IsoRay, Inc.
Form 10-K
September 30, 2013

United States Securities And Exchange Commission

Washington, D.C. 20549

FORM 10-K

x Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended June 30, 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	99354
Richland, Washington	(Zip code)

(Address of principal executive offices)

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

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

(NYSE MKT)

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

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

Class	Outstanding as of September 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 x

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

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

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

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

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

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

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

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

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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.)

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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)).

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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

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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 subs