FORM 10-K

IsoRay, Inc. - ISR

Filed: September 30, 2013 (period: June 30, 2013)

Annual report with a comprehensive overview of the company

United States Securities And Exchange Commission
Washington, D.C. 20549

FORM 10-K

☒ **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the fiscal year ended June 30, 2013

or

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

Commission File No. 001-33407

IsoRay, Inc
(Exact name of registrant as specified in its charter)

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

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

Securities registered pursuant to Section 12(b) of the Exchange Act – Common Stock – $0.001 par value
(NYSE 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 27, 2013
Common stock, $0.001 par value	38,419,502

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

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

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

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which 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 – $26,996,983 as of December 31, 2012.

Documents incorporated by reference – none.

ISORAY, INC.

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Caution Regarding Forward-Looking Information

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

All statements contained in this Form 10-K, other than statements of historical facts, that address future activities, events or developments are forward-looking statements, including, but not limited to, statements containing the words "believe," "expect," "anticipate," "intends," "estimate," "forecast," "project," and similar expressions. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any statements of the plans, strategies and objectives of management for future operations; any statements concerning proposed new products, services, developments or industry rankings; any statements regarding future revenue, economic conditions or performance; any statements of belief; and any statements of assumptions underlying any of the foregoing. These statements are based on certain assumptions and analyses made by us in light of our experience and our assessment of historical trends, current conditions and expected future developments as well as other factors we believe are appropriate under the circumstances. However, whether actual results will conform to the expectations and predictions of management is subject to a number of risks and uncertainties described under Item 1A – Risk Factors beginning on page 29 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 on 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. The Company obtained clearance in August 2009 from the FDA to permit loading Cesium-131 into bioabsorbable braided strands, facilitating treatment of lung, head and neck tumors as well as tumors in other organs with Proxcelan Cs-131. 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, 2011, 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.

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. In June 2012, the first Cesium-131 brachytherapy seed sutured mesh was implanted on a patient suffering from a recurring meningioma tumor.

Management focused in fiscal 2012 and 2013 on obtaining its regulatory clearances and final research and development of its GliaSite® Radiation Therapy System, entering into international distribution agreements to sell the product in Europe and Australia, 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. In fiscal 2013, the Company began using a system developed at the Barrow Neurologic Institute to deliver doses of Cesium-131 to treat malignant meningioma, brain metastases, and primary cancers of the brain. A multi-institutional study was conducted to explore use by Cesium-131 laden strands placed directly into the cavity following surgical resection of brain metastases.

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 August 2013, IsoRay Medical received an approval for an extension to the scope of the CE mark for the GliaSite Radiation Therapy System. This approval allows IsoRay Medical to implement certain product improvements that management believes will enhance GliaSite's acceptance by customers in the European market.

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 238,590 new cases of prostate cancer diagnosed and an estimated 29,720 deaths associated with the disease in the United States in 2013. (American Cancer Society, 2013)

Prostate cancer accounts for about 10% of cancer related deaths in men. Prostate cancer incidence and mortality increase with age. The American Cancer Society has reported that the average age of diagnosis for prostate cancer is 67. Almost 2 of 3 prostate cancers are found in men over the age of 65. (American Cancer Society, 2013)

Incidence of Lung Cancer

An estimated 228,190 new cases of lung cancer are expected in 2013, 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 159,480 deaths, accounting for about 27% of all cancer deaths, are expected to occur in 2013. (American Cancer Society 2013) 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 80% of cases of lung cancer. The risk increases depending on duration of time smoking and number of packs smoked. 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, 2013)

The 5-year survival rate is 49% for cases detected when the disease is still localized. (American Cancer Society, 2013)

Incidence of Brain Cancer

An estimated 23,130 new cases of malignant tumors of the brain or spinal cord are expected in 2013. 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 14,080 (approximately 7,930 men and 6,150 women). (American Cancer Society, 2013)

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, 2013)

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 42% and 60%, anaplastic astrocytoma between 9% and 49%, glioblastoma between 4% and 17%, oligodendroglioma between 64% and 85%, anaplastic oligodendroglioma between 36% and 65%, and ependymoma/anaplastic ependymoma between 84% and 91%. (American Cancer Society, 2013)

Incidence of Head and Neck Cancers

An estimated 53,640 new cases of head and neck cancer are expected to be diagnosed in the United States in 2013 including 27,450 cases of oral cavity cancer (i.e. tongue, mouth and other oral cavity), 12,260 cases of laryngeal cancer, and 13,930 cases of pharyngeal cancer. (American Cancer Society, 2013)

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, numbness of the mouth, voice changes, 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, 2013)

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. Other risk factors for developing head and neck cancers include genetic syndromes, poor nutrition, and a weakened immune system. (American Cancer Society, 2013)

Incidence of Gynecological Cancers (Vaginal and Vulvar Cancer)

An estimated 7,590 new cases of vaginal (2,890) and vulvar (4,700) cancers are expected to be diagnosed in the United States in 2013. The estimated deaths related to vaginal and vulvar cancer are estimated to be 1,830 (990 vaginal and 840 vulvar). (American Cancer Society, 2013)

There are different types of vaginal and vulvar cancers. Vaginal cancers and vulvar cancer can include squamous cell carcinoma, adenocarcinoma, melanoma, sarcoma, and basal cell carcinoma (vulvar cancer only). Vaginal cancer is rare and about 1 in 100 cancers that occur in the female reproduction system is a vaginal cancer. Vulvar cancer makes up 4% of cancers within the female reproductive organs and it accounts approximately 0.6% of all cancers in women. (American Cancer Society, 2013)

Common known risk factors for vaginal cancers (cancers that start in the vagina) and vulvar cancers (cancers that start in the vulva) include age, human papilloma virus (HPV), cervical cancer or other genital cancers, smoking, and human immunodeficiency virus. (American Cancer Society, 2013)

Incidence of Ocular Melanoma

The American Cancer Society estimates that 2,800 new cases of cancers of the eye and orbit (primarily melanoma) will be diagnosed in 2013 and about 320 deaths from cancer of the eye will occur in 2013 in the United States. Primary eye cancer can occur at any age but most occur in people over 50 years of age. Secondary eye cancers, i.e. cancers that spread to the eye from a different part of the body, are more common than primary eye cancer. (American Cancer Society, 2013)

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, 2013)

Incidence of Colorectal Cancer

An estimated 142,820 new cases of colorectal cancer are expected in the United States in 2013 including 102,480 new cases of colon cancer and 40,340 new cases of rectal cancer. (American Cancer Society, 2013)

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. The symptoms generally occur in the more advanced disease stage. (American Cancer Society, 2013)

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%. Colorectal cancer is the third leading cancer death in the Unites States when men and women are combined and third when they are considered separately. (American Cancer Society, 2013)

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 inherited syndromes (i.e. gene changes or inherited mutations) and racial or ethnic background. (American Cancer Society, 2013)

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, 2013)

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, 2013)

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), three-dimensional conformal radiation therapy (3D-CRT), intensity modulated radiation therapy (IMRT), dual or combination therapy, permanent low dose rate brachytherapy (LDR), 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, 2013)

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 seven to nine weeks. Today, standard EBRT is used much less often than in the past. Side effects of EBRT can include bowel problems, bladder problems, urinary incontinence, impotence, fatigue, lymphedema, and urethral stricture. (American Cancer Society, 2013)

Three-dimensional Conformal Radiation Therapy (3D-CRT). 3D-CRT uses a special computer to map the location of the prostate and then radiation beams are aimed at the prostate from several directions. This makes it less likely that the radiation will damage healthy normal tissue. This radiation therapy has been determined to be at least as effective as EBRT with fewer side effects. (American Cancer Society, 2013)

Intensity Modulated Radiation Therapy. IMRT is considered a more advanced form of 3D-CRT 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, 2013)

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, 2013) Management estimates that at least 25% of all U.S. prostate implants are now dual therapy cases.

Low Dose Rate Permanent Brachytherapy. LDR permanent brachytherapy involves placing pellets or seeds of radioactive material inside thin needles which are then placed into the prostate. The pellets/seeds are left in place and emit low dose rate radiation for weeks or months. The pellets/seeds can deliver a large dose of radiation to a small area of the body thereby reducing the damage done to healthy tissue that is close to the prostate. (American Cancer Society, 2013)

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-192 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, 2013)

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, and 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, 2013)

Additional Treatments. Additional treatments include hormone therapy, vaccine treatment 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 a 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. The vaccine is made specifically for each individual man and it is made with the man's own white blood cells and the cells are used to help other immune system cells fight the prostate cancer. 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, hot flashes, 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, loss of appetite, diarrhea, mouth sores, 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, 2013)

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 ultrasound exams to see if the cancer is growing. If the cancer seems 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 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, 2013)

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 in the treatment of clinically localized cancer of the prostate gland. 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, perhaps due to its shorter half-life. The most recent evidence is described in the multi-institutional 5 year outcome presentation by Prestidge and others, wherein a group of nearly 100 patients, heavily weighted towards "intermediate risk" patients (who are at greater risk of failure compared to most prostate cancer patients) exhibited a PSA disease-free rate of 98% at five years (Prestidge B. et al. Five-year biochemical control following Cesium-131 Permanent Prostate Brachytherapy in a Multi-Institutional Trial. *Brachytherapy* 2011 10(3S1)S27.)

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 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 majority 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 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 studies 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). These irritative symptoms can range from an increased frequency of urination to significant pain upon urination. Because the portion of the urethra that runs through the prostate takes high doses from the implant, these side effects are fairly common following prostate brachytherapy.

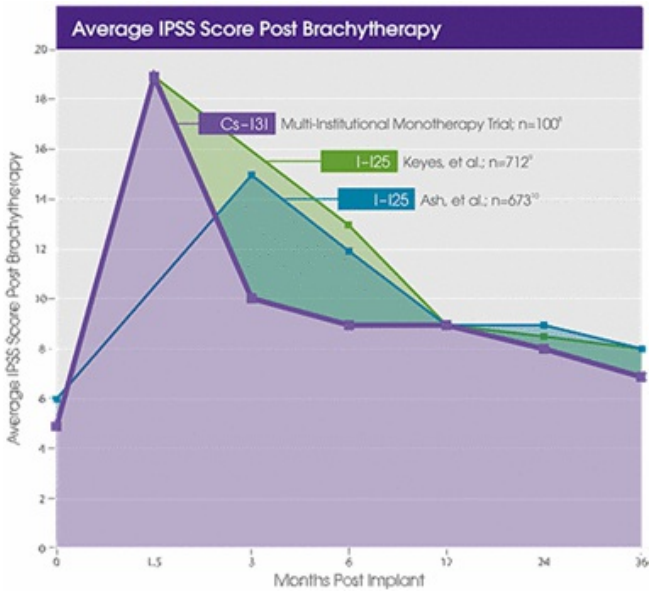
Recent completed studies show that Cesium-131, with the shortest available half-life of the commonly used implantable isotopes, results in a quicker resolution of these irritative symptoms based on the shorter time interval over which normal tissue receives radiation from the implanted sources than for longer lived isotopes such as I-125. (Shah H, et al. A comparison of AUA symptom scores following permanent low-dose-rate prostate brachyhtherapy with iodine-125 and cesium-131. Brachytherapy 2013:12(SI)S64)).

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) summarize the side effect profile of Cesium-131 treatment, and (3) 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 studies 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 – the radiation dose covering 90% of the prostate gland) while keeping unnecessary gland over-dosing (typically measured by V150 or V200 – the volume of the gland absorbing, respectively, 1.5 and 2 times the target dose) to a minimum (Musmacher JS, et al, "Dosimetric Comparison of Cesium-131 and Palladium-103 for Permanent Prostate Brachytherapy" *International Journal of Radiation Oncology Biology Physics*, Volume 69, (Supplement 3), 2007, S730-1; Yaparpalvi R, et al, "Is Cs-131 or I-125 or Pd-103 the Ideal Isotope for Prostate Boost Brachytherapy? A Dosimetric View Point." *International Journal of Radiation Oncology Biology Physics*, Volume 69 (Supplement 3), 2007, S677-8; Sutlief S and Wallner K, "Cs-131 Prostate Brachytherapy and Treatment Plan Parameters." *Medical Physics*, Volume 34, 2007, 2431; Kurtzman S, "Dosimetric Evaluation of Permanent Prostate Brachytherapy Using Cs-131 Sources" *International Journal of Radiation Oncology Biology Physics*, Volume 66 (Supplement 3), S395).

The 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. To date, the combined therapy study has accrued 44 patients.

