

IsoRay, Inc.
Form 10-K
September 29, 2008

Table of Contents

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

FORM 10-K

Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended June 30, 2008

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
(State of incorporation)

41-1458152
(I.R.S. Employer Identification No.)

350 Hills St., Suite 106
Richland, Washington 99354
(Address of principal executive offices)

(509) 375-1202
(Registrant's telephone number)

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
(American Stock Exchange)

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
Common stock, \$0.001 par value

Outstanding as of September 16, 2008
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

Edgar Filing: IsoRay, Inc. - Form 10-K

Act. Yes No

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

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

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

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

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked prices of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter – \$44,350,379 as of December 31, 2007.

Documents incorporated by reference – none.

Table of Contents

ISORAY, INC.

Table of Contents

	Page
<u>PART I</u>	
<u>ITEM 1 – BUSINESS</u>	1
<u>ITEM 1A – RISK FACTORS</u>	21
<u>ITEM 1B – UNRESOLVED STAFF COMMENTS</u>	28
<u>ITEM 2 – PROPERTIES</u>	28
<u>ITEM 3 – LEGAL PROCEEDINGS</u>	28
<u>ITEM 4 – SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u>	28
<u>PART II</u>	
<u>ITEM 5 – MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	28
<u>ITEM 6 – SELECTED FINANCIAL DATA</u>	30
<u>ITEM 7 – MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	30
<u>ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	42
<u>ITEM 8 – FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	42
<u>ITEM 9 – CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	42
<u>ITEM 9A – CONTROLS AND PROCEDURES</u>	43
<u>ITEM 9B – OTHER INFORMATION</u>	44
<u>PART III</u>	
<u>ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	44
<u>ITEM 11 – EXECUTIVE COMPENSATION</u>	48
<u>ITEM 12 – SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	51
<u>ITEM 13 – CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE</u>	52
<u>ITEM 14 – PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	54
<u>ITEM 15 – EXHIBITS AND REPORTS ON FORM 8-K</u>	54
<u>SIGNATURES</u>	58

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 21 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 to serve as an owner in a Russian LLC that will distribute the Company's products to the Russian market and also license the Company's technology for use in manufacturing Cs-131 brachytherapy seeds in Russia. International is a

wholly-owned subsidiary of the Company.

1

Table of Contents

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

IsoRay began production and sales of Proxcelan Cesium-131 (Cs-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. Cs-131 could also be applied as a treatment for other solid tumor applications such as breast, lung, liver, brain and pancreatic cancer, expanding the total available market opportunity for Cs-131 brachytherapy. Management believes its Cs-131 technology will allow it to capture a major position in the brachytherapy market. The beneficial characteristics of the Cs-131 isotope are expected to result in decreased radiation exposure to the patient and reduced severity and duration of side effects, while treating cancer cells as effectively as other isotopes used in seed brachytherapy.

Brachytherapy seeds are small devices used in an internal radiation therapy procedure. In recent years 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. 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.

Management believes that the IsoRay Proxcelan Cesium-131 brachytherapy seed represents the first major advancement in brachytherapy technology in over 20 years with attributes that could make it the long-term "seed of choice" for internal radiation therapy procedures. The Cs-131 seed has an FDA cleared 510(k) for treatment of malignant disease (e.g. cancers of the head and neck, brain, liver, lung, breast, prostate, etc.) and may be used in surface, interstitial, and intracavity applications for tumors with known radiosensitivity.

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 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.)

Table of Contents

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. 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. (R Yang, J Wang, Dosimetric Comparison of Permanent Prostate Brachytherapy Plans Utilizing Cs-131, I-125 and Pd-103 Seeds. *Abstract presented at the AAPM Annual Meeting*, July 2008, Houston TX)

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); Prestidge B, et al. Cesium-131 Permanent Prostate Brachytherapy: An Initial Report. *Int. J. Radiation Oncology Biol. Phys.* 2005; 63 (1) 5336-5337)

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 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 tumor control to I-125, long considered the gold standard in permanent seed brachytherapy. (Moran, B, et. al. Cesium-131 Prostate Brachytherapy” An Early Experience. *Brachytherapy*. 2007; 6 (2). Bice W, et. al. Recommendations for permanent prostate brachytherapy with 131Cs: a consensus report from the Cesium Advisory Group. *Oral Presentation at ABS Annual Meeting*, May 2008, Boston MA)

The following graph was presented in William Bice, PhD’s presentation at the 2008 ABS Annual Meeting in May 2008 and shows Cs-131’s PSA response rate compared to I-125 and Pd-103.

Table of Contents

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. The American Cancer Society estimates there will be about 186,320 new cases of prostate cancer diagnosed and an estimated 28,660 deaths associated with the disease in the United States in 2008. 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.

Table of Contents

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%.

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). IsoRay's management believes that the Proxcelan seed will add incremental growth to the existing brachytherapy seed market as physicians who are currently reluctant to recommend brachytherapy for their prostate patients due, in part, to side effects caused by longer-lived isotopes, become comfortable with the shorter half-life of Cs-131, and the anticipated related reduction of side effects that it offers.

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).

Management expects that market growth in all brachytherapy in the U.S. will increase at the rate of 4% per year through 2011. Independent research firms have estimated Cs-131 growth alone in the U.S. marketplace to average 32% a year from 2009 through 2014 (Source: iData Research Inc., 2008). The competing isotopes Pd-103 and I-125 are projected to decrease by .5% and increase 1.6% respectively per year during this same time period (Source: iData Research Inc., 2008).

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).

Table of Contents

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).

Table of Contents

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 effects 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.

Brachytherapy 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 on the use of I-125 and Pd-103 brachytherapy in the treatment of early-stage prostate cancer have been very positive, the most recent of which was as follows:

- § Results of a trial published in 2007 in the International Journal of Radiation Oncology looking at 15-year survival in 223 patients with stage T1-T3 prostate cancer and treated with brachytherapy in combination with external beam demonstrated excellent long-term biochemical control. Fifteen-year biochemical relapse free survival (BRFS) for the entire treatment group was 74%. (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", Int. J. Rad. Onc. Biol., Vol. 67, 2007, 57-64.).

Reduced Incidence of Side Effects. Sexual potency and urinary incontinence are two major concerns men face when choosing among various forms of treatment for prostate cancer. Because the Proxcelan Cesium-131 brachytherapy seed delivers a highly concentrated and confined dose of radiation directly to the prostate, healthy surrounding tissues and organs typically experience less radiation exposure. Management believes, and initial results appear to support, that this should result in lower incidence of side effects and complications than may be incurred with other conventional therapies or isotopes. Additionally when side effects do occur, they should resolve more rapidly than those experienced with I-125 and Pd-103 isotopes.

Table of Contents

Cs-131 Clinical Results and Ongoing Trials

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 to observe the dosimetric characteristics of Cs-131 and its side effect profile. The results of the monotherapy trial have demonstrated that Cs-131 is a viable alternative as an isotope for permanent seed prostate brachytherapy. Some of the significant and specific findings were as follows:

§ Patient reported symptoms (IPSS Scores) were mild to moderate with relatively rapid resolution within 4-6 months.

§ Prostate Specific Antigen, or PSA, response over 30 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*) (Moran BJ, Braccioforte MH, “Cesium-131 prostate brachytherapy: An early experience”. *Brachytherapy, Volume 6, Issue 2, April-June 2007, Page 80*). (Bice, W, et. al. “Recommendations for permanent prostate brachytherapy with ¹³¹Cs: a consensus report from the Cesium Advisory Group”. *Oral Presentation at ABS Annual Meeting, May 2008, Boston MA*).

§ The resolution of acute side effects proved to be much quicker with Cs-131 compared to I-125 thus validating the theoretical argument that dose related side effects dissipate faster with shorter lived isotopes. (Prestidge BR, “Cesium-131; the isotope of choice in permanent prostate brachytherapy”. Oral Presentation at the American Brachytherapy Society annual conference, April 2007.).

§ The dosimetric observations of the trial demonstrated that it was possible to deliver adequate dose to the prostate while maintaining dose uniformity across the gland. The dose delivered to critical structures 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.*).

The monotherapy Cs-131 trial will continue to follow patients with annual updates on symptoms and patient long-term survival data.

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 acute morbidity profile are very encouraging. Dr. Moran will continue to track these patients in order to collect long-term outcomes.

A third ongoing study first presented at the American Association of Physicists in Medicine (AAPM) meeting in July 2007 compared the dosimetry of Cs-131 and Pd-103 directly. The study showed a 17.5% reduction in the number of seeds, 6% reduction in planned needles, 35.5% reduction in V150 (percent of gland that receives more than 150% of the prescription dose), and 44.2% reduction in R100 (percent of rectal tissue that receives the full prescription dose of radiation). (Musmacher, J., “Dosimetric comparison of Cesium-131 and Palladium-103 for permanent prostate brachytherapy”, poster presented at 49th AAPM Annual Conference, Minneapolis, MN, April 22-26, 2007.)

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 is slated to be 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 to date 50 patients have been enrolled.

Table of Contents

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.

Our Strategy

The key elements of IsoRay's strategy for fiscal year 2009 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.
- § *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.
- § *Introduce Cs-131 therapies for other cancers.* The Company's first sale for ocular melanoma occurred in late 2007 and periodic sales have occurred since then. Although the ocular melanoma market is not a large one, this continues to support the application of Cs-131 in other solid tumors. IsoRay will continue to explore partnering with other companies to develop the appropriate technologies and therapeutic delivery systems for treatment of other solid tumors such as breast, lung, liver, pancreas, neck, and brain cancers.
- § *Support clinical research and sustained product development.* The Company plans to structure and support clinical studies on the therapeutic benefits of Cs-131 for the treatment of solid tumors and other patient benefits. We are and will continue to support clinical studies with several leading radiation oncologists to clinically document patient outcomes, provide support for our product claims, and compare the performance of our seeds to competing seeds. IsoRay plans to sustain long-term growth by implementing research and development programs with leading medical institutions in the U.S. and other countries to identify and develop other applications for IsoRay's core radioisotope technology.
- § *Improve our manufacturing efficiencies.* Over the past several months the Company has been working on improving its gross margin by reviewing its manufacturing processes. Over the next year, the Company will continue reviewing its manufacturing processes, implementing improvements, and automating either certain portions or all of its manufacturing process. Management believes that it will be able to lower its costs of production relative to its sales revenue through this evaluation.
- § *Introduce Proxcelan Cesium-131 brachytherapy seeds to the Canadian and Russian market.* In August 2008, the Company obtained its ISO 13485 certification. This was an important step to allow the Company to register and eventually sell its Proxcelan Cs-131 brachytherapy seeds in Canada and Russia. The Company anticipates finalizing its registrations of Proxcelan Cs-131 brachytherapy seeds in Canada and Russia during fiscal year 2009. The Company is now focusing on the Canadian and Russian markets and is no longer pursuing sales in the European Union (EU). Management does not believe a strategic alliance with IBt, SA, a Belgian company, will be consummated nor will management leverage IBt's distribution channels in the EU.

Table of Contents**Products**

IsoRay markets the Proxcelan Cs-131 brachytherapy seed for the treatment of prostate cancer and ocular melanomas, and intends to market Cs-131 for the treatment of other malignant disease in the future. Additionally, the Company may market other radioactive isotopes in the future.

Competitive Advantages of Proxcelan Cs-131

General. Management believes that the Proxcelan Cesium-131 brachytherapy seed has specific clinical advantages for treating cancer over I-125 and Pd-103, the other isotopes currently used in brachytherapy seeds. The table below highlights the key differences of the three seeds. The Company believes that the short half-life, high-energy characteristics of Cs-131 will increase industry growth and facilitate meaningful penetration into the treatment of other forms of cancer such as lung cancer.

Brachytherapy Isotope Comparison

	Cesium-131	Palladium-103	Iodine-125
Half Life	9.7 Days	17.5 days	60 days
Avg. Energy	30.4 keV ⁺	20.8 keV ⁺	28.5 keV ⁺
Dose Delivery	90% in 33 days	90% in 58 days	90% in 204 days
Total Dose	115 Gy	125 Gy	145 Gy
Anisotropy Factor*	0.969	0.877 (TheraSeed® 200)	0.930 (OncoSeed® 6711)

*Degree of symmetry of therapeutic dose, a factor of 1.00 indicates symmetry.

+keV = kiloelectron volt, a standard unit of measurement for electrical energy.

Shorter half-life. The Company believes that Cs-131's shorter half-life of 9.7 days will prove to have greater biological effectiveness, will mitigate the negative effects of long radiation periods on healthy tissue, and will reduce the duration of any side effects. Our early clinical data supports the Company's belief that there is a reduced duration of side effects post implant. A shorter half-life produces more intense therapeutic radiation over a shorter period of time and may reduce the potential for cancer cell survival and tumor recurrence. Radiobiological studies indicate that shorter-lived isotopes are more effective against faster growing tumors (Dicker, et. al., *Semin. Urol. Onc.* 18:2, May 2000). Other researchers conclude that "half-lives in the approximate range 4-17 days are likely to be significantly better for a wide range of tumor types for which the radiobiologic characteristics may not be precisely known in advance." (Armpilia CI, et. al., *Int. J. Rad. Oncol. Biol. Phys.* 55:2, February 2003).

Higher energy. The Cs-131 isotope average decay energy of 30.4 keV (versus 21 keV for Pd-103 and 28.5 keV for I-125) generates a therapeutic radiation field that extends beyond the current dosimetry reference point of one centimeter. Pd-103 seeds emit radiation that does not penetrate as far into tissue (up to 40% lower than Cs-131). To compensate for this lack of penetration, more Pd-103 seeds are required to attain the equivalent dose than are required for Proxcelan seeds. This increase in the number of seeds implanted increases the time and cost required to perform Pd-103-based procedures.

Quality of Life. Because IsoRay's Proxcelan Cesium-131 brachytherapy seed delivers a highly concentrated and confined dose of radiation directly to the prostate, healthy surrounding tissues and organs are exposed to less radiation than with other treatments. Initial results indicate that the side effects experienced, if any, are mild to moderate and urinary symptoms resolve more rapidly, within 4-6 months, when compared to I-125. Management believes that as the data matures it will continue to support fewer and less severe side effects and complications when compared to other

conventional therapies.

10

Table of Contents

Shape of radiation field. The shape of the radiation field generated by a Proxcelan seed is more uniform than most brachytherapy seed designs, and this uniformity may result in better radiation dose coverage and improved therapeutic effectiveness. The higher energy of Cs-131 makes the isotope more “forgiving” for treatment planning purposes. IsoRay has conducted extensive computer modeling of its Proxcelan Cs-131 seed design. The dosimetric characteristics of the Cs-131 seed were recently confirmed through American Association of Physicists in Medicine (AAPM) evaluations of the seed design (Med Phys, 34:2). The results of these tests showed superior dose characteristics relative to the leading I-125 and Pd-103 seeds. The IsoRay seed has also met all Nuclear Regulatory Commission (NRC) requirements for sealed radioactive sources.

Cs-131 Manufacturing Process and Suppliers

Product Overview. Cs-131 is a radioactive isotope that can be produced by the neutron bombardment of Barium-130 (Ba-130). When placed into a nuclear reactor and exposed to a flux of neutrons, Ba-130 becomes Ba-131, the radioactive material that is the parent isotope of Cs-131. The radioactive isotope Cs-131 is normally produced by placing a quantity of stable non-radioactive barium (ideally barium enriched in isotope Ba-130) into the neutron flux of a nuclear reactor. The irradiation process converts a small fraction of this material into a radioactive form of barium (Ba-131). The Ba-131 decays by electron capture to the radioactive isotope of interest (Cs-131).

To produce the Proxcelan seed, the purified Cs-131 isotope is adsorbed onto a ceramic core containing a gold X-ray marker. This internal core assembly is subsequently inserted into a titanium capsule that is then welded shut and becomes a sealed radioactive source and a biocompatible medical device. The dimensional tolerances for the ceramic core, gold X-ray marker, and the titanium capsule are extremely important. To date the Company has used sole-source providers for certain components such as the gold X-ray marker and the titanium capsule as these suppliers have been validated by our quality department and they have been cost effective.

Barium Enrichment Device. The Company has retained an independent contractor to develop an enrichment device to produce “enriched barium” having a higher concentration of the Ba-130 isotope than is found in naturally occurring barium. Irradiating enriched barium will result in higher yields of Cs-131. The Company anticipates the use of enriched barium will also streamline the manufacturing process and reduce Cs-131 production costs. The Company’s prototype enrichment device is expected to be tested in October 2008 but there is no assurance this testing will occur by then or whether or not it will be successful.

Isotope Suppliers. Due to the short half-life of both the Ba-131 and Cs-131 isotopes, potential suppliers must be capable of removing irradiated materials from the reactor core on a routine basis for subsequent processing to produce ultra-pure Cs-131. In addition, the supplier’s nuclear reactor facility must have sufficient irradiation capacity to accommodate barium targets and the nuclear reactors must have sufficient neutron flux to economically produce commercially viable quantities of Cs-131. Ideally, the irradiation facility will also have a radiochemical separation infrastructure to carry out the initial separation steps. The Company has identified key reactor facilities in the U.S. and the former Soviet Union that are capable of meeting these requirements. As of the date of this report, IsoRay has agreements in place with three suppliers of irradiated Ba-131 or Cs-131. For the fiscal year ended June 30, 2008, approximately sixty-five percent (65%) of our Cs-131 was supplied by one of two Russian suppliers, but the Company has begun taking steps to reduce its reliance on a single source for Cs-131.

