IsoRay, Inc.
Form 10-K
September 23, 2009

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

FORM 10-K

þ Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended June 30, 2009

or

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

Commission File No. 001-33407

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

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

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

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

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

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

Class	Outstanding as of September 14, 2009
Common stock, $0.001 par value	22,942,088

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o 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 o 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 o

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 o

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

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

Large accelerated filer o Accelerated filer o Non-accelerated filer o

Smaller reporting company x

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter – $4,509,712 as of December 31, 2008.

Documents incorporated by reference – none.

ISORAY, INC.

Table of Contents

Caution Regarding Forward-Looking Information

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

All statements contained in this Form 10-K, other than statements of historical facts, that address future activities, events or developments are forward-looking statements, including, but not limited to, statements containing the words "believe," "expect," "anticipate," "intends," "estimate," "forecast," "project," and similar expressions. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any statements of the plans, strategies and objectives of management for future operations; any statements concerning proposed new products, services, developments or industry rankings; any statements regarding future revenue, economic conditions or performance; any statements of belief; and any statements of assumptions underlying any of the foregoing. These statements are based on certain assumptions and analyses made by us in light of our experience and our assessment of historical trends, current conditions and expected future developments as well as other factors we believe are appropriate under the circumstances. However, whether actual results will conform to the expectations and predictions of management is subject to a number of risks and uncertainties described under Item 1A – Risk Factors beginning on page 23 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.

1

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 (Cs-131). Such applications include prostate cancer; ocular melanoma; head, neck and lung tumors; and breast, liver, brain and pancreatic cancer. The seed may be used in surface, interstital and intracavity applications for tumors with known radio sensitivity. Management believes its Cs-131 technology will allow it to become a leader in the brachytherapy market. Management believes that the IsoRay Proxcelan Cesium-131 brachytherapy seed represents the first major advancement in brachytherapy technology in over 21 years with attributes that could make it the long-term "seed of choice" for internal radiation therapy procedures.

IsoRay began production and sales of Proxcelan Cesium-131 brachytherapy seeds in October 2004 for the treatment of prostate cancer after clearance of its premarket notification (510(k)) by the Food and Drug Administration (FDA). In December 2007, IsoRay began selling its Proxcelan Cs-131 seeds for the treatment of ocular melanoma. On June 1, 2009, the Company again expanded its application of Cs-131 with the treatment of a head and neck tumor that could not be accessed by other treatment modalities. More recently the Company has focused on other applications which require revising the delivery system from those historically used by the Company.

In August 2009, IsoRay Medical received clearance from the FDA for its Premarket Notification (510(k)) for Proxcelan™ Cesium-131 brachytherapy seeds that are preloaded into bioabsorbable braided strands. This clearance permits the product to be commercially distributed for treatment of lung, head and neck tumors as well as tumors in other organs. While Cs-131 brachytherapy seeds themselves have been cleared for treatment in all organs since 2003, this 510(k) allows Cs-131 seeds to be delivered in a convenient and sterile format that can be implanted without additional seed loading by the facility. The 510(k) also clears the application of braided strands onto a bioabsorbable mesh matrix to further facilitate the implant procedure.

Brachytherapy seeds are small devices used in an interstital radiation procedure. The procedure has become one of the primary treatments for prostate cancer. The brachytherapy procedure places radioactive seeds as close as possible to (in or near) the cancerous tumor (the word "brachytherapy" means close therapy). The seeds deliver therapeutic radiation thereby killing the cancerous tumor cells while minimizing exposure to adjacent healthy tissue. This procedure allows doctors to administer a higher dose of radiation directly to the tumor. Each seed contains a radioisotope sealed within a welded titanium capsule. When brachytherapy is the only treatment (monotherapy), approximately 70 to 120 seeds are permanently implanted in the prostate in an outpatient procedure lasting less than one hour. The number of seeds used varies based on the size of the prostate and the activity level specified by the physician. When brachytherapy is combined with external beam radiation or intensity modulated radiation therapy (dual therapy), then approximately 40-80 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 10-12 to as many at 80-100 depending on the

location of the tumor being treated.