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, 2013)

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. (American Cancer Society, 2013)

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. (American Cancer Society, 2013)

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 5 to 7 weeks. Newer types of this type of radiation are called 3D-CRT, IMRT, and stereotactic body radiation therapy (SBRT). (American Cancer Society, 2013)

- 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. (American Cancer Society, 2013)

- Low Dose Rate Brachytherapy is most often used in combination with surgery in early stage (stages I and II) non-small 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 (faster rate of decay) and relatively high energy, 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).

In April 2012, the Company initiated a 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, 2013, thirty-one 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 which may include 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, 2013)

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.

The treatment of brain cancer with Cesium-131 now has several delivery methods, including the implantable mesh described above, single seed applications, implantable strands, and by implantable device, including GliaSite® Radiation Therapy System (which uses only Iotrex, a form of liquid Iodine, as of the date of this report, and not Cesium-131), the world's only liquid radiation balloon catheter device used in the treatment of brain cancer. During the year ended June 30, 2013, there were forty-one patients treated with Company products for brain cancer.

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; full or partial glossectomy (tongue); 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, 2013)

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, 2013)

Management believes Proxcelan Cesium-131 continues to represent an improved approach to brachytherapy treatment of specific head and neck cancers. During the year ended June 30, 2013, there were eight patients that were treated with Company products for head and neck cancers.

Gynecological Cancer Treatment Options (Vaginal and Vulvar Cancer)

In addition to brachytherapy to treat gynecological cancers such as vaginal and vulvar cancers, other treatment options include surgery, laser surgery, radiation therapy, chemotherapy, and topical treatments. Surgery is often only used for vaginal cancers when it is a small stage I tumor and for cancers that have not been cured by radiation alone. (American Cancer Society, 2013)

Surgery for vaginal cancers can include local excision, vaginectomy, trachelectomy, hysterectomy, vaginal reconstruction, lymphadenectomy, and pelvic exenteration. Surgery options for vulvar cancer include laser surgery, excision, vulvectomy, pelvic exenteration, inguinal lymph node dissection, and sentinel lymph node biopsy. (American Cancer Society, 2013)

Radiation therapy options for vaginal cancer and vulvar cancer includes external beam radiation and is delivered much like getting a diagnostic x-ray. The common side effects of radiation therapy include upset stomach, fatigue, and loose bowels. (American Cancer Society, 2013)

Chemotherapy uses anti-cancer drugs most often prescribed intravenously, taken by mouth or applied to the skin as an ointment. Often it may be given before or after surgery to assist in shrinking the cancer or to make radiation work better for vaginal cancers. In more advanced vulvar cancers, it is can be given with radiation therapy before surgery to attempt to shrink the tumor before surgery. The common side effects of chemotherapy for both vaginal and vulvar cancers include nausea and vomiting, temporary loss of hair, increased or decreased appetite, mouth or vaginal sores, and changes in menstrual cycles, premature menopause, or infertility. (American Cancer Society, 2013). During the year ended June 30, 2013, there were eleven patients treated with Company products for gynecological 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. (American Cancer Society, 2013)

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 is 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, 2013) 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, which requires it to be ordered and manufactured and unable to be inventoried. Most patients are unwilling to wait for it to be ordered when the other products are often available immediately. The treatment of ocular melanoma was the first opportunity for the Company to utilize the Cs-131 brachytherapy seed in a treatment other than a prostate application but does not comprise a significant portion of the Company’s business.

Colorectal Treatment Options

Colorectal cancer has historically been treated using surgery, radiation therapy, chemotherapy, immunotherapy and other targeted therapies. (American Cancer Society, 2013)

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, 2013)

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, and Stivarga) can be used. (American Cancer Society, 2013)

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. The treatment of colorectal cancer is an additional non-prostate application of the Company's product which by itself is not a significant portion of the Company's business. However, when aggregated with the other non-prostate applications, it contributes to the overall growth in the Company's non-prostate applications.

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.) Later 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.)

A study presented during the 2013 fiscal year provides confirmatory data to the hypothesis that the shorter half-life of Cesium-131 leads to a shorter duration of irritative side effects as compared to longer lived isotopes such as the more commonly used Iodine-125. Dr. Amit Shah reported at the Annual Meeting of the American Brachytherapy Society that "Our data suggests that shorter half-life of Cs-131 versus I-125 (10 versus 60 days) results in a more rapid resolution of urinary side effects and lower intensity of urinary morbidity beyond the initial three months." (Shah H, et al. A comparison of AUA symptom scores following permanent low-dose-rate prostate brachyhtherapy with iodine-125 and cesium-131. Brachytherapy 2013:12(SI)S64)).

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(3) Suppl. 1:S27.)

A recent report from the University of Pittsburgh Medical Center confirms these high rates of prostate cancer control with definitive Cesium-131 treatment – 162 patients exhibited PSA control of 93% at five years (Rajagopalan M, et al. Five year biochemical outcome in patients treated with 131 Cs brachytherapy as monotherapy for prostate cancer. Brachytherapy 2013:12(SI)S66)).

Our Strategy

The key elements of IsoRay's strategy for fiscal year 2014 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.

Improve distribution of the GliaSite® radiation therapy system in the United States, European Union (EU), New Zealand and Australia. 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. The Company distributes the product using a German distributor to Germany (the location of the first European sale in July 2012) and other European nations. To date, three cases in Europe and five cases in the U.S. have been treated with GliaSite RTS sold by the Company directly or through a distributor. In fiscal 2013, the Company entered into distribution agreements with independent distributors in Greece, New Zealand and Australia. Management believes that all regulatory requirements will be met in those countries in fiscal 2014 and sales in these countries will then be permitted. 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, brain, 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.

Early clinical data support management’s initiatives into brain cancers and early stage non-small cell lung cancers. Local control – defined as success in preventing the re-growth of cancer in the immediate vicinity of the treatment area – has been excellent to date.

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 structures and supports 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 2013, four presentations were accepted by and presented at the annual meeting of the American Brachytherapy Society describing Cesium-131 treatment of prostate and ocular cancers. Six presentations were accepted by and presented at the annual meeting of the American Society for Radiation Oncology (ASTRO). 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 June 2013. 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; pelvic/abdominal 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.

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 IsoRay entered into a supply agreement with a new supplier, The Open Joint Stock Company ‹‹Isotope››, a Russian company ("JSC Isotope"), during January 2013 to provide Cesium-131 isotope from Russia to the Company's facility in Richland, WA through June 30, 2014. JSC Isotope relies on a single Russian reactor for its supply of Cesium-131. In June 2013, the Company negotiated a contract with E&H Scientific, LLC to provide logistical support related to the packaging, export and import of the supply of Cs-131 being shipped from Russia. The contract will expire on June 30, 2014.

The Company also receives irradiated barium from the MURR reactor located in the United States. For the fiscal year ended June 30, 2013, we obtained more Cesium from our domestic source than ever before as approximately seventy percent (70%) of our Cesium-131 was supplied by our Russian supplier and approximately thirty percent (30%) 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 (JSC Isotope) 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 2013, 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. An additional inspection of IsoRay was conducted by FDA in April 2013. Again the FDA reported no deviations from Good Manufacturing Practices and did not list any observations, (FDA Form 483).

In July 2011, 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 its short half-life, the Company relies on sales forecasts and historical knowledge to estimate the proper inventory levels of isotope needed to fulfill all customer orders. Consequently, some portion of the isotope is lost through decay and is not used in an end product. Management continues to reduce the variances between ordered isotope and isotope deliveries and is continually improving its ordering process efficiencies.

Automated Manufacturing Process

In fiscal 2013, IsoRay continued to evaluate opportunities for automation as identified by management to reduce cost and increase radiation safety while allowing an expansion of product loading configurations. There were no significant opportunities to automate processes that were identified in FY2013, however, the Company continued to identify and refine previously implemented solutions. In fiscal year 2014, the Company intends to continue to evaluate and implement automation in the future that supports process improvement, employee safety and resource management. The Company continued to contract with a third party to outsource certain sub-processes where cost effective throughout the fiscal year ended June 30, 2013.

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

In fiscal year 2013, the Company delivered approximately 54% of its Proxcelan seeds to customers configured in Mick cartridges, approximately 35% of the Proxcelan seed configured in both stranded and braided strand forms and the remaining 11% 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.

As of June 30, 2013, IsoRay had no radiopharmacies that were able to assay, preload, and sterilize loose seeds but did have radiopharmacies which were capable of providing these services at other times during the fiscal year. Shipping Cs-131 brachytherapy seeds to independent radiopharmacies requires loading the seeds with additional isotope activity than would be required if the seeds were to be preloaded utilizing our in-house loading facility which causes the Company to incur additional isotope cost to allow for the additional isotope decay created by the additional processing time. The Company pre-loaded 93% and 88% of the Cs-131 brachytherapy seeds that it sold to customers during the fiscal years ended June 30, 2013 and June 30, 2012, respectively. The Company has historically utilized external loading services to supplement our own custom preloading operation and to meet the specific requests of the ordering physicians.

We loaded approximately 95% of Mick cartridges in our own facility in fiscal year 2013 which accounted for approximately 60% of seeds sold. Approximately 29% of seeds sold are strand configurations including strands pre-loaded in needles and the remaining 11% of seeds are sold as loose seeds. The Company anticipates continuing to load 100% of its customer orders during fiscal year 2014 unless there is a specific customer requirement for which the Company does not have the loading capability or capacity.

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.

In fiscal year 2012, IsoRay obtained a CE mark which allows 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. In August 2013, the Company successfully amended its CE mark on the GliaSite RTS which incorporated five changes. These changes included a change in the sterilization method of the right angle clip; a change in the packaging of the right angle clip; an extension of the GliaSite RTS catheter tray expiration date to 3 years; the qualification of a second manufacturer of the Iotrex solution and the extension of the shelf life of Iotrex from 19 days to 30 days.

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 filled with Iotrex radiotherapy solution and on the other end is an infusion port which is attached to the skull and punctured by a needle to get the solution to the balloon at the end of the catheter. The GliaSite catheter is available in 3 different 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 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 manage 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. An additional inspection of IsoRay was conducted by FDA in April 2013. Again the FDA reported no deviations from Good Manufacturing Practices and did not list any observations (FDA Form 483).

In July 2011, 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. 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 June 2013. 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 encourages hospitals to have 6 GliaSite catheters available 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 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 or Anazao, the Company's contracted manufacturers of Iotrex. The Iodine-125 is tested by the manufacturer 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 or Anazao, testing is performed on the product and the test results are sent to IsoRay along with the batch record for review and acceptance. Facilities performing the implants can choose to receive the isotope in vials or the vials can be preloaded into dose-specific vials.

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 respectively. Consequently, some portions of the product including the Iotrex or the 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 8 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 second of three three-year renewal options to extend the APEL facility lease through April 2016 and it believes that the Company will exercise the third three-year renewal option through April 2019.

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-125 and Palladium-103 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);
- 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 have independently published 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 solicit 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. As of September 27, 2013, the Company had independent distributors in Germany (with a territory covering Germany, Austria, Switzerland, Italy and Luxembourg), Greece, New Zealand and Australia. 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 2014 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 although the Company experienced 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 following top five customers, facilities or physician practices that utilize multiple surgical facilities at which primarily prostate brachytherapy procedures are performed accounted for approximately 48.38% of the total Company product sales for the twelve months ended June 30, 2013:

El Camino, Los Gatos, & other facilities (Northern CA) (1)	24.68% of revenue
University of Pittsburgh Medical Center	8.42% of revenue
Biocompatibles, Inc.	5.36% of revenue
York Cancer Center	5.08% of revenue
New York Presbyterian Hospital	4.84% of revenue
Total	48.38% of revenue

(1) The head of the single largest physician practice also serves as the Company's medical director. As the medical director, this physician is a member of the Medical Advisory Board; advises the Company Board of Directors and management; provides technical advice related to product development and research and development; and provides internal training to the Company sales staff and professional training to our sales staff and to other physicians. During the fiscal year ended June 30, 2013, this physician added additional physicians to the practice which is expected to reduce risk associated with seasonality.

The loss of either the single largest physician practice or a combination of the other significant facilities and customers 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 April 28, 2019. 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 2013 and 2012, the Company recorded royalty expense of $14,168 and $19,497, 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, 2013, IsoRay and its subsidiaries incurred approximately $1.8 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) premarket notification for any significant 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 has had no success in selling the product in the Canadian or Russian markets and through its distributors is currently focusing on the markets in Germany, Austria, Switzerland, Luxembourg, Italy, Greece, Australia and New Zealand. The Company reached agreements with distributors for Greece, Australia and New Zealand during the fiscal year ended June 30, 2013 and has actively supported these distributors in achieving regulatory clearance in their distribution market. The Company extended its agreement to August 31, 2014 with the German distributor whose market includes Germany, Austria, Switzerland, Luxembourg and Italy. The agreement with the distributor for Greece was effective on May 1, 2013 with a two year term and may be renewed upon mutual agreement of the parties. The agreement with the distributor for New Zealand and Australia was effective on June 1, 2013 with a termination date of May 31, 2015 with certain conditions that provide for 12 month renewal periods if those conditions are mutually agreed upon.