With the development of barium enrichment capabilities, the Company plans to expand Cs-131 manufacturing capability at the MURR reactor in the United States but will continue to obtain Cs-131 from multiple suppliers. Failure to obtain deliveries of Cs-131 from multiple sources could have a material adverse effect on seed production. Management believes it will continue to rely solely on its three suppliers in the near future and shutdowns from these suppliers could cause delays in deliveries and production.

Table of Contents

Quality Controls. We have established procedures and controls to comply with the FDA's Quality System Regulation. The Company constantly monitors these procedures and controls to ensure that they are operating properly, thereby working to maintain a high-quality product. Also, the quality, production, and customer service departments maintain open communications to ensure that all regulatory requirements for the FDA, DOT, and applicable nuclear radiation and health authorities are fulfilled.

In July 2008, IsoRay had its baseline inspection by the FDA at its manufacturing and administrative offices in Richland, WA. This inspection was carried out over a five day period of time during which the investigator performed an inspection following Quality Systems Inspection Techniques (QSIT). This was a complete and very thorough inspection. At the end of the inspection no report of deviations from Good Manufacturing Practices or list of observations (form FDA 483) was issued to IsoRay.

Order Processing. The Company has implemented a just-in-time production process that is responsive to customer input and orders to ensure that individual customers receive a higher level of customer service than received from our competitors who have the luxury of longer lead times due to longer half-life products. Time from order confirmation to completion of product manufacture is reduced to several working days, including receipt of irradiated barium (from a supplier's reactor), separation of Cs-131, isotope labeling of the core, and loading of cores into pre-welded titanium "cans" for final welding, testing, quality assurance and shipping.

It is up to each physician to determine the dosage necessary for implants and acceptable dosages vary among physicians. Many of the physicians who order our seeds order more seeds than necessary to assure themselves that they have a sufficient quantity. Upon receipt of an order, the Company either delivers the seeds from its facility directly to the physician or sends the order to an independent preloading service that delivers the seeds preloaded into needles or cartridges just prior to implant. If the implant is postponed or rescheduled, the short half-life of the seeds makes them unsuitable for use and therefore they must be re-ordered.

Due to the lead time for obtaining and processing the Cs-131 isotope and the short half-life, the Company relies on sales forecasts and historical knowledge to estimate the proper inventory levels of isotope needed to fulfill all customer orders. Consequently, some portion of the isotope is lost through decay and is not used in an end product. Management continues to reduce the variances between ordered isotope and isotope deliveries and is continually improving its ordering process efficiencies.

Automated Manufacturing Process

Based on evaluations of automation options by management, IsoRay has elected to automate its current manufacturing process in phases. Phased implementation of automation is expected to be less costly than fully automated production lines and will benefit IsoRay by reducing labor costs and ensuring consistent manufacturing quality. The Company has purchased some automation equipment and is reviewing options for the development of additional automated equipment. The Company also has a contract with a third party to outsource certain sub-processes.

Manufacturing Facility

The Company has replaced its original manufacturing facility located at PEcoS-IsoRay Radioisotope Laboratory (PIRL) with a production facility located at Applied Process Engineering Laboratory (APEL). The APEL facility became operational in September 2007, which was three months earlier than the original scheduled opening. The facility has over 15,000 square feet and includes space for isotope separation, seed production, order dispensing, a clean room for radiopharmacy work, and a dedicated shipping area. A description of the lease terms for the APEL facility is located in the Other Commitments and Contingencies section of Item 7 below. Management believes that the APEL facility will be utilized for manufacturing space through fiscal year 2016 which is the original lease term

plus the two three-year renewal options. Management currently anticipates exercising both three-year renewal options to extend the APEL facility lease through April 2016.

Table of Contents*Isotope Testing in Idaho*

On December 14, 2005, IsoRay and Idaho's Advanced Test Reactor (ATR) entered into a collaboration and partnership agreement for the design, analysis and fabrication of a capsule containing barium carbonate, to be irradiated at the ATR and then shipped to IsoRay for processing and analysis of the Cs-131 product. As an adjunct to this testing, IsoRay and the Pocatello Development Authority entered into an Economic Development Agreement, dated December 14, 2005, under which the Pocatello Development Authority provided IsoRay with \$200,000 (subject to repayment under certain conditions) to apply to the cost of testing at the ATR. ATR is currently working to install a shuttle system that would make the production of Cs-131 possible in the reactor. There is no assurance that even though the capsules irradiated in 2006 performed as designed that the shuttle system will provide adequate conditions for Cs-131 production. The Company has no agreement with ATR to either produce Cs-131 or irradiate Ba-130 and there is no assurance that this will ultimately occur.

Repackaging Services

Most brachytherapy manufacturers offer their seed product to the end user packaged in four principal configurations provided in a sterile or non-sterile package depending on the customer's preference. These include:

	§	<i>Loose seeds</i>
§		<i>Pre-loaded needles</i> (loaded typically with three to five seeds and spacers)
§		<i>Strands of seeds</i> (consists of seeds and spacers in a biocompatible "shrink wrap")
	§	<i>Pre-loaded Mick cartridges</i> (fits the Mick applicator)

In 2008, the Millenium Research Group reported that the estimated market shares for each of the four packaging types are: loose seeds and preloaded loose seeds (8%), Mick cartridges (26%), and all strand configurations including preloaded strands (66%). Market trends indicate significant movement toward the stranded configuration, as there are some clinical data suggesting less potential for post-implant seed migration when a stranded configuration is used.

The role of the preloading service is to package, assay and certify the contents of the final product configuration shipped to the customer. A commonly used method of providing this service is through independent radiopharmacies. Manufacturers send loose seeds along with the physician's instructions to the radiopharmacy which, in turn, loads needles and/or strands the seeds according to the doctor's instructions. These radiopharmacies then sterilize the product and certify the final packaging prior to shipping directly to the end user.

IsoRay currently has agreements with several independent radiopharmacies to assay, preload, and sterilize loose seeds. This creates additional loss of our isotope due to decay and is prohibitive on a long-term basis. While the Company pre-loads many of its current orders, we have continued to utilize these services to supplement our own custom preloading operation and when they are requested by the ordering physician.

We currently load most Mick cartridges in our own facility which in recent months accounted for approximately 53% of total orders. The remaining approximately 47% of total orders are strand configurations including preloaded strands. During fiscal year 2008, the Company began offering a 100% confirmation assay performed by in-house analytical services. Providing the assay and ultimately the preloading services in-house allows the Company to eliminate approximately 25% loss in isotope activity due to radioactive decay. The cost of priority overnight shipment of each order of seeds to a third-party provider is also eliminated. However, we will continue to utilize the independent radiopharmacies to back up our own preloading operation, to handle periodic increases in demand, and to cater to certain doctor's preferences.

Table of Contents

Independent radiopharmacies usually provide the final packaging of the product delivered to the end user thereby eliminating the opportunity for reinforcing the "branding" of our seed product. By providing our own repackaging service, we will preserve the product branding opportunity and eliminate any concerns related to the handling of our product by a third party prior to delivery to the end user.

Providing custom packaging configurations enhances our product while providing an additional revenue stream and incremental margins to the Company through pricing premiums charged to our customers. The end users of these packaging options are willing to pay a premium because of the savings they realize by eliminating the need for loose seed handling and loading capabilities on site, eliminating the need for additional staffing to sterilize seeds and needles, and eliminating the expense of additional assaying of the seeds.

Marketing and Sales

Marketing Strategy

The Company is marketing Proxcelan Cesium-131 brachytherapy seeds as the "seed of choice" for prostate brachytherapy. Based on current and preliminary clinical studies, management believes there is no apparent clinical reason to use other isotopes when Cs-131 is available. The advantages associated with a higher energy and shorter half-life isotope are generally accepted within the clinical community and the Company intends to help educate potential patients about the clinical benefits from Cs-131 for their brachytherapy seed treatment.

IsoRay has chosen to identify its proprietary Cs-131 seed with the brand of "Proxcelan." Management is using this brand to differentiate Cs-131 seeds from seeds using the other isotopes. We continue to target the competing isotope products of iodine and palladium rather than the various manufacturers and distributors of these isotopes. Using this strategy, the choice of brachytherapy isotopes should be less dependent on the name and distribution strengths of the various iodine and palladium manufacturers and distributors and more dependent on the therapeutic benefits of Cs-131.

The professional and patient market segments each play a role in the ultimate choice of cancer treatment and the specific isotope chosen for seed brachytherapy treatment. The Company has developed a customized brand message for each audience. For medical professionals, IsoRay has created print and visual medias (including physician brochures discussing the clinical advantages of Cs-131, clinical information binders, informational DVDs, single sheet glossies with targeted clinical data, etc.), advertisements in the leading medical journals and a physician targeted website. In addition, the Company attends national professional meetings, including the following:

- § American Brachytherapy Society (ABS),
- § American Society for Therapeutic Radiation and Oncology (ASTRO), and
- § Association of American Physicists in Medicine (AAPM).

The Company also continues to consult with noted contributors from the medical physics community and will have articles submitted to professional journals such as *Medical Physics*, *the Brachytherapy Journal*, and the *International Journal of Radiation Oncology, Biology, and Physics* regarding the benefits of and clinical trials involving Cs-131.

Beginning in January 2008, IsoRay implemented a variety of physician Cs-131 training outreach programs including the following: a two day training course held approximately three times per year at Chicago Prostate Cancer Center (CPCC); proctoring and mentoring programs led by Steve Kurtzman, MD, IsoRay's Medical Director; and a training DVD for physicians who choose not to leave their practices to attend a training course.

The objective of the training programs is to increase the physician's confidence in using the product. To track the impact of the courses held in January 2008 and in May 2008, IsoRay has compared physicians' average monthly order activity for the six month periods prior to and after attending the course. To date there has been a 42% increase in average monthly order activity when comparing these two time periods for those physicians participating in the January and May training courses.

Table of Contents

In today's U.S. health care market, patients are more informed and involved in the management of their health than in the past. Many physicians relate incidents of their patients coming for consultations armed with articles researched on the Internet and other sources describing new treatments and medications. In many cases, these patients are demanding a certain therapy or drug and the physicians are complying when medically appropriate.

Because of this consumer-driven market factor, we also promote our products directly to the general public. We target the prostate cancer patient, his spouse, family and care givers. We emphasize to these segments the specific advantages of the Proxcelan Cesium-131 brachytherapy seed through our websites (located at www.isoray.com, www.cesium.com, and www.proxcelan.com), patient advocacy efforts, informational patient brochures and DVDs with patient testimonials, patient focused informational website (www.proxcelan.com), and advertisements in specific markets supporting brachytherapy. None of the websites mentioned in the preceding sentence are part of this report.

In addition, the Company continues to promote the clinical findings of the various protocols through presentations by respected thought leaders. The Company will continually review and update all marketing materials as more clinical information is gathered from the protocols and studies.

Apart from clinical studies and papers sponsored by the Company, several physicians across the country are now independently publishing papers and studies extolling the benefits of Cs-131.

Sales and Distribution

According to a recent industry survey, approximately 2,000 hospitals and free standing clinics are currently offering radiation oncology services in the United States. Not all of these facilities offer seed brachytherapy services. These institutions are staffed with radiation oncologists and medical physicists who provide expertise in radiation therapy treatments and serve as consultants for urologists and prostate cancer patients. We target the radiation oncologists and the medical physicists as well as urologists as key clinical decision-makers in the type of radiation therapy offered to prostate cancer patients.

IsoRay has a direct sales organization to introduce Proxcelan Cesium-131 brachytherapy seeds to radiation oncologists and medical physicists. Currently IsoRay has six direct sales persons and a National Sales Director. These sales people include those experienced in the brachytherapy market and the medical device market. IsoRay is evaluating all options for distribution of the Proxcelan Cesium-131 seed and may in the future add additional distribution channels.

With the restructuring of the compensation structure by new management, the Company lost several members of its sales force who did not want to rely on a reduced base salary and increased commissions approach. From the date of the changes in compensation structure until September 22, 2008, the Company has lost four sales representatives and replaced them with four new sales representatives. As management increasingly focuses on improving sales, additional changes may be necessary.

The Company expects to continue to expand its customer base in fiscal year 2009. When the Company implements its plans to expand outside the U.S. market, it plans to use established distributors in the key markets in these other countries. This strategy should reduce the time and expenses required to identify, train and penetrate the key implant centers and establish relationships with the key opinion leaders in these markets. Using established distributors also should reduce the time spent acquiring the proper radiation handling licenses and other regulatory requirements of these markets.

Table of Contents

Reimbursement

Payment for IsoRay products comes from third-party payers including the Centers for Medicare and Medicaid Services (CMS) and private insurance companies. These payers reimburse the hospitals and clinics via well-established payment procedures. In 2003, the Company was approved for an initial HCPCS code for Cs-131 brachytherapy seeds. In July 2007 CMS divided the HCPCS code into two codes for all manufacturers of brachytherapy seeds. The current method has assigned one HCPCS code for loose seeds and a second HCPCS code for stranded seeds. Medicare is the most significant U.S. payer for prostate brachytherapy services, and is the payer in approximately 65% of all U.S. prostate brachytherapy cases.

Prostate brachytherapy is typically performed in an outpatient setting, and as such, is covered by the CMS Outpatient Prospective Payment System. Currently, when charges for the seeds are correctly submitted to CMS, the total cost of the seeds is reimbursed to the hospital or clinic by CMS. CMS had proposed that a fixed price per seed be reimbursed; however, Congress (after postponing a decision on the Medical Bill which included brachytherapy seed reimbursement) voted on July 15, 2008 to continue the pass-through reimbursement for brachytherapy seeds through December 31, 2009. Other insurance companies have historically followed CMS's reimbursement policies.

Other Information

Customers

Customers representing ten percent or more of total Company sales for the twelve months ended June 30, 2008 include:

Various Northern California facilities (a)	18.6% of revenue
Chicago Prostate Cancer Center Westmont, IL	15.7% of revenue

(a) The following facilities located in northern California are used by one doctor (the Company's Medical Director): Community Hospital of Los Gatos (11.0% of total revenue), Mills Peninsula Health Services (4.3%), and all others used by this doctor combined (3.3%).

The loss of any of these significant customers would have an adverse effect on the Company's revenues, which would continue until the Company located new customers to replace them.

Proprietary Rights

The Company relies on a combination of patent, copyright and trademark laws, trade secrets, software security measures, license agreements and nondisclosure agreements to protect its proprietary rights. Some of the Company's proprietary information may not be patentable.

The Company intends to vigorously defend its proprietary technologies, trademarks, and trade secrets. Members of management, employees, and certain equity holders have previously signed non-disclosure, non-compete agreements, and future employees, consultants, advisors, with whom the Company engages, and who are privy to this information, will be required to do the same. A patent for the cesium separation and purification process was granted on May 23, 2000 by the U.S. Patent and Trademark Office (USPTO) under Patent Number 6,066,302, with an expiration date of May 23, 2020. The process was developed by Lane Bray, Chief Chemist and a shareholder of the Company, and has been assigned exclusively to IsoRay. IsoRay's predecessor also filed for patent protection in four European countries

under the Patent Cooperation Treaty. Those patents have been assigned to IsoRay.

Table of Contents

Our management believes that certain aspects of the IsoRay seed design and construction techniques are patentable innovations. These innovations have been documented in IsoRay laboratory records, and a patent application was filed with the USPTO on November 12, 2003. In August 2008, this patent was granted by the USPTO under Patent Number 7,410,458, with an expiration date of November 12, 2023. Certain methodologies regarding isotope production, separation, and seed manufacture are retained as trade secrets and are embodied in IsoRay's procedures and documentation. In June 2004, July 2004, and February 2007, five patent applications were filed relating to methods of deriving Cs-131 developed by IsoRay employees. The Company is currently working on developing and patenting additional methods of deriving Cs-131 and other isotopes.

There are specific conditions attached to the assignment of the Cs-131 patent from Lane Bray. In particular, the associated Royalty Agreement provides for 1% of gross profit payment from seed sales to Lane Bray and 1% of gross profit from any use of the Cs-131 process patent for non-seed products. If IsoRay reassigns the Royalty Agreement to another company, these royalties increase to 2%. The Royalty Agreement has an anti-shelving clause which requires IsoRay to return the patent if IsoRay permanently abandons sales of products using the invention. During fiscal years 2008 and 2007, the Company recorded royalty expense of \$21,219 and \$2,161, respectively, related to this patent.

The terms of a license agreement with the Lawrence Family Trust (successor to Don Lawrence) for a patent application and related "know-how" require the payment of a royalty based on the Net Factory Sales Price, as defined in the agreement, of licensed product sales. Because the licensor's patent application was ultimately abandoned, only a 1% "know-how" royalty remains applicable. To date, management believes that there have been no product sales incorporating the "know-how;" and therefore believes no royalty is due pursuant to the terms of the agreement. Management believes that ultimately no royalties should be paid under this agreement as there is no intent to use this "know-how" in the future.

