Revenue Service and recorded in prepaid expense and other current assets. These amounts were the result of the receipt of three grants awarded from the Internal Revenue Service in October 2010 as part of the IRS Qualified Therapeutic Discovery Project, which covered expenses incurred during the fiscal and tax years ended June 30, 2012 and 2011, respectively.

Advertising and Marketing Costs

Advertising costs are expensed as incurred except for the cost of tradeshows and related marketing materials which are deferred until the tradeshow occurs. Advertising and marketing costs expensed (including tradeshows) were $57,410 and $83,815 for the years ended June 30, 2012 and 2011, respectively. Marketing costs of $8,675 and $4,300 were included in prepaid expenses at June 30, 2012 and 2011, respectively.

Legal Contingencies

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 2010 through 2012 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, 2012 and 2011 are as follows:

| | 2012 | 2011 |
|---|---|---|
| Preferred stock | 59,065 | 59,065 |
| Common stock warrants | 1,959,799 | 3,819,185 |
| Common stock options | 2,381,306 | 2,423,806 |
| Total potential dilutive securities | 4,400,170 | 6,302,056 |

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.

## 3. Inventory

Inventory consisted of the following at June 30, 2012 and 2011:

| | 2012 | 2011 |
|---|---|---|
| Raw materials | $261,835 | $625,394 |

| | | |
|---|---|---|
| Work in process | 114,124 | 120,180 |
| Finished goods | 68,386 | 4,275 |
| Total inventory | $444,345 | $749,849 |

In June 2007, the Company purchased $469,758 of enriched barium that will be used in future production of its isotope. The enriched barium is held at an off-site storage location in Richland, Washington and was included in raw materials at June 30, 2011, and is now classified as inventory, non-current at June 30, 2012. The Company reclassified the material based on revised plans of management for utilizing the material.

**4. Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consisted of the following at June 30, 2012 and 2011:

| | 2012 | 2011 |
|---|---|---|
| Prepaid insurance | $23,798 | $26,285 |
| Prepaid rent | 23,367 | 23,697 |
| Other prepaid expenses | 70,258 | 64,479 |
| Other current assets | 26,693 | 26,693 |
| | $144,116 | $141,154 |

**5. Other Receivables**

Other receivables consisted of receivables that are not the result of revenue creating activities of the Company. The other receivable recorded as of June 30, 2012 was primarily comprised of employee advances and refunds due to the Company in the amount of $9,925. The other receivable recorded as of June 30, 2011 was primarily a receivable that was created as the result of Qualified Therapeutic Discovery Project grants received by the Company in October 2010. Research and development reimbursements for project related costs are recorded as operational expense recoveries with the related entry being recorded in other receivables as earned. The payment of this other receivable was received in July 2011 and was $406,537 of the total other receivables amount of $425,901.

**6. Fixed Assets**

Fixed assets consisted of the following at June 30, 2012 and 2011:

| | 2012 | 2011 |
|---|---|---|
| Production equipment | $3,133,305 | $3,047,899 |
| Office equipment | 189,301 | 103,597 |
| Furniture and fixtures | 148,265 | 148,265 |
| Leasehold improvements | 4,129,977 | 4,122,417 |
| Construction in progress | - | 123,613 |
| | 7,600,848 | 7,545,791 |
| Less accumulated depreciation | (5,183,995) | (4,336,880) |

| | |
|---|---|
| $2,416,853 | $3,208,911 |

Depreciation and amortization expense related to fixed assets totaled $847,115 and $888,568 for 2012 and 2011, respectively.

## 7. 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 termed restricted cash and classified as a long-term asset 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 remaining 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, 2012 and 2011 was $218 and $655, respectively. These funds will be used to settle a portion of the Company's remaining asset retirement obligations (Note 9).