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 to 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. In August 2013, the Company successfully amended its CE mark on the GliaSite RTS which incorporated five changes. These changes included a change in the sterilization method of the right angle clip; a change in the packaging of the right angle clip;an extension of the GliaSite RTS catheter tray expiration date to 3 years; the qualification of a second manufacturer of the Iotrex solution and the extension of the shelf life of Iotrex from 19 days to 30 days.

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 customers, physician practices or facilities, simultaneous vacations by the physicians at these four physician practices or facilities or supplied by the one customer that supplies multiple facilities could cause significant drops in the Company's productivity during those reporting periods.

Employees

As of September 17, 2013, IsoRay employed thirty-six full-time individuals and two part-time individuals. 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, 2013, the Company employed eight direct sales people, which has decreased 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 lower 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 the European Union (EU), New Zealand and Australian markets and later into other international markets through partnerships and strategic alliances with channel partners for manufacturing and/or distribution and has distribution agreements or partnerships in place for brachytherapy seeds as of September 27, 2013 in Greece, New Zealand and Australia. The Company also has 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, Luxembourg and Italy. During fiscal 2013, the Company negotiated agreements for the distribution of the GliaSite RTS in Greece, New Zealand and Australia and is supporting those distributors in their efforts to obtain regulatory clearance to sell the product in their respective markets. 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 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. A 510(k) has been submitted by the Company to the FDA and the Company is waiting for a response from the FDA to the submittal.

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, the European Union (EU), Greece, New Zealand and Australia; 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-two percent of our sales). We have been treating lung cancer which amounted to approximately 8% of our product sales and other cancers including head and neck; colorectal; gynecological and brain that combined constituted approximately 6% of our product sales in fiscal year 2013. The GliaSite Radiation Therapy System contributed 4% of our product sales in fiscal year 2013. 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 primarily 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 September 27, 2013 will be sufficient to meet our anticipated cash requirements for operations, debt service, and capital expenditure requirements through at least the next two fiscal years. 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 Five Customers. Approximately forty-eight percent (48%) of the Company's revenues are dependent on five customers and approximately twenty five percent (25%) on one customer. The loss of any of these customers would have a material adverse effect on the Company's revenues which may not be replaced by other customers particularly as these customers are in the prostate sector which is facing substantial declines on an annual basis.

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 2013, approximately seventy percent (70%) of our Cesium-131 was supplied through JSC Isotope from a reactor located in Russia. Our current contract with JSC Isotope terminates on June 30, 2014 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 two 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 either supplier. 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 2013 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. In May 2012 the U.S. Preventive Services Task Force recommended against routine PSA screenings for healthy men without symptoms. We believe this recommendation has led to a renewed decline in PSA screenings. In addition, we believe there has been an increase in "active surveillance", a practice where no immediate medical treatment is provided; but the physician and patient closely monitor the patient's cancer for signs that the cancer is growing. We believe that declines in PSA screenings have led to a decline in the number of men diagnosed with prostate cancer. A decline in the number of PSA screenings would in turn lead to a decline in the number of procedures to treat prostate cancer, including brachytherapy procedures. An increase in the proportion of men diagnosed with prostate cancer but not seeking immediate medical treatment would also lead to a decline in the number of procedures to treat prostate cancer.

As of the end of fiscal 2013, the American Cancer Society has not further revised its advice regarding PSA testing, continuing to advise that the decision to be screened for prostate cancer should be made after getting information about the uncertainties, risks, and potential benefits of prostate cancer screening. This advice has led to an increased number of men electing to forgo PSA testing.

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 2013, 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 2014.

Doctors And Hospitals May Not Adopt Our Products And Technologies At Levels Sufficient To Sustain Our Business Or To Achieve Our Desired Growth Rate. To date, we have attained very limited penetration of the total potential market for most of our products, particularly our non-prostate applications. Our future growth and success depends upon creating broad awareness and acceptance of our products by doctors, hospitals and freestanding clinics, as well as patients. This will require substantial marketing and educational efforts, which will be costly and may not be successful. The target customers for our products may not adopt these technologies or may adopt them at a rate that is slower than desired. In addition, potential customers who decide to utilize any of our devices may later choose to purchase competitors' products. Important factors that will affect our ability to attain broad market acceptance of our products include:

- doctor and/or patient awareness and acceptance of our products;
- the real or perceived effectiveness and safety of our products;
- the relationship between the cost of our products and the real or perceived medical benefits of our products;
- the relationship between the cost of our products and the financial benefits to our customers using our products, which will be greatly affected by the coverage of, and reimbursement for, our products by governmental and private third-party payors; and
- market perception of our ability to continue to grow our business and develop enhanced products.

Failure of our products to gain broad market acceptance could cause our revenues to decline and our business to suffer.

We Have Entered Into An Agreement With A Single Supplier For Our Cesium-131 From Russia. In January 2013, the Company entered into a new agreement through June 30, 2014, with JSC Isotope to purchase Cesium-131 directly from JSC Isotope 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 LLC in December 2008. As a result, the Company now relies on JSC Isotope to obtain Cesium-131 from its single Russian source. Through the JSC Isotope agreement we have obtained set pricing for our Russian Cesium-131 through the end of June 2014. There can be no guarantee that JSC Isotope will always be able to supply us with sufficient Cesium-131 or will renew our existing contract on favorable terms in June 2014, which could be due in part to risks associated with foreign operations and beyond either our or JSC Isotope'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. While recent testing of regions within the reactor at MURR has found that Cesium-131 can be produced in economically viable quantities at a viable price, there is no assurance that we can obtain the increased quantity of isotope at the pricing and quantities that the Company requires in the long term. However the due diligence that has been conducted by the Company and the University of Missouri at the Missouri University Research Reactor has demonstrated that the Company would be able to continue producing enough Cesium-131 utilizing its existing three target locations and naturally occurring barium that has been enriched using the inventory of enriched barium that the Company currently owns. Management estimates that the supply of enriched barium that it currently owns should last from 24 to 36 months which would allow time to expand into other irradiation sites within MURR or at another reactor to supplement its supply of Cs-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 2014 but there is no assurance this will occur.

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 2014. 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. Hospitals are less receptive to treatments which require out of pocket costs.

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 2.3% excise tax on medical devices effective January 2013;
- 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 brachytherapy product could be negatively affected and our revenues from our brachytherapy 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 and robotic surgery 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 or the GliaSite Radiation Therapy System 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 or the GliaSite Radiation Therapy System 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, 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. Our revenues have faced annual historical declines as our non-brachytherapy competitors gain greater market share of prostate treatments.

Medical Device Tax. Significant reforms to the healthcare system were adopted in the form of the Patient Protection and Affordable Care Act (the PPACA). The PPACA includes provisions that, among other things, require the medical device industry to subsidize healthcare reform in the form of a 2.3% excise tax (the Medical Device Tax) on the U.S. sales of most medical devices beginning in 2013. The Internal Revenue Service (IRS) has only recently issued the final regulations for the Medical Device Tax, and many questions remain regarding the applicability of this tax to varying points in the supply chain. While we continue to evaluate the impact of the Medical Device Tax on our overall business, we currently believe this tax will be applicable to 100% of our product sales. Our estimate is subject to change due to, among other things, future IRS guidance and interpretations of the Medical Device Tax regulations, and changes in our product mix. This revenue-based tax will have a material impact on our consolidated results of operations, cash flows, and financial condition

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. We are also subject to the federal anti-kickback statute, False Claims Act, Foreign Corrupt Practices Act and the Physician Payment Sunshine Act.

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.

Significant reforms to the healthcare system were adopted in the form of the PPACA. CMS has published final regulations that would implement provisions in PPACA related to disclosure of payments made by manufacturers to physicians and teaching hospitals, effective April 2013. Because we manufacture a number of devices that are covered by the regulations, all payments that we make to physicians and teaching hospitals would be subject to this reporting requirement even if the payment relates to a device that is not considered a covered device. The tracking and reporting of these payments could have an adverse impact on our business and/or consolidated results of operations and financial condition and on our relationships with customers and potential customers.

In addition to the PPACA, various healthcare reform proposals have also emerged at the state level. Like the PPACA, these proposals could reduce medical procedure volumes and impact the demand for our products or the prices at which we sell our products. The impact of these proposals could have a material adverse effect on our business and/or consolidated results of operations and financial condition.

The automatic spending cuts of nearly $1 trillion over the next 10 years that were included under the Budget Control Act of 2011, including a 2% cut to Medicare providers and suppliers, took effect in 2013. Medicaid is exempt from these cuts. Any cuts to Medicare reimbursement which affect our products could have a material adverse effect on our business and/or our consolidated results of operations and financial condition.

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. Our brachytherapy seed products deliver a highly concentrated and confined dose of radiation directly to the organ in which it is implanted from within the patient's body. Surrounding tissues and organs are typically spared excessive radiation exposure. It is an inherent risk of the industries in which we operate that we might be sued in a situation where one of our products results in, or is alleged to result in, a personal injury to a patient, health care provider, or other user. Although we believe that as of the current date we have adequate insurance to address anticipated potential liabilities associated with product liability, any unforeseen product liability exposure in excess of, or outside the scope of, such insurance coverage could adversely affect our financial condition and operating results. Any such claim brought against us, with or without merit, could result in significant damage to our business. 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. The FDA's medical device reporting regulations require us to report any incident in which our products may have caused or contributed to a death or serious injury, or in which our products malfunctioned in a way that would be likely to cause or contribute to a death or serious injury if the malfunction reoccurred. Any required filing could result in an investigation of our products and possibly subsequent regulatory action against us if it is found that one of our products caused the death or serious injury of a patient.

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 the European Union (EU), New Zealand and Australia. 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 JSC Isotope.

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, 2013, the Company determined that there was a single deficiency that constituted a material weakness. The Company is assessing additional steps that may be taken in fiscal year 2014 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.

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 for 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 for most of 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, 2013, we had 34,618,517 outstanding shares of common 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 outstanding as of September 26, 2013 were converted or exercised into shares of common stock, including the warrants and preferred stock issued in the most recent offering in September 2013, there would be approximately an additional 13,098,388 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. Our warrants issued in September 2013 to purchase 5,648,738 shares of our common stock to institutional investors with an exercise price of $0.72 per share (subject to possible reduction via Company shareholder approval to $0.535 per share) do not expire until August 29, 2015. Until these warrants are fully exercised or expire, it may depress the price of our common stock to below the warrants' exercise price.

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, 2013, but raised additional capital in September 2013 with net proceeds of approximately $3.3 million. We may need to raise additional capital sooner than anticipated to meet listing standards if the warrants sold in September 2013 are not exercised. 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, 2013. 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 15,300 square feet of office and laboratory space for approximately $22,566 per month plus monthly janitorial expenses of approximately $400 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 2013, expires on April 30, 2016. The lease modification and renewal entered into in May 2013 added one additional three-year renewal option.

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: 192,998,329 shares of common stock, par value of $0.001 per share; and 7,001,671 shares of preferred stock, par value of $0.001 per share. As of September 23, 2013, we had 38,419,502 outstanding shares of Common Stock, 59,065 outstanding shares of Series B Preferred Stock and 1,670 outstanding units of Series D Convertible 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 our common stock is listed on the NYSE MKT 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, 2013	High	Low
First quarter	$ 1.47	$ 0.72
Second quarter	0.87	0.38
Third quarter	0.82	0.47
Fourth quarter	0.71	0.48

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

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 21, 2012, the Board of Directors declared a dividend on the Series B Preferred Stock of all outstanding and cumulative dividends through December 31, 2012. The total Series B accrued dividends of $10,632 were paid as of December 31, 2012. At June 30, 2013, there were 59,065 Series B preferred shares outstanding and cumulative dividends in arrears were $5,316. There are no Series A or Series C shares of Preferred Stock outstanding as of the date of this Report.

As of September 23, 2013, we had approximately 290 shareholders of record, exclusive of shares held in street name. The closing price of our common stock was $0.58 on September 23, 2013

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, 2013, 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	2,305,072	$ 1.83	1,388,046
Total	2,305,072	$ 1.83	1,388,046

Sales of Unregistered Securities

All sales of unregistered securities during the 2013 fiscal year were previously reported.

