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

United States Securities and Exchange Commission

Washington, d.c. 20549

FORM 10-K

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

or

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

Commission File No. 001-33407

IsoRay, Inc

(Exact name of registrant as specified in its charter)

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

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

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

(NYSE MKT)

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

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

Class	Outstanding as of September 25, 2012
Common stock, $0.001 par value	34,584,868

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

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

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

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

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

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

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

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter – $19,348,762 as of December 31, 2011.

Documents incorporated by reference – none.

ISORAY, INC.

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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 27 below that may cause actual results to differ materially.

Consequently, all of the forward-looking statements made in this Form 10-K are qualified by these cautionary statements and there can be no assurance that the actual results anticipated by management will be realized or, even if substantially realized, that they will have the expected consequences to or effects on our business operations. Readers are cautioned not to place undue reliance on such forward-looking statements as they speak only of the Company's views as of the date the statement was made. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I

As used in this Form 10-K, unless the context requires otherwise, "we" or "us" or the "Company" means IsoRay, Inc. and its subsidiaries.

ITEM 1 – BUSINESS

General

Century Park Pictures Corporation (Century) was organized under Minnesota law in 1983. Century had no operations since its fiscal year ended September 30, 1999 through June 30, 2005.

On July 28, 2005, IsoRay Medical, Inc. (Medical) became a wholly-owned subsidiary of Century pursuant to a merger. Century changed its name to IsoRay, Inc. (IsoRay or the Company). In the merger, the Medical stockholders received approximately 82% of the then outstanding securities of the Company.

Medical, a Delaware corporation, was incorporated on June 15, 2004 to develop, manufacture and sell isotope-based medical products and devices for the treatment of cancer and other malignant diseases. Medical is headquartered in Richland, Washington.

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

Available Information

The Company electronically files its annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to these reports and other information with the Securities and Exchange Commission (SEC). These reports can be obtained by accessing the SEC's website at www.sec.gov. The public can also obtain copies by visiting the SEC's Public Reference Room at 100 F Street NE, Washington, DC 20549 or by calling the SEC at 1-800-SEC-0330. In addition, the Company makes copies of its annual and quarterly reports available to the public at its website at www.isoray.com. Information on this website is not a part of this Report.

Business Operations

Overview

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

Brachytherapy seeds are small devices used in an interstitial radiation procedure. The procedure has become one of the primary treatments for prostate cancer. The brachytherapy procedure places radioactive seeds as close as possible to (in or near) the cancerous tumor (the word "brachytherapy" means close therapy). The seeds deliver therapeutic radiation thereby killing the cancerous tumor cells while minimizing exposure to adjacent healthy tissue. This procedure allows doctors to administer a higher dose of radiation directly to the tumor. Each seed contains a radioisotope sealed within a welded titanium capsule. When brachytherapy is the only treatment (monotherapy) used in the prostate, approximately 70 to 120 seeds are permanently implanted in the prostate in an outpatient procedure lasting less than one hour. The number of seeds used varies based on the size of the prostate and the activity level specified by the physician. When brachytherapy is combined with external beam radiation or intensity modulated radiation therapy (dual therapy), then approximately 40 to 80 seeds are used in the procedure. The isotope decays over time and eventually the seeds become inert. The seeds may be used as a primary treatment or in conjunction with other treatment modalities, such as chemotherapy, or as treatment for residual disease after excision of primary tumors. The number of seeds for other treatment sites will vary from as few as 8 to16 to as many as 117 to 123 depending on the type of cancer, the location of the tumor being treated and the type of therapy being utilized.

IsoRay began production and sales of Proxcelan Cesium-131 brachytherapy seeds in October 2004 for the treatment of prostate cancer after clearance of its premarket notification (510(k)) by the Food and Drug Administration (FDA). In December 2007, IsoRay began selling its Proxcelan Cs-131 seeds for the treatment of ocular melanoma, however, the market for the treatment has been limited generating a minimal amount of revenue for the Company. The Company continues to make the treatment available to interested physicians and medical facilities. In June 2009, the Company began selling its Proxcelan Cs-131 seeds for treatment of head and neck tumors, commencing with treatment of a tumor that could not be accessed by other treatment modalities. Upon obtaining clearance in August 2009 from the FDA to permit loading Cesium-131 into bioabsorbable braided strands, this clearance permits the product to be commercially distributed for treatment of lung, head and neck tumors as well as tumors in other organs. During the fiscal year ended June 30, 2010, the Company expanded the number of areas of the body in which the Proxcelan Cs-131 seeds were being utilized for treatment by adding lung cancer in August 2009, colorectal cancer in October 2009, and chest wall cancer in December 2009. During the fiscal year ended June 30, 2012, the Company