## 8. Other Assets

Other assets, net of accumulated amortization, consisted of the following at June 30, 2012 and 2011:

| | 2012 | 2011 |
|---|---|---|
| Deferred charges | $98,435 | $73,988 |
| Patents and trademarks, net of accumulated amortization of $71,244 and $55,513 | 203,256 | 203,194 |
| | $301,691 | $277,182 |

Amortization of patents and trademarks was $15,731 and $15,130 for the years ended June 30, 2012 and 2011, respectively.

| | |
|---|---|
| FY2013 | $16,597 |
| FY 2014 | 16,597 |
| FY 2015 | 16,597 |
| FY 2016 | 16,597 |
| FY 2017 | 14,109 |
| Thereafter | $122,758 |

## 9. Asset Retirement Obligation

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 facility using level 3 fair value inputs.

During the years ended June 30, 2012 and 2011, the asset retirement obligations changed as follows:

| | 2012 | 2011 |
|---|---|---|
| Beginning balance | $662,181 | $605,391 |
| Accretion of discount | 62,117 | 56,790 |
| Ending balance | $724,298 | $662,181 |

Because the Company does not expect to incur any expenses related to its asset retirement obligations in fiscal year 2013, the entire balance as of June 30, 2012 is classified as a noncurrent liability.

## 10. Share-Based Compensation

The following table presents the share-based compensation expense recognized during the years ended June 30, 2012 and 2011:

| | 2012 | 2011 |
|---|---|---|
| Cost of product sales | $47,463 | $35,087 |
| Research and development | 30,480 | 22,380 |
| Sales and marketing expenses | 10,182 | 10,004 |
| General and administrative expenses | 85,198 | 175,218 |
| Total share-based compensation | $173,323 | $242,689 |

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, 2012, total unrecognized compensation cost related to stock-based options and awards was $179,509 and the weighted-average period over which it is expected to be recognized is approximately 0.95 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 as of June 30, 2012 is as follows:

| | Shares | Price (a) | Life (b) | Value (c) |
|---|---|---|---|---|
| Outstanding at June 30, 2012 | 2,381,306 | $1.82 | 5.64 | $473,951 |
| Vested and expected to vest at June 30, 2012 | 2,283,968 | $1.86 | 5.59 | $432,860 |
| Vested and exercisable at June 30, 2012 | 2,102,964 | $1.92 | 5.36 | $460,950 |

(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, 2012 and 2011 was $13,764 and $15,598, 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 years ended June 30, 2012 and 2011:

| | Years ended June 30, |
|---|---|

| | 2012 (a) | 2011 (b) |
|---|---|---|
| Weighted average fair value of options granted | $0.80 | $0.84 |
| Key assumptions used in determining fair value: | | |
| Weighted average risk-free interest rate | 0.71 % | 1.54 % |
| Weighted average life of the option (in years) | 4.77 | 4 .83 |
| Weighted average historical stock price volatility | 132.47% | 130.04% |
| Expected dividend yield | 0.00 % | 0.00 % |

(a) During the year ended June 30, 2012, the Company granted 110,000 stock options.
(b) During the year ended June 30, 2011, the Company granted 357,500 stock options.

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.

A summary of the Company's stock option activity and related information for the years ended June 30, 2012 and 2011 is as follows:

| | 2012 | | 2011 | |
|---|---|---|---|---|
| | Shares | Price (a) | Shares | Price (a) |
| Beginning balance outstanding | 2,423,806 | $1.78 | 2,274,706 | $1.96 |
| Granted (b) | 110,000 | 0.80 | 357,500 | 0.99 |
| Expired | (132,900) | 0.68 | (133,267) | 3.28 |
| Exercised | (19,600) | 0.26 | (75,133) | 0.75 |
| Ending balance outstanding | 2,381,306 | $1.82 | 2,423,806 | $1.78 |
| Exercisable at end of year | 2,102,964 | $1.92 | 1,951,114 | $2.01 |

(a) Weighted average exercise price per share.