Brachytherapy Isotope Comparison

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

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

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

Improved Coverage of the Prostate
Permanent prostate brachytherapy utilizing Cs-131 seeds allows for better dose homogeneity and sparing of the urethra and rectum while providing comparable prostate coverage compared to I-125 or Pd-103 seeds with comparable or fewer seeds and needles. Several studies have demonstrated dosimetric advantages of Cs-131 over the other commonly used prostate brachytherapy isotopes. (Musmacher JS, et al. Dosimetric Comparison of Cesium-131 and Palladium-103 for Permanent Prostate Brachytherapy. Int. J. Radiation Oncology Biol. Phys. 2007:69(3)S730-1.) (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.) More stringent studies are underway to more fully characterize any advantage in side effect resolution experienced by patients undergoing Cs-131 prostate brachytherapy versus brachytherapy with other isotopes.

Higher Biologically Effective Dose

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

PSA Control

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

Industry Information

Incidence of Prostate Cancer

The prostate is a walnut-sized gland surrounding the male urethra, located below the bladder and adjacent to the rectum. 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 in six men will be diagnosed with prostate cancer during his lifetime. It is the most common form of cancer in men after skin cancer, and the second leading cause of cancer deaths in men following lung and bronchus cancers that account for 30% of deaths from cancer in men. The American Cancer Society estimates there will be about 192,280 new cases of prostate cancer diagnosed and an estimated 27,360 deaths associated with the disease in the United States in 2009. Because of early detection techniques (e.g., screening for prostate specific antigen, or PSA), approximately nine out of ten prostate cancers are found in the local and regional stages (local means it is still confined to the prostate; regional means it has spread from the prostate to nearby areas, but not to distant sites, such as bone).

Prostate cancer accounts for about 9% of cancer related deaths in men. Prostate cancer incidence and mortality increase with age. The National Cancer Institute has reported that the incidence of prostate cancer increases dramatically in men over the age of 55. At the age of 70, the chance of having prostate cancer is 12 times greater than at age 50.

The American Cancer Society recommends that men without symptoms, risk factors and who have a life expectancy of at least ten years, should begin regular annual medical exams at the age of 50, and believes that health care providers should offer as part of the exam the prostate-specific antigen (PSA) blood test and a digital rectal examination. The PSA blood test determines the amount of prostate specific antigen present in the blood. PSA is found in a protein secreted by the prostate, and elevated levels of PSA can be associated with either prostatitis (a noncancerous inflammatory condition) or a proliferation of cancer cells in the prostate. Transrectal ultrasound tests and biopsies are typically performed on patients with elevated PSA readings to confirm the existence of cancer. Early screening has fostered a decline in the prostate cancer death rate since 1990. When compared to men of the same age

and race who do not have cancer (called relative survival), the 5-year relative survival rate for men when the cancer is found in the local and regional stages is nearly 100%. During this past year the national press publicized a meeting among urologists at the annual American Urology Association meeting debating the need for annual PSA testing. Results of this publicity may result in future recommendations to begin testing at a later age and not test annually unless there are risk factors. Based on its own industry knowledge, management believes this could lead to an increase in prostate cancer, which has not been experienced since 2000.

Incidence of Lung Cancer

An estimated 219,440 new cases of lung cancer are expected in 2009, accounting for 15% of all cancer diagnoses in the United States. Lung cancer accounts for the most cancer related deaths in both men and women in the United States. An estimated 159,390 deaths, accounting for about 28% of all cancer deaths, are expected to occur in 2009. This exceeds the combined number of deaths from the leading causes of cancer (breast, prostate, and colon cancers). It also accounts for 6% of all deaths from any source in the United States. (Cancer Management: A Multidisciplinary Approach, 11th Edition (2008). Richard Pazdur, Lawrence R. Coia, William J. Hoskins, Lawrence D. Wagman; American Cancer Society, 2009.)

Cigarette smoking is the most important risk factor for lung cancer. Risk increases with quantity and length of time a person has smoked during his or her life time. Other risk factors include occupational or environmental exposure to secondhand smoke, radon, asbestos (particularly among smokers), certain metals (chromium, cadmium, arsenic), some organic chemicals, radiation, air pollution, and a history of tuberculosis. Genetic susceptibility plays a contributing role in the development of lung cancer, especially in those who develop the disease at a younger age. (American Cancer Society, 2009)

The 1-year relative survival for lung cancer increased from 35% in 1975-1979 to 41% in 2001-2004, largely due to improvements in surgical techniques and combined therapies. However, the 5-year survival rate for all stages combined is only 15%. The 5-year survival rate is 50% for cases detected when the disease is still localized, but only 16% of lung cancers are diagnosed at this early stage. (American Cancer Society, 2009)

Incidence of Head and Neck Cancers

In 2008 it was estimated that there were a total of 47,560 head and neck cancer cases, which includes 22,900 cases of oral cavity cancer, 12,250 cases of laryngeal cancer, and 12,410 cases of pharyngeal cancer, diagnosed in the United States. (Cancer Management: A Multidisciplinary Approach, 11th Edition (2008). Richard Pazdur, Lawrence R. Coia, William J. Hoskins, Lawrence D. Wagman; American Cancer Society, 2009.)