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

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

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

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

Industry Information

Incidence of Prostate Cancer

The prostate is a walnut-sized gland located in front of the rectum and underneath the urinary bladder. Prostate cancer is a malignant tumor that begins most often in the periphery of the gland and, like other forms of cancer, may spread beyond the prostate to other parts of the body. According to the American Cancer Society, approximately one man in six will be diagnosed with prostate cancer during his lifetime and one man in thirty-six will die of prostate cancer. It is the most common form of cancer in men after skin cancer, and the second leading cause of cancer deaths in men following lung and bronchus cancers. The American Cancer Society estimates there will be about 241,740 new cases of prostate cancer diagnosed and an estimated 28,170 deaths associated with the disease in the United States in 2012. Because of early detection techniques (e.g., screening for prostate specific antigen, or PSA), approximately nine out of ten prostate cancers are found in the local and regional stages (local means it is still confined to the prostate; regional means it has spread from the prostate to nearby areas, but not distant sites, such as bone).

Prostate cancer accounts for about 9% of cancer related deaths in men. Prostate cancer incidence and mortality increase with age. The American Cancer Society has reported that the incidence of prostate cancer rises rapidly after age 50. Almost 2 of 3 prostate cancers are found in men over the age of 65.

Incidence of Lung Cancer

An estimated 226,160 new cases of lung cancer are expected in 2012, accounting for 14% of all cancer diagnoses in the United States. Lung cancer accounts for the most cancer related deaths in both men and women in the United States. An estimated 160,340 deaths, accounting for about 28% of all cancer deaths, are expected to occur in 2012. (American Cancer Society 2012) This exceeds the combined number of deaths from the next three leading causes of cancer (breast, prostate, and colon cancers). Lung cancer also accounts for 6% of all deaths from any source in the United States. (*Cancer Management: A Multidisciplinary Approach*, 11th ed. (2008). Richard Pazdur, Lawrence R. Coia, William J. Hoskins, Lawrence D. Wagman; American Cancer Society, 2009.)

Cigarette smoking is by far the most important risk factor for lung cancer. Tobacco smoke causes nearly 8 out of 10 cases of lung cancer. The longer a person has been smoking and the more packs a day smoked, the greater the risk. Other risk factors include occupational or environmental exposure to secondhand smoke, radon, asbestos (particularly among smokers), certain minerals and metals (chromium, cadmium, arsenic), some organic chemicals, radiation, air pollution, family history of lung cancer, certain vitamins (beta carotene supplements), radiation treatment to the lungs to treat other cancers, and a history of tuberculosis. Genetic susceptibility plays a contributing role in the development of lung cancer, especially in those who develop the disease at a younger age. (American Cancer Society, 2012)

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

Incidence of Brain Cancer

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

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

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

Incidence of Head and Neck Cancers

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

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

Known risk factors include all forms of smoked and smokeless tobacco products and excessive consumption of alcohol. Many studies have reported a synergism between smoking and alcohol use, resulting in more than a 100 times the risk of these cancers to those individuals who both smoke and drink heavily. Human Papilloma Virus (HPV) infection is associated with certain types of oropharyngeal cancer. (American Cancer Society, 2012)

Incidence of Ocular Melanoma

The American Cancer Society estimates that 2,610 new cases of cancers of the eye and orbit (primarily melanoma) will be diagnosed in 2012 and about 270 deaths from cancer of the eye will occur in 2012 in the United States. Primary eye cancer can occur at any age but most occur in people over 50 years of age. (American Cancer Society, 2012)

Many patients with eye melanoma (cancer) have no symptoms unless the cancer grows in certain parts of the eye or becomes more advanced. Signs and symptoms of eye melanomas can include problems with vision including blurry vision or sudden loss of vision, floaters or flashes of light, visual field loss, a growing dark spot on the iris, change in the size or shape of the pupil, change in position of the eyeball within its socket, bulging of the eye, and/or change in the way the eye moves within the socket. Known risk factors for ocular melanoma include sun exposure, certain occupations (e.g. welders, farmers, fishermen, chemical workers and laundry workers), race/ethnicity/eye and skin color, and certain inherited conditions such as dysplastic nevus syndrome. (American Cancer Society, 2012)