(b) All options granted had exercise prices equal to or greater than the ending closing market price of the Company's common stock on the grant date. The options were granted to employees and management by the Board of Directors and had vesting periods from immediate to three years.

**11. 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 7,000,000 shares of $0.001 par value preferred stock available for issuance with such rights and preferences, including liquidation, dividend, conversion, and voting rights, as described

below.

Series A

Series A preferred shares are entitled to a 10% dividend annually on the stated par value per share. These shares are convertible into shares of common stock at the rate of one share of common stock for each share of Series A preferred stock, and are subject to automatic conversion into common stock upon the closing of an underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933 covering the offer and sale of common stock in which the gross proceeds to the Company are at least $4 million. Series A preferred shareholders have voting rights equal to the voting rights of common stock, except that the vote or written consent of a majority of the outstanding preferred shares is required for any changes to the Company's Articles of Incorporation, Bylaws or Certificate of Designation, or for any bankruptcy, insolvency, dissolution or liquidation of the Company. Upon liquidation of the Company, the Company's assets are first distributed ratably to the Series A preferred shareholders. At June 30, 2012 and 2011, there were no Series A preferred shares outstanding.

Series B

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

On December 16, 2011, the Board of Directors declared a dividend on the Series B Preferred Stock of all outstanding and cumulative dividends through December 31, 2011. The total dividends of $10,632 were paid as of December 31, 2011. At June 30, 2012, there were 59,065 Series B preferred shares outstanding and cumulative dividends in arrears were $5,316 and upon any liquidation, dissolution, or winding up of the Company, whether voluntary or involuntary, the assets of the Company legally available for distribution, if any, shall be distributed ratably first, to the holders of the Series A Preferred Stock, second, to the holders of the Series B Preferred Stock and third, to the holders of the Common Stock.

Series C

Series C preferred shares are entitled to a quarterly dividend equal, per share, to the greater of $1.00 or 100 times the dividends declared on the common stock in such quarter. Each share of Series C preferred stock has voting rights equal to the voting rights of 100 shares of common stock. The Series C preferred stock was created upon adoption of the Company's share rights plan in 2007. Upon liquidation of the Company, the Company's assets are first distributed ratably to the Series A preferred shareholders, then the Series B preferred shareholders, then the Series C preferred shareholders. At June 30, 2012 and 2011, there were no Series C preferred shares outstanding.

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, 2012 and 2011.

Common Stock Offering

On October 1, 2010, the Company made an “at the market” sale of common stock. Through October 31, 2010, 304,227 shares of common stock were sold on behalf of the Company.

The gross cash proceeds and offering costs are described below.

| | October 1, 2010<br>At the market offering |
|---|---|
| Gross cash proceeds | $ 368,781 |
| Commission expense | (7,302) |
| Legal and accounting expense | (110,276) |
| Other costs | (571) |
| Net cash proceeds | $ 250,632 |

In October 2010, the Company offered a temporary reduction in the exercise price of certain warrants to purchase shares of common stock previously issued.

On October 20, 2010 the Company commenced soliciting warrant exercises from existing holders at a reduced exercise price of $0.95 per warrant exercised prior to October 31, 2010. Warrant holders exercised warrants to purchase 226,344 shares of common stock.

| | October 20, 2010<br>Warrant solicitation |
|---|---|
| Gross cash proceeds | $ 215,027 |
| Legal and accounting expense | (15,208) |
| Net cash proceeds | $ 199,819 |

On November 22, 2010, the Company entered into a Securities Purchase Agreement (as amended on December 27, 2010 and March 31, 2011) as part of the Company's registered offering with an institutional investor and closed the transaction on November 24, 2010 for the sale of 2,250,000 shares of common stock and four series of warrants.