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

The Company's Proxcelan trademark has been preliminarily approved and the Company is currently waiting for the final approval letter from the USPTO.

Research and Development

During the three-year period ended June 30, 2008, IsoRay and its predecessor companies incurred more than \$3.2 million in costs related to research and development activities. The Company expects to continue ongoing research and development activities for the foreseeable future.

Whether successful or not, the Company anticipates ending its major research and development project to develop a proprietary separation process to manufacture enriched barium during fiscal year 2009. During fiscal year 2008, the Company spent approximately \$483,000 on this project. The remaining project costs are anticipated to be approximately \$150,000.

Government Regulation

The Company's present and future intended activities in the development, manufacture and sale of cancer therapy products are subject to extensive laws, regulations, regulatory approvals and guidelines. Within the United States, the Company's therapeutic radiological devices must comply with the U.S. Federal Food, Drug and Cosmetic Act, which is enforced by the FDA. The Company is also required to adhere to applicable FDA Quality System Regulations, also

known as the Good Manufacturing Practices, which include extensive record keeping and periodic inspections of manufacturing facilities. The Company's predecessor obtained FDA 510(k) clearance in March 2003 to market the Proxcelan Cs-131 seed for the treatment of localized solid tumors and other malignant disease and IsoRay obtained FDA 510(k) clearance in November 2006 to market preloaded brachytherapy seeds.

Table of Contents

In the United States, the FDA regulates, among other things, new product clearances and approvals to establish the safety and efficacy of these products. We are also subject to other federal and state laws and regulations, including the Occupational Safety and Health Act and the Environmental Protection Act.

The Federal Food, Drug, and Cosmetic Act and other federal statutes and regulations govern or influence the research, testing, manufacture, safety, labeling, storage, record keeping, approval, distribution, use, reporting, advertising and promotion of such products. Noncompliance with applicable requirements can result in civil penalties, recall, injunction or seizure of products, refusal of the government to approve or clear product approval applications, disqualification from sponsoring or conducting clinical investigations, preventing us from entering into government supply contracts, withdrawal of previously approved applications, and criminal prosecution.

In the United States, medical devices are classified into three different categories over which the FDA applies increasing levels of regulation: Class I, Class II, and Class III. Most Class I devices are exempt from premarket notification (510(k)); most Class II devices require premarket notification (510(k)); and most Class III devices require premarket approval. Our Proxcelan Cs-131 seed is a Class II device and received 510(k) clearance in March 2003.

Approval of new Class III medical devices is a lengthy procedure and can take a number of years and require the expenditure of significant resources. There is a shorter FDA review and clearance process for Class II medical devices, the premarket notification or 510(k) process, whereby a company can market certain Class II medical devices that can be shown to be substantially equivalent to other legally marketed devices. Since brachytherapy seeds have been classified by the FDA as a Class II device, we have been able to achieve market clearance for our Cs-131 seed using the 510(k) process.

As a registered medical device manufacturer with the FDA, we are subject to inspection to ensure compliance with their current Good Manufacturing Practices, or cGMP. These regulations require that we and any of our contract manufacturers design, manufacture and service products, and maintain documents in a prescribed manner with respect to manufacturing, testing, distribution, storage, design control, and service activities. Modifications or enhancements that could significantly affect the safety or effectiveness of a device or that constitute a major change to the intended use of the device require a new 510(k) notice for any product modification.

The Medical Device Reporting regulation requires that we provide information to the FDA on deaths or serious injuries alleged to be associated with the use of our devices, as well as product malfunctions that are likely to cause or contribute to death or serious injury if the malfunction were to recur. Labeling and promotional activities are regulated by the FDA and, in some circumstances, by the Federal Trade Commission.

As a medical device manufacturer, we are also subject to laws and regulations administered by governmental entities at the federal, state and local levels. For example, our facility is licensed as a medical product manufacturing facility in the State of Washington and is subject to periodic state regulatory inspections. Our customers are also subject to a wide variety of laws and regulations that could affect the nature and scope of their relationships with us.

In support of IsoRay's global strategy to expand marketing to Canada and Russia, as well as other foreign markets, we initiated the process in fiscal year 2008 to obtain the European CE Mark, Canadian registration, and certification to ISO 13485, an internationally recognized quality system. European law requires that medical devices sold in any EU Member State comply with the requirements of the European Medical Device Directive (MDD) or the Active Implantable Medical Device Directive (AIMDD). IsoRay's products are classified in Europe as an active implantable and are subject to the AIMDD. Compliance with AIMDD and obtaining a CE Mark involves being certified to ISO 13485 and obtaining approval of the product technical file by a notified body that is recognized by competent authorities of a Member State. Compliance with ISO 13485 is also required for registration of a company for sale of its products in Canada. Many of the recognized EU Notified Bodies are also recognized by Health Canada to conduct

the ISO 13485 inspections for Canadian registration. In August 2008, the Company received its certification to ISO 13485 and is continuing to seek Canadian registration and the European CE Mark. The Company is now focusing on the Canadian and Russian markets and is no longer pursuing sales in the European Union (EU). Management does not believe a strategic alliance with IBt, SA, a Belgian company, will be consummated nor will management leverage IBt's distribution channels in the EU.

Table of Contents

In the United States, as a manufacturer of medical devices and devices utilizing radioactive byproduct material, we are subject to extensive regulation by not only federal governmental authorities, such as the FDA, but also by state and local governmental authorities, such as the Washington State Department of Health, to ensure such devices are safe and effective. In Washington State, the Department of Health, by agreement with the federal Nuclear Regulatory Commission (NRC), regulates the possession, use, and disposal of radioactive byproduct material as well as the manufacture of radioactive sealed sources to ensure compliance with state and federal laws and regulations. Our Cs-131 brachytherapy seeds constitute both medical devices and radioactive sealed sources and are subject to these regulations.

Moreover, our use, management, and disposal of certain radioactive substances and wastes are subject to regulation by several federal and state agencies depending on the nature of the substance or waste material. We believe that we are in compliance with all federal and state regulations for this purpose.

Washington voters approved Initiative 297 in late 2004, which may impose additional restrictions on sites at which mixed radioactive and hazardous wastes are generated and stored, as it prohibits additional mixed radioactive and hazardous waste from being brought to sites until the existing on-site waste conforms to all state and federal environment laws. In June 2006, a U.S. District court judge ruled that Initiative 297 was unconstitutional in its entirety and the Ninth Circuit upheld this decision in May 2008. However, the State of Washington may choose to appeal the decision. If this decision is overturned and Initiative 297 is enforced it could impact our ability to manufacture our seeds in the State of Washington.

Seasonality

The Company believes that some seed implantation procedures are deferred around physician vacations (particularly in the summer months), holidays, and medical conventions and conferences resulting in a seasonal influence on the Company's business. These factors cause a momentary decline in revenue which management believes is ultimately realized later. Because almost thirty percent (30%) of the Company's business relies on three physicians, simultaneous vacations by these three physicians could cause significant drops in the Company's productivity during those periods.

Employees

As of September 12, 2008, IsoRay employed 49 full-time individuals and one part-time individual. The Company's future success will depend, in part, on its ability to attract, retain, and motivate highly qualified sales, technical and management personnel. From time to time, the Company may employ independent consultants or contractors to support its research and development, marketing, sales, and administrative organizations. None of the Company's employees are represented by any collective bargaining unit. IsoRay estimates that successful implementation of its growth plan would result in up to five to seven additional employees by the end of fiscal year 2009. The significant decrease in anticipated employees from those projected in fiscal year 2008 is a result of the greater manufacturing efficiencies realized by the Company and lower than anticipated sales growth.

Table of Contents

Competition

The Company competes in a market characterized by technological innovation, extensive research efforts, and significant competition. In general, the Proxcelan Cesium-131 brachytherapy seed competes with conventional methods of treating localized cancer, including, but not limited to, all forms of prostatectomy surgery and external beam radiation therapy which includes intensity modulated radiation therapy, as well as competing permanent brachytherapy devices. Surgery has historically represented the most common medical treatment for early-stage, localized prostate cancer but radical prostatectomies have declined in recent years. EBRT is also a well-established method of treatment and is widely accepted for patients who represent a poor surgical risk or whose prostate cancer has advanced beyond the stage for which surgical treatment is indicated. Management believes that if general conversion from these treatment options (or other established or conventional procedures) to the Proxcelan Cesium-131 brachytherapy seed does occur, such conversion will likely be the result of a combination of equivalent or better efficacy, reduced incidence and duration of side effects and complications, lower cost, better quality of life outcomes, and pressure by health care providers and patients.

History has shown the advantage of being the first to market a new brachytherapy product. For example, Theragenics Corp., which introduced the original Pd-103 seed, currently claims over 59% of the Pd-103 market share (through CR Bard, other distributors, and direct distribution). Although factors other than being first to market contribute to becoming a market leader, the Company believes it has the opportunity to obtain a similar and significant advantage by being the first to introduce a Cs-131 seed. (Source: Millennium Research Corp, 2008)

The Company's patented Cs-131 separation process is likely to provide a sustainable competitive advantage. Production of Cs-131 also requires specialized facilities that represent high cost and long lead time if not readily available. In addition, a competitor would need to develop a method for isotope attachment and seed assembly, would need to conduct testing to meet NRC and FDA requirements, and would need to obtain regulatory clearances before marketing a competing device.

Several companies have obtained regulatory clearance to produce and distribute Pd-103 and I-125 seeds, which compete directly with our seed. Six of those companies represent nearly 100% of annual brachytherapy seed sales worldwide: CR Bard, Inc (32.3%), Oncura (21.7%) (part of GE Healthcare), Theragenics Corp (direct sales 9.5%), North American Scientific, Inc. (13.1%), Core Oncology (10.7%), and Best Medical International, Inc. (6.5%) (Source: Millennium Research Corp, 2008).

It is possible that three or four of the current I-125 or Pd-103 seed manufacturers (e.g., CR Bard, Oncura, Theragenics, North American Scientific, etc.) are capable of producing and marketing a Cs-131 seed, but none have reported efforts to do so. Best Medical obtained a seed core patent in 1992 that named ten different isotopes, including Cs-131, for use in their seeds. Best Medical received FDA 510(k) clearance to market a Cs-131 seed on June 6, 1993 but to date has not produced any products for sale. In addition to the FDA and the NRC, Best Medical would be required to submit a Cs-131 seed to the TG-43 task group of the American Association of Physicists in Medicine to determine the seed's characteristics such as anisotropy, dose rate constant, etc. To date there has been no submission to the TG-43 task group for a competing Cs-131 seed.

Additional Growth Opportunities

Management of the Company sees growth opportunities through expansion into international markets and additional treatment applicability to cancers other than prostate. The Company plans to introduce Cs-131 for prostate brachytherapy initially into Canada and Russia and later into Europe and other international markets through partnerships and strategic alliances with channel partners for manufacturing and distribution.

Cs-131 has FDA clearance to be used for treatments for a broad spectrum of cancers including breast, brain, lung, and liver cancer, and the Company believes that a major opportunity exists as an adjunct therapy for the treatment of residual lung cancer and ocular melanoma. The Company has already begun treating ocular melanoma. The Company has had discussions with prominent physicians and is looking at treatment of lung and brain cancer.

Table of Contents

There is also an opportunity to develop and market other radioactive isotopes to the United States market, and to market Cs-131 isotope itself, separate from its use in our seeds. The Company is also in the preliminary stages of exploring alternate methods of delivering our isotopes to various organs of the body, as it may be advantageous to use delivery methods other than a titanium-encapsulated seed to deliver radiation to certain organs.

ITEM 1A – RISK FACTORS

Our Revenues Depend Upon One Product. Until such time as we develop additional products, our revenues depend upon the successful production, marketing, and sales of the Proxcelan Cs-131 brachytherapy seed. The rate and level of market acceptance of this product may vary depending on the perception by physicians and other members of the healthcare community of its safety and efficacy as compared to that of competing products, if any; the clinical outcomes of the patients treated; the effectiveness of our sales and marketing efforts in the United States, Canada, and Russia; any unfavorable publicity concerning our product or similar products; our product's price relative to other products or competing treatments; any decrease in current reimbursement rates from the Centers for Medicare and Medicaid Services or third-party payers; regulatory developments related to the manufacture or continued use of the product; availability of sufficient supplies of enriched barium (now coming from Russia) for Cs-131 seed production; ability to produce sufficient quantities of this product; and the ability of physicians to properly utilize the device and avoid excessive levels of radiation to patients. Because of our reliance on this product as the sole source of our revenue, any material adverse developments with respect to the commercialization of this product may cause us to continue to incur losses rather than profits in the future.

Although Cleared To Treat Any Malignant Tissue, Our Sole Product Is Currently Used To Treat Two Types Of Cancer. Currently, the Proxcelan Cs-131 seed is used exclusively for the treatment of prostate cancer and ocular melanoma (less than one percent of our sales). We believe the Proxcelan Cs-131 seed will be used to treat other types of cancers, as is currently the case with our competitors' I-125 and Pd-103 seeds. However, we believe that clinical data gathered by select groups of physicians under treatment protocols specific to other organs will be needed prior to widespread acceptance of our product for treating other cancer sites. If our current and future products do not become accepted in treating cancers of other sites, our sales will depend solely on treatment of prostate cancer and will require ever increasing market share to increase revenues.

We Have Increasing Cash Requirements. IsoRay has generated material operating losses since inception. We expect to continue to experience significant net operating losses. Due to previous capital investments, management believes cash and cash equivalents on hand at June 30, 2008 will be sufficient to meet our anticipated cash requirements for operations, debt service, and capital expenditure requirements through at least the next twelve months. If operating costs expand proportionately with revenue increases, other applications are pursued for seed usage outside the prostate market, if protocols are expanded to support the integrity of our product, and marketing expenses increase, management believes approximately \$1.5 million in monthly revenue will be needed to reach break-even. This is a decrease from the previous estimate of \$2 million in monthly revenue due to recent improvements in the Company's production operating efficiencies and its cost structure implemented by new management. However, there is no assurance as to when break-even will occur. If we are unable to generate profits and unable to obtain additional financing to meet our working capital requirements, we may have to curtail our business.

We Rely Heavily On A Limited Number Of Suppliers. Some materials used in our products are currently available only from a limited number of suppliers. In fiscal 2008, approximately sixty-five percent (65%) of our cesium was supplied through either the Institute of Nuclear Materials (INM) or from the Russian Research Institute of Atomic Reactors (RIAR) both of which are located in Russia. Beginning in January 2008, we were unable to obtain any Cs-131 from INM and instead obtained all of our supply of Cs-131 in Russia from RIAR until August 2008, when RIAR was shut down for regularly scheduled maintenance and we resumed purchasing from INM. However, beginning in October 2008, we will obtain Cs-131 from both INM and RIAR. At current production levels the

Company cannot meet the minimum purchase requirements necessary to purchase the product at the reduced prices presently offered. Unless the Company substantially increases its purchase requirements resulting from significant increases in demand for its product, the cost of Cs-131 in Russia could significantly increase from current pricing. Management will seek to negotiate favorable pricing but there is no assurance as to the outcome of these negotiations.

Table of Contents

If the development of barium enrichment capabilities is successful, the Company plans to expand Cs-131 manufacturing capability at the MURR reactor in the United States. Reliance on any single supplier increases the risks associated with concentrating isotope production at a single reactor facility which are subject to unanticipated shutdowns. Failure to obtain deliveries of cesium from multiple sources could have a material adverse effect on seed production and there may be a delay before we could locate alternative suppliers beyond the three currently used.

We may not be able to locate additional suppliers outside of Russia capable of producing the level of output of cesium at the quality standards we require. Additional factors that could cause interruptions or delays in our source of materials include limitations on the availability of raw materials or manufacturing performance experienced by our suppliers and a breakdown in our commercial relations with one or more suppliers. Some of these factors may be completely out of our and our suppliers' control.

Virtually all titanium tubing used in brachytherapy seed manufacture comes from a single source, Accellent Corporation. We currently obtain a key component of our seed core from another single supplier. We do not have formal written agreements with Accellent Corporation. Any interruption or delay in the supply of materials required to produce our products could harm our business if we were unable to obtain an alternative supplier or substitute equivalent materials in a cost-effective and timely manner. To mitigate any potential interruptions, the Company continually evaluates its inventory levels and management believes that the Company maintains a sufficient quantity on hand to alleviate any potential disruptions.

Future Production Increases Will Depend on Our Ability to Acquire Larger Quantities of Cs-131 and Hire More Employees. IsoRay currently obtains Cs-131 through its contracts with INM and RIAR, and through reactor irradiation of natural barium and subsequent separation of cesium from the irradiated barium targets. The amount of Cs-131 that can be produced from a given reactor source is limited by the power level and volume available within the reactor for irradiating targets. This limitation can be overcome by utilizing barium feedstock that is enriched in the stable isotope Ba-130. However, the number of suppliers of enriched barium is limited and they may be unable to produce this material in sufficient quantities at a reasonable price.