Incidence of Colorectal Cancer

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

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

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

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

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

The 5-year relative survival rates for colon cancer are 74% in stage I, a range of 37% to 67% in stage II, a range of 28% to 73% in stage III and 6% in stage IV. The 5-year relative survival rates for rectal cancer are 74% in stage I, a range of 32% to 65% in stage II, a range of 33% to 74% in stage III and 6% in stage IV. (American Cancer Society, 2012)

Prostate Cancer Treatment Options and Protocol

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

Minimally invasive brachytherapy has significant advantages over competing treatments including lower cost, equal or better survival data, fewer side effects, faster recovery time and the convenience of a single outpatient implant procedure that generally lasts less than one hour (Grimm, et al., British Journal of Urology International, Vol. 109 (Suppl 1), 2012; Merrick, et al., Techniques in Urology, Vol. 7, 2001; Potters, et al., Journal of Urology, May 2005; Sharkey, et al., Current Urology Reports, 2002).

In addition to brachytherapy, localized prostate cancer can be treated with prostatectomy surgery (RP for radical prostatectomy), external beam radiation therapy (EBRT), intensity modulated radiation therapy (IMRT), dual or combination therapy, high dose rate brachytherapy (HDR), cryosurgery, hormone therapy, and watchful waiting. The

success of any treatment is measured by the feasibility of the procedure for the patient, morbidities associated with the treatment, overall survival, and cost. When the cancerous tissue is not completely eliminated, the cancer typically returns to the primary site, often with metastases to other areas of the body.

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

According to a study published in the *Journal of the American Medical Association* in January 2000, approximately 60% of men who had a RP reported erectile dysfunction as a result of surgery. This same study stated that approximately 40% of the patients observed reported at least occasional incontinence.

New methods such as laparoscopic and robotic prostatectomy surgeries are currently being used more frequently in order to minimize the nerve damage that leads to impotence and incontinence, but these techniques require a high degree of surgical skill. (American Cancer Society, 2012)

Primary External Beam Radiation Therapy (EBRT). EBRT involves directing a beam of radiation from outside the body at the prostate gland to destroy cancerous tissue. EBRT treatments are received on an outpatient basis five days per week usually over a period of four to six weeks. Today, standard EBRT is used much less often than in the past. Side effects of EBRT can include bowel problems, bladder problems, incontinence, impotence, fatigue, lymphedema, and urethral stricture. (American Cancer Society, 2012)

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Intensity Modulated Radiation Therapy. IMRT is considered a more advanced form of EBRT in which sophisticated computer control is used to aim the beam at the prostate from multiple different angles and to vary the intensity of the beam. Thus, damage to normal tissue and critical structures is minimized by distributing the unwanted radiation over a larger geometric area. This course of treatment is similar to EBRT but requires daily doses over a period of seven to nine weeks to deliver the total dose of radiation prescribed to kill the tumor. An increasingly popular therapy for patients with more advanced prostate cancer is a combination of IMRT with seed brachytherapy, known as combination or dual therapy. IMRT is generally more expensive than other common treatment modalities. (American Cancer Society, 2012)

Dual or Combination Therapy. Dual therapy is the combination of IMRT or 3-dimensional conformal external beam radiation and seed brachytherapy to treat extra-prostatic extensions or high risk prostate cancers that have grown outside the prostate. Combination therapy treats high risk patients with a full course of IMRT or EBRT over a period of several weeks. When this initial treatment is completed, the patient must then wait for several more weeks to months to have the prostate seed implant. (American Cancer Society, 2012) Management estimates that at least 25% of all prostate implants are now dual therapy cases.

High Dose Rate Temporary Brachytherapy. HDR temporary brachytherapy involves placing very tiny plastic catheters into the prostate gland, and then giving a series of radiation treatments through these catheters. The catheters are then removed, and no radioactive material is left in the prostate gland. A computer-controlled machine inserts a single highly radioactive iridium seed into the catheters one by one. This procedure is typically repeated at least three times while the patient is hospitalized for at least 24 hours. (American Cancer Society, 2012)

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

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

hair loss, diarrhea, mouth sores, and lowered resistance to infection, and fatigue. The vaccine treatment is milder than the hormone or chemotherapy treatments but some common side effects include fever, back and joint pain, chills, fatigue, and headaches. (American Cancer Society, 2012)

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

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

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

Long-term survival data is now available for brachytherapy with I-125 and Pd-103, which support the efficacy of brachytherapy. Clinical data indicate that brachytherapy offers success rates for early-stage prostate cancer treatment that are equal to or better than those of RP or EBRT. While historically clinical studies of brachytherapy have focused primarily on results from brachytherapy with I-125 and Pd-103, management believes that these data are also relevant for brachytherapy with Cesium-131. In fact, it appears that Cesium-131 offers improved clinical outcomes over I-125 and Pd-103, given its shorter half-life and higher energy.