By letter agreement dated October 27, 2010, LifeTech Capital, a division of Aurora Capital, LLC, acted as placement agent in connection with the placement of the securities in this offering. LifeTech received a cash fee of 5% of the gross proceeds received under the Offering (excluding proceeds received on the exercise of C or D Warrants), and warrants to purchase 3% of the common stock sold in the Offering and 3% of the Series A, B and C Warrants exercised at any time, which warrants issued to LifeTech were not exercisable for six months following the closing, have a five year term, and an exercise price of $1.56 per share.

| | November 22, 2010<br>Registered public offering |
|---|---|
| Gross cash proceeds | $ 2,250,000 |
| Commission expense | (112,500) |
| Legal and accounting expense | (108,927) |
| Other costs | (2,318) |
| Financing costs | 193,051 |
| Net cash proceeds | $ 2,219,306 |

On October 13, 2011, the Company entered into an Underwriting Agreement with WestPark Capital, Inc. as managing underwriter for a best efforts all or nothing underwritten registered offering of 2,500,000 shares of the Company's common stock, par value $0.001 per share, at an offering price to the public of $0.92 per share. With every five shares of common stock purchased, the purchaser received a warrant to purchase one share of common stock with an exercise price of $1.058 with a five year term for a total of 500,003 warrants issued in the initial transaction. Under the terms of the Underwriting Agreement, the Company also granted the underwriters a 45 day option to sell up to an additional 1,027,173 shares of Common Stock (with warrants to purchase up to an additional 205,435 shares of common stock) to cover over-allotments, if any, at the offering price. There were 317,988 shares of common stock sold from the over-allotment and 63,598 warrants issued as part of the sale of the over-allotment shares. None of the warrants from either the initial sale of shares of common stock or from those sold as part of the over-allotment sale of shares of common stock have been exercised. The gross proceeds and net proceeds to the Company from the sale of the initial 2.5 million shares of common stock and from the over-allotment sale of 317,988 shares of common stock were as described in the table below.

| | October 19, 2011 Registered offering | December 7, 2011 Over-allotment | Total |
|---|---|---|---|
| Gross cash proceeds | $ 2,300,000 | $ 292,549 | $2,592,549 |
| Underwriting costs [1] | (140,087) | (15,696) | (155,783) |
| Legal costs | (100,050) | (14,230) | (114,280) |
| Other costs | (46,500) | (1,500) | (48,000) |
| Net cash proceeds | $ 2,013,363 | $ 261,123 | 2,274,486 |

[1] – Underwriting costs include commissions paid directly to the underwriter and underwriting fees.

Warrants to Purchase Common Stock

On November 22, 2010, the Company entered into a Securities Purchase Agreement (as amended on December 27, 2010 and March 31, 2011) as part of the Company's registered offering with an institutional investor and closed the transaction on November 24, 2010 for the sale of 2,250,000 shares of common stock and four series of warrants. The total warrants exercisable in Series A, Series B and Series C will be a maximum aggregate of 2,168,026 for a maximum number of below market securities issued, together with the shares of common stock sold in the offering, of no greater than 4,418,026 shares of common stock, which is the maximum issuable under the NYSE MKT requirements without obtaining shareholder approval for the issuance. Series D Warrants which are not below market securities are expected to be exercisable to purchase 1,873,641 shares of common stock.

By letter agreement dated October 27, 2010, LifeTech Capital, a division of Aurora Capital, LLC, acted as placement agent in connection with the placement of the securities in this offering. LifeTech received a cash fee of 5% of the gross proceeds received under the Offering (excluding proceeds received on the exercise of C or D Warrants), and warrants to purchase 3% of the common stock sold in the Offering and 3% of the Series A, B and C Warrants exercised at any time, which warrants issued to LifeTech were not exercisable for six months following the closing, have a five year term, and an exercise price of $1.56 per share.

Based on the guidance contained in ASC 815, management had concluded that the warrants in Series A, Series B, and Series C should be classified a liability and had recorded a liability at fair value. The Company determined the fair value of the warrants using the Black-Scholes fair value model. The Company determined the fair value of the warrants on the date of the offering. The Company has recognized a gain on the change in fair value during the year ended June 30, 2011.