IsoRay has entered into exclusive agreements with INM and RIAR in Russia to provide Cs-131 in quantities sufficient to supply a significant percentage of future demand for this isotope. Delivery of the isotope from INM began in January 2006 and delivery from RIAR began in January 2008. INM has unique capabilities due to its large irradiation capacity which will allow the Company to meet all of its Cs-131 demands without the use of enriched material for the foreseeable future. Due to the purchase of enriched barium in June 2007, IsoRay has access to sufficient quantities of enriched barium that may be recycled to increase the production of Cs-131. Although the agreements provide for supplying Cs-131 in significant quantities, there is no assurance that this will result in IsoRay gaining access to a continuing sufficient supply of enriched barium feedstock. If we were unable to obtain supplies of isotopes from Russia in the future, our overall supply of cesium and barium would be reduced significantly unless the Company has a source of enriched barium for utilization in domestic reactors.

We Are Subject To Uncertainties Regarding Reimbursement For Use Of Our Products. Hospitals and freestanding clinics may be less likely to purchase our products if they cannot be assured of receiving favorable reimbursement for treatments using our products from third-party payers, such as Medicare and private health insurance plans. Currently, Medicare reimburses hospitals, clinics and physicians for the cost of seeds used in brachytherapy procedures on a pass through basis, and will continue this method of reimbursement through December 31, 2009. Historically, private insurers have followed Medicare guidelines in establishing reimbursement rates. However, third-party payers are increasingly challenging the pricing of certain medical services or devices, and we cannot be sure that they will reimburse our customers at levels sufficient for us to maintain favorable sales and price levels for our products. There is no uniform policy on reimbursement among third-party payers, and we can provide no assurance that our products will continue to qualify for reimbursement from all third-party payers or that reimbursement rates will not be reduced.

A reduction in or elimination of third-party reimbursement for treatments using our products would likely have a material adverse effect on our revenues.

Table of Contents

In 2003, we applied to the Centers for Medicare and Medicaid Services (CMS) and received a reimbursement code for use of our Cs-131 seed. As of July 1, 2007, CMS revised the coding system for brachytherapy seeds and separated the single code into two codes – one code for loose seeds and a second code for stranded seeds. This methodology was applied to all companies manufacturing and distributing brachytherapy seeds. Reimbursement amounts are reviewed and revised annually. Adjustments could be made to these reimbursement amounts or policies, which could result in reduced reimbursement for brachytherapy services, which could negatively affect market demand for our products.

Furthermore, any federal and state efforts to reform government and private healthcare insurance programs could significantly affect the purchase of healthcare services and products in general and demand for our products in particular. Medicare is the payer in approximately 70% of all U.S. prostate brachytherapy cases and management anticipates this percentage to increase annually. We are unable to predict whether potential healthcare reforms will be enacted, whether other healthcare legislation or regulations affecting the business may be proposed or enacted in the future or what effect any such legislation or regulations would have on our business, financial condition or results of operations.

Our Operating Results Will Be Subject To Significant Fluctuations. Our quarterly revenues, expenses, and operating results are likely to fluctuate significantly in the future. Fluctuation may result from a variety of factors, which are discussed in detail throughout this “RISK FACTORS” section, including:

- § our achievement of product development objectives and milestones;
- § demand and pricing for the Company’s products;
- § effects of aggressive competitors;
- § hospital, clinic and physician buying decisions;
- § research and development and manufacturing expenses;
- § patient outcomes from our therapy;
- § physician acceptance of our products;
- § government or private healthcare reimbursement policies;
- § our manufacturing performance and capacity;
- § incidents, if any, that could cause temporary shutdown of our manufacturing facility;
- § the amount and timing of sales orders;
- § rate and success of future product approvals;
- § timing of FDA clearance, if any, of competitive products and the rate of market penetration of competing products;
- § seasonality of purchasing behavior in our market;
- § overall economic conditions; and
- § the successful introduction or market penetration of alternative therapies.

We Have Limited Data on the Clinical Performance of Cs-131. As of June 1, 2008, the Proxcelan Cs-131 seed has been implanted in over 2,800 patients and research papers are being published on the use of the Proxcelan seed. However, we have less statistical data than is available for I-125 and Pd-103 seeds. While this limited data may prevent us from drawing statistically significant conclusions, the side effects experienced by these patients were less severe than side effects observed in seed brachytherapy with I-125 and Pd-103 and in other forms of treatment such as radical prostatectomy. These early results indicate that the onset of side effects generally occurs between one and three weeks post-implant, and the side effects are resolved between five and eight weeks post-implant, side effects resolved more quickly than the side effects that occur with competing seeds or with other forms of treatment. These limited findings support management’s belief that the Cs-131 seed will result in less severe side effects than competing treatments, but we may have to gather data on outcomes from additional patients before we can establish statistically valid conclusions regarding the incidence of side effects from our seeds.

Table of Contents

We Are Subject To The Risk That Certain Third Parties May Mishandle Our Product. We rely on third parties, such as Federal Express, to deliver our Proxcelan Cs-131 seed, and on other third parties, including various radiopharmacies, to package our Proxcelan Cs-131 seed in certain specialized packaging forms requested by customers. We are subject to the risk that these third parties may mishandle our product, which could result in adverse effects, particularly given the radioactive nature of our product.

It Is Possible That Other Treatments May Be Deemed Superior To Brachytherapy. Our Proxcelan Cs-131 seed faces competition not only from companies that sell other radiation therapy products, but also from companies that are developing alternative therapies for the treatment of cancers. It is possible that advances in the pharmaceutical, biomedical, or gene therapy fields could render some or all radiation therapies, whether conventional or brachytherapy, obsolete. If alternative therapies are proven or even perceived to offer treatment options that are superior to brachytherapy, physician adoption of our product could be negatively affected and our revenues from our product could decline.

Our Industry Is Intensely Competitive. The medical device industry is intensely competitive. We compete with both public and private medical device, biotechnology and pharmaceutical companies that have been in existence longer than we have, have a greater number of products on the market, have greater financial and other resources, and have other technological or competitive advantages. In addition, centers that wish to offer the Proxcelan Cs-131 seed must comply with licensing requirements specific to the state in which they do business and these licensing requirements may take a considerable amount of time to comply with. Certain centers may choose to not offer our Proxcelan Cs-131 seed due to the time required to obtain necessary license amendments. We also compete with academic institutions, government agencies, and private research organizations in the development of technologies and processes and in acquiring key personnel. Although we have patents granted and patents applied for to protect our isotope separation processes and Cs-131 seed manufacturing technology, we cannot be certain that one or more of our competitors will not attempt to obtain patent protection that blocks or adversely affects our product development efforts. To minimize this potential, we have entered into exclusive agreements with key suppliers of isotopes and isotope precursors, which are subject to becoming non-exclusive as we have failed to meet minimum purchase requirements.

We May Be Unable To Adequately Protect Or Enforce Our Intellectual Property Rights Or Secure Rights To Third-Party Patents. Our ability and the abilities of our partners to obtain and maintain patent and other protection for our products will affect our success. We are assigned, have rights to, or have exclusive licenses to patents and patents pending in the U.S. and numerous foreign countries. The patent positions of medical device companies can be highly uncertain and involve complex legal and factual questions. Our patent rights may not be upheld in a court of law if challenged. Our patent rights may not provide competitive advantages for our products and may be challenged, infringed upon or circumvented by our competitors. We cannot patent our products in all countries or afford to litigate every potential violation worldwide.

Because of the large number of patent filings in the medical device and biotechnology field, our competitors may have filed applications or been issued patents and may obtain additional patents and proprietary rights relating to products or processes competitive with or similar to ours. We cannot be certain that U.S. or foreign patents do not exist or will not be issued that would harm our ability to commercialize our products and product candidates.

The Value Of Our Granted Patent, and Our Patents Pending, Is Uncertain. Although our management strongly believes that our patent on the process for producing Cs-131, our patent pending on the manufacture of the brachytherapy seed, our patent applications on additional methods for producing Cs-131 and other isotopes which have been filed, and anticipated future patent applications, which have not yet been filed, have significant value, we cannot be certain that other like-kind processes may not exist or be discovered, that any of these patents is enforceable, or that any of our patent applications will result in issued patents.

Table of Contents

Failure To Comply With Government Regulations Could Harm Our Business. As a medical device and medical isotope manufacturer, we are subject to extensive, complex, costly, and evolving governmental rules, regulations and restrictions administered by the FDA, by other federal and state agencies, and by governmental authorities in other countries. Compliance with these laws and regulations is expensive and time-consuming, and changes to or failure to comply with these laws and regulations, or adoption of new laws and regulations, could adversely affect our business.

In the United States, as a manufacturer of medical devices and devices utilizing radioactive by-product material, we are subject to extensive regulation by federal, state, and local governmental authorities, such as the FDA and the Washington State Department of Health, to ensure such devices are safe and effective. Regulations promulgated by the FDA under the U.S. Food, Drug and Cosmetic Act, or the FDC Act, govern the design, development, testing, manufacturing, packaging, labeling, distribution, marketing and sale, post-market surveillance, repairs, replacements, and recalls of medical devices. In Washington State, the Department of Health, by agreement with the federal Nuclear Regulatory Commission (NRC), regulates the possession, use, and disposal of radioactive byproduct material as well as the manufacture of radioactive sealed sources to ensure compliance with state and federal laws and regulations. Our Proxcelan Cs-131 brachytherapy seeds constitute both medical devices and radioactive sealed sources and are subject to these regulations.

Under the FDC Act, medical devices are classified into three different categories, over which the FDA applies increasing levels of regulation: Class I, Class II, and Class III. Our Proxcelan Cs-131 seed has been classified as a Class II device and has received clearance from the FDA through the 510(k) pre-market notification process. Any modifications to the device that would significantly affect safety or effectiveness, or constitute a major change in intended use, would require a new 510(k) submission. As with any submittal to the FDA, there is no assurance that a 510(k) clearance would be granted to the Company.

In addition to FDA-required market clearances and approvals for our products, our manufacturing operations are required to comply with the FDA's Quality System Regulation, or QSR, which addresses requirements for a company's quality program such as management responsibility, good manufacturing practices, product and process design controls, and quality controls used in manufacturing. Compliance with applicable regulatory requirements is monitored through periodic inspections by the FDA Office of Regulatory Affairs (ORA). We anticipate both announced and unannounced inspections by the FDA. Such inspections could result in non-compliance reports (Form 483) which, if not adequately responded to, could lead to enforcement actions. The FDA can institute a wide variety of enforcement actions, ranging from public warning letters to more severe sanctions such as fines, injunctions, civil penalties, recall of our products, operating restrictions, suspension of production, non-approval or withdrawal of pre-market clearances for new products or existing products, and criminal prosecution. There can be no assurance that we will not incur significant costs to comply with these regulations in the future or that the regulations will not have a material adverse effect on our business, financial condition and results of operations.

The marketing of our products in foreign countries will, in general, be regulated by foreign governmental agencies similar to the FDA. Foreign regulatory requirements vary from country to country. The time and cost required to obtain regulatory approvals could be longer than that required for FDA clearance in the United States and the requirements for licensing a product in another country may differ significantly from FDA requirements. We will rely, in part, on foreign distributors to assist us in complying with foreign regulatory requirements. We may not be able to obtain these approvals without incurring significant expenses or at all, and the failure to obtain these approvals would prevent us from selling our products in the applicable countries. This could limit our sales and growth.

Our Business Exposes Us To Product Liability Claims. Our design, testing, development, manufacture, and marketing of products involve an inherent risk of exposure to product liability claims and related adverse publicity. Insurance coverage is expensive and difficult to obtain, and, although we currently have a five million dollar policy, in the future we may be unable to obtain or renew coverage on acceptable terms, if at all. If we are unable to obtain or renew

sufficient insurance at an acceptable cost or if a successful product liability claim is made against us, whether fully covered by insurance or not, our business could be harmed.

Table of Contents

Our Business Involves Environmental Risks. Our business involves the controlled use of hazardous materials, chemicals, biologics, and radioactive compounds. Manufacturing is extremely susceptible to product loss due to radioactive, microbial, or viral contamination; material or equipment failure; vendor or operator error; or due to the very nature of the product's short half-life. Although we believe that our safety procedures for handling and disposing of such materials comply with state and federal standards there will always be the risk of accidental contamination or injury. In addition, radioactive, microbial, or viral contamination may cause the closure of the respective manufacturing facility for an extended period of time. By law, radioactive materials may only be disposed of at state-approved facilities. At our leased facility we use commercial disposal contractors. We may incur substantial costs related to the disposal of these materials. If we were to become liable for an accident, or if we were to suffer an extended facility shutdown, we could incur significant costs, damages, and penalties that could harm our business.

We Rely Upon Key Personnel. Our success will depend, to a great extent, upon the experience, abilities and continued services of our executive officers, sales staff and key scientific personnel. If we lose the services of several officers, sales personnel, or key scientific personnel, our business could be harmed. Our success also will depend upon our ability to attract and retain other highly qualified scientific, managerial, sales, and manufacturing personnel and their ability to develop and maintain relationships with key individuals in the industry. Competition for these personnel and relationships is intense and we compete with numerous pharmaceutical and biotechnology companies as well as with universities and non-profit research organizations. We may not be able to continue to attract and retain qualified personnel.

Our Ability To Operate In Foreign Markets Is Uncertain. Our future growth will depend in part on our ability to establish, grow and maintain product sales in foreign markets, particularly in Canada and Russia. However, we have limited experience in marketing and distributing products in other countries. Any foreign operations would subject us to additional risks and uncertainties, including our customers' ability to obtain reimbursement for procedures using our products in foreign markets; the burden of complying with complex and changing foreign regulatory requirements; speedy delivery requirements due to the short half-life of our product; language barriers and other difficulties in providing long-range customer service; potentially longer accounts receivable collection times; significant currency fluctuations, which could cause third-party distributors to reduce the number of products they purchase from us because the cost of our products to them could fluctuate relative to the price they can charge their customers; reduced protection of intellectual property rights in some foreign countries; and the possibility that contractual provisions governed by foreign laws would be interpreted differently than intended in the event of a contract dispute. Any future foreign sales of our products could also be adversely affected by export license requirements, the imposition of governmental controls, political and economic instability, trade restrictions, changes in tariffs, and difficulties in staffing and managing foreign operations. Many of these factors may also affect our ability to import Cs-131 from Russia under our contracts with INM and RIAR.

Our Ability To Expand Operations And Manage Growth Is Uncertain. Our efforts to expand our operations will result in new and increased responsibilities for management personnel and will place a strain upon the entire company. To compete effectively and to accommodate growth, if any, we may be required to continue to implement and to improve our management, manufacturing, sales and marketing, operating and financial systems, procedures and controls on a timely basis and to expand, train, motivate and manage our employees. There can be no assurance that our personnel, systems, procedures, and controls will be adequate to support our future operations. If the Proxcelan Cs-131 seed were to rapidly become the "seed of choice," it is unlikely that we could meet demand. We could experience significant cash flow difficulties and may have difficulty obtaining the working capital required to manufacture our products and meet demand. This would cause customer discontent and invite competition.

Table of Contents

Our Reporting Obligations As A Public Company Are Costly. Operating a public company involves substantial costs to comply with reporting obligations under federal securities laws that are continuing to increase as provisions of the Sarbanes Oxley Act of 2002 are implemented. As a smaller reporting company, the Company needs to implement additional provisions of the Sarbanes Oxley Act during fiscal year 2009. These reporting obligations will increase our operating costs.

Our Stock Price Is Likely To Be Volatile. There is generally significant volatility in the market prices and limited liquidity of securities of early stage companies, and particularly of early stage medical product companies. Contributing to this volatility are various events that can affect our stock price in a positive or negative manner. These events include, but are not limited to: governmental approvals of or refusals to approve regulations or actions; market acceptance and sales growth of our products; litigation involving the Company or our industry; developments or disputes concerning our patents or other proprietary rights; changes in the structure of healthcare payment systems; departure of key personnel; future sales of our securities; fluctuations in our financial results or those of companies that are perceived to be similar to us; swings in seasonal demands of purchasers; investors' general perception of us; and general economic, industry and market conditions. If any of these events occur, it could cause our stock price to fall.

Future Sales By Shareholders, Or The Perception That Such Sales May Occur, May Depress The Price Of Our Common Stock. The sale or availability for sale of substantial amounts of our shares in the public market, including shares issuable upon conversion of outstanding preferred stock or exercise of common stock warrants and options, or the perception that such sales could occur, could adversely affect the market price of our common stock and also could impair our ability to raise capital through future offerings of our shares. As of June 30, 2008, we had 22,942,088 outstanding shares of common stock, and the following additional shares were reserved for issuance: 2,803,393 shares upon exercise of outstanding options, 3,245,082 shares upon exercise of outstanding warrants, and 59,065 shares upon conversion of preferred stock. Any decline in the price of our common stock may encourage short sales, which could place further downward pressure on the price of our common stock and may impair our ability to raise additional capital through the sale of equity securities.

The Issuance Of Shares Upon Exercise Of Derivative Securities May Cause Immediate And Substantial Dilution To Our Existing Shareholders. The issuance of shares upon conversion of the preferred stock and the exercise of common stock warrants and options may result in substantial dilution to the interests of other shareholders since these selling shareholders may ultimately convert or exercise and sell all or a portion of the full amount issuable upon exercise. If all derivative securities were converted or exercised into shares of common stock, there would be approximately an additional 6,100,000 shares of common stock outstanding as a result. The issuance of these shares will have the effect of further diluting the proportionate equity interest and voting power of holders of our common stock.