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. 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 Series 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 September 12, 2012, the holder of the remaining Series C warrants exercised warrants for 2,666 shares of common stock at an exercise price of $0.6715 for a total of $1,791. On November 26, 2012, the holder of the final Series C warrants exercised the remaining warrants for 100 shares of common stock at an exercise price of $0.3497 for a total of $34.92.

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.

On July 13, 2012, the Company entered into a securities purchase agreement with certain institutional investors, with Ladenburg Thalmann & Co. Inc. acting as placement agent, for a registered direct offering to sell 3,626,943 shares of the Company's common stock, par value $0.001 per share, with an aggregate purchase price of $3.5 million at a price per share of $0.965. The offering yielded $3,291,977 in cash after expenses. The shares were issued pursuant to the Registration Statement, as supplemented by the Form S-3 registration statement filed on July 16, 2012 (Reg. No. 333-182678), and a prospectus supplement filed on July 17, 2012.

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, 2013 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
Proceeds from sales of common stock, pursuant to registered public offering, net		3,291,977
Proceeds from sales of common stock, pursuant to exercise of Series C warrants, net		1,825
Total proceeds from public offerings through June 30, 2013	$	9,348,023

Proceeds used in the year ended June 30, 2013:		
Indirect payment to directors and officers for database development	$	13,960
Direct payments of compensation to directors		135,000
Direct payments of salaries to officers		705,843
Working capital		2,211,783
Total proceeds used in the year ended June 30, 2013	$	3,066,586

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, 2013, 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.

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 $0 and $61,511 for the years ended June 30, 2013 and 2012, respectively, is included in financing and interest expense on the consolidated statements of operations. Deferred financing costs were fully amortized during the year ended June 30, 2012.

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, 2013 and 2012, respectively. Based on the licenses recorded at June 30, 2013, 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 2014, $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 $31,302 and $15,731 for the years ended June 30, 2013 and 2012 respectively. Based on the patents and other intangible assets recorded in other assets at June 30, 2013, and assuming no subsequent impairment of the underlying assets, the annual amortization expense for each fiscal year ending June 30, 2013 is expected to be as follows: $19,021 for each year 2014 through 2017, $15,333 for 2018 and $123,759 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, 2013 and 2012, the asset retirement obligations changed as follows:

	2013	2012
Beginning balance	$ 724,298	$ 662,181
Accretion of discount	67,944	62,117
Ending balance	$ 792,242	$ 724,298

Because the Company does not expect to incur any expenses related to its asset retirement obligations in fiscal year 2014, the entire balance as of June 30, 2013 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, 2013 and 2012.

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, 2013 and 2012 was derived primarily from sales of the Proxcelan Cs-131 brachytherapy seed, which is used in the treatment of cancer. The Company also had sales from the Gliasite Radiation Therapy System, which is used in the treatment of brain cancer, in the fiscal year ended June 30, 2013. 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, 2011 is 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 and are still subject to examination by the Service.

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 Medical, and its predecessors are subject to examination of their income tax filings in the United States and state jurisdictions for the 2011 through 2013 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, 2013 and 2012 were as follows:

	2013	2012
Preferred stock	59,065	59,065
Common stock warrants	1,957,033	1,959,799
Common stock options	2,305,072	2,381,306
Total potential dilutive securities	4,321,170	4,400,170

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 2013 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, 2013 and 2012. 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 29 of this Annual Report on Form 10-K.

Year ended June 30, 2013 compared to year ended June 30, 2012

Product sales.

Prostate Brachytherapy.
Revenue generated from treatment with prostate brachytherapy decreased from 86% of total revenue in the fiscal year ended June 30, 2012 to 82% of total revenue in the fiscal year ended June 30, 2013. The overall decrease in revenue generated by prostate brachytherapy is consistent with revenue decreases experienced by this segment of the industry as a whole. Management believes that the overall market for prostate brachytherapy has continued to receive increased pressure from other treatment options with higher reimbursement rates such as Intensity–Modulated Radiation Therapy (IMRT) and robotic-assisted surgery. Although combination treatments incorporating brachytherapy with other modalities in the prostate and treatment of other body sites with brachytherapy have increased, these increases are insufficient to offset the overall decrease in use of prostate brachtherapy.

Other Brachytherapy including Brain and Lung.

The strategy implemented by management in the prior year in diversifying the number of body sites being actively treated with the Proxcelan Cs-131 brachytherapy seed has continued to partially mitigate the lost revenue from the prostate brachytherapy segment. The timeline of developing and bringing new products from concept to revenue production in the pharmaceutical/medical device segment is lengthy and is typically measured in years. The probability of any new cancer treatment product reaching the stage at which it produces revenue is very low.

Company management has been investing in development of alternative uses for the Company's brachytherapy seed that management believes have the ability to generate revenue in the near-term to offset development costs. New treatments such as those being initiated by the Company can be expected to experience a staged entry to market in which primary adopters demonstrate the suitability of a treatment, after which wider adoption is possible. The products being implemented by the Company are very dependent on first adopters as a source of revenue, and there is initially a steep growth in revenue that will reach a plateau due to capacity until the mainstream adoption occurs, when and if there is favorable publication of the experiences and treatment outcomes of the first adopters. However, to date the Company has only experienced nominal sales to first adopters. In the fiscal year ended June 30, 2013, there were over eight hundred fifty cases treated with the Company's Cs-131 brachytherapy seeds, with approximately 14% of the cases being non-prostate applications. Management strategy includes soliciting the use of other applications for the Company's brachytherapy seeds at major medical institutions that are more likely to publish their outcomes and that are training the next generation of decision makers. Company management intends to actively pursue alternative uses for the Company's brachytherapy seeds in treatments consistent with the FDA clearance granted permitting the Company to utilize other FDA cleared application methods as a means of administering the treatments.

During the year ended June 30, 2013, the revenue from other brachytherapy treatments increased an additional 9% over the year ended June 30, 2012. The most significant contributors to the growth in revenue from other brachytherapy treatments is the 134% growth in the treatment of brain cancers and the 167% growth in the treatment of head and neck cancers. Overall, other brachytherapy treatments increased by approximately 10% during the year which partially offset the continued reduction in revenue from prostate brachytherapy treatment.

GliaSite Radiation Therapy System.

The Company made the first sales of its FDA cleared and CE marked GliaSite Radiation Therapy System (GliaSite RTS) during the three months ended December 31, 2011. The Company sold additional catheters and an initial delivery of the Iotrex liquid isotope to the distributor in Germany during the fiscal year ended June 30, 2012. During the fiscal year ended June 30, 2013, revenue from the GliaSite RTS increased by approximately 6% or $9,000 compared to the fiscal year ended June 30, 2012. All product sales are generated by the brachytherapy seeds and the related methods of application except for the revenue generated by the sales of GliaSite RTS which come from sale of the liquid isotope, catheter trays and access trays.

The conversion of prospects to new GliaSite RTS customers has been a longer process than originally anticipated by the Company. The Company has experienced lengthy timelines in the internal processes of the medical facilities in reviewing and approving the use of the product at the request of their physician(s). These longer than anticipated internal processes are compounded by uncertain timelines and delays in receiving the approval for the requested modification of each facility's nuclear materials license, which is required to begin using GliaSite RTS and is dependent on external government regulators.

Description	June 30, 2013	June 30, 2012	Variance ($)	Variance (%)
Product sales (Prostate)	$ 3,730,129	$ 4,342,897	$ (612,768)	(14)%
Product sales (Other[1])	795,104	728,191	66,913	9%
Total product sales	$ 4,525,233	$ 5,071,088	$ (545,855)	(11)%

[1] - Other sales include brachytherapy seed treatment of brain cancer, lung cancer, head and neck cancer, colorectal cancer, gynecological cancer, ocular cancer and other body site cancers that have been treated previously with the Company's Cs-131 brachytherapy seeds as well as the sale of GliaSite RTS and its related components for use.

Cost of product sales.

Cost of product sales overall have remained substantially unchanged during the fiscal year ended June 30, 2013 compared to the fiscal year ended June 30, 2012. Cost of product sales remained unchanged primarily as the result of production labor and benefits that are no longer being utilized on research and development projects which is reflected in the overall reduction in payroll expense in research and development. The additional payroll expense represented an increase in cost of approximately 3%. Additionally, the Company has minimum purchase obligations with isotope suppliers which remains in cost of product sales as the result of the short half-life of Cesium-131. This excess isotope, which decays rapidly, and the required minimum staffing to meet customer demands allows for a significant portion of each additional sale to contribute to an increased gross margin assuming sales continue to increase.

Description	June 30, 2013	June 30, 2012	Variance ($)	Variance (%)
Cost of product sales	$ 4,375,057	$ 4,367,884	$ 7,173	0%

Gross margin.

Gross profit for the fiscal year ended June 30, 2013 decreased substantially when compared to the fiscal year ended June 30, 2012. The change in gross profit was primarily as a result of the previously discussed reduction in sales in the prostate market as the cost of product sales was substantially unchanged during the fiscal year ended June 30, 2013 when compared to June 30, 2012.

Description	June 30, 2013	June 30, 2012	Variance ($)	Variance (%)
Gross margin	$ 150,176	$ 703,204	$ (553,028)	(79)%

Research and development expenses.

Research and development costs were decreased by three key operating factors for the fiscal year ended June 30, 2013 as compared to June 30, 2012. The first key operating factor was other organ research expense which decreased as development related to isotope development projects and brain application development projects was completed, which was partially offset by the initiation of additional research surrounding our GliaSite RTS product. The second key operating factor that decreased was payroll, benefits and share-based compensation as there was a decreased need for personnel as projects came to an end thereby decreasing the wage, benefit and overhead expenses related to those personnel. The third key operating factor was protocol expense which increased as the Company entered into additional protocols in combined therapy and lung. The Company continued to invest in protocols in support of products that have been developed and sales have begun in support of gaining general acceptance in the market. During the fiscal year ended June 30, 2013, the Company accrued protocol costs in accordance with its agreements with participating facilities.

Description	June 30, 2013	June 30, 2012	Variance ($)	Variance (%)
Other organ research	$ 24,337	$ 79,356	$ (55,019)	(69)%
Protocol expense	106,362	69,223	37,139	54%
Payroll	266,060	438,453	(172,393)	(39)%
Other expense	230,348	193,547	36,801	19%
Total R&D expense	$ 627,107	$ 780,579	$ (153,472)	(20)%

Research and development reimbursement.

Research and development reimbursement costs were reduced for the fiscal year ended June 30, 2013 as compared to the fiscal year ended June 30, 2012. This reduction was the result of a reimbursement of developmental expenses that were recorded in the amount of $50,000 during the fiscal year ended June 30, 2012 that did not recur during the fiscal year ended June 30, 2013. This reimbursement amount represented the amount of cost sharing that was negotiated with the future distributor of the GliaSite RTS received from the German based distributor in support of the development of the product.

Description	June 30, 2013	June 30, 2012	Variance ($)	Variance (%)
Research and development reimbursement	$ -	$ (50,000)	$ 50,000	(100)%

Sales and marketing expenses.

Sales and marketing expenses increased during the fiscal year ended June 30, 2013 when compared to the fiscal year ended June 30, 2012 primarily as a result of additional sales staff, the additional travel associated with establishing new facilities as customers, and the addition of the new GliaSite RTS products which required additional travel expense during its introduction to the market.

Description	June 30, 2013	June 30, 2012	Variance ($)	Variance (%)
Payroll	$ 843,337	$ 783,047	$ 60,290	8%
Travel expense	274,003	252,974	21,029	8%
Other expense	178,809	179,559	(750)	0%
Total sales & marketing expense	$ 1,296,149	$ 1,215,580	$ 80,569	7%

General and administrative expenses.

General and administrative expenses were substantially unchanged during the fiscal year ended June 30, 2013 when compared to the fiscal year ended June 30, 2012.

Description	June 30, 2013	June 30, 2012	Variance ($)	Variance (%)
Legal expense	$ 153,663	$ 173,209	$ (19,546)	(11)%
Payroll benefits and related taxes	1,080,134	1,046,321	33,813	3%
Share-based compensation	32,328	85,198	(52,870)	(62)%
Other expense	1,028,048	1,050,287	(22,239)	(2)%
Total sales & marketing expense	$ 2,294,173	$ 2,355,015	$ (60,842)	(3)%

Operating loss.

Operating loss for the year ended June 30, 2013 compared to the year ended June 30, 2012 increased as a result of decreased revenue generated from the sales of brachytherapy seeds for the treatment of prostate cancer; which was not offset by a sufficient increase in product sales from other seed brachytherapy and sales of GliaSite RTS; coupled with cost of product sales which failed to decrease commensurate with the decrease in revenues even with a decrease in research and development expense. The changes in sales and marketing expense and general and administrative expense were immaterial to the change in operating loss.