Improved patient outcomes. A number of published studies describing the use of I-125 and Pd-103 brachytherapy in the treatment of early-stage prostate cancer have been very positive when compared to other treatment options. A recent study of 2,963 prostate cancer patients who underwent brachytherapy as their sole therapeutic modality at 11 institutions across the U.S. concluded that low-risk patients (who make up the preponderance of localized cases) who underwent adequate implants experienced rates of PSA relapse survival of greater than 90% between eight and ten years (Zelefsky MJ, et al, "Multi-institutional analysis of long-term outcome for stages T1-T2 prostate cancer treated with permanent seed implantation" *International Journal of Radiation Oncology Biology Physics*, Volume 67, Issue 2, 2007, 327-333).

Other recent studies have demonstrated similar, durably high rates of control following brachytherapy for localized prostate cancer out to 15 years post-treatment (Sylvester J, et al. "15-year biochemical relapse free survival in clinical stage T1-T3 prostate cancer following combined external beam radiotherapy and brachytherapy; Seattle experience", *International Journal of Radiation Oncology Biology Physics*, Vol. 67, Issue 1, 2007, 57-64). The cumulative effect of these series has been the conclusion by leaders in the field that brachytherapy offers a disease control rate as high as surgery, though with a lesser side-effect profile than surgery (Ciezki JP. "Prostate brachytherapy for localized prostate cancer" *Current Treatment Options in Oncology*, Volume 6, 2005, 389-393).

Reduced Incidence of Side Effects. Sexual impotence and urinary incontinence are two major concerns men face when choosing among various forms of treatment for prostate cancer. Studies have shown that brachytherapy with existing sources results in lower rates of impotence and incontinence than surgery (Buron C, et al. "Brachytherapy versus prostatectomy in localized prostate cancer: results of a French multicenter prospective medico-economic study". *International Journal of Radiation Oncology, Biology, Physics*, Volume 67, 2007, 812-822). Combined with the high disease control rates described in many studies, these findings have driven the adoption of brachytherapy as a front-line therapy for localized prostate cancer.

It has been noted, however, that a significant proportion of patients who undergo I-125 or Pd-103 brachytherapy experience acute urinary irritative symptoms following treatment – in fact more so than with surgery or external beam radiation therapy (Frank SJ, et al, "An assessment of quality of life following radical prostatectomy, high dose external beam radiation therapy, and brachytherapy iodine implantation as monotherapies for localized prostate

cancer" *Journal of Urology*, Volume 177, 2007, 2151-2156). It was postulated that Cesium-131, with the shortest available half-life for a low-dose rate therapy isotope, should result in a quicker resolution of these irritative symptoms based on the shorter time interval over which normal tissue receives radiation from the implanted sources.

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

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A Cesium-131 monotherapy trial for the treatment of prostate cancer was fully enrolled in February 2007. The trial was a 100 patient multi-institutional study that sought to (1) document the dosimetric characteristics of Cesium-131, (2) to summarize the side effect profile of Cesium-131 treatment, and (3) to track biochemical (PSA) results in patients following Cesium-131 therapy.

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

Some of the significant and specific findings were as follows:

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

2. Gland coverage was excellent and the dose delivered to critical structures outside the prostate was well within acceptable limits. (Bice WS, Prestidge BR, "Cesium-131 permanent prostate brachytherapy: The dosimetric analysis of a multi-institutional Phase II trial". *Brachytherapy* 2007(6); 88-89.).

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

Several other series have been reported that have compared dosimetric parameters (indicators of dose) among Cesium-131, Pd-103, and I-125. These comparative studies have shown a clear advantage to Cesium-131 from a dosimetric point-of-view, in terms of successful gland coverage obtained (typically measured by D90) while keeping unnecessary gland over-dosing (typically measured by V150 or V200) to a minimum (Musmacher JS, et al, "Dosimetric Comparison of Cesium-131 and Palladium-103 for Permanent Prostate Brachytherapy" *International Journal of Radiation Oncology Biology Physics*, Volume 69, (Supplement 3), 2007, S730-1; Yaparpalvi R, et al, "Is

Cs-131 or I-125 or Pd-103 the Ideal Isotope for Prostate Boost Brachytherapy? A Dosimetric View Point." *International Journal of Radiation Oncology Biology Physics*, Volume 69 (Supplement 3), 2007, S677-8; Sutlief S and Wallner K, "Cs-131 Prostate Brachytherapy and Treatment Plan Parameters." *Medical Physics*, Volume 34, 2007, 2431; Kurtzman S, "Dosimetric Evaluation of Permanent Prostate Brachytherapy Using Cs-131 Sources" *International Journal of Radiation Oncology Biology Physics*, Volume 66 (Supplement 3), S395).