Initial fair value of warrants at November 24, 2010:

| | |
|---|---|
| Series A | $191,000 |
| Series B | 236,000 |
| Series C | 1,297,000 |
| Total initial fair value | $1,724,000 |

Change in fair value of warrants through June 30, 2011

| | |
|---|---|
| Series A | $72,000 |
| Series B | 84,000 |

| | |
|---|---|
| Series C | 178,000 |
| Total change in on fair value | $334,000 |

The inputs to the Black-Scholes fair value model are listed in the table below:

Series A warrants

| Transaction Date | Description | Quantity | Stock Price | Exercise Price | Estimated Term | Expected Volatility | Risk-Free Rate | Valuation |
|---|---|---|---|---|---|---|---|---|
| 11/24/2010 | Registered offering | 481,696 | $1.36 | $1.038 | 3 mo. | 71.70 % | 0.187 % | $191,000 |
| 12/31/2010 | Fair value adjust. | 508,130 | 1.13 | 0.984 | 3 mo. | 59.28 % | 0.167 % | (75,000) |
| 03/24/2011 | Fair value adjust. | 538,660 | 1.07 | 0.921 | 3 mo. | 58.81 % | 0.143 % | 3,000 |
| 03/24/2011 | Reclassify to equity | | | | | | | (119,000) |
| Total derivative warrants outstanding | | | | | | | | $- |

Series B warrants

| Transaction Date | Description | Quantity | Stock Price | Exercise Price | Estimated Term | Expected Volatility | Risk-Free Rate | Valuation |
|---|---|---|---|---|---|---|---|---|
| 11/24/2010 | Registered offering | 562,500 | $1.36 | $1.038 | 6 mo. | 66.50 % | 0.200 % | $236,000 |
| 12/31/2010 | Fair value adjust. | 562,500 | 1.13 | 0.984 | 6 mo. | 62.22 % | 0.190 % | (86,000) |
| 03/31/2011 | Fair value adjust. | 562,500 | 1.26 | 0.921 | 6 mo. | 63.41 % | 0.170 % | 79,000 |
| 05/24/2011 | Fair value adjust. | 562,500 | 1.07 | 0.876 | 6 mo. | 56.88 % | 0.110 % | (77,000) |
| 05/24/2011 | Warrant expiration | | | | | | | (152,000) |
| Total derivative warrants outstanding | | | | | | | | $- |

Series C warrants

| Transaction Date | Description | Quantity | Stock Price | Exercise Price | Estimated Term | Expected Volatility | Risk-Free Rate | Valuation |
|---|---|---|---|---|---|---|---|---|
| 11/24/2010 | Registered Offering | 1,122,825 | $1.36 | $1.038 | 3 yrs | 156.60 % | 0.810 % | $1,297,000 |
| 12/31/2010 | Fair value adjust. | 1,096,391 | 1.13 | 0.984 | 3 yrs | 155.92 % | 1.020 % | (259,000) |
| 03/31/2011 | Fair value adjust. | 1,049,701 | 1.26 | 0.921 | 3 yrs | 153.35 % | 1.290 % | 81,000 |
| 03/31/2011 | Reclassify to equity | | | | | | | (1,119,000) |
| Total derivative warrants outstanding | | | | | | | | $- |

On March 24, 2011, the warrant holder exercised the Series A warrants and received 538,660 shares of common stock at exercise in exchange for cash. The Company reclassified the remaining fair value as of the exercise date of the Series A warrant liability to additional paid in capital.

| | Exercise of Series A warrants |
|---|---|
| Gross cash proceeds | $ 500,000 |
| Commissions expense | (25,000) |
| Net cash proceeds | $ 475,000 |

The warrant derivative liability that was reclassified to equity at February 24, 2011 was $119,000 upon the exercise of the Series A Warrants for shares of common stock.