Description	June 30, 2013	June 30, 2012	Variance ($)	Variance (%)
Operating loss	$ (4,067,253)	$ (3,597,970)	$ (469,283)	13%

Change in fair value of warrant liability.

During the years ended June 30, 2013 and June 30, 2012, there were changes in the fair value of the warrant derivative liabilities established upon issuance of the warrants during October 2011 and December 2011 to the purchasers and underwriters in the Company's registered public offering. Per ASC 820, the warrant derivative liability requires periodic evaluation for changes in fair value. As required at June 30, 2013 and June 30, 2012, the Company evaluated the fair value of the warrant derivative liability using the Black-Scholes option pricing model on which the original warrant derivative liability was based and applied updated inputs as of those dates. The resulting change in fair value was recorded as of June 30, 2013 and June 30, 2012, respectively.

Description	June 30, 2013	June 30, 2012	Variance ($)	Variance (%)
Change in fair value of warrant derivative liability	$ 210,000	$ 170,000	$ 40,000	24%

Financing and interest expense. Financing and interest expense decreased for the year ended June 30, 2013 compared to the year ended June 30, 2012 as the result of a decrease in the deferred cost of financing.

Financing expense included interest expense and the amortization of deferred equity financing costs related to equity transactions.

Description	June 30, 2013	June 30, 2012	Variance ($)	Variance (%)
Deferred financing expense	-	(61,511)	61,511	(100)%
Other income / (expense)	(7)	(171)	164	96%
Total interest and financing expense	$ (7)	$ (61,682)	$ 61,675	(100)%

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 2013, the Company used existing cash reserves and cash received through sales of common stock of approximately $3 million and in 2012 of approximately $2.5 million to fund its operations and capital expenditures.

Cash flows from operating activities

Cash used by operating activities is the net loss adjusted for non-cash items and changes in operating assets and liabilities.

The increase in net cash used in operating activities for the year ended June 30, 2013 when compared to the year ended June 30, 2012 is primarily the result of the increased net loss that is primarily the result of decreased revenues. Management has continued to maintain prior reductions of expenses that consumed cash in operating activities through a combination of cost reductions and operational efficiencies that were previously identified and implemented in operations. The remaining increase in cash used by operating activities is the net of an increase from the changes in operating assets and liabilities partially reduced by the decrease in non-cash operating expenses.

Key operating factor

Description	Fiscal year ended 06-30-13	Fiscal year ended 06-30-12	Variance ($)	Variance (%)
Net loss	$ (3,856,596)	$ (3,488,905)	$ (367,691)	11%
Non-cash items	731,738	983,534	(251,796)	(26)%
Non-cash changes in operating assets and liabilities	68,591	57,596	10,995	19%
Net cash used by operating activities	$ (3,056,267)	$ (2,447,775)	$ (608,492)	25%

Cash flows from investing activities

Cash used by investing activities during the year ended June 30, 2013 was primarily related to the capitalization of costs related to other assets and in the year ended June 30, 2012 was primarily that required to bring the GliaSite RTS to market.

Key operating factor

Description	Fiscal year ended 06-30-13	Fiscal year ended 06-30-12	Variance ($)	Variance (%)
Purchases of fixed assets	$ (6,576)	$ (55,057)	$ 48,481	(88)%
Additions to licenses and other assets	(6,118)	(40,240)	34,122	(85)%
Change in restricted cash	(122)	(218)	96	(44)%
Net cash used by investing activities	$ (12,816)	$ (95,515)	$ 82,699	(87)%

Cash flows from financing activities

Cash provided by financing activities in the year ended June 30, 2013 and June 30, 2012 was the result of sales of common stock in a registered direct offering and through warrant exercises and option exercises. Cash used during the fiscal years ended June 30, 2013 and June 30, 2012 was the result of dividend payments to the preferred shareholders.

Key operating factor

Description	Fiscal year ended 06-30-13	Fiscal year ended 06-30-12	Variance ($)	Variance (%)
Preferred dividend payments	$ (10,632)	$ (10,632)	$ -	0%
Proceeds from sale of common stock	3,306,931	3,114,379	192,552	6%
Net cash provided by financing activities	$ 3,296,299	$ 3,103,747	$ 192,552	6%

Projected 2014 Liquidity and Capital Resources

Balances at:	09-17-13	06-30-13	06-30-12
Cash and cash equivalents	$ 5,514,119	$ 2,899,927	$ 2,672,711
Short-term investments	-	-	-

The Company's monthly required cash operating expenditures increased during the fiscal year ended June 30, 2013 when compared to the fiscal year ended June 30, 2012. Net cash used by operating activities increased by the net effect of the increased net loss when adjusted for the increase in cash used by non-cash expenses and for the increase in cash used by operating assets and liabilities.

Key operating factor

Description	Fiscal year ended 06-30-13	Fiscal year ended 06-30-12	Variance ($)	Variance (%)
Net loss	$ (3,856,596)	$ (3,488,905)	$ (367,691)	11%
Increase in non-cash expenses	731,738	983,534	(251,796)	(26)%
Increase in operating assets and liabilities	68,591	57,596	10,995	19%
Net cash used by operating activities	$ (3,056,267)	$ (2,447,775)	$ (608,492)	25%
Number of months to calculate	12	12		
Average monthly cash required for operating expense	$ (255,000)	$ (204,000)	$ (51,000)	25%

During fiscal year 2014, the Company intends to continue its existing protocol studies and to begin new protocol studies on lung and inter-cranial cancer treatments using Cesium-131 brachytherapy seeds and the GliaSite RTS. The Company believes that approximately $180,000 in expense will be incurred during fiscal year 2014 related to protocol expenses relating to lung cancer, inter-cranial cancer and both dual therapy and mono therapy prostate cancer protocols.

Based on the foregoing assumptions, management believes cash and cash equivalents on hand at June 30, 2013 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® RTS to current customers, adding new customers in the United States through the Company's direct sales force, through international sales with the existing distribution agreements which cover Germany, Austria, Switzerland, Italy, Luxembourg, Greece, Australia and New Zealand and the addition of other distribution channels to European Union countries covered by the ISO certifications.

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 three fiscal years and these sales continued to decline during the year ended June 30, 2013. Sales of other applications and of the GliaSite RTS have been nominal and historically have not been a substantial contributor to total revenue.

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 10% comparing fiscal year 2013 to fiscal year 2012, management believes the Company may need to continue to raise additional capital after fiscal year 2014 to maintain compliance with NYSE MKT listing standards as this entry into new markets may take longer to generate revenues.

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 Company's Form S-3 shelf registration statement filed in 2009 and a prospectus supplement filed on July 17, 2012.

Series C warrant exercises in September and November of 2012 resulted in proceeds of less than $ 2,000.

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, 2013 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 any of our offerings 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 (FY 2011)	$ 2,219,306
Proceed from sales of common stock, pursuant to registered public offering, net (FY 2012)	2,274,486
Proceeds from sales of common stock, pursuant to exercise of Series C warrants, net	834,797
Proceeds from sales of common stock, pursuant to registered public offering, net (FY 2013)	3,291,977
Proceeds from sales of common stock, pursuant to exercise of Series C warrants, net	1,825
Total proceeds from public offerings through June 30, 2013	$ 8,622,391

Offering description	Period	Net proceeds	Remaining net proceeds
Registered direct offering	Oct / Dec 2011	$ 2,274,486	$ -
Registered direct offering	July 2012	3,291,977	2,898,102
Total proceeds from registered public offerings		$ 5,566,463	$ 2,898,102

Proceeds used in the year ended June 30, 2013:	
Indirect payments to directors and officers for database development	$ 13,960
Direct payments of salaries to directors and officers	840,843
Working capital	2,211,783
Total proceeds used in the year ended June 30, 2013	$ 3,066,586

On August 29, 2013, the Company entered into an agreement to sell 3,800,985 common units, each consisting of 1 share of the Company's common stock and a warrant to purchase 0.816 shares of common stock (the Common Units), and 1,670 preferred units, each consisting of 1 share of Series D Convertible Preferred Stock and a warrant to purchase 1,525.23 shares of common stock (the Preferred Units) on a firm commitment underwritten basis. The Common Units were sold at an initial per unit purchase price of $0.535 and the Preferred Units were sold at an initial per unit purchase price of $1,000. The warrants are all exercisable at $0.72 per share and have a twenty-four month term, with the exercise price and term subject to reduction to $0.535 per share and an eighteen month term if shareholder approval is obtained. Each share of the Series D Convertible Preferred Stock is convertible into 1,869.15 shares of common stock at any time at the option of the holder, subject to adjustment, provided that the holder will be prohibited from converting Series D Convertible Preferred Stock into shares of the Company's common stock if, as a result of such conversion, the holder, together with affiliates, would own more than 9.99% of the total shares of the Company's common stock then issued and outstanding. The offering yielded approximately $3,287,520 in cash after expenses.

As a result of this recent capital raise, management does not anticipate needing to raise financing during fiscal 2014. If financing is obtained, it may be dilutive to shareholders. Of course, needed funding may not be available to us on acceptable terms, or at all. If the Company is unable to raise needed additional funds, it may have to discontinue or significantly curtail operations.

Other Commitments and Contingencies

In April 2013, Medical exercised the second 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, 2016. The Company agreed to modification number 14 which became effective on May 1, 2013. The lease modification provided for a contractually permitted rent increase based on a CPI index which was 1.9%. The modification also provided the Company with an additional (third) three year option to extend their tenancy beyond the current expiration date of April 30, 2016. The rent contained in lease modification number 14 beginning on May 1, 2013 is $22,566.

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,	
2014	270,796
2015	270,796
2016	270,796
2017	270,796
2018	270,796
2019	225,663
	$ 1,579,643

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

The Company reviewed all Accounting Standards Update issued from the beginning of calendar year 2011 through ASU 2013-10 and determined that the only ASU for which the effective date for the Company was prior to June 30, 2013 was ASU 2012-03. All others ASU's that have not been previously adopted were determined to not be applicable to the Company as of June 30, 2013.

Effective August 2012, the Company adopted ASU 2012-03 "Technical Amendments and Corrections to SEC Sections". This Accounting Standards Update addresses amendments to SEC paragraphs pursuant to SEC Staff Accounting Bulletin No. 114, technical amendments pursuant to SEC Release No. 33-9250, and corrections related to FASB Accounting Standards Update 2010-22. 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, 2013. 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, 2013, the Company determined that there was a single deficiency that constituted a material weakness.

- *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.

As a result of the significant deficiency which itself constitutes a material weakness, management concluded that our internal control over financial reporting was not effective as of June 30, 2013.

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

During fiscal year 2013, the Company took the following actions to improve internal control over financial reporting:

- In April 2013, the Company hired a staff accountant with a BA in Business Administration, Accounting Major to allow for further segregation of the Controller from daily transactional processing and to support the senior accountant as her role in the financial reporting of the Company has expanded.
- The Company continued 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, 2013. 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, 2013 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, 2013 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, 2013 were as follows:

Name	Age	Position Held	Term*
Dwight Babcock	65	Chairman, Chief Executive Officer	Annual
Brien Ragle	44	Controller, Principal Financial and Accounting Officer	
Robert Kauffman	73	Vice-Chairman	Annual
Thomas LaVoy	53	Director	Annual
Albert Smith	69	Director	Annual
Fredric Swindler#	66	Vice-President, Regulatory and Quality Affairs	
William Cavanagh III	47	Vice President, Research and Development	

* For directors only

Mr. Swindler transitioned to part-time employment in September 2013, as part of retirement planning, and serves as Vice President as of the date of this Report.