We Do Not Expect To Pay Any Dividends For The Foreseeable Future. We do not anticipate paying any dividends to our shareholders for the foreseeable future. The terms of certain of our and our subsidiary's outstanding indebtedness substantially restrict the ability of either company to pay dividends. Accordingly, shareholders must be prepared to rely on sales of their common stock after price appreciation to earn an investment return, which may never occur. Any determination to pay dividends in the future will be made at the discretion of our Board of Directors and will depend on our results of operations, financial conditions, contractual restrictions, restrictions imposed by applicable laws and other factors our Board deems relevant.

Table of Contents

Certain Provisions of Minnesota Law and Our Charter Documents Have an Anti-Takeover Effect. There exist certain mechanisms under Minnesota law and our charter documents that may delay, defer or prevent a change of control. Anti-takeover provisions of our articles of incorporation, bylaws and Minnesota law could diminish the opportunity for shareholders to participate in acquisition proposals at a price above the then-current market price of our common stock. For example, while we have no present plans to issue any preferred stock, our Board of Directors, without further shareholder approval, may issue shares of undesignated preferred stock and fix the powers, preferences, rights and limitations of such class or series, which could adversely affect the voting power of the common shares. In addition, our bylaws provide for an advance notice procedure for nomination of candidates to our Board of Directors that could have the effect of delaying, deterring or preventing a change in control. Further, as a Minnesota corporation, we are subject to provisions of the Minnesota Business Corporation Act, or MBCA, regarding “business combinations,” which can deter attempted takeovers in certain situations. Pursuant to the terms of a shareholder rights plan adopted in February 2007, each outstanding share of common stock has one attached right. The rights will cause substantial dilution of the ownership of a person or group that attempts to acquire the Company on terms not approved by the Board of Directors and may have the effect of deterring hostile takeover attempts. The effect of these anti-takeover provisions may be to deter business combination transactions not approved by our Board of Directors, including acquisitions that may offer a premium over the market price to some or all shareholders. We may, in the future, consider adopting additional anti-takeover measures. The authority of our Board to issue undesignated preferred or other capital stock and the anti-takeover provisions of the MBCA, as well as other current and any future anti-takeover measures adopted by us, may, in certain circumstances, delay, deter or prevent takeover attempts and other changes in control of the Company not approved by our Board of Directors.

ITEM 1B – UNRESOLVED STAFF COMMENTS

None.

ITEM 2 – PROPERTIES

The Company’s executive offices are located at 350 Hills Street, Suite 106, Richland, WA 99354, (509) 375-1202, where IsoRay currently leases approximately 17,600 square feet of office and laboratory space for approximately \$24,200 per month plus monthly janitorial expenses of approximately \$600 from Energy Northwest, the owner of the Applied Process Engineering Laboratory (the APEL facility). The Company is not affiliated with this lessor. The monthly rent is subject to annual increases based on the Consumer Price Index. The current lease was entered into in May 2007, expires on April 30, 2010, and has two three-year renewal options.

The Company’s management believes that all facilities occupied by the Company are adequate for present requirements, and that the Company’s current equipment is in good condition and is suitable for the operations involved.

ITEM 3 – LEGAL PROCEEDINGS

The Company is not involved in any material legal proceedings as of the date of this Report.

ITEM 4 – SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matter was submitted to a vote of the Company’s security holders during the fourth quarter of the fiscal year covered by this Annual Report.

PART II

ITEM 5 – MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

The Company’s Articles of Incorporation provide that the Company has the authority to issue 200,000,000 shares of capital stock, which are currently divided into two classes as follows: 194,000,000 shares of common stock, par value of \$0.001 per share; and 6,000,000 shares of preferred stock, par value of \$0.001 per share. As of September 16, 2008, we had 22,942,088 outstanding shares of Common Stock and 59,065 outstanding shares of Preferred Stock.

Table of Contents

On April 19, 2007, our common stock began trading on the American Stock Exchange (AMEX) under the symbol "ISR." Prior to this our common stock was quoted on the OTC Bulletin Board and the Pink Sheets under the symbols "ISRY.OB" and "ISRY.PK," respectively. Even though we have obtained our AMEX listing, there is still limited trading activity in our securities.

The following table sets forth, for the fiscal quarters indicated, the high and low sales prices for our common stock as reported on the American Stock Exchange and the OTC Bulletin Board. The OTC Bulletin Board quotations are high and low last reported bid prices representing inter-dealer prices without retail mark-ups, mark-downs or commissions, and may not necessarily represent actual transactions. The quotations may be rounded for presentation. In the past, there was an absence of an established trading market for the Company's common stock, as the market was limited, sporadic and highly volatile, which may have affected the prices listed below.

Year ended June 30, 2008	High	Low
First quarter	\$ 5.20	\$ 3.44
Second quarter	3.51	1.85
Third quarter	2.27	1.00
Fourth quarter	1.00	0.55
Year ended June 30, 2007	High	Low
First quarter	\$ 3.50	\$ 2.75
Second quarter	6.00	3.00
Third quarter	4.90	3.80
Fourth quarter	5.18	3.51

The Company has never paid any cash dividends on its Common Stock and does not plan to pay any cash dividends in the foreseeable future. On February 1, 2007, the Board of Directors declared a dividend on the Series B Preferred Stock of all outstanding and cumulative dividends through December 31, 2006. There is no Series A Preferred Stock outstanding. The total Series B dividends of \$38,458 were paid on February 15, 2007. The Company does not plan on paying any cash dividends on the Series B Preferred Stock in the foreseeable future. There is no Series A Preferred Stock outstanding.

As of September 16, 2008, we had approximately 365 shareholders of record, exclusive of shares held in street name.

Equity Compensation Plans

On May 27, 2005, the Company adopted the 2005 Stock Option Plan (the Option Plan) and the 2005 Employee Stock Option Plan (the Employee Plan), pursuant to which it may grant equity awards to eligible persons. On August 15, 2006, the Company adopted the 2006 Director Stock Option Plan (the Director Plan) pursuant to which it may grant equity awards to eligible persons. Each of the Plans has subsequently been amended. The Option Plan allows the Board of Directors to grant options to purchase up to 1,800,000 shares of common stock to directors, officers, key employees and service providers of the Company, and the Employee Plan allows the Board of Directors to grant options to purchase up to 2,000,000 shares of common stock to officers and key employees of the Company. The Director Plan allows the Board of Directors to grant options to purchase up to 1,000,000 shares of common stock to directors of the Company. Options granted under all of the Plans have a ten year maximum term, an exercise price equal to at least the fair market value of the Company's common stock (based on the trading price on the American Stock Exchange or the OTC Bulletin Board) on the date of the grant, and with varying vesting periods as determined by the Board.

Table of Contents

As of June 30, 2008, the following options had been granted under the option plans.

Plan Category	Number of securities to be issued on exercise of outstanding options, warrants, and rights #	Weighted-average exercise price of outstanding options, warrants, and rights \$	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by shareholders	N/A	N/A	N/A
Equity compensation plans not approved by shareholders	2,803,393	\$ 2.62	1,129,824
Total	2,803,393	\$ 2.62	1,129,824

Issuer Purchases of Equity Securities

In June 2008, the Board of Directors of IsoRay authorized the repurchase of up to 1,000,000 shares of the Company's common stock (FY2009 Plan). The FY2009 Plan will expire on June 30, 2009. The table below shows the activity in the FY2009 Plan from inception to June 30, 2008.

Beginning	Period	Ending June 30, 2008	FY 2009 PLAN		Total Number of Shares Purchased as Part of Publicly Announced Plan	Maximum Number of Shares that May Yet be Purchased Under the Plan ⁽²⁾
			Total Number of Shares Purchased ⁽¹⁾	Average Price Paid per Share		
June 1, 2008			5,000	\$ 0.731	5,000	995,000
Total			5,000	\$ 0.731	5,000	995,000

(1) There were no shares purchased during fiscal year 2008 other than in June 2008.

(2) In June 2008, the Company announced a new stock repurchase plan to purchase up to 1,000,000 shares of the Company's common stock. The Plan will expire on June 30, 2009.

Sales of Unregistered Securities

All sales of unregistered securities were previously reported.

ITEM 6 – SELECTED FINANCIAL DATA

As a smaller reporting company, the Company is not required to provide Item 6 disclosure in this Annual Report.

ITEM 7 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Critical Accounting Policies and Estimates

Management's discussion and analysis of the Company's financial condition and results of operations is based upon its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent liabilities. On an on-going basis, management evaluates past judgments and estimates, including those related to bad debts, inventories, accrued liabilities, and contingencies. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Table of Contents

The Company believes the following critical accounting policies affect its more significant judgments and estimates used in the preparation of its consolidated financial statements.

Short-Term Investments

The Company invests certain excess cash in marketable securities consisting primarily of commercial paper, auction rate securities, and money market funds. The Company classifies all debt securities as “available-for-sale” and records the debt securities at fair value with unrealized gains and temporary unrealized losses included in other comprehensive income/loss within shareholders’ equity, if material. Declines in fair values that are considered other than temporary are recorded in the Consolidated Statements of Operations.

Accounts Receivable

Accounts receivable are stated at the amount that management of the Company expects to collect from outstanding balances. Management provides for probable uncollectible amounts through an allowance for doubtful accounts. Additions to the allowance for doubtful accounts are based on management’s judgment, considering historical write-offs, collections and current credit conditions. Balances which remain outstanding after management has used reasonable collection efforts are written off through a charge to the allowance for doubtful accounts and a credit to the applicable accounts receivable. Payments received subsequent to the time that an account is written off are considered bad debt recoveries.

Inventory

Inventory is reported at the lower of cost or market. Cost of raw materials is determined using the weighted average method. Cost of work in process and finished goods is computed using standard cost, which approximates actual cost, on a first-in, first-out basis. As the Company has operated at a gross loss throughout the past fiscal years, inventories have generally been recorded at market or net realizable value.

Fixed Assets

Fixed assets are capitalized and carried at the lower of cost or net realizable value. Normal maintenance and repairs are charged to expense as incurred. When assets are sold or otherwise disposed of, the cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized in operations.

Depreciation is computed using the straight-line method over the following estimated useful lives:

Production equipment	3 to 7 years
Office equipment	2 to 5 years
Furniture and fixtures	2 to 5 years

Leasehold improvements and capital lease assets are amortized over the shorter of the life of the lease or the estimated useful life of the asset.

The Company has adopted the provisions of Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. The provisions of SFAS No. 144 require that an impairment loss be recognized when the estimated future cash flows (undiscounted and without interest) expected to

result from the use of an asset are less than the carrying amount of the asset. Measurement of an impairment loss is based on the estimated fair value of the asset if the asset is expected to be held and used.

Table of Contents

Management of the Company periodically reviews the net carrying value of all of its equipment on an asset by asset basis. These reviews consider the net realizable value of each asset, as measured in accordance with the preceding paragraph, to determine whether an impairment in value has occurred, and the need for any asset impairment write-down.

Although management has made its best estimate of the factors that affect the carrying value based on current conditions, it is reasonably possible that changes could occur which could adversely affect management's estimate of net cash flows expected to be generated from its assets, and necessitate asset impairment write-downs.

Deferred Financing Costs

Financing costs related to the acquisition of debt are deferred and amortized over the term of the related debt using the effective interest method. Deferred financing costs include the fair value of common shares issued to certain shareholders for their guarantee of certain Company debt in accordance with Accounting Principles Board (APB) Opinion No. 21, *Interest on Receivables and Payables* and Emerging Issues Task Force (EITF) Issue No. 95-13, *Classification of Debt Issue Costs in the Statement of Cash Flows*. The value of the shares issued was the estimated market price of the shares as of the date of issuance. Amortization of deferred financing costs, totaling \$30,504 and \$178,633 for the years ended June 30, 2008 and 2007, respectively, is included in financing expense on the statements of operations.

Licenses

Amortization of licenses is computed using the straight-line method over the estimated economic useful lives of the assets. In fiscal year 2006, the Company entered into an agreement with IBt, SA, a Belgian company (IBt) to use IBt's proprietary "Ink Jet" production process and its proprietary polymer seed technology for use in brachytherapy procedures using Cesium-131 (Cs-131). The Company paid license fees of \$225,000 and \$275,000 during fiscal years 2008 and 2006, respectively, and is amortizing the license over the 15-year term of the license agreement.

In the fourth quarter of fiscal year 2008, the Company reviewed the carrying values of licenses. Although the Company has not currently integrated this technology into its products, management will reevaluate the potential of this technology during fiscal year 2009 after the Company has further improved its current processes. Therefore, the Company did not believe that any impairment had occurred to this intangible asset.

Amortization of licenses was \$43,452 and \$23,426 for the years ended June 30, 2008 and 2007, respectively. Based on the licenses recorded at June 30, 2008, and assuming no subsequent impairment of the underlying assets, the annual amortization expense for each fiscal year ending June 30 is expected to be as follows: \$47,670 for 2009, \$35,354 for 2010, \$35,208 for 2011, \$35,208 for 2012, \$35,208 for 2013, and \$266,998 thereafter.

Other Assets

Other assets, which include deferred charges and patents, are stated at cost, less accumulated amortization. Amortization of patents is computed using the straight-line method over the estimated economic useful lives of the assets. The Company periodically reviews the carrying values of patents and any impairments are recognized when the expected future operating cash flows to be derived from such assets are less than their carrying value.

Based on the patents and other intangible assets recorded in other assets at June 30, 2008, and assuming no subsequent impairment of the underlying assets, the annual amortization expense for each fiscal year ending June 30 is expected to be as follows: \$7,798 for 2009, \$4,353 for 2010, \$2,632 for 2011, \$2,632 for 2012, \$2,632 for 2013, and \$9,560 thereafter.

Table of ContentsAsset Retirement Obligation

SFAS No. 143, *Asset Retirement Obligations*, establishes standards for the recognition, measurement and disclosure of legal obligations associated with the costs to retire long-lived assets. Accordingly, under SFAS No. 143, the fair value of the future retirement costs of the Company's leased assets are recorded as a liability on a discounted basis when they are incurred and an equivalent amount is capitalized to property and equipment. The initial recorded obligation is discounted using the Company's credit-adjusted risk free-rate and is reviewed periodically for changes in the estimated future costs underlying the obligation. The Company amortizes the initial amount capitalized to property and equipment and recognizes accretion expense in connection with the discounted liability over the estimated remaining useful life of the leased assets.

In fiscal year 2006, the Company established an initial asset retirement obligation of \$63,040 which represented the discounted cost of cleanup that the Company anticipated it would have to incur at the end of its equipment and property leases in its old production facility. This amount was determined based on discussions with qualified production personnel and on historical evidence. During fiscal year 2007, the Company reevaluated its obligations based on discussions with the Washington Department of Health and determined that the initial asset retirement obligation should be increased by an additional \$56,120. During the second quarter of fiscal year 2008, the Company removed all radioactive residuals and tenant improvements from its old production facility and returned the facility to the lessor. The Company had an asset retirement obligation of \$135,120 accrued for this facility but total costs incurred to decommission the facility were \$274,163 resulting in an additional expense of \$139,043 that is included in cost of products sold. The additional expense was mainly due to unanticipated construction costs to return the facility to its previous state. The Company originally believed that the lessor would retain many of the leasehold improvements in the building, but the lessor instead required their removal.

In September 2007, another asset retirement obligation of \$473,096 was established representing the discounted cost of the Company's estimate of the obligations to remove any residual radioactive materials and all leasehold improvements at the end of the lease term at its new production facility. The estimate was developed by qualified production personnel and the general contractor of the new facility. The Company has reviewed the estimate again based on its experience with decommissioning its old facility and believes that the original estimate continues to be applicable.

During the years ended June 30, 2008 and 2007, the asset retirement obligation changed as follows:

	2008	2007
Beginning balance	\$ 131,142	\$ 67,425
New obligations	473,096	-
Settlement of existing obligation	(135,120)	-
Changes in estimates of existing obligations	-	56,120
Accretion of discount	36,887	7,597
Ending balance	\$ 506,005	\$ 131,142

Because the Company does not expect to incur any expenses related to its asset retirement obligations in fiscal year 2009, the entire balance as of June 30, 2008 is classified as a noncurrent liability.

Financial Instruments

The Company discloses the fair value of financial instruments, both assets and liabilities, recognized and not recognized in the balance sheet, for which it is practicable to estimate the fair value. The fair value of a financial

instrument is the amount at which the instrument could be exchanged in a current transaction between willing parties, other than a forced liquidation sale.

Table of Contents

The carrying amounts of financial instruments, including cash and cash equivalents, short-term investments, accounts receivable, accounts payable, notes payable, and capital lease obligations, approximated their fair values at June 30, 2008 and 2007.

Revenue Recognition

The Company applies the provisions of SEC Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition*. SAB No. 104, which supersedes SAB No. 101, *Revenue Recognition in Financial Statements*, provides guidance on the recognition, presentation and disclosure of revenue in financial statements. SAB No. 104 outlines the basic criteria that must be met to recognize revenue and provides guidance for the disclosure of revenue recognition policies. The Company recognizes revenue related to product sales when (i) persuasive evidence of an arrangement exists, (ii) shipment has occurred, (iii) the fee is fixed or determinable, and (iv) collectability is reasonably assured.