At March 31, 2011, the Company and the warrant holder agreed to a modification of the Series C warrants that allowed the Company to reclassify these warrants as equity. The Company reclassified the remaining fair value as of March 31, 2011 of the Series C warrant liability to additional paid in capital.

The amount reclassified to equity as part of this modification of warrants at March 31, 2011 was $1,119,000.

The warrant holder allowed the Series B warrants to expire unexercised on May 24, 2011. The Company reclassified the remaining fair value as of the expiration date of the Series B warrant liability to additional paid in capital.

The amount reclassified to equity as part of this expiration of warrants at May 24, 2011 was $152,000.

In October 2010, the Company offered a temporary reduction in the exercise price of certain warrants to purchase shares of common stock previously issued.

On October 20, 2010 the Company commenced soliciting warrant exercises from existing holders at a reduced exercise price of $0.95 per warrant exercised prior to October 31, 2010. Warrant holders exercised warrants to purchase 226,344 shares of common stock. This solicitation of warrants yielded $199,819 net of offering costs.

At various times during the year ended June 30, 2012, the warrant holder exercised Series C warrants and received shares of common stock in exchange at the time of the exercise.

| | Warrants exercised | Gross proceeds |
|---|---|---|
| July 2011 | 50,000 | $ 40,244 |
| May 2012 | 1,579,402 | 773,032 |
| June 2012 | 40,000 | 21,521 |
| Total | 1,669,402 | $ 834,797 |

The warrants activity is summarized as follows for the years ended June 30, 2012 and 2011:

| | 2012 | | 2011 | |
|---|---|---|---|---|
| | Warrants | Price (a) | Warrants | Price (a) |
| Beginning balance outstanding | 3,819,185 | $ 3.69 | 3,165,768 | $ 5.62 |
| Cancelled/expired | (2,092,324) | 5.89 | (816,100 ) | 5.00 |
| Warrants exercised | (1,669,402) | .050 | (765,004 ) | 0.97 |
| Granted | 1,902,340 | 1.36 | 2,234,521 | 1.00 |
| Ending balance outstanding | 1,959,799 | $ 1.38 | 3,819,185 | $ 3.69 |

(a) Weighted average exercise price per share.

The following table summarizes additional information about the Company's common warrants outstanding as of June 30, 2012:

| Number of Warrants | Range of Exercise Prices | Expiration Date |
|---|---|---|
| 6,000 | $ 1.180 | June 2015 |
| 25,000 | 2.000 | July 2015 |
| 2,766 | 0.984 | November 2015 |
| 1,207,832 | 1.560 | November 2015 |
| 650,003 | 1.058 | October 2016 |
| 63,198 | 1.058 | December 2016 |
| 5,000 | 0.980 | June 2017 |
| 1,959,799 | | |

**12. Income Taxes**

The Company did not record an income tax provision or benefit for the years ending 2012 and 2011.

The significant deferred tax components using a 35% federal income tax rate for the years ended June 30, 2012 and 2011 are as follows:

| | 2012 | 2011 |
|---|---|---|
| Property, plant and equipment | $62,756 | $85,305 |
| Stock based compensation | 241,166 | 180,503 |

| | | |
|---|---|---|
| Reserves | 20,161 | 22,353 |
| Other accruals | 30,145 | 19,798 |
| Asset retirement obligation | 253,504 | 231,763 |
| Net operating loss | 13,608,723 | 12,533,730 |
| | | |
| Total deferred tax assets | 14,216,455 | 13,073,452 |
| Valuation allowance | (14,216,455) | (13,073,452) |
| Net deferred tax asset | $- | $- |

As management of the Company cannot determine that it is more likely than not that the Company will realize the benefit of the net deferred tax asset, a valuation allowance equal to 100% of the net deferred tax asset has been recorded at year ends June 30, 2012 and 2011.