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 in Hospitality Management from Washington State University. Mr. Ragle is a Certified Public Accountant in the State of Washington and designated as a Chartered Global Management Accountant by the American Institute of Certified Public Accountants. 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 also 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, serving as Vice President, Regulatory and Quality Affairs until September 6, 2013, when he began serving as Vice President on a part-time basis as a part of his transition to retirement. Mr. Swindler has over 40 years experience in manufacturing and regulatory compliance. Mr. Swindler also served as Secretary for IsoRay, Inc., from June 11, 2008 through September 6, 2013. 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 and serves as Vice President, Research and Development. Immediately prior to joining IsoRay Medical, Mr. Cavanagh was 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	85	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, 2013, except as follows – Brien Ragle (one Form 4). This Form 4 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, 2005, 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 and employees are set or recommended to the Board by the Compensation Committee, 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	2013	284,394	-	-	-	-	-	-	284,394
Chairman and CEO	2012	276,212	-	-	42,078	-	-	-	318,290
Frederic Swindler	2013	167,908	-	-	-	-	-	-	167,908
VP–QA / RA	2012	163,077	-	-	5,680	-	-	-	168,757
William Cavanagh	2013	154,327	-	-	-	-	-	-	154,327
VP – R&D	2012	154,039	-	-	15,148	-	-	-	169,187
Robert Bilella	2013	97,200	63,275	-	-	-	-	-	160,475
NE Area Sales Director	2012	97,200	85,270	-	-	-	-	-	182,470

- Amounts represent the ASC 718, *Compensation – Stock Compensation* valuation for the fiscal years ended June 30, 2013 and 2012, 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 options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity Incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date
Dwight Babcock,	50,000(1)	-	-	6.30	03/31/2016
Chairman and CEO	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	10,000(3)	-	-	4.40	03/02/2017
Vice-President, Regulatory and Quality Affairs	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
	13,333(8)	6,667(8)	-	0.99	06/07/2021
	2,500(10)	5,000(10)	-	0.98	06/27/2022
William Cavanagh	30,000(9)	-	-	0.84	01/08/2020
Vice-President, Research and Development	35,000(7)	-	-	1.43	06/30/2020
	23,333(8)	11,667(8)	-	0.99	06/07/2021
	6,666(10)	13,334(10)	-	0.98	06/27/2022
Robert Bilella	84,236(2)	-	-	4.15	06/23/2015
NE Area Sales Director	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, all of which were exercisable as of June 30, 2013.
8) Represents a June 7, 2011 grant, one-third of which became exercisable on June 30, 2012, one-third of which became exercisable on June 30, 2013, and the final third will become exercisable on June 30, 2014.
9) Represents a January 8, 2010 grant, all of which were exercisable as of January 8, 2013.
10) Represents a June 27, 2012 grant, one-third of which became 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 2013, 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 received 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, 2013 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 27, 2013 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 27, 2013, the Company had 38,419,502 shares of common stock, 59,065 shares of Series B preferred stock outstanding and 1,670 shares of Series D convertible preferred stock. 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 (1)	Common Stock Warrants (1)	Convertible Preferred Stock (1)	Percent of Class (2)
Dwight Babcock (3)	259,068	750,000	12,500	-	2.61%
Brien Ragle	-	40,333	-	-	0.10%
Robert Kauffman	113,802	150,000	-	-	0.68%
Thomas LaVoy	83,523	150,000	-	-	0.61%
Albert Smith	198,101	175,000	-	-	0.97%
Fredric Swindler	-	115,833	-	-	0.30%
William Cavanagh III	-	94,999	-	-	0.25%
Directors and Executive Officers as a group	654,494	1,476,165	12,500	-	5.28%
Sabby Management, LLC (4)	3,800,895	-	-	3,121,481(5)	16.66%(6)

(1) Only includes those common stock options, common stock warrants and convertible preferred stock that could be exercised or converted into common stock within 60 days after September 27, 2013.

(2) Percentage ownership is based on 38,419,502 shares of Common Stock outstanding on September 27, 2013. Shares of Common Stock subject to convertible preferred stock, stock options or warrants which are currently convertible or exercisable or will become convertible or exercisable within 60 days after September 27, 2013 are deemed outstanding for computing the percentage ownership of the person or group holding such convertible preferred stock, options or warrants, but are not deemed outstanding for computing the percentage ownership of any other person or group.

(3) Mr. Babcock's common shares owned include 2,695 shares owned by his spouse.

(4) Sabby Management, LLC, with an address of 10 Mountainview Road, Suite 205, Upper Saddle River, New Jersey 07458, is the beneficial owner of these shares and warrants, held of record by Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd., based on the information contained in the Schedule 13G filed on September 3, 2013.

(5) Represents the shares of common stock to be received upon conversion of the Series D Convertible Preferred Stock, which were convertible as of September 27, 2013, held by the beneficial owner.

(6) This beneficial owner may not convert the preferred stock into shares of the Company's common stock if, as a result of the conversion, the owner, together with affiliates, would own more than 9.99% of the total shares of the Company's common stock then issued and outstanding.

Series B Preferred Stock Share Ownership

Name of Beneficial Owner	Series B 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 Series B Preferred Stock outstanding on September 27, 2013.
(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 any class of Preferred Stock.

ITEM 13 – CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

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, 2013	Year ended June 30, 2012
1. Audit fees	$ 60,372	$ 61,750
2. Audit-related fees	2,733	-
3. Tax fees	8,250	11,500
4. All other fees	3,750	2,275
Totals	$ 75,105	$ 75,525

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 cost of attendance at the annual shareholder meeting. 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 review of documents related to equity offerings that occurred in the years ended June 30, 2013 and 2012, respectively.

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 and all omitted exhibits are intentionally omitted)

Exhibit #	Description
2.1	Merger Agreement dated as of May 27, 2005, by and among Century Park Pictures Corporation, Century Park Transitory Subsidiary, Inc., certain shareholders and IsoRay Medical, Inc. incorporated by reference to the Form 8-K filed on August 3, 2005.
2.2	Certificate of Merger, filed with the Delaware Secretary of State on July 28, 2005 incorporated by reference to the Form 8-K filed on August 3, 2005.
3.1	Articles of Incorporation and By-Laws are incorporated by reference to the 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	Certificate of Designation of Rights, Preferences and Privileges of Series C Junior Participating Preferred Stock, incorporated by reference to the Company's Registration Statement on Form 8-A filed February 7, 2007.
3.5	Amended and Restated By-Laws of the Company dated as of January 8, 2008, incorporated by reference to the Form 8-K filed on January 14, 2008.
3.6	Certificate of Designation and Preferences, Rights and Limitations of Series D Convertible Preferred Stock dated August 29, 2013 of IsoRay, Inc., incorporated by reference to the Form 8-K filed on August 29, 2013.
4.8	Amended and Restated 2005 Employee Stock Option Plan incorporated by reference to the Form S-8 filed on August 19, 2005.
4.11	Form of IsoRay, Inc. Common Stock Purchase Warrant, incorporated by reference to the Form SB-2/A1 filed on March 24, 2006.
4.14	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.
4.16	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.
4.19	Rights Agreement, dated as of February 1, 2007, between the Computershare Trust Company N.A., as Rights Agent, incorporated by reference to the Company's Registration Statement on Form 8-A filed on February 7, 2007.
4.23	Form of Series D Warrant to Purchase Common Stock, incorporated by reference to the Form 8-K filed on November 22, 2010.
4.26	Form of Common Stock Purchase Warrant, incorporated by reference to the Form 8-K filed on October 13, 2011.
4.28	Form of Indenture (Subordinated Debt Securities) of IsoRay, Inc., incorporated by reference to the Form S-3/A filed on May 28, 2013.
4.29	Form of Indenture (Senior Debt Securities) of IsoRay, Inc., incorporated by reference to the Form S-3/A filed on May 28, 2013.
4.30	Specimen of Series D Convertible Preferred Stock Certificate of IsoRay, Inc., incorporated by reference to the Form 8-K filed on August 29, 2013.
4.31	Form of Common Stock Greenshoe Warrant of IsoRay, Inc., incorporated by reference to the Form 8-K filed on August 29, 2013.
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.
10.5	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.
10.10	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.
10.18	State of Washington Radioactive Materials License dated October 6, 2005, incorporated by reference to the Form SB-2 filed on November 10, 2005.
10.22	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).
10.25	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.

10.33	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.
10.35	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.
10.39	Form of Common Stock Purchase Warrant dated March 21, 2007, incorporated by reference to the Form 8-K filed on March 23, 2007.
10.59	License Agreement, dated effective June 14, 2010, by and between IsoRay Medical, Inc. and Hologic Inc., incorporated by reference to the Form 8-K filed on June 23, 2010 (confidential treatment requested for redacted portions).
10.63	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.
10.65	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/A filed on August 19, 2011 (confidential treatment requested for redacted portions).
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 (confidential treatment requested for redacted portions).
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 (confidential treatment requested for redacted portions).
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.
10.72	Contract, dated January 9, 2013, by and between IsoRay Medical, Inc. and The Open Joint Stock Company ‹‹Isotope›› (confidential treatment requested for redacted portions), incorporated herein by reference to the 8-K/A filed on March 21, 2013.
10.73	Employment Agreement dated September 6, 2013, by and among Fredric Swindler, IsoRay Medical, Inc. and IsoRay, Inc. incorporated by reference to the Form 8-K filed on September 12, 2013.
10.74*	Letter Agreement, dated August 27, 2013, between IsoRay Medical, Inc. and Karlheinz Goehl-Medizintechnik Göhl.
14.1	Code of Conduct and Ethics, incorporated by reference to the Form 10-KSB filed on October 11, 2005.
14.2	Code of Ethics for Chief Executive Officer & Senior Financial Officers, incorporated by reference to the Form 10-KSB filed on October 11, 2005.
21.1*	Subsidiaries of the Company.
23.1*	Consent of DeCoria, Maichel & Teague, P.S.
31.1*	Rule 13a-14(a)/15d-14(a) Certification - Chief Executive Officer.
31.2*	Rule 13a-14(a)/15d-14(a) Certification - Principal Financial Officer.
32.1**	Section 1350 Certifications.
101.INS***	XBRL Instance Document.
101.SCH***	XBRL Taxonomy Extension Schema Document.
101.CAL***	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF***	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB***	Taxonomy Extension Label Linkbase Document.
101.PRE***	XBRL Taxonomy Extension Presentation Linkbase Document.

* Filed herewith.
** Furnished herewith.
*** Furnished herewith. Users of this data to be submitted electronically are advised pursuant to Rule 406T of Regulation S-T that this interactive data file will not be deemed filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, will not be deemed filed for purposes of section 18 of the Securities Exchange Act of 1934, and otherwise will not be subject to liability under these sections.

Reports on Form 8-K

On May 15, 2013, the Company filed a Current Report on Form 8-K announcing its financial results for the quarter ended March 31, 2013.

On August 29, 2013, the Company filed a Current Report on Form 8-K announcing its entry into an Amended and Restated Underwriting Agreement with Maxim Group LLC providing for the sale of 3,800,985 common units and 1,670 preferred units, each consisting of shares and warrants. This Report also announced the designation of the Series D Convertible Preferred Stock.

On August 30, 2013, the Company filed a Current Report on Form 8-K announcing the renewal through August 31, 2014 of its subsidiary's International Distribution Agreement with Karlheinz Goehl-Medizintechnik Gohl.

On September 12, 2013, the Company filed a Current Report on Form 8-K announcing its and its subsidiary's entry into an Employment Agreement with Fredric Swindler.

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, 2013 and 2012, 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, 2013 and 2012, 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 25, 2013

IsoRay, Inc and Subsidiaries
Consolidated Balance Sheets

	June 30, 2013	June 30, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 2,899,927	$ 2,672,711
Accounts receivable, net of allowance for doubtful accounts of $52,598 and $57,604, respectively	923,780	865,056
Inventory	405,571	444,345
Other receivables	11,502	9,925
Prepaid expenses and other current assets	202,880	144,116
Total current assets	4,443,660	4,136,153
Fixed assets, net of depreciation and amortization	1,684,282	2,416,853
Restricted cash	181,149	181,027
Inventory, non-current	469,758	469,758
Other assets, net of accumulated amortization	276,507	301,691
Total assets	$ 7,055,356	$ 7,505,482
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 432,566	$ 389,105
Accrued protocol expense	25,305	-
Accrued radioactive waste disposal	100,000	52,000
Accrued payroll and related taxes	127,419	119,881
Accrued vacation	107,578	88,006
Total current liabilities	792,868	648,992
Warrant derivative liability	104,000	314,000
Asset retirement obligation	792,242	724,298
Total liabilities	1,689,110	1,687,290
Commitments and contingencies (Note 16)		
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: 1,000,0000 shares allocated; no shares issued and outstanding	-	-
Common stock, $.001 par value; 193,000,000 shares authorized; 34,618,517 and 30,950,108 shares issued and outstanding	34,618	30,950
Treasury stock, at cost 13,200 shares	(8,390)	(8,390)
Additional paid-in capital	57,431,293	54,030,311
Accumulated deficit	(52,091,334)	(48,234,738)
Total shareholders' equity	5,366,246	5,818,192
Total liabilities and shareholders' equity	$ 7,055,356	$ 7,505,482