Revenue for the fiscal years ended June 30, 2008 and 2007 was derived solely from sales of the Proxcelan Cs-131 brachytherapy seed, which is used in the treatment of cancer. The Company recognizes revenue once the product has been shipped to the customer. Prepayments, if any, received from customers prior to the time that products are shipped are recorded as deferred revenue. In these cases, when the related products are shipped, the amount recorded as deferred revenue is recognized as revenue. The Company accrues for sales returns and other allowances at the time of shipment. Although the Company does not have an extensive operating history upon which to develop sales returns estimates, we have used the expertise of our management team, particularly those with extensive industry experience and knowledge, to develop a proper methodology.

Stock-Based Compensation

The Company measures and recognizes expense for all share-based payments at fair value in accordance with SFAS No. 123 (Revised 2004), *Share-Based Payment* (SFAS No. 123R). The Company uses the Black-Scholes option valuation model to estimate fair value for all stock options on the date of grant. For stock options that vest over time, the Company recognizes compensation cost on a straight-line basis over the requisite service period for the entire award.

Research and Development Costs

Research and development costs, including salaries, research materials, administrative expenses and contractor fees, are charged to operations as incurred. The cost of equipment used in research and development activities which has alternative uses is capitalized as part of fixed assets and not treated as an expense in the period acquired. Depreciation of capitalized equipment used to perform research and development is classified as research and development expense in the year recognized.

Legal Contingencies

In the ordinary course of business, the Company is involved in legal proceedings involving contractual and employment relationships, product liability claims, patent rights, environmental matters, and a variety of other matters. The Company is also subject to various local, state, and federal environmental regulations and laws due to the isotopes used to produce the Company's product. As part of normal operations, amounts are expended to ensure that the Company is in compliance with these laws and regulations. While there have been no reportable incidents or compliance issues, the Company believes that if it relocates its current production facilities then certain decommissioning expenses will be incurred and has recorded an asset retirement obligation for these expenses.

Table of Contents

The Company records contingent liabilities resulting from asserted and unasserted claims against it, when it is probable that a liability has been incurred and the amount of the loss is reasonably estimable. Estimating probable losses requires analysis of multiple factors, in some cases including judgments about the potential actions of third-party claimants and courts. Therefore, actual losses in any future period are inherently uncertain. Currently, the Company does not believe any probable legal proceedings or claims will have a material adverse effect on its financial position or results of operations. However, if actual or estimated probable future losses exceed the Company's recorded liability for such claims, it would record additional charges as other expense during the period in which the actual loss or change in estimate occurred.

Income Taxes

Income taxes are accounted for under the liability method. Under this method, the Company provides deferred income taxes for temporary differences that will result in taxable or deductible amounts in future years based on the reporting of certain costs in different periods for financial statement and income tax purposes. This method also requires the recognition of future tax benefits such as net operating loss carryforwards, to the extent that realization of such benefits is more likely than not. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment of the change.

On July 1, 2007, the Company adopted Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN No. 48). FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in accordance with SFAS No. 109, *Accounting for Income Taxes*, prescribing a recognition threshold and measurement attribute for the recognition and measurement of a tax position taken or expected to be taken in a tax return. In the course of its assessment, management has determined that the Company, its subsidiary, and its predecessors are subject to examination of their income tax filings in the United States and state jurisdictions for the 2005 through 2007 tax years. In the event that the Company is assessed penalties and or interest, penalties will be charged to other operating expense and interest will be charged to interest expense.

The Company adopted FIN No. 48 using the modified prospective transition method, which requires the application of the accounting standard as of July 1, 2007. There was no impact on the financial statements as of and for the year ended June 30, 2008 as a result of the adoption of FIN No. 48. In accordance with the modified prospective transition method, the financial statements for prior periods have not been restated to reflect, and do not include, the impact of FIN No. 48.

Income (Loss) Per Common Share

The Company accounts for its income (loss) per common share according to SFAS No. 128, *Earnings Per Share*. Basic earnings per share is calculated by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding, and does not include the impact of any potentially dilutive common stock equivalents. Common stock equivalents, including warrants and options to purchase the Company's common stock, are excluded from the calculations when their effect is antidilutive. At June 30, 2008 and 2007, the calculation of diluted weighted average shares does not include preferred stock, common stock warrants or options that are potentially convertible into common stock as those would be antidilutive due to the Company's net loss position.

Securities that could be dilutive in the future as of June 30, 2008 and 2007 are as follows:

	2008	2007
Preferred stock	59,065	59,065

Edgar Filing: IsoRay, Inc. - Form 10-K

Common stock warrants	3,245,082	3,627,764
Common stock options	2,803,393	3,683,439
Total potential dilutive securities	6,107,540	7,370,268

Table of Contents

Use of Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management of the Company to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Accordingly, actual results could differ from those estimates and affect the amounts reported in the financial statements.

Results of Operations

Financial Presentation

The following sets forth a discussion and analysis of the Company's financial condition and results of operations for the two years ended June 30, 2008 and 2007. This discussion and analysis should be read in conjunction with our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. The following discussion contains forward-looking statements. Our actual results may differ significantly from the results discussed in such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in "Item 1A — Risk Factors," beginning on page 21 of this Annual Report on Form 10-K.

Year ended June 30, 2008 compared to year ended June 30, 2007

Product sales. Sales for the year ended June 30, 2008 were \$7,158,690 compared to sales of \$5,738,033 for the year ended June 30, 2007. The increase of \$1,420,657 or 25% was due to increased sales volume of the Company's Proxcelan Cs-131 brachytherapy seeds. During the year ended June 30, 2008 the Company sold its Cs-131 seeds to 99 different medical centers as compared to 79 centers during the fiscal year ended June 30, 2007.

Cost of product sales. Cost of product sales were \$7,310,124 for the year ended June 30, 2008 which represents an increase of \$1,517,494 or 26% compared to cost of product sales of \$5,792,630 for the year ended June 30, 2007. The major components of the increase were depreciation, materials, preload expenses, occupancy costs, and expenses related to the transition to the Company's new production facility and decommissioning the Company's old production facility. These increases were partially offset by decreases in consulting and shipping expenses.

Depreciation increased approximately \$613,000 due to moving operations into a new production facility and purchasing new production equipment. This new production facility allowed the Company to increase its available capacity by approximately 300% using its current production techniques and should fulfill the Company's production needs for the near future. The cost of materials increased approximately \$313,000 mainly due to higher sales volumes. Preload expenses increased approximately \$250,000 due to higher sales volumes and due to the start-up costs of the Company's internal preload facility. Occupancy costs increased approximately \$164,000 as the Company entered into a lease for a new production facility in March 2007 and continued to pay rent on its old production facility through mid-December 2007. The Company also recorded an impairment charge of \$85,000 in fiscal year 2008 for a hot cell that is not currently in use.

The Company also experienced increases in cost of product sales expenditures directly related to the new facility that was opened in September 2007. To ensure a smooth transition with no missed order shipments, the Company ordered an additional \$38,000 of isotope in September 2007 that was not utilized as the removal and transportation of the isotope from the old facility to the new facility presented logistical challenges that made it cost prohibitive. As part of opening the new facility, the Company incurred approximately \$20,000 of wages and related taxes for personnel to perform equipment set-up and validation. The Company also expensed approximately \$82,000 of production materials and small tools for the new facility, none of which individually exceeded the \$2,500 threshold the Company uses in determining whether to capitalize production equipment.

Table of Contents

The Company removed all radioactive residuals and tenant improvements from its old production facility and returned the facility to the lessor. The Company had an asset retirement obligation of \$135,120 accrued for this facility but total costs incurred to decommission the facility were \$274,163 resulting in an additional expense of \$139,043 that is included in cost of products sold. The additional expense was mainly due to unanticipated construction costs to return the facility to its previous state. The Company originally believed that the lessor would retain many of the leasehold improvements in the building, but instead required their removal.

These increases were partially offset by a decrease of approximately \$75,000 in consulting expenses as the previous year included costs related to medical physics and equipment design and approximately \$72,000 in shipping and freight as the Company eliminated certain shipping services.

Gross loss. Gross loss was \$151,434 for the year ended June 30, 2008. This represents an increase of \$96,837 or 177% over the prior year's gross loss of \$54,597. The increase is due to the increase in production costs more than offsetting the increase in revenues. However, the Company has worked to reduce its production costs over the past six months and is producing its Proxcelan Cs-131 brachytherapy seeds more efficiently now.

Research and development expenses. Research and development expenses for the year ended June 30, 2008 were \$1,358,075 which represents an increase of \$12,912 or 1% over the research and development expenses of \$1,345,163 for the year ended June 30, 2007. Although the overall research and development expenses were consistent with the prior year, consulting expenses increased approximately \$189,000 due to the Company's ongoing project to increase the efficiency of isotope production and travel expenses increased approximately \$25,000 due to work in Russia regarding isotope efficiencies. These increases were offset by a decrease of approximately \$205,000 in legal expenses as the Company continues to focus on its key patents and trademarks in strategic countries and deemphasized the protection of patents and trademarks in less strategic countries.

Sales and marketing expenses. Sales and marketing expenses were \$3,725,164 for the year ended June 30, 2008. This represents an increase of \$340,692 or 10% compared to the year ended June 30, 2007 sales and marketing expenses of \$3,384,472. The change is mainly due to increased personnel costs and consulting expenses partially offset by a decrease in conventions and tradeshow. Personnel costs increased approximately \$333,000 due to higher commissions paid on increased revenues and an increase in the average headcount. Consulting expenses increased approximately \$103,000 mainly due to payments to consultants to develop technical publications and other materials, to represent the Company at professional society meetings, to serve as members of the Company's Cesium Advisory Group, and increased expenses for a lobbying group. Conventions and tradeshow decreased approximately \$130,000 as the Company has reduced its budgets for many of the tradeshow, particularly the smaller tradeshow.

General and administrative expenses. General and administrative expenses for the year ended June 30, 2008 were \$3,568,048 compared to general and administrative expenses of \$4,915,598 for the year ended June 30, 2007. The decrease of \$1,347,550 or 27% is primarily due to a decrease in share-based compensation, personnel costs, and travel. These decreases were partially offset by an increase in legal expenses. Share-based compensation decreased approximately \$1.2 million due to reduced option awards in fiscal year 2008 and the reversal of expense for unvested and forfeited options for Roger Girard, the former CEO. Personnel costs decreased approximately \$115,000 mainly due to the resignation of Mr. Girard in February 2008. Travel decreased approximately \$104,000. Legal expenses increased approximately \$159,000 due to costs to draft contracts regarding the Company's interest in UralDial, LLC, a new Russian entity, the IBT strategic global alliance agreements, and mediation costs related to negotiations to settle a dispute with the Lawrence Family Trust.

Table of Contents

Operating loss. The Company continues to focus its resources on marketing and sales and retaining the administrative infrastructure to increase the level of demand for the Company's product. These costs, coupled with product revenues not covering production costs, and significant research and development expenditures, have resulted in operating losses since its inception. For the year ended June 30, 2008, the Company had an operating loss of \$8,802,721 which is a decrease of \$897,109 or 9% below the operating loss of \$9,699,830 for the year ended June 30, 2007.

Interest and investment income. Interest and investment income was \$612,077 for the year ended June 30, 2008 compared to interest income of \$406,921 for the year ended June 30, 2007. Interest and investment income is mainly derived from excess funds held in money market and investment accounts. The increase of \$205,156 or 50% was due to the higher average cash and short-term investment balances during the year ended June 30, 2008 partially offset by decreasing interest rates.

Loss on short-term investments. The loss of \$274,000 for the year ended June 30, 2008 is due to the recent uncertainties in the credit markets particularly for certain auction rate securities held by the Company. The loss represents the amount to write-down these securities to their estimated fair market value. The Company has recognized these losses as other than temporary and recorded them in the statement of operations rather than in other comprehensive income as the Company may need access to these funds before the uncertainties in the credit markets are fully resolved.

Financing expense. Financing expense for the year ended June 30, 2008 was \$92,863 or a decrease of \$219,383 or 70% compared to financing expense of \$312,246 for the year ended June 30, 2007. Included in financing expense is interest expense of approximately \$62,000 and \$134,000 for the years ended June 30, 2008 and 2007, respectively. The decrease is due to the lower average debt balances in the year ended June 30, 2008. The remaining balance of financing expense represents the amortization of deferred financing costs which decreased due to the write-off in fiscal year 2007 of the deferred financing costs relating to the Columbia River Bank line of credit.

Liquidity and capital resources. We have historically financed our operations through the sale of common stock and related warrants. During fiscal year 2008, the Company's primary source of cash was the exercise of common stock warrants and options for \$1,022,813 and the Company used existing cash reserves to fund its operations and capital expenditures.

Cash flows from operating activities

Cash used in operating activities was \$7.7 million in fiscal year 2008 compared to \$7.2 million in fiscal year 2007, an increase of approximately \$500,000. Cash used by operating activities is net loss adjusted for non-cash items and changes in operating assets and liabilities.

Cash flows from investing activities

In 2008, the Company invested its excess cash generated from shareholder investments. During 2008, the Company purchased approximately \$13.3 million of various short-term investments (mainly commercial paper and municipal auction rate securities) and sold approximately \$19.4 million of short-term investments. As of June 30, 2008, short-term investments held by the Company amounted to approximately \$3.7 million.

Table of Contents

Cash expenditures for fixed assets were approximately \$3.1 million in fiscal 2008 and approximately \$2.4 million in fiscal 2007. The increase is mainly due to construction to complete our new production facility and equipment purchases for the new facility.

Cash flows from financing activities

The Company issued 300,876 shares of common stock pursuant to the exercise of common stock options and warrants. The Company received \$1,022,813 in cash pursuant to these exercises.

Projected 2009 Liquidity and Capital Resources

At June 30, 2008, cash and cash equivalents amounted to \$4,820,033 and short-term investments amounted to \$3,726,000 compared to \$9,335,730 of cash and cash equivalents and \$9,942,840 of short-term investments at June 30, 2007.

The Company had approximately \$4.0 million of cash and \$3.7 million of short-term investments as of September 16, 2008. As of that date management believed that the Company's monthly required cash operating expenditures were approximately \$400,000. Management believes that approximately \$200,000 to \$500,000 will be spent on capital expenditures during fiscal year 2009, but there is no assurance that unanticipated needs for capital equipment may not arise.

If the Company is able to complete its major research and development project to develop a proprietary separation process to manufacture enriched barium, this process should improve isotope production efficiency during fiscal year 2009. Regardless of whether the Company is ultimately successful in developing this process, the remaining project costs are anticipated to be approximately \$150,000.

During fiscal year 2009, the Company intends to continue its existing protocol studies and is currently budgeting approximately \$278,000 for protocol expense in fiscal year 2009.

Assuming operating costs expand proportionately with revenue increases, other applications are pursued for seed usage outside the prostate market, protocols are continued supporting the integrity of our product and sales and marketing expenses remain steady, management believes the Company will reach breakeven with revenues of approximately \$1.5 million per month. This is a decrease from the previous estimate of \$2 million in monthly revenue based on actions taken by new management that have over the past six months begun to improve the Company's production operating efficiencies and its cost structure.

Based on the foregoing assumptions, management believes cash, cash equivalents, and short-term investments on hand at June 30, 2008 will be sufficient to meet our anticipated cash requirements for operations, debt service, and capital expenditure requirements through at least the next twelve months. Management's plans to attain breakeven and generate additional cash flows include increasing revenues from both new and existing customers and maintaining cost control. However, there can be no assurance that the Company will attain profitability or that the Company will be able to attain its aggressive revenue targets. If we do not experience the necessary increases in sales or if we experience unforeseen manufacturing constraints, we may need to obtain additional funding.

The Company expects to finance its future cash needs through the sale of equity securities and possibly strategic collaborations or debt financing or through other sources that may be dilutive to existing shareholders. If the Company needs to raise additional money to fund its operations, funding may not be available to it on acceptable terms, or at all. If the Company is unable to raise additional funds when needed, it may not be able to market its products as planned or continue development and regulatory approval of its future products. If the Company raises additional funds

through equity sales, these sales may be dilutive to existing investors.

Table of Contents*Long-Term Debt and Capital Lease Agreements*

The Company has two loan facilities in place as of June 30, 2008. The first loan is from the Benton-Franklin Economic Development District (BFEDD) in an original principal amount of \$230,000 and was funded in December 2004. It bears interest at eight percent and has a 60-month term with a final balloon payment. As of June 30, 2008, the principal balance owed was \$145,745. This loan is secured by certain equipment, materials and inventory of IsoRay, and also required personal guarantees, for which the guarantors were issued approximately 70,455 shares of common stock. The second loan is from the Hanford Area Economic Investment Fund Committee (HAEIFC) and was originated in June 2006. The loan originally had a total facility of \$1,400,000 which was reduced in September 2007 to the amount of the Company's initial draw of \$418,670. The principal balance owed on the loan as of June 30, 2008 was \$263,639. This loan is secured by receivables, equipment, materials and inventory, and certain life insurance policies and also required personal guarantees.