The Company has federal net operating loss carry-forwards of approximately $38.9 million at June 30, 2012 and approximately $35.8 million at June 30, 2011 in available losses that can be used to offset future regular taxable income. These net operating loss carry-forwards losses expire at various times through the years 2025 to 2032.

The Company's statutory rate reconciliation is as follows:

| | 2012 | 2011 |
|---|---|---|
| Expected income tax benefit base on statutory rate of 35% | $(1,221,117) | $(994,775 ) |
| Travel and entertainment | 17,999 | 11,891 |
| Officer’s life insurance | - | 84 |
| Non deductible penalties | 614 | 2,459 |
| Warrant liability | 59,500 | (116,900 ) |
| Increase in valuation allowance | 1,143,004 | 1,097,241 |
| Income tax expense (benefit) | $- | $- |

The Company has reviewed the tax positions taken and concluded that it does not have to book a liability for uncertain tax positions.

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 2010 through 2012 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.

## 13. 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.

## 14. 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 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.

In December 2010, the Company negotiated a contract to purchase Cs-131 from UralDial which was renewed in December 2011. Under the contract, 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 Company has an existing distribution agreement with UralDial that allows UralDial to distribute Proxcelan Cs-131 brachytherapy seeds in Russia. There was no revenue from this agreement in the years ended June 30, 2012 or June 30, 2011.

**15. Distribution Agreement**

On October 31, 2011, the Company entered into a distribution agreement with Karlheinz Goehl-Medizintechnik Goehl (Distributor) located in Germany. The agreement appoints the Distributor as the exclusive distributor of the GliaSite Radiation Therapy System within the defined territory of Germany, Austria, Switzerland, Italy, and Luxembourg. The agreement terminates on August 30, 2013 unless terminated earlier as provided for within the agreement and may be extended by mutual agreement of the Company and the Distributor. The terms of the agreement make the Distributor the importer of record and liable for any value added taxes for the shipments into the European Union. The Distributor paid $50,000 towards the costs of returning the GliaSite RTS to market in the European Union.

## 16. Commitments and Contingencies

Royalty Agreement for Invention and Patent Application

A shareholder of the Company previously assigned his rights, title and interest in an invention to IsoRay Products LLC (a predecessor company) in exchange for a royalty equal to 1% of the Gross Profit, as defined, from the sale of "seeds" incorporating the technology. The patent and associated royalty obligations were transferred to the Company in connection with the merger 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 2012 and 2011, the Company recorded royalty expenses of $19,497 and $26,474, 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 the possibility of a negative outcome in this matter is remote.

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

Operating Lease Agreements

The Company leases office and laboratory space and production and office equipment under 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.

Future minimum lease payments under operating leases are as follows:

| Year ending June 30, | Amount |
|---|---|
| 2013 | $286,212 |
| 2014 | 286,212 |
| 2015 | 286,212 |
| 2016 | 238,510 |
| | $1,097,146 |

Rental expense amounted to $290,670 and $282,654 for the years ended June 30, 2012 and 2011, respectively.

Qualified Therapeutic Discovery Project Grant

The Company received three grants during the fiscal year ended June 30, 2011 under the Internal Revenue Service administered Qualified Therapeutic Discovery Project. These grants are subject to examination by the Service. Management believes that the Company complied with the guidance provided by the service for "Qualified Investments" includible in the QTDP. The QTDP guidance provided broad language allowing the Service the ability to disallow costs. The total amount of the grants is included in the research and development reimbursement section of the Consolidated Statement of Operations in the amount of $0 and $515,853 for the years ended June 30, 2012 and 2011, respectively, and this amount is subject to examination by the Service.