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, 2013	June 30, 2012
Product sales	$ 4,525,233	$ 5,071,088
Cost of product sales	4,375,057	4,367,884
Gross profit	150,176	703,204
Operating expenses:		
Research and development expenses	627,107	780,579
Research and development reimbursement	-	(50,000)
Sales and marketing expenses	1,296,149	1,215,580
General and administrative expenses	2,294,173	2,355,015
Total operating expenses	4,217,429	4,301,174
Operating loss	(4,067,253)	(3,597,970)
Non-operating income (expense):		
Interest income	664	747
Change in fair value of warrant liability	210,000	170,000
Financing and interest expense	(7)	(61,682)
Non-operating income (expense), net	210,657	109,065
Net loss	(3,856,596)	(3,488,905)
Preferred stock dividends	(10,632)	(10,632)
Net loss applicable to common shareholders	$ (3,867,228)	$ (3,499,537)
Basic and diluted loss per share	$ (0.11)	$ (0.12)
Weighted average shares used in computing net loss per share:		
Basic and diluted	34,423,420	28,621,831

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		Additional	Accumulated	
	Shares	Amount	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Total
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 public offering, net			2,817,988	2,818			2,271,668		2,274,486
Initial deferral of financing expense							61,511		61,511
Initial fair value of derivative liability							(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
Issuance of common stock pursuant to a registered public offering, net			3,626,943	3,627			3,288,350		3,291,977
Issuance of common stock pursuant to exercise of warrants, net			2,766	3			1,822		1,825
Issuance of common stock pursuant to exercise of options			38,700	38			13,091		13,129
Payment of dividend to preferred shareholders							(10,632)		(10,632)
Share-based compensation							108,351		108,351
Net loss								(3,856,596)	(3,856,596)
Balances at June 30, 2013	59,065	$ 59	34,618,517	$ 34,618	13,200	$ (8,390)	$ 57,431,293	$ (52,091,334)	$ 5,366,246

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, 2013	June 30, 2012
Cash flows from operating activities:		
Net loss	$ (3,856,596)	$ (3,488,905)
Adjustments to reconcile net loss to net cash used by operating activities:		
Allowance for doubtful accounts	(5,006)	(6,263)
Depreciation and amortization of fixed assets	739,147	847,115
Amortization of deferred financing expense and other assets	31,302	77,242
Change in fair value of warrant liabilities	(210,000)	(170,000)
Accretion of asset retirement obligation	67,944	62,117
Share-based compensation	108,351	173,323
Changes in operating assets and liabilities:		
Accounts receivable	(53,718)	(65,958)
Inventory	38,774	(164,254)
Other receivables	(1,577)	415,976
Prepaid expenses, other current assets and other assets	(58,764)	(2,962)
Accounts payable and accrued expenses	43,461	16,846
Accrued protocol expense	25,305	(98,159)
Accrued radioactive waste disposal	48,000	(56,060)
Accrued payroll and related taxes	7,538	(5,133)
Accrued vacation	19,572	17,300
Net cash used by operating activities	(3,056,267)	(2,447,775)
Cash flows from investing activities:		
Purchases of fixed assets	(6,576)	(55,057)
Additions to licenses and other assets	(6,118)	(40,240)
Change in restricted cash	(122)	(218)
Net cash used by investing activities	(12,816)	(95,515)
Cash flows from financing activities:		
Preferred dividends paid	(10,632)	(10,632)
Proceeds from sales of common stock, pursuant to registered public offering, net	3,291,977	2,274,486
Proceeds from sales of common stock, pursuant to exercise of warrants, net	1,825	834,797
Proceeds from sales of common stock, pursuant to exercise of options	13,129	5,096
Net cash provided by financing activities	3,296,299	3,103,747
Net increase in cash and cash equivalents	227,216	560,457
Cash and cash equivalents, beginning of year	2,672,711	2,112,254
Cash and cash equivalents, end of year	$ 2,899,927	$ 2,672,711
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 7	$ 171
Non-cash investing and financing activities:		
Initial deferral of financing expense	$ -	$ 61,511
Initial fair value of warrant liabilities	-	484,000

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

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 with 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 impairment. Any impairment is 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, 2013 and 2012, the carrying value of financial instruments such as accounts receivable, 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, 2013 and 2012, there were no assets or liabilities measured at fair-value on a recurring basis which were measured using Level 1 or Level 3 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, 2013 and 2012. 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 or liabilities measured at fair value on a nonrecurring basis during the years ended June 30, 2013 or 2012.

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.

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.

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.

Share-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 cost sharing arrangements for product research and development. Research and development reimbursements were $0 and $50,000 for the years ended June 30, 2013 and 2012, 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 $86,705 and $57,410 for the years ended June 30, 2013 and 2012, respectively. Marketing costs of $10,590 and $8,675 were included in prepaid expenses at June 30, 2013 and 2012, 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 Medical, and its predecessors are subject to examination of their income tax filings in the United States and state jurisdictions for the 2011 through 2013 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, 2013 and 2012 are as follows:

	2013	2012
Preferred stock	59,065	59,065
Common stock warrants	1,957,033	1,959,799
Common stock options	2,305,072	2,381,306
Total potential dilutive securities	4,321,170	4,400,170

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; inputs used in the calculation of expense related to share-based compensation including volatility, estimated lives and forfeiture rates of options granted; and the inputs to the Black-Scholes calculation to estimate the fair value of the derivative warrant liability and the related gain or loss. 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, 2013 and 2012:

	2013	2012
Raw materials	$ 167,671	$ 261,835
Work in process	195,323	114,124
Finished goods	42,577	68,386
Total inventory	$ 405,571	$ 444,345

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 is classified as inventory, non-current at both June 30, 2013 and 2012.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following at June 30, 2013 and 2012:

	2013	2012
Prepaid insurance	$ 48,421	$ 23,798
Prepaid rent	22,419	23,367
Other prepaid expenses	105,347	70,258
Other current assets	26,693	26,693
	$ 202,880	$ 144,116

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, 2013 was primarily comprised of employee advances and refunds due to the Company in the amount of $11,502 as compared to $9,925 recorded as of June 30, 2012. The other receivable long term recorded as of June 30, 2013 was also primarily comprised of long term employee advances due to the Company in the amount of $2,938 as compared to $9,988 recorded as of June 30, 2012.

6. Fixed Assets

Fixed assets consisted of the following at June 30, 2013 and 2012:

	2013	2012
Production equipment	$ 3,133,305	$ 3,133,305
Office equipment	195,877	189,301
Furniture and fixtures	148,265	148,265
Leasehold improvements	4,129,977	4,129,977
	7,607,424	7,600,848
Less accumulated depreciation	(5,923,142)	(5,183,995)
	$ 1,684,282	$ 2,416,853

Depreciation expense related to fixed assets totaled $739,147 and $847,115 for 2013 and 2012, respectively.

7. Restricted Cash

The Washington Department of Health requires 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 2019. 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 years ended June 30, 2013 and 2012 was $122 and $218, respectively. These funds will be used to settle a portion of the Company's remaining asset retirement obligations (see Note 9).

8. Other Assets

Other assets, net of accumulated amortization, consisted of the following at June 30, 2013 and 2012:

	2013	2012
Deferred charges	$ 61,331	$ 98,435
Patents and trademarks, net of accumulated amortization of $90,824 and $71,244	215,176	203,256
	$ 276,507	$ 301,691

Amortization of patents and trademarks was $19,581 and $15,731 for the years ended June 30, 2013 and 2012, respectively. Future amortization is expected to be as follows:

FY 2014	$ 19,021
FY 2015	19,021
FY 2016	19,021
FY 2017	19,021
FY 2018	15,333
Thereafter	123,759
	$ 215,176

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, 2013 and 2012, the asset retirement obligations changed as follows:

	2013	2012
Beginning balance	$ 724,298	$ 662,181
Accretion of discount	67,944	62,117
Ending balance	$ 792,242	$ 724,298

Because the Company does not expect to incur any expenses related to its asset retirement obligations in fiscal year 2014, the entire balance as of June 30, 2013 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, 2013 and 2012:

	2013	2012
Cost of product sales	$ 38,729	$ 47,463
Research and development	30,350	30,480
Sales and marketing expenses	6,943	10,182
General and administrative expenses	32,329	85,198
Total share-based compensation	$ 108,351	$ 173,323

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, 2013, total unrecognized compensation cost related to stock-based options and awards was $62,354 and the weighted-average period over which it is expected to be recognized is approximately 0.73 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, 2013 is as follows:

	Shares	Price (a)	Life (b)	Value (c)
Outstanding at June 30, 2013	2,305,072	$ 1.83	4.93	$ 115,302
Vested and expected to vest at June 30, 2013	2,215,260	$ 1.87	4.86	$ 105,157
Vested and exercisable at June 30, 2013	2,030,064	$ 1.94	4.49	$ 115,302

(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, 2013 and 2012 was $16,246 and $13,764, respectively. The Company's current policy is to issue new shares to satisfy option exercises.

The weighted average fair value of stock option awards granted and the key assumptions used in the Black-Scholes valuation model to calculate the fair value are as follows for the year ended June 30, 2012:

	Year ended June 30, 2012
Weighted average fair value of options granted	$ 0.80
Key assumptions used in determining fair value:	
Weighted average risk-free interest rate	0.71%
Weighted average life of the option (in years)	4.77
Weighted average historical stock price volatility	132.47%
Expected dividend yield	0.00%

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

A summary of the Company's stock option activity and related information for the years ended June 30, 2013 and 2012 is as follows:

	2013		2012	
	Shares	Price (a)	Shares	Price (a)
Beginning balance outstanding	2,381,306	$ 1.82	2,423,806	$ 1.78
Granted (b)	-	-	110,000	0.80
Expired	(37,534)	2.58	(132,900)	0.68
Exercised	(38,700)	0.34	(19,600)	0.26
Ending balance outstanding	2,305,072	$ 1.83	2,381,306	$ 1.82
Exercisable at end of year	2,030,064	$ 1.94	2,102,964	$ 1.92

(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, 2013 and 2012, 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 21, 2012, the Board of Directors declared a dividend on the Series B Preferred Stock of all outstanding and cumulative dividends through December 31, 2012. The total dividends of $10,632 were paid as of December 31, 2012. At June 30, 2013, 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, 2013 and 2012, 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, 2013 and 2012.

Common Stock Offerings

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.

On July 13, 2012, the Company entered into a securities purchase agreement with certain institutional investors, with Ladenburg Thalmann & Co. Inc. acting as placement agent, for a registered direct offering to sell 3,626,943 shares of the Company's common stock, par value $0.001 per share, with an aggregate purchase price of $3.5 million at a price per share of $0.965. The offering yielded $3,291,977 in cash after expenses.

Based on the guidance contained in ASC 815 "Derivatives and Hedging", management has concluded that the warrants issued in the October 13, 2011 underwritten registered offering of 2,500,000 shares of common stock should be classified as a derivative liability and has 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 to be as disclosed in the tables below. The Company has recognized a change in the change in fair value as described in the table below:

	Fiscal year ended June 30, 2013
Change in fair value	$ 210,000

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

Issue Date	Type	Quantity	Initial Fair Value
10/19/2011	Purchaser Warrants	500,003	$ 343,000
10/19/2011	Underwriter Warrants	150,000	103,000
12/07/2011	Purchaser Warrants	63,598	38,000
Total		713,601	$ 484,000

Transaction Date	Description	Quantity[1]	Stock Price	Exercise Price	Est. Term	Expected Volatility	Risk-Free Rate	Valuation
10/19/2011	Registered offering	650,003	$ 0.900	$ 1.058	3	141.07%	0.460%	$ 446,000
12/31/2011	Fair Value Adjust.	650,003	0.660	1.058	3	129.98	0.360	(156,000)
03/31/2012	Fair Value Adjust.	650,003	0.480	1.058	2.48	85.20	0.510	(194,445)
06/30/2012	Fair Value Adjust.	650,003	1.010	1.058	2.30	78.04	0.345	190,445
09/30/2012	Fair Value Adjust.	650,033	0.720	1.049	2.05	85.02	0.278	(118,000)
12/31/2012	Fair Value Adjust.	650,003	0.780	1.049	1.81	100.96	0.220	50,000
03/31/2013	Fair Value Adjust	650,003	0.540	1.049	1.57	108.29	0.213	(99,000)
06/30/2013	Fair Value Adjust	650,003	0.480	1.049	1.31	116.10	0.290	(25,000)
Fair value of warrant liability from registered direct offering:								$ 94,000

Transaction Date	Description	Quantity[1]	Stock Price	Exercise Price	Est. Term	Expected Volatility	Risk-Free Rate	Valuation
12/07/2011	Over-allotment	63,598	$ 0.820	$ 1.058	3	133.00%	0.360%	$ 38,000
12/31/2011	Fair Value Adjust.	63,598	0.660	1.058	3	129.98	0.360	(10,000)
03/31/2012	Fair Value Adjust.	63,598	0.480	1.058	2.48	85.20	0.510	(18,650)
06/30/2012	Fair Value Adjust.	63,598	1.010	1.058	2.44	77.16	0.345	18,650
09/30/2012	Fair Value Adjust.	63,598	0.720	1.049	2.19	84.53	0.278	(11,000)
12/31/2012	Fair Value Adjust.	63,598	0.78	1.049	1.941	98.25	0.220	5,000
03/31/2013	Fair Value Adjust.	63,598	0.54	1.049	1.70	106.39	0.213	(10,000)
06/30/2013	Fair Value Adjust.	63,598	0.48	1.049	1.45	112.70	0.290	(2,000)
Fair value of warrant liability from over-allotment offering:								$ 10,000

Total fair value of warrant liability at June 30, 2013:	$ 104,000

[1] Quantity of warrants either issued or outstanding as of the date of valuation.