The BFEDD has granted the Company a waiver from enforcing violations of paying officers in excess of \$100,000 per year and maintaining a certain current asset ratio. The waiver is effective through June 30, 2009 and also waives non-compliance with covenants prohibiting fixed asset or lease obligations in excess of \$24,000 per year, covenants prohibiting mergers, and covenants requiring maintenance of a certain long-term debt to equity ratio.

HAEIFC has also granted the Company a waiver from enforcing a fixed charge coverage ratio. The waiver is effective through June 30, 2009.

The Company has certain capital leases for production equipment that expire at various times from September 2008 to April 2009. These leases currently call for total monthly payments of \$3,876. The total of all capital lease obligations at June 30, 2008 was \$25,560.

Principal maturities on notes payable as of June 30, 2008 are due as follows:

Year ending June 30,	
2009	\$ 64,486
2010	168,008
2011	49,736
2012	54,379
2013	59,503
Thereafter	13,272
	\$ 409,384

Future minimum lease payments under capital lease obligations are as follows:

Year ending June 30, 2009	\$ 27,627
Total future minimum lease payments	27,627
Less amounts representing interest	(2,067)
Present value of net minimum lease payments	25,560
Less amounts due in one year	(25,560)

Amounts due after one year \$ –

40

Table of Contents*Other Commitments and Contingencies*

On May 2, 2007, Medical entered into a lease for its new production facility with Energy Northwest, the owner of the Applied Process Engineering Laboratory (the APEL lease). The APEL lease has a three-year term expiring on April 30, 2010, an option to renew for two additional three-year terms, and original monthly rent of approximately \$26,700, subject to annual increases based on the Consumer Price Index, plus monthly janitorial expenses of approximately \$700. This new facility became operational in September 2007.

Future minimum lease payments under operating leases, including the two three-year renewals of the APEL lease, are as follows:

Year ending June 30,	
2009	\$ 315,027
2010	314,884
2011	310,782
2012	299,540
2013	297,015
Thereafter	841,541
	\$ 2,378,789

On October 12, 2007, the Company entered into Amendment No. 1 (the Amendment) to its License Agreement dated February 2, 2006 with IBt. The original License Agreement provided the Company with access to IBt's proprietary polymer based seed encapsulation technology for use in brachytherapy procedures using Cesium-131 in the United States for a fifteen year term. A payment of \$225,000 was made on October 12, 2007 pursuant to the Amendment. As the parties agreed that the ink jet technology was not viable for Cesium-131 seeds, the Amendment eliminated the previously required royalty payments based on net sales revenue, and the parties intend to negotiate terms for future payments by the Company for polymer seed components to be purchased from IBt at IBt's cost plus a to-be-determined profit percentage. No agreement has been reached on these terms and there is no assurance that the parties will consummate an agreement pursuant to such terms.

The Company is subject to various local, state, and federal environmental regulations and laws due to the isotopes used to produce the Company's product. As part of normal operations, amounts are expended to ensure that the Company is in compliance with these laws and regulations. While there have been no reportable incidents or compliance issues, the Company believes that if it relocates its current production facilities then certain decommissioning expenses will be incurred. An asset retirement obligation was established in the first quarter of fiscal year 2008 for the Company's obligations at its new production facility. This asset retirement obligation will be for obligations to remove any residual radioactive materials and to remove all leasehold improvements.

The industry that the Company operates in is subject to product liability litigation. Through its production and quality assurance procedures, the Company works to mitigate the risk of any lawsuits concerning its product. The Company also carries product liability insurance to help protect it from this risk.

The Company has no off-balance sheet arrangements.

Inflation

Management does not believe that the current levels of inflation in the United States have had a significant impact on the operations of the Company. If current levels of inflation hold steady, management does not believe future

operations will be negatively impacted.

41

Table of Contents

New Accounting Standards

In December 2007, FASB issued SFAS No. 141(R), *Business Combinations* (“SFAS 141R”), which replaces SFAS No. 141, *Business Combinations* (“SFAS 141”). SFAS 141R applies to all transactions and other events in which one entity obtains control over one or more other businesses. The standard requires the fair value of the purchase price, including the issuance of equity securities, to be determined on the acquisition date. SFAS 141R requires an acquirer to recognize the assets acquired, the liabilities assumed, and any noncontrolling interests in the acquiree at the acquisition date, measured at their fair values as of that date, with limited exceptions specified in the statement. SFAS 141R requires acquisition costs to be expensed as incurred and restructuring costs to be expensed in periods after the acquisition date. Earn-outs and other forms of contingent consideration are to be recorded at fair value on the acquisition date. Changes in accounting for deferred tax asset valuation allowances and acquired income tax uncertainties after the measurement period will be recognized in earnings rather than as an adjustment to the cost of the acquisition. SFAS 141R generally applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008 with early adoption prohibited. The implementation of this standard did not have a material impact on the Company’s consolidated financial position or results of operations.

In December 2007, the FASB issued statement No. 160, *Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB No. 51* (SFAS 160). The statement requires noncontrolling interests or minority interests to be treated as a separate component of equity, not as a liability or other item outside of permanent equity. Upon a loss of control, the interest sold, as well as any interest retained, is required to be measured at fair value, with any gain or loss recognized in earnings. Based on SFAS 160, assets and liabilities will not change for subsequent purchase of sales transactions with noncontrolling interests as long as control is maintained. Differences between the fair value of consideration paid or received and the carrying value of noncontrolling interests are to be recognized as an adjustment to the parent interest’s equity. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008 and earlier adoption is prohibited. The Company is currently evaluating the impact that the implementation of SFAS 160 will have with respect to the Company’s interest in UralDial.

In February 2007, the FASB issued statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* (SFAS 159). The statement allows entities to value financial instruments and certain other items at fair value. The statement provides guidance over the election of the fair value option, including the timing of the election and specific items eligible for the fair value accounting. Changes in fair values would be recorded in earnings. The statement is effective for fiscal years beginning after November 15, 2007. The Company does not believe the adoption of SFAS 159 will have a material effect on its consolidated financial statements.

In September 2006, the FASB issued statement No. 157, *Fair Value Measurements*, (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007, with earlier application encouraged. Any amounts recognized upon adoption as a cumulative effect adjustment will be recorded to the opening balance of retained earnings in the year of adoption. The Company does not believe the adoption of SFAS 157 will have a material effect on its consolidated financial statements.

ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, the Company is not required to provide Item 7A disclosure in this Annual Report.

ITEM 8 – FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The required accompanying financial statements begin on page F-1 of this document.

ITEM 9 – CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

There were no disagreements or reportable events with DeCoria, Maichel & Teague, P.S.

42

Table of Contents

ITEM 9A – CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined under Rules 13a-14(c) and 15d-14(c) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of June 30, 2008. Based on that evaluation, our principal executive officer and our principal financial officer concluded that the design and operation of our disclosure controls and procedures were effective in timely alerting them to material information required to be included in the Company's periodic reports filed with the SEC under the Exchange Act. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote. However, management believes that our system of disclosure controls and procedures is designed to provide a reasonable level of assurance that the objectives of the system will be met.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control – Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of June 30, 2008.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

Changes in Internal Control over Financial Reporting

There have not been any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

Our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls and internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management or board override of the control.

Table of Contents

The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

ITEM 9B – OTHER INFORMATION

There were no items required to be disclosed in a report on Form 8-K during the fourth quarter of the fiscal year ended June 30, 2008 that have not been already disclosed on a Form 8-K filed with the SEC.

PART III

ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Each member of the Board of Directors serves a one-year term and is subject to reelection at the Company's Annual Meeting of Shareholders held each year.

Board Committees

The Board has established an Audit Committee consisting of Thomas LaVoy (Chairman), Robert Kauffman, and Albert Smith; a Compensation Committee consisting of Albert Smith (Chairman) and Robert Kauffman; and a Nominating Committee consisting of Robert Kauffman (Chairman), Thomas LaVoy, and Albert Smith. No other committees have been formed.

Audit Committee

The Audit Committee was established on December 8, 2006, the date on which its Charter was adopted. The Audit Committee Charter lists the purposes of the Audit Committee as overseeing the accounting and financial reporting processes of the Company and audits of the financial statements of the Company and providing assistance to the Board of Directors in monitoring (1) the integrity of the Company's financial statements, (2) the Company's compliance with legal and regulatory requirements, (3) the independent auditor's qualifications and independence, and (4) the performance of the Company's internal audit function, if any, and independent auditor.

The Board of Directors has determined that Mr. LaVoy and Mr. Kauffman are each an "audit committee financial expert" as defined in Item 407(d)(5) of Regulation S-K promulgated by the Securities and Exchange Commission, and each Audit Committee member is independent. The Board's conclusions regarding the qualifications of Mr. LaVoy as an audit committee financial expert were based on his service as a chief financial officer of a public company, his experience as a certified public accountant and his degree in accounting. The Board's conclusions regarding the qualifications of Mr. Kauffman as an audit committee financial expert were based on his service as a chief executive officer of multiple public companies, his active supervision of the principal financial and accounting officers of the public companies for which he served as chief executive officer, and his M.B.A. in Finance.

Executive Officers and Directors

The executive officers and directors serving the Company as of June 30, 2008 were as follows:

Name	Age	Position Held	Term*
------	-----	---------------	-------

Edgar Filing: IsoRay, Inc. - Form 10-K

D w i g h t Babcock	60	Chairman, Interim Chief Executive Officer	Annual
Jonathan Hunt	41	Chief Financial Officer, Treasurer	
Lori Woods	46	Acting Chief Operating Officer	
R o b e r t Kauffman	67	Vice-Chairman	Annual
T h o m a s LaVoy	48	Director	Annual
Albert Smith	64	Director	Annual

* For directors only

Table of Contents

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

Jonathan Hunt – Mr. Hunt has over 15 years of finance and accounting experience, including financial reporting, SEC knowledge, and operational analysis. Before joining IsoRay in 2006, he was employed by Hypercom Corporation, a global provider of electronic payment solutions and manufacturer of credit card terminals, serving as its Assistant Corporate Controller from 2005 to 2006. His finance background also includes serving as both a Manager and Director of Financial Reporting and a Director of Operational Planning and Analysis for Circle K Corporation and its affiliates from 2000 to 2005 and working for PricewaterhouseCoopers LLP from 1992 to 1999 where his last position held was Business Assurance Manager. Mr. Hunt holds Masters of Accountancy and Bachelor of Science degrees from Brigham Young University and is a Certified Public Accountant.

Lori Woods – Ms. Woods joined the Company in July 2006 and was appointed Acting Chief Operating Officer on February 26, 2008. Ms. Woods has over 20 years experience in medical device technology and healthcare services. Ms. Woods served as the CEO of Pro-Qura, a medical services company focusing on brachytherapy quality assurance and education, from 2002 until joining the Company. During her tenure at Pro-Qura, Ms. Woods developed its business strategy, expanded its business portfolio in quality assurance beyond prostate brachytherapy into other areas of cancer, and increased funding by 50%. Prior to this, she served as the Vice President of Sales at ATI Medical in 2002, Vice President of Sales – West and Vice President of Marketing and Business Development for Imagyn Medical Technologies from 2000 to 2002, Director of Business Development for Seattle Prostate Institute from 1998 to 2000, and Regional Vice President and Regional Manager of Interdent from 1994 to 1998. Ms. Woods holds a Bachelor of Science degree in Business Administration – Marketing from Loma Linda University.

Robert Kauffman – Mr. Kauffman has been a Director of the Company since 2005 and was appointed Vice-Chairman of the Company on February 26, 2008. Mr. Kauffman has served as Chief Executive Officer and Chairman of the Board of Alanco Technologies, Inc. (NASDAQ: ALAN), an Arizona-based information technology company, since July 1, 1998. Mr. Kauffman was formerly President and Chief Executive Officer of NASDAQ-listed Photocomm, Inc., from 1988 until 1997 (since renamed Kyocera Solar, Inc.). Photocomm was the nation's largest publicly owned manufacturer and marketer of wireless solar electric power systems with annual revenues in excess of \$35 million. Prior to Photocomm, Mr. Kauffman was a senior executive of the Atlantic Richfield Company (ARCO) whose varied responsibilities included Senior Vice President of ARCO Solar, Inc., President of ARCO Plastics Company and Vice President of ARCO Chemical Company. Mr. Kauffman earned an M.B.A. in Finance at the Wharton School of the University of Pennsylvania, and holds a B.S. in Chemical Engineering from Lafayette College, Easton, Pennsylvania.

Table of Contents

Thomas LaVoy – Mr. LaVoy has been a Director of the Company since 2005. Mr. LaVoy has served as Chief Financial Officer of SuperShuttle International, Inc., since July 1997 and as Secretary since March 1998. SuperShuttle is one of the largest providers of shuttle services in major cities throughout the West and Southwest regions of the United States. He has also served as a director of Alanco Technologies, Inc. (NASDAQ: ALAN) since 1998. From September 1987 to February 1997, Mr. LaVoy served as Chief Financial Officer of NASDAQ-listed Photocomm, Inc. Mr. LaVoy was a Certified Public Accountant with the firm of KPMG Peat Marwick from 1980 to 1983. Mr. LaVoy has a Bachelor of Science degree in Accounting from St. Cloud University, Minnesota, and is a Certified Public Accountant.

Albert Smith – Mr. Smith has been a Director of the Company since 2006. Mr. Smith was the co-founder of and served as Vice Chairman of CSI Leasing, Inc., a private computer leasing company from 1972 until March 2005. He founded Extreme Video Solutions, LLC, a private video conferencing company with headquarters in Scottsdale, Arizona in December 2005. In January 2008, he formed Face to Face Live, Inc. where he presently serves as CEO. Mr. Smith presently serves as Chairman of the Board for Doulos Ministries, Inc. Mr. Smith has extensive experience in marketing and sales having managed a national sales force of over fifty people while at CSI Leasing, Inc. Mr. Smith holds a BS in Business Administration from Ferris State College.

The Company's directors, as named above, will serve until the next annual meeting of the Company's shareholders or until their successors are duly elected and have qualified. Directors will be elected for one-year terms at the annual shareholders meeting. There is no arrangement or understanding between any of the directors or officers of the Company and any other person pursuant to which any director or officer was or is to be selected as a director or officer, and there is no arrangement, plan or understanding as to whether non-management shareholders will exercise their voting rights to continue to elect the current directors to the Company's board. There are also no arrangements, agreements or understandings between non-management shareholders that may directly or indirectly participate in or influence the management of the Company's affairs.

There are no agreements or understandings for any officer or director to resign at the request of another person, and none of the officers or directors are acting on behalf of, or will act at the direction of, any other person. There are no family relationships among our executive officers and directors.

Significant Employees

Certain significant employees of our subsidiary, IsoRay Medical, Inc., and their respective ages as of the date of this report are set forth in the table below. Also provided is a brief description of the experience of each significant employee during the past five years.

Name	Age	Position Held and Tenure
Fredric Swindler	60	VP, Regulatory Affairs and Quality Assurance
Lane Bray	80	Chemist
Oleg Egorov	38	Director of Research and Development

Fredric Swindler – Mr. Swindler joined the Company in October 2006 and has over 30 years experience in manufacturing and regulatory compliance. Mr. Swindler served as VP, Quality Assurance and Regulatory Affairs for Medisystems Corporation, a manufacturer and distributor of medical devices, from 1994 until joining the Company. During his tenure at Medisystems Corporation, Mr. Swindler developed a quality system to accommodate vertically integrated manufacturing, developed regulatory strategies, policies and procedures, and submitted nine pre-market notifications (510(k)) to the FDA. Prior to this, Mr. Swindler held various positions with Marquest Medical Products from 1989 to 1994, Sherwood Medical Products from 1978 to 1989, Oak Park Pharmaceuticals in 1978, and Mead

Johnson & Company from 1969 to 1978. Mr. Swindler holds a Bachelor of Science degree in Biomedical Engineering from Rose Hulman Institute of Technology and a Masters of Business Administration from the University of Evansville.

Table of Contents

Lane Bray – Mr. Bray is known nationally and internationally as a technical expert in separations, recovery, and purification of isotopes and is a noted authority in the use of cesium and strontium ion exchange for Department of Energy’s West Valley and Hanford nuclear waste cleanup efforts. In 2000, Mr. Bray received the ‘Radiation Science and Technology’ award from the American Nuclear Society. Mr. Bray has authored or co-authored over 110 research publications, 12 articles for nine technical books, and holds 24 U.S. and foreign patents. Mr. Bray patented the USDOE/PNNL process for purifying medical grade Yttrium-90 that was successfully commercialized in 1999. Mr. Bray also invented and patented the proprietary isotope separation and purification process that is assigned to IsoRay. Mr. Bray was elected ‘Tri-Citizen of the Year’ in 1988, nominated for ‘Engineer of the Year’ by the American Nuclear Society in 1995, and was elected ‘Chemist of the Year for 1997’ by the American Chemical Society, Eastern Washington Section. Mr. Bray retired from the Pacific Northwest National Laboratory in 1998. Since retiring in 1998, Mr. Bray worked part time for PNNL on special projects until devoting all of his efforts to IsoRay in 2004. Mr. Bray has been a Washington State Legislator, a Richland City Councilman, and a Mayor of Richland. Mr. Bray has a B.A. in Chemistry from Lake Forest College.

Oleg Egorov – Dr. Egorov is recognized nationally and internationally for his work in radiochemistry, radioanalytical chemistry, analytical chemistry and instrumentation. Prior to joining IsoRay in December of 2005 as Director of Radiochemical Development and then Director of Research and Development, Dr. Egorov worked from May 1998 as a Senior Research Scientist at the Pacific Northwest National Laboratory (PNNL). Prior to that time, he served the Environmental Molecular Sciences Laboratory at PNNL as a Graduate Research Fellow from August 1994 to May 1998 and as a Graduate Research Assistant to the University of Washington’s Center for Process Analytical Chemistry from September 1992 to August 1993. Former positions included a tenure as a Research Engineer at the Department of Radiochemistry at the Moscow State University, Moscow, Russia between September 1998 to August 1992, and Field Chemist at the Institute of Volcanology, at the Russian Academy of Science at Petropavlovsk-Kamchatsky, Russia, during the summers of 1989 and 1990 concurrent to studies that lead to his acquisition of Master of Science in Radiochemistry from the Moscow State University. During his tenure at PNNL, Dr. Egorov had led world-class basic and applied R&D programs directed at new chemistries and instrumentation for automated production of short-lived medical isotopes for the treatment of cancer, automated process monitoring, radionuclide sensors for groundwater monitoring, and laboratory automation. Dr. Egorov pioneered the application of flow-based techniques for automating radiochemical analyses of nuclear wastes, renewable surface sensing and separations, and equilibration-based radionuclide sensing. He has authored/co-authored numerous peer-reviewed publications in these areas, including several book chapters. Dr. Egorov holds four U.S./international patents, three of which have been licensed to industry. Dr. Egorov has been a recipient of numerous outstanding performance and key contributor awards. In 2003, Dr. Egorov was nominated for the American Chemical Society Arthur F. Findeis Award for Achievements by a Young Analytical Scientist. In 2004, Dr. Egorov was a recipient of a Federal Laboratory Consortium Award for Excellence in Technology Transfer for “Alpha Particle Immunotherapy for Treating Leukemia and Solid-Tumor Metastases”. Dr. Egorov holds a M.S. in Radiochemistry from Moscow State University, Moscow, Russia; a M.S. in Environmental and Analytical Chemistry; and a Ph.D. in Analytical Chemistry from the University of Washington.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 (the Exchange Act) requires the Company’s directors and executive officers, and persons who beneficially own more than ten percent of a registered class of our equity securities, to file with the Securities and Exchange Commission (the Commission) initial reports of beneficial ownership and reports of changes in beneficial ownership of our Common Stock. The rules promulgated by the Commission under Section 16(a) of the Exchange Act require those persons to furnish us with copies of all reports filed with the Commission pursuant to Section 16(a). The information in this section is based solely upon a review of Forms 3, Forms 4, and Forms 5 received by us.

Edgar Filing: IsoRay, Inc. - Form 10-K

We believe that IsoRay's executive officers, directors and 10% shareholders timely complied with their filing requirements during the year ended June 30, 2008 except as follows: Albert Smith (two Form 4s) and Dwight Babcock (one Form 4). We believe all of these forms have been filed as of the date of this Report.

Table of ContentsCode of Ethics

We have adopted a Code of Conduct and Ethics that applies to all of our officers, directors and employees and a separate Code of Ethics for Chief Executive Officer and Senior Financial Officers that supplements our Code of Conduct and Ethics. The Code of Conduct and Ethics was previously filed as Exhibit 14.1 to our Form 10-KSB for the period ended June 30, 2006, and the Code of Ethics for Chief Executive Officer and Senior Financial Officers was previously filed as Exhibit 14.2 to this same report. The Code of Ethics for Chief Executive Officer and Senior Financial Officers is also available to the public on our website at <http://www.isoray.com/ethicsForCeo.htm>. Each of these policies comprises written standards that are reasonably designed to deter wrongdoing and to promote the behavior described in Item 406 of Regulation S-K promulgated by the Securities and Exchange Commission.

Nominating Procedures

There have been no material changes to the procedures by which our shareholders may recommend nominees to the Board of Directors during our last fiscal year.

ITEM 11 – EXECUTIVE COMPENSATION

The following summary compensation table sets forth information concerning compensation for services rendered in all capacities during our past two fiscal years awarded to, earned by or paid to each of the following individuals. Salary and other compensation for these officers, employees and former officers are set by the Compensation Committee of the Board of Directors, except for employee compensation which is set by officers of the Company.

Summary Compensation Table

Name and principal position	Year	Salary (\$)	Bonus (\$)	Stock awards (\$)	Option awards (\$)	Nonequity incentive plan compensation (\$)	Nonqualified	All other compensation (\$)	Total (\$)
							deferred earnings (\$)		
Dwight Babcock, Chairman and Interim CEO (2)	2008	22,000	—	—	70,000	—	—	—	92,000
	2007	—	—	—	—	—	—	—	—
Roger Girard, former Chairman and CEO (3) (4)	2008	204,231	—	—	—	—	—	250,000	454,231
	2007	298,042	—	—	600,500	—	—	—	898,542
David Swanberg, former Executive Vice President - Operations (3) (5) (6)	2008	179,615	50,000	—	—	—	—	25,962	255,577
	2007	161,539	—	—	372,228	—	—	—	533,767

Edgar Filing: IsoRay, Inc. - Form 10-K

Lori Woods, Vice President (7)	2008	179,615	—	—	—	—	—	—	179,615
	2007	155,692	—	—	327,150	—	—	—	482,842
Fred Swindler, VP - Regulatory Affairs and Quality Assurance (8)	2008	159,808	—	—	—	—	—	—	159,808
	2007	109,615	—	—	57,200	—	—	9,973	176,788
Robert Bilella, Territory Sales Manager	2008	117,283	121,150	—	—	—	—	—	238,433
	2007	131,557	78,927	—	—	—	—	—	210,484

(1) Amounts represent the FAS 123R valuation for the fiscal years ended June 30, 2008 and 2007, respectively. All such options were awarded under one of the Company's stock option plans. All options awarded (with the exception of Mr. Babcock's fiscal year 2008 stock option grant that was immediately vested on the grant date) vest in three equal annual installments beginning with the first anniversary from the date of grant and expire ten years after the date of grant. All options were granted at the fair market value of the Company's stock on the date of grant and the Company used a Black-Scholes methodology as discussed in the footnotes to the financial statements to value the options.

(2) Mr. Babcock became the Chairman and Interim CEO on February 26, 2008. He is serving as Interim CEO on a contract basis. Mr. Babcock also received compensation as a Director of the Company during fiscal year 2008 which is disclosed in the Non-Employee Director Compensation table.

Table of Contents

- (3) Mr. Girard and Mr. Swanberg were granted 150,000 and 100,000 options, respectively, on June 1, 2007. These options have an exercise price of \$4.14 and vest over three years. On July 25, 2007, the Board discussed the issue of director compensation and each director (including Mr. Girard and Mr. Swanberg) elected to cancel 50,000 of their options from the June 1, 2007 grant. After the cancellation, Mr. Girard and Mr. Swanberg had 100,000 and 50,000 options, respectively, from the June 1, 2007 grant. The terms of these options were not changed as part of the cancellation. Under FAS 123R, the value of the cancelled options to Mr. Girard and Mr. Swanberg were \$128,500 each. The value of these options has been included in the table above in fiscal year 2007.
- (4) On February 26, 2008, Mr. Girard resigned from all positions held with the Company and its subsidiaries, including resigning from Board service. In connection with Mr. Girard's resignation, the Company made a one time payment to Mr. Girard of \$250,000 and this amount is included in the "All other compensation" column.
- (5) The value of Mr. Swanberg's options includes \$7,728 relating to options granted to his wife who was an employee of the Company at the time of the grant.
- (6) Mr. Swanberg resigned from the Company on June 11, 2008. In connection with Mr. Swanberg's resignation, the Company agreed to continue paying Mr. Swanberg his salary for an additional six months subject to the conditions of his agreement. These amounts have not been included in this table as the amounts had not been paid as of June 30, 2008. In addition, Mr. Swanberg was paid the balance of his vacation in a lump sum and this amount is included in the "All other compensation" column.
- (7) Ms. Woods became an employee of the Company in July 2006.
- (8) Mr. Swindler became an employee of the Company in October 2006. The Company reimbursed Mr. Swindler for certain of his relocation costs and this amount is included in the "All other compensation" column for fiscal year 2007.

Ms. Woods has an employment contract with the Company dated February 14, 2007. The agreement is for an initial term of two years but will be automatically extended for an additional year on each anniversary date unless terminated in accordance with the provisions of the agreement. The agreement entitles Ms. Woods to a salary of at least \$160,000 with increases as determined by the Compensation Committee of the Board and annual bonus payments under a bonus plan as established by the Compensation Committee. In the event that Ms. Woods is terminated without cause, becomes disabled, or terminates her employment for good reason, she will be entitled to her salary and benefits for the remaining term of the agreement or 18 months, whichever is shorter. Good reason is defined in the agreement to mean a reduction of salary or benefits, a change in Ms. Woods' title, position, authority, or responsibilities, causing Ms. Woods to relocate, or any breach by the Company of this agreement. If Ms. Woods is terminated within one year of a change of control then she shall be entitled to her salary and benefits for the remaining term of the agreement or 18 months, whichever is longer, in addition to a one-time payment equal to her most recently received bonus. In the event of Ms. Woods' termination without cause or termination within one year of a change of control, all of her unvested stock options shall immediately vest in full and shall be exercisable as provided in the applicable stock option plan. The agreement also includes certain restrictive covenants that prohibit Ms. Woods from providing services to a competing business for the period of this agreement plus one year.

Table of Contents**Outstanding Equity Awards at Fiscal Year-End**

Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option awards			
			Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option exercise price (\$)	Option expiration date	
Dwight Babcock, Chairman and Interim CEO	50,000	—	—	6.30	3/31/2016	
	50,000	—	—	3.80	6/23/2016	
	50,000	—	—	3.11	8/15/2016	
	100,000	—	—	0.75	5/13/2018	
Roger Girard, former Chairman and CEO	513,840	—	—	1.19	5/31/2009	
	33,333	—	—	3.11	5/31/2009	
David Swanberg, former Executive Vice President - Operations	150,000	—	—	1.00	8/18/2015	
	16,666	—	—	3.11	8/15/2016	
	16,666	—	—	4.14	6/1/2017	
Lori Woods, Vice President	16,666	33,334	(1)	—	3.50	7/5/2016
	16,666	33,334	(2)	—	3.10	10/17/2016
	5,000	15,000	(3)	—	4.40	3/2/2017
	6,666	13,334	(4)	—	4.14	6/1/2017
Fred Swindler, VP - Regulatory Affairs and Quality Assurance	3,333	6,667	(3)	—	4.40	3/2/2017
	3,333	6,667	(4)	—	4.14	6/1/2017
	84,236	—	—	—	4.15	6/23/2015

Robert Bilella, Territory Sales
Manager

- (1) Represents a July 5, 2006 grant, one-third of which became exercisable on July 1, 2007, one-third of which will become exercisable on July 1, 2008, and the final third will become exercisable on July 1, 2009.
- (2) Represents the October 17, 2006 grant, one-third of which became exercisable on October 17, 2007, one-third of which will become exercisable on October 17, 2008, and the final third will become exercisable on October 17, 2009.
- (3) Represents the March 2, 2007 grant, one-third of which became exercisable on March 2, 2008, one-third of which will become exercisable on March 2, 2009, and the final third will become exercisable on March 2, 2010.
- (4) Represents the June 1, 2007 grant, one-third of which became exercisable on June 1, 2008, one-third of which will become exercisable on June 1, 2009, and the final third will become exercisable on June 1, 2010.

The Company has a 401(k) plan that covers all eligible full-time employees of the Company. Contributions to the 401(k) plan are made by participants to their individual accounts through payroll withholding. Additionally, the 401(k) plan provides for the Company to make contributions to the 401(k) plan in amounts at the discretion of management. The Company has not made any contributions to the 401(k) plan and does not maintain any other retirement plans for its executives or employees.

Table of Contents**Non-Employee Director Compensation**

Name	Fees earned or paid in cash (\$)	Stock awards (\$)	Option awards (\$)	Non-equity incentive plan compensation (\$)	Non-qualified deferred compensation earnings (\$)	All other compensation (\$)	Total (\$)
Dwight Babcock	52,000	—	—	—	—	—	52,000
Stephen Boatwright	11,500	—	—	—	—	—	11,500
Robert Kauffman	48,000	—	—	—	—	—	48,000
Thomas LaVoy	43,500	—	—	—	—	—	43,500
Albert Smith	39,500	—	—	—	—	—	39,500

Beginning in fiscal year 2008, each non-employee director received cash compensation of \$3,000 per month, except for Mr. Boatwright who received \$1,000 per month until his resignation in February 2008. In addition, each non-employee director received \$1,000 per Board meeting attended in person or \$500 per Board meeting attended via telephone and \$500 per committee meeting attended. Beginning in March 2008, Mr. Babcock began receiving an additional \$3,000 per month for serving as Chairman, Mr. Kauffman began receiving an additional \$2,000 per month for serving as Vice-Chairman, and Mr. LaVoy began receiving an additional \$1,000 per month for serving as Audit Committee Chairman.

Each director had stock options to purchase 150,000 shares of the Company's common stock outstanding as of June 30, 2008, except for Mr. Babcock who was granted options to purchase an additional 100,000 shares of the Company's common stock on May 13, 2008 for serving as Interim CEO. This grant of 100,000 shares is noted in the executives' Outstanding Equity Awards at Fiscal Year-End table above.

Compensation Committee Interlocks and Insider Participation

As a smaller reporting company, the Company is not required to provide this disclosure.

Compensation Committee Report

As a smaller reporting company, the Company is not required to provide this disclosure.

ITEM 12 – SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following tables set forth certain information regarding the beneficial ownership of the Company's common stock and preferred stock as of September 16, 2008 for (a) each person known by the Company to be a beneficial owner of five percent or more of the outstanding common or preferred stock of the Company, (b) each executive officer, director and nominee for director of the Company, and (c) directors and executive officers of the Company as a group. As of September 16, 2008, the Company had 22,942,088 shares of common stock and 59,065 shares of preferred stock outstanding.

Table of Contents**Common Stock Share Ownership**

Name of Beneficial Owner	Common Shares Owned	Common Stock Options Exercisable Within 60 Days	Common Warrants	Percent of Class (1)
Dwight Babcock (2)	66,002	250,000	12,500	1.42%
Roger Girard	222,922	547,173	—	3.28%
David Swanberg (3)	343,627	196,665	5,500	2.36%
Lori Woods	8,000	78,332	—	—%
Jonathan Hunt	—	64,999	—	—%
Robert Kauffman	63,802	150,000	—	—%
Thomas LaVoy	8,423	150,000	—	—%
Albert Smith	122,147	150,000	—	1.18%
Directors and Executive Officers as a group	268,374	843,331	12,500	4.72%

(1) Percentage ownership is based on 22,942,088 shares of Common Stock outstanding on September 16, 2008. Shares of Common Stock subject to stock options which are currently exercisable or will become exercisable within 60 days after September 16, 2008 are deemed outstanding for computing the percentage ownership of the person or group holding such options, but are not deemed outstanding for computing the percentage ownership of any other person or group.

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

(3) Mr. Swanberg's options include 13,333 options granted to his spouse.

Preferred Stock Share Ownership

Name of Beneficial Owner	Preferred Shares Owned	Percent of Class (1)
Aissata Sidibe (2)	20,000	33.86%
William and Karen Thompson Trust (3)	14,218	24.07%
Jamie Granger (4)	10,529	17.83%
Hostetler Living Trust (5)	9,479	16.05%
Leslie Fernandez (6)	3,688	6.24%

(1) Percentage ownership is based on 59,065 shares of Preferred Stock outstanding on September 16, 2008.

(2) The address of Ms. Sidibe is 229 Lasiandra Ct, Richland, WA 99352.

(3) The address of the William and Karen Thompson Trust is 285 Dondero Way, San Jose, CA 95119.

(4) The address of Jamie Granger is 53709 South Nine Canyon Road, Kennewick, WA 99337.

- (5) The address of the Hostetler Living Trust is 9257 NE 175th Street, Bothell, WA 98011.
- (6) The address of Leslie Fernandez is 2615 Scottsdale Place, Richland, WA 99352.

No officers or directors beneficially own shares of Preferred Stock.

ITEM 13 – CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

IsoRay Medical, Inc.'s patent rights to its Cs-131 process were acquired from Lane Bray, a shareholder and employee of the Company, and are subject to a 1% royalty on gross profits and certain contractual restrictions. Pursuant to the royalty agreement, the Company must also pay a royalty of 2% of Gross Sales, as defined, for any sub-assignments of the aforesaid patented process to any third parties. The royalty agreement will remain in force until the expiration of the patents on the assigned technology, unless earlier terminated in accordance with the terms of the underlying agreement. During fiscal year 2007, the Company achieved its first gross margin and began making quarterly payments to Mr. Bray as outlined in the royalty agreement. The Company recorded royalty expense of \$21,219 and \$2,161 for the years ended June 30, 2008 and 2007, respectively, related to these payments.

Table of Contents

Roger Girard, the Company