Symptoms may include a sore in the throat or mouth that bleeds easily and does not heal, a lump or thickening, ear pain, a neck mass, coughing up blood, and a red or white patch that persists. Difficulties in chewing, swallowing, or moving the tongue or jaws are often late symptoms. (American Cancer Society, 2009)

Known risk factors include all forms of smoked and smokeless tobacco products and excessive consumption of alcohol. Many studies have reported a synergism between smoking and alcohol use, resulting in more than a 30-fold increased risk in individuals who both smoke and drink heavily. HPV infection is associated with certain types of oropharyngeal cancer. (American Cancer Society, 2009)

Incidence of Ocular Melanoma

The American Cancer Society estimates that 2,350 new cases of cancers of the eye and orbit (primarily melanoma) will be diagnosed in 2009 and about 230 deaths from cancer of the eye will occur in 2009. Eye cancer can occur at any age but typically occurs in people over 50 years of age. (American Cancer Society, 2009)

Eye cancer may not present symptoms unless it grows in certain parts of the eye or is in an advanced stage. Some signs and symptoms may include decreased ability to see, floaters or flashes of light, visual field loss, a glowing dark spot on the iris, change in position of the eyeball within its socket, bulging of the eye, and/or change in the movement of the eye within the socket. Known risk factors for ocular melanoma include sun exposure, certain occupations (e.g. welders, farmers, fishermen, and chemical workers), race/ethnicity/eye color, and certain inherited conditions such as dysplastic nevus syndrome. (American Cancer Society, 2009)

Prostate Brachytherapy

There is a large potential market for the Company's products. Several significant clinical and market factors are contributing to the increasing popularity of the brachytherapy procedure. Over 61,000 procedures were forecasted to occur in the U.S. in 2007 (Source: iData Research, Inc., 2008). In 1996 only 4% of prostate cancer cases were treated with brachytherapy, or about 8,000 procedures. The number of brachytherapy cases has consistently increased and in 2007 approximately 61,000 brachytherapy procedures were performed to treat prostate cancer. (Source: iData Research Inc., 2008)

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

Treatment Options and Protocol

In addition to brachytherapy, localized prostate cancer can be treated with prostatectomy surgery (RP for radical prostatectomy), external beam radiation therapy (EBRT), intensity modulated radiation therapy (IMRT), dual or combination therapy, high dose rate brachytherapy (HDR), cryosurgery, hormone therapy, and watchful waiting. The success of any treatment is measured by the feasibility of the procedure for the patient, morbidities associated with the treatment, overall survival, and cost. When the cancerous tissue is not completely eliminated, the cancer typically returns to the primary site, often with metastases to other areas of the body.

Prostatectomy Surgery Options. Historically the most common treatment option for prostate cancer, radical prostatectomy is the removal of the prostate gland and some surrounding tissue through an invasive surgical procedure. RP is performed under general anesthesia and involves a hospital stay of three days on average for patient observation and recovery. Possible side affects of RP include impotence and incontinence. According to a study published in the Journal of the American Medical Association in January 2000, approximately 60% of men who had a RP reported erectile dysfunction as a result of surgery. This same study stated that approximately 40% of the patients observed reported at least occasional incontinence. New methods such as laparoscopic and robotic prostatectomy surgeries are currently being used more frequently in order to minimize the nerve damage that leads to impotence and incontinence, but these techniques require a high degree of surgical skill. RP and laparoscopic prostatectomy are projected to decrease approximately 31% in the U.S. from the 2004 high of 66,567 to 20,838 procedures in 2014. However, robotic surgeries are projected to more than replace the decrease in the RP and laparoscopic procedures (Source: iData Research Inc., 2008).