Warrants to Purchase Common Stock

At various times during the year ended June 30, 2013, 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
September 2012	2,666	$ 1,790
November 2012	100	35
Total	2,766	$ 1,825

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, 2013 and 2012:

	2013		2012	
	Warrants	Price (a)	Warrants	Price (a)
Beginning balance outstanding	1,959,799	$ 1.38	3,819,185	$ 3.69
Cancelled/expired	-	-	(2,092,324)	5.89
Warrants exercised	(2,766)	0.66	(1,669,402)	0.50
Granted	-	-	1,902,340	1.36
Ending balance outstanding	1,957,033	$ 1.38	1,959,799	$ 1.38

(a) Weighted average exercise price per share.

The following table summarizes additional information about the Company's common warrants outstanding as of June 30, 2013:

Number of Warrants	Range of Exercise Prices	Expiration Date
6,000	$ 1.180	June 2015
25,000	2.000	July 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
1,957,033		

12. Income Taxes

The Company did not record an income tax provision or benefit for the years ending June 30, 2013 and 2012.

The significant deferred tax components using a 35% federal income tax rate for the years ended June 30, 2013 and 2012 are as follows:

	2013	2012
Fixed assets	$ 408,223	$ 328,524
Share based compensation	279,089	241,166
Reserves	18,409	20,161
Other accruals	24,627	30,145
Asset retirement obligation	277,285	253,504
Net operating loss carry forwards	14,791,279	13,667,918
Total deferred tax assets	15,798,912	14,541,418
Valuation allowance	(15,798,912)	(14,541,418)
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 both June 30, 2013 and 2012.

The Company has federal net operating loss carry forwards of approximately $42.3 million at June 30, 2013 and approximately $39.1 million at June 30, 2012, that can be used to offset future regular taxable income. These net operating loss carry forwards expire at various times through the years 2025 to 2032.

The Company's statutory rate reconciliation is as follows:

	2013	2012
Expected income tax benefit based on statutory rate of 35%	$ (1,349,809)	$ (1,221,117)
Meals and entertainment	17,966	17,999
Non-deductible penalties	849	614
Warrant liability	73,500	59,500
Increase in valuation allowance	1,257,494	1,143,004
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 Medical, and its predecessors are subject to examination of their income tax filings in the United States and state jurisdictions for the 2011 through 2013 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. Foreign Isotope Supply

In January 2013, the Company completed negotiations on a contract to purchase Cs-131 from The Open Joint Stock Company ‹‹Isotope››, from Russia. Under the contract, the Company will purchase Cs-131 from The Open Joint Stock Company ‹‹Isotope››, rather than from UralDial. The contract provides for the supply of Cs-131 from a single reactor at the Institute of Nuclear Materials. The contract will expire on June 30, 2014.

In June 2013, the Company negotiated a contract with E&H Scientific, LLC to provide logistical support in the packaging, export and import support for the supply of Cs-131 being shipped from Russia. The contract will expire on June 30, 2014.

15. Distribution Agreements

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. Prior to the expiration of the agreement on August 30, 2013, the parties agreed to extend the term of the agreement until August 31, 2014.

In May 2013, the Company entered into an exclusive distribution agreement with IASIS Medical for the sale of IsoRay's complete product line in Greece. 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 and the distributor is responsible for achieving regulatory clearance. The agreement terminates on May 1, 2015 unless terminated earlier as provided for within the agreement and may be extended by mutual agreement of the parties.

In June 2013, the Company entered into an exclusive distribution agreement with Aurora BioScience for the sale of IsoRay's complete product line in New Zealand and Australia. The terms of the agreement make the Distributor the importer of record and liable for any value added taxes for the shipments into the New Zealand or Australia and the distributor is responsible for achieving regulatory clearance. The agreement terminates on June 1, 2015 unless terminated earlier as provided for within the agreement and may be extended by mutual agreement of the parties.

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 2013 and 2012, the Company recorded royalty expenses of $14,168 and $19,497, 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 2019 (including renewal dates). The Company agreed to a modification which became effective on May 1, 2013. The lease modification included a contractually permitted rent increase which is based on a CPI index which was 1.9% and provided the Company with an additional three year option to extend their tenancy beyond the current expiration date of April 30, 2016, to April 30, 2019. The Company's significant lease is described below.

Future minimum lease payments including the one three year option to extend remaining under operating leases are as follows:

Year ending June 30,	Amount
2014	$ 270,796
2015	270,796
2016	270,796
2017	270,796
2018	270,796
2019	225,663
	$ 1,579,643

Rental expense amounted to $284,097 and $290,670 for the years ended June 30, 2013 and 2012, 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 (“QTDP”). 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 $0 for the years ended June 30, 2013 and 2012, respectively. The amount of $515,853 from the Qualified Therapeutic Discovery Project received through the Internal Revenue Service during the fiscal year ended June 30, 2011 which was included in the Research and development reimbursement section of the Consolidated Statement of Operations for the fiscal year ended June 30, 2011 continues to be subject to examination by the Internal Revenue 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 Laboratory Ltd for the exclusive use of its intellectual property in the field of treating brain cancer related to the production of Iotrex, which is a component of 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
Calendar Year 2013	$ 10,000
Calendar Year 2014	20,000
Calendar Year 2015	25,000
Calendar Year 2016 and beyond	30,000

During 2013 and 2012, the Company recorded a royalty expense of $5,440. During 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.

The Company is required to pay a royalty to Hologic, Inc. for the exclusive worldwide use of intellectual property associated with the GliaSite Radiation Therapy System in the field of intracavity radiation therapy of the brain exclusive of the radioisotope. 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 the fiscal years ended June 30, 2013 and 2012, respectively, the Company recorded aggregate royalty expenses of $2,394 and $3,370 related to the licensed intellectual property utilized in the manufacture and sale of the GliaSite Radiation Therapy System.

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, 2013, all cash balances are insured by the FDIC.

The Company's accounts receivable are the result of sales on credit to our customers. The Company had two customers whose unpaid sales on credit were greater than 10% of the outstanding accounts receivable balance for the year ended June 30, 2013 and three customers whose unpaid sales on credit were greater than 10% of the outstanding accounts receivable balance for the year ended June 30, 2012. These customers' outstanding accounts receivable balances represented a combined 8.7% and 9.1% of the Company's total revenues for the years ended June 30, 2013 and 2012, respectively. These same customers accounted for a combined 40.4% and 50.1% of the Company's net accounts receivable balance at June 30, 2013 and 2012, respectively.

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, 2013 and June 30, 2012, 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. The Company incurred maintenance costs related to the registries in the amount of $1,960, website modifications and maintenance in the amount of $13,000 and implementation support for a CRM system in the amount of $1,000 for the fiscal year 2013. The Company incurred maintenance costs related to the registries in the amount of $13,080 for the fiscal year 2012. The amount accrued for payment to APEX Data Systems, Inc. was $2,000 and $1,000 at June 30, 2013 and 2012, respectively.

19. Subsequent Event

On August 29, 2013, the Company entered into an agreement to sell 3,800,985 common units, each consisting of 1 share of our common stock and a warrant to purchase 0.816 shares of common stock (the "Common Units"), and 1,670 preferred units, each consisting of 1 share of Series D Convertible Preferred Stock and a warrant to purchase 1,525.23 shares of common stock (the "Preferred Units") on a firm commitment underwritten basis. The Common Units were sold at an initial per unit purchase price of $0.535 and the Preferred Units were sold at an initial per unit purchase price of $1,000. The warrants are all exercisable at $0.72 per share and have a twenty-four month term, with the exercise price and term subject to reduction if shareholder approval is obtained. Each share of the Series D Convertible Preferred Stock is convertible into 1,869.15 shares of common stock at any time at the option of the holder, subject to adjustment, provided that the holder will be prohibited from converting Series D Convertible Preferred Stock into shares of the Company's common stock if, as a result of such conversion, the holder, together with affiliates, would own more than 9.99% of the total shares of the Company's common stock then issued and outstanding. This public offering resulted in gross proceeds of $3.7 million. The offering yielded approximately $3,287,520 in cash after expenses.

Gross proceeds from public offering	$ 3,703,527
Underwriter discount	(185,176)
Legal and accounting expense	(176,286)
Listing expense	(48,500)
Other expense	(6,045)
Net proceeds	$ 3,287,520

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 30, 2013

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 30, 2013

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

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

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

Thomas LaVoy, Director

/s/ Albert Smith
Albert Smith, Director

August 27, 2013

Karlheinz Goehl-Medizintechnik Göhl
Hermann-Glockner-Str.
590763 Fuerth, Germany
Attn: Charly Goehl, CEO

Re: Extension of Term of the International Distribution Agreement

Dear Mr. Goehl:

The purpose of this letter is to confirm the extension of the term contained in Section 4.1 of the International Distribution Agreement entered into between IsoRay Medical, Inc., a Delaware corporation ("IsoRay"), and Karlheinz Goehl-Medizintechnik ("Distributor"), dated as of October 31, 2011 (collectively, the "Agreement").

Under the Agreement, the Agreement's term expires on August 31, 2013. IsoRay and Distributor now agree to extend the term to August 31, 2014.

Except as set forth herein, all terms and conditions of the Agreement shall remain in full force and effect. Each party hereto hereby expressly ratifies and affirms all such terms and conditions as of the effective date hereof.

IsoRay and Distributor each represent and acknowledge that it has the power and authority to enter into this letter. This letter may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IsoRay Medical, Inc.

By /s/ Dwight Babcock
Dwight Babcock, CEO

The foregoing is accepted and agreed to on and as of the date first shown above,

Karlheinz Goehl-Medizintechnik Göhl

By /s/ Charly Goehl
Charly Goehl, CEO

6464 East Grant Road, Suite 250 – Tucson, AZ 85715
Phone: 520-298-1991 ext 109 Cell: 520-240-4840 Fax: 520-296-7948 Dbabcock@isoray.com

EXHIBIT 21

SUBSIDIARIES OF THE REGISTRANT

IsoRay Medical, Inc., a Delaware corporation

IsoRay International LLC, a Washington limited liability company

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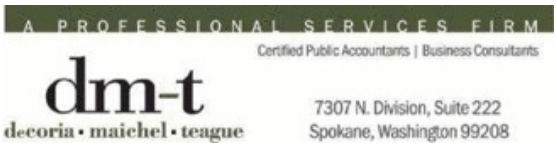

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the registration statements Nos. 333-127717 and 333-136728 on Form S-8 and Nos. 333-188579, 333-184868 and 333-171118 on Form S-3 of our report dated September 25, 2013, with respect to the consolidated balance sheets of IsoRay, Inc. and Subsidiaries as of June 30, 2013 and 2012, and the related consolidated statements of operations, changes in shareholders' equity and cash flows for the years then ended, which report appears in the Form 10-K filing for IsoRay, Inc. to be filed on or about September 27, 2013.

DeCoria, Maichel & Teague, P.S.

DeCoria, Maichel & Teague, P.S.
Spokane, Washington
September 25, 2013

Exhibit 31.1

CERTIFICATION

I, Dwight Babcock, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: September 30, 2013

/s/Dwight Babcock
Dwight Babcock
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Brien L Ragle, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: September 30, 2013

/s/Brien L. Ragle

Brien L. Ragle
Principal Financial and Accounting Officer

Exhibit 32

Section 1350 Certifications

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

To my knowledge, the Annual Report on Form 10-K of the Company for the annual period ended June 30, 2013 (the Report) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: September 30, 2013

/s/Dwight Babcock

Dwight Babcock
Chief Executive Officer
(Principal Executive Officer)

Dated: September 30, 2013

/s/Brien L. Ragle

Brien l. ragle
Controller
(Principal Financial and Accounting Officer)