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

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

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

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

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

Non-Prostate Product Offerings

Lung Cancer Treatment Options

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

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

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

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

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

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

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

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

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

Brain Cancer Treatment Options

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

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

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

Head and Neck Cancer Treatment Options

Most head and neck cancers historically have been treated with some combination of surgery including tumor resection; Mohs micrographic surgery; full or partial mandible (jaw bone) resection; maxillectomy; laryngectomy; neck dissection; pedicle or free flap reconstruction; tracheostomy; gastrostomy tube or dental extraction and implants; chemotherapy and radiation therapy including external beam radiation therapy (EBRT), accelerated and hyperfractionated radiation therapy, three-dimensional conformal radiation therapy (3D-CRT) and intensity modulated radiation therapy (IMRT), and brachytherapy (both high-dose rate (HDR) and low-dose rate (LDR)). (American Cancer Society, 2012)

Surgery is the most common option. Chemotherapy is often used in conjunction with surgery or radiation therapy depending on the type and stage of the cancer. External beam radiation therapy and brachytherapy have been used together or in combination with surgery or chemotherapy. (American Cancer Society, 2012)

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

Ocular Melanoma Treatment Options

In addition to brachytherapy to treat ocular melanoma, other treatment options include surgery, external beam radiation, chemotherapy, and laser therapy. Surgery could include removal of part of the iris, a portion of the outer eyeball, or the removal of the entire eyeball, and is used less often than in the past as the use of radiation therapy has grown. External beam radiation (including conformal proton beam radiation therapy and stereotactic radiosurgery) involves sending radiation from a source outside the body that is focused on the cancer but has not been as widely used to date for ocular melanoma. Laser therapy, rarely used now to treat ocular melanoma, burns the cancerous tissue by using a highly focused, high-energy light beam. Laser therapy can be effective for very small melanomas but it is more often used to treat side effects from radiation. (American Cancer Society, 2012)

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

the other products are often available immediately.

Colorectal Treatment Options

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

For the treatment of early stage colon and rectal cancers, surgery is often the main treatment. Colorectal surgeries include open colectomy, laparoscopic-assisted colectomy, and polypectomy and local excision. Rectal surgeries include polypectomy and local excision, local transanal resection, transanal endoscopic microsurgery (TEM), lower anterior resection, proctectomy with coloanal anastomosis, abdominoperineal resection and pelvic exenteration. (American Cancer Society, 2012)

For the treatment of colorectal cancers beyond early stage, other surgery treatments (radiofrequency ablation, ethanol ablation, cryosurgery and hepatic artery embolization), radiation therapy (external beam radiation, endocavitary radiation, brachytherapy, yttrium-90 microsphere radioembolization), chemotherapy, and targeted therapies (Avastin, Erbitux, Vectibix) can be used. (American Cancer Society, 2012)

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

Brachytherapy Isotope Comparison

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

Higher Energy

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

Shorter Half-Life

Cesium-131 has the shortest half-life of any commonly used prostate brachytherapy isotope at 9.7 days. Cesium-131 delivers 90% of the prescribed dose in just 33 days compared to 58 days for Pd-103 and 204 days for I-125. By far the most commonly reported side effects of prostate brachytherapy are irritative and obstructive symptoms in the acute phase post-implant (Neill B, et al. The Nature and Extent of Urinary Morbidity in Relation to Prostate Brachytherapy Urethral Dosimetry. *Brachytherapy* 2007:6(3)173-9.). The short half-life of Cesium-131 reduces the duration of time during which the patient experiences the irritating effects of the radiation.