Royalty Agreements for Licensed Intellectual Property related to the GliaSite Radiation Therapy System

The Company is required to pay a royalty to Dr.Reddy’s for the exclusive use in the field of treating brain cancer related to the intellectual property utilized in the production of Iotrex which is a component of the the GliaSite Radiation Therapy System. The term of the royalty agreement is from the date of first sale until the expiration of the last patent. The agreement provides for certain minimum payments based on calendar year periods and a rate of 2.75% of net sales as defined in the agreement. The initial royalty year began on January 1, 2012.

| Royalty Period | Minimum Royalty |
|---|---|
| CY 2012 | $ 5,000 |
| CY 2013 | 10,000 |
| CY 2014 | 20,000 |
| CY 2015 | 25,000 |
| CY 2016 and beyond | $ 30,000 |

During the fiscal year ended June 30, 2012, the Company recorded the initial royalty expense under the agreement of $1,694 for the first six months of the initial calendar year minimum royalty period. There was no royalty expense in the fiscal year ended June 30, 2011.

The Company is required to pay a royalty to Hologic, Inc for the exclusive worldwide use of intellectual property exclusive of the radioisotope associated with the GliaSite Radiation Therapy System in the field of intracavity radiation therapy of the brain. The term of the royalty agreement is from the effective date of the agreement (January 1, 2012) and continues thereafter unless terminated earlier as defined in the agreement. The agreement provides for a royalty payment based on a rate of 5% of net sales as defined in the agreement.

During fiscal year 2012, the Company recorded aggregate royalty expenses of $3,370 related to the licensed intellectual property utilized in the manufacture and sale of the GliaSite Radiation Therapy System. There was no royalty expense in the fiscal year ended June 30, 2011.

## 17. Concentrations of Credit and Other Risks

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents, 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, 2012, cash balances uninsured by the FDIC totaled approximately $300,000.

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, 2012 and two customers whose sales were greater than 10% for the year ended 2011. These customers represented a combined 9.1% and 28.4% of the Company's total revenues for the years ended June 30, 2012 and 2011, respectively. These same customers accounted for a combined 50.1% and 28.8% of the Company's net accounts receivable balance at June 30, 2012 and 2011, 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.

Virtually all of the components used in the production of the GliaSite RTS are from single sources. We do not have formal written agreements with those suppliers. Any interruption or delay in the supply of these components could harm our business as the cost and/or time required meet the regulatory requirements of the Food and Drug Administration for the United States and our notified body for our CE mark (the British Standards Institute) in the European Union may be prohibitive.

**18. Related Party Transaction**

During the fiscal years ended June 30, 2012 and June 30, 2011, the Company engaged the services of APEX Data Systems, Inc., owned by Dwight Babcock, Chairman and Chief Executive Officer, to build and maintain a web interfaced data collection application to aggregate patient data in a controlled environment. The Company incurred $18,270 in costs related to the development of a mono-therapy registry and a combo-therapy registry which are recorded as fixed assets as of June 30, 2012 and maintenance costs related to the registries in the amount of $13,080

for the fiscal year 2012. The Company incurred $62,401 in costs related to this application, which are recorded as a fixed asset at June 30, 2011. The amount accrued for payment to APEX Data Systems, Inc. was $1,000 and $5,320 at June 30, 2012 and 2011, respectively.

## 19. Subsequent Event

On July 13, 2012, the Company entered into an agreement to sell 3,626,943 shares of common stock in a registered direct offering with an aggregate purchase price of $3.5 million at a price per share of $0.965. The offering yielded $3,296,128 in cash after expenses.

| | |
|---|---|
| Gross proceeds of registered direct offering | $3,500,000 |
| Commissions expense | (87,500) |
| Legal expense | (65,785) |
| Listing expense | (47,000) |
| Other expense | (3,587) |
| Net proceeds | $3,296,128 |

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, 2012

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, 2012

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

/s/ Brien L. Ragle
Brien L. Ragle, Controller,

Principal Financial and Accounting Officer

Robert Kauffman, Director and Vice-Chairman

/s/ Thomas LaVoy
Thomas LaVoy, Director

/s/ Albert Smith
Albert Smith, Director