Primary External Beam Radiation Therapy. EBRT involves directing a beam of radiation from outside the body at the prostate gland to destroy cancerous tissue. EBRT treatments are received on an outpatient basis five days per week usually over a period of eight or nine weeks. Some studies have shown, however, that the ten-year disease free survival rates with treatment through EBRT are less than the disease free survival rates after RP or brachytherapy treatment. Side effects of EBRT can include diarrhea, rectal leakage, irritated intestines, frequent urination, burning while urinating, and blood in the urine. Also the incidence of incontinence and impotence five to six years after

EBRT is comparable to that for surgery. EBRT procedures are projected to increase slightly from 22,000 procedures in 2006 to 24,900 in 2012 (Source: Millennium Research Group, 2008).

Intensity Modulated Radiation Therapy. IMRT is considered a more advanced form of EBRT in which sophisticated computer control is used to aim the beam at the prostate from multiple different angles and to vary the intensity of the beam. Thus, damage to normal tissue and critical structures is minimized by distributing the unwanted radiation over a larger geometric area. This course of treatment is similar to EBRT and requires daily doses over a period of seven to eight weeks to deliver the total dose of radiation prescribed to kill the tumor. Because IMRT is a new treatment, less clinical data regarding treatment effectiveness and the incidence of side effects is available. One advantage of IMRT, and to some extent EBRT, is the ability to treat cancers that have begun to spread from the tumor site. An increasingly popular therapy for patients with more advanced prostate cancer is a combination of IMRT with seed brachytherapy, known as combination or dual therapy. IMRT in the U.S. (including dual therapy) is projected to grow 9% per year from 31,500 procedures in 2007 to 48,500 procedures in 2012 (Source: Millennium Research Group, 2008). IMRT is generally more expensive than other common treatment modalities.

Dual or Combination Therapy. Dual therapy is the combination of IMRT or 3-dimensional conformal external beam radiation and seed brachytherapy to treat extra-prostatic extensions or high risk prostate cancers that have grown outside the prostate. Combination therapy treats high risk patients with a full course of IMRT or EBRT over a period of several weeks. When this initial treatment is completed, the patient must then wait for several more weeks to months to have the prostate seed implant.

With the arrival of Proxcelan Cs-131, with its short half life, patients may now complete their course of treatment sooner and have shorter duration of side-effects. Management estimates that at least 30% of all prostate implants are now dual therapy cases.

High Dose Rate Temporary Brachytherapy. HDR temporary brachytherapy involves placing very tiny plastic catheters into the prostate gland, and then giving a series of radiation treatments through these catheters. The catheters are then removed, and no radioactive material is left in the prostate gland. A computer-controlled machine inserts a single highly radioactive iridium seed into the catheters one by one. This procedure is typically repeated at least three times while the patient is hospitalized for at least 24 hours. HDR is projected to grow approximately 1.3% per year from 26,200 procedures in 2007 through 2012 (Source: Millennium Research Group, 2008).

Cryosurgery. Cryosurgery involves placing cold metal probes into the prostate and freezing the tissue in order to destroy the tumor. Cryosurgery patients typically stay in the hospital for a day or two and have had higher rates of impotence and other side effects than those who have used seed implant brachytherapy. Market research firms project that cryosurgery will grow steadily through 2012. To date the market has remained almost flat (Source: Millennium Research Group, 2008).

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

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

7

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

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

Improved patient outcomes. A number of published studies describing the use of I-125 and Pd-103 brachytherapy in the treatment of early-stage prostate cancer have been very positive. 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, Kuban DA, 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 (Frank, Buron). 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, Pisters LL, et al, "An assessment of quality of life following radical prostatectomy, high dose external beam radiation therapy, and brachytherapy iodine implantation as monotherapies for localized prostate cancer" Journal of Urology, Volume 177, 2007, 2151-2156). It has been postulated that Cs-131, with the shortest available half-life for a low-dose rate therapy isotope, will result in a quicker resolution of these irritative symptoms based on the shorter time interval over which normal tissue receives radiation from the implanted sources.

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

A Cs-131 monotherapy trial for the treatment of prostate cancer was fully enrolled in February 2007. The trial was a 100 patient multi-institutional study that sought to (1) document the dosimetric characteristics of Cs-131, (2) to

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

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

Some of the significant and specific findings were as follows:

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

- Prostate Specific Antigen, or PSA, response over 36 months has been very encouraging to date with similar tumor control rates to that of I-125. (Prestidge BR, Bice WS, “Clinical outcomes of a Phase II, multi-institutional Cesium-131 permanent prostate brachytherapy trial”. Brachytherapy, Volume 6, Issue 2, April-June 2007, Page 78). The graph below depicts the median PSAs to date from the 100 patient Cs-131 brachytherapy series as compared to previously published I-125 series. There have been no PSA failures in the Cs-131 monotherapy study to date. (A PSA failure is a rise in the blood level of PSA in prostate cancer patients after treatment with radiation or surgery.)

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

Several other series have been reported that have compared dosimetric parameters (indicators of dose) among Cs-131, Pd-103, and I-125. These comparative studies have shown a clear advantage to Cesium-131 from a dosimetric point-of-view, in terms of successful gland coverage obtained (typically measured by D90) while keeping unnecessary gland over-dosing (typically measured by V150 or V200) to a minimum (Musmacher JS, et al, "Dosimetric Comparison of Cesium-131 and Palladium-103 for Permanent Prostate Brachytherapy" International Journal of Radiation Oncology Biology Physics, Volume 69, (Supplement 3), 2007, S730-1; Yaparpalvi R, et al, "Is Cs-131 or I-125 or Pd-103 the Ideal Isotope for Prostate Boost Brachytherapy? A Dosimetric View Point." International Journal of Radiation Oncology Biology Physics, Volume 69 (Supplement 3), 2007, S677-8; Sutlief S and Wallner K, "Cs-131 Prostate Brachytherapy and Treatment Plan Parameters." Medical Physics, Volume 34, 2007, 2431; Kurtzman S, "Dosimetric Evaluation of Permanent Prostate Brachytherapy Using Cs-131 Sources" International Journal of Radiation Oncology Biology Physics, Volume 66 (Supplement 3), S395).

The monotherapy Cs-131 trial will continue to follow patients with annual updates on symptoms and patient long-term survival data. The Company anticipates maintaining this ongoing monitoring over several years to prove the long-term effectiveness of Cs-131.

The prospective randomized monotherapy trial headed by Dr. Brian Moran of The Chicago Prostate Cancer Center directly compared Cs-131 to I-125 PSA response and treatment related morbidities following brachytherapy for localized carcinoma of the prostate in low to intermediate risk patients. Dr. Moran concluded that prostate brachytherapy with Cs-131 is effective and well-tolerated; both PSA response and the acute morbidity profile were very encouraging. Dr. Moran will continue to track these patients in order to collect long-term outcomes.

Recently accepted for publication was the Cs-131 Advisory Group's (CAG) article entitled "Recommendations for permanent prostate brachytherapy with 131Cs: a consensus report from the Cesium Advisory Group". The objective of the article was to provide consensus recommendations for Cs-131 prostate brachytherapy based on experience to date for physicians still unfamiliar with Cs-131. The recommendations are based on three clinical trials, one of which has completed accrual and has been published in the peer reviewed literature, and combined CAG experience of more than 1,200 Cs-131 implants. The recommendations from the group are designed to aid practitioners in the safe and effective delivery of Cs-131 prostate brachytherapy. The Consensus Paper was published in Brachytherapy in the fourth quarter of calendar year 2008. The CAG is sponsored by the Company.

The Company has also commissioned a dual therapy protocol. This multi-institutional trial observes the dosimetric characteristics of Cs-131 and health related quality of life (HRQOL) results following combined Cs-131 transperineal permanent prostate brachytherapy and external beam radiotherapy in patients with intermediate to high risk prostate cancer. This protocol is being conducted to confirm clinically what radiobiological data suggests regarding this treatment modality. The quantified dosimetric variables collected will be correlated to the reported HRQOL data and ultimately compared to existing data in the literature for similar investigations using I-125 and Pd-103. Patient enrollment for this study began in April 2007 and 65 patients had been enrolled through June 30, 2009.

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

Lung Cancer Treatment Options

Lung cancer has historically been treated by surgery and chemotherapy but in recent years various forms of radiation have also been used. Surgery generally involves removing a portion of the lung or the entire lung. Chemotherapy may be used either as a primary treatment or a secondary treatment depending on the type and stage of the lung cancer. External beam radiation therapy is sometimes used as the primary treatment if the tumor cannot be removed by surgery due to the tumor's location or the patient's health.

Brachytherapy is now being used in conjunction with surgery to kill small areas of cancer that might be missed during surgery. The Company believes that Cs-131, with its shorter half-life and high energy, is better suited for treating lung cancer than either I-125 or Pd-103. The bioabsorbable mesh used in this procedure generally dissolves after about 45 days. Cs-131 delivers 90% of its dose in 33 days and is therefore well-suited to use with the bioabsorbable mesh in this procedure.

Head and Neck Cancer Treatment Options

Most head and neck cancers are treated with some combination of surgery, chemotherapy, and radiation therapy. Surgery is the most common option and takes many different forms in an effort to remove any cancerous tissue. 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.

Ocular Melanoma Treatment Options

In addition to brachytherapy to treat ocular melanoma, other treatment options include surgery, external beam radiation, and laser therapy. Surgery could include removal of part of the iris, a portion of the outer eyeball, or the removal of the entire eyeball. External beam radiation (including 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 burns the cancerous tissue by using a highly focused, high-energy light beam and is effective for small melanomas near the optic nerve as it causes less nerve damage. (American Cancer Society, 2009)

Brachytherapy using Cs-131, I-125, or Pd-103 is done by placing the seeds in a plaque (shaped like a small cap) that is attached to the eyeball with minute stitches for 2 to 5 days. The patient generally stays in the hospital until the plaque is removed from the eye. Brachytherapy cures approximately 9 out of 10 small tumors and can preserve the vision of some patients. (American Cancer Society, 2009)

Our Strategy

The key elements of IsoRay's strategy for fiscal year 2010 include:

- Continue to introduce the Proxcelan Cs-131 brachytherapy seed into the U.S. market. Utilizing our direct sales organization, IsoRay intends to continue expanding the use of Proxcelan Cs-131 seeds in brachytherapy procedures for prostate cancer by increasing the number of treatment centers offering Cs-131 and increasing the number of patients treated at each center using Cs-131. IsoRay hopes to capture much of the incremental market growth in seed implant brachytherapy and take market share from existing competitors.

- Work with our distribution partner, BrachySciences, to increase prostate market penetration. With BrachyScience's additional sales personnel, IsoRay expects to reach an increasing number of centers and physicians across the country that have not had access to a sales representative in their area. IsoRay received its first order from BrachySciences in August 2009. The increases from this distribution channel have been slow due to many of the same issues that IsoRay's direct sales force encounters (e.g. facility license amendments). However, management believes that distribution sales will become an important sales channel in the future.

- Increase utilization of Cs-131 in treatment of other solid tumor applications such as head and neck and lung cancers. IsoRay Medical has received clearance from the FDA for its Premarket Notification, (510(k)) for Proxcelan™ brachytherapy seeds that are preloaded into bioabsorbable braided strands. This order clears the product for commercial distribution for treatment of lung and head and neck tumors as well as tumors in other organs. IsoRay has received interest from some physicians who wish to use Cs-131 for other tumor sites including lung, and head and neck, due to the short half life that may potentially help reduce the migration of the radioactivity to the other parts of the body before the treatment dose has been delivered to the tumor. While Cs-131 brachytherapy seeds themselves have been cleared for these applications since 2003, this current 510(k) allows Cesium-131 seeds to be delivered in a convenient and sterile format that can be implanted without additional seed loading by the facility. The 510(k) also permits the application of the braided strands onto a bioabsorbable mesh matrix to further facilitate the implant procedure. The material (mesh) used to hold the flexible suture material in place dissolves within 45 days. With the treatment dose from Cs-131 being delivered in 33 days, many physicians feel confident that the treatment dose needed to treat the tumor will be delivered prior to the mesh dissolving. IsoRay will continue to explore joint ventures with other companies to develop the appropriate technologies and therapeutic delivery systems for treatment of other solid tumors such as breast, liver, pancreas, and brain cancers.

- Continue to develop an enriched barium manufacturing process. Working with leading scientists, IsoRay is working to design and create a proprietary process for manufacturing enriched barium, a key source material for Cs-131. This will ensure adequate future supply of Cs-131 and greater efficiencies in producing the isotope.

- Continue to develop data on Cs-131 for treatment of ocular melanoma. The Company's first sale for ocular melanoma occurred in late 2007 and periodic sales have occurred since then. IsoRay is sponsoring a prospective review of the patients treated with Cs-131 to date. This clinical data is expected to be available for the American Brachytherapy Society annual meeting in the Spring of 2010. Although the ocular melanoma market is not a large one, this application of Cs-131 shows potential viability for other solid tumors.