Improved Coverage of the Prostate

Permanent prostate brachytherapy utilizing Cesium-131 seeds allows for better dose homogeneity and sparing of the urethra and rectum while providing comparable prostate coverage compared to I-125 or Pd-103 seeds with comparable or fewer seeds and needles. Several studies have demonstrated dosimetric advantages of Cesium-131 over the other commonly used prostate brachytherapy isotopes. (Musmacher JS, et al. Dosimetric Comparison of

Cesium-131 and Palladium-103 for Permanent Prostate Brachytherapy. *Int. J. Radiation Oncology Biol. Phys.* 2007:69(3)S730-1.) (Yaparpalvi R, et al. Is Cs-131 or I-125 or Pd-103 the "Ideal" Isotope for Prostate Boost Brachytherapy? A Dosimetric View Point. *Int. J. Radiation Oncology Biol. Phys.* 2007:69(3)S677-8) (Sutlief S, et al. Cs-131 Prostate Brachytherapy and Treatment Plan Parameters. *Medical Physics* 2007:34(6)2431.) (Yang R, et al. Dosimetric Comparison of Permanent Prostate Brachytherapy Plans Utilizing Cs-131, I-125 and Pd-103 Seeds. *Medical Physics* 2008:35(6)2734.)

Rapid Resolution of Side Effects

Studies demonstrate that objective measures of common side-effects showed an early peak in symptoms in the 2-week to 1-month time frame. Resolution of morbidity resolved rapidly within 4-6 months. (Prestidge B, et. al. Clinical Outcomes of a Phase-II, Multi-institutional Cesium-131 Permanent Prostate Brachytherapy Trial. *Brachytherapy.* 2007: 6 (2)78.) (Moran B, et al. Cesium-131 Prostate Brachytherapy: An Early Experience. *Brachytherapy* 2007:6(2)80.) (Jones A, et al. IPSS Trends for Cs-131 Permanent Prostate Brachytherapy. *Brachytherapy* 2008:7(2)194.) (DeFoe SG, et al. Is There Decreased Duration of Acute Urinary and Bowel Symptoms after Prostate Brachytherapy with Cesium 131 Radioisotope? *Int. J. Radiation Oncology Biol. Phys.* 2008:72(S1)S317.) Recent studies with longer follow-up periods continue to support the resolution of urinary and rectal side effects in a rapid fashion following treatment with Cesium-131. (Jacobs B, et al. Acute lower urinary tract symptoms after prostate brachytherapy with Cesium-131. *Urology.* 2010:76(5)1143.)

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Higher Biologically Effective Dose

Another benefit to the short half-life of Cesium-131 is what is known as the "biological effective dose" or BED. BED is a way for health care providers to predict how an isotope will perform against cancers exhibiting different characteristics – for instance, slow versus fast growing tumors. Studies have shown Cesium-131 is able to deliver a higher BED across a wide range of tumor types than either I-125 or Pd-103. Although prostate cancer is typically viewed as a slow growing cancer it can present with aggressive features. Cesium-131's higher BED may be particularly beneficial in such situations. (Armpilia CI, *et al.* The Determination of Radiobiologically Optimized Half-lives for Radionuclides Used in Permanent Brachytherapy Implants. *Int. J. Radiation Oncology Biol. Phys.* 2003; 55 (2): 378-385.)

PSA Control

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

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

Our Strategy

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

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

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

Return the GliaSite® radiation therapy system to market in the United States and European Union (EU). In June of 2010, the Company acquired exclusive worldwide distribution rights to the GliaSite® Radiation Therapy System, the only FDA-cleared balloon catheter device used in the treatment of brain cancer, from Hologic Inc. The Company received a CE Mark in May 2012 allowing distribution in 31 countries. Management believes that the European market will be receptive to this treatment option and the product faces fewer regulatory hurdles there than in the United States. The Company intends to distribute the product from Germany (the location of the first European sale in July 2012) to other European nations. The Company plans to contact previous users of the product and leverage significant existing clinical data related to the safety and effectiveness of the GliaSite system in order to restore GliaSite as a strong treatment option for patients suffering from primary and metastatic brain cancers.

Increase utilization of Cesium-131 in treatment of other solid tumor applications such as lung, head and neck, chest wall, and colorectal cancers. IsoRay Medical has clearance from the FDA for its premarket notification (510(k)) for Proxcelan™ brachytherapy seeds that are preloaded into bioabsorbable braided strands and bioabsorbable braided strands attached to bioabsorbable mesh. This order cleared the product for commercial distribution for treatment of lung and head and neck tumors as well as tumors in other organs. IsoRay has successfully launched an initiative to market its Proxcelan™ source in bioabsorbable carrier material as a lung cancer treatment. It has begun selling its lung cancer treatment product but has not been in the market long enough to determine long-term success of the product. IsoRay will continue to explore licenses or joint ventures with other companies to develop the appropriate technologies and therapeutic delivery systems for treatment of other solid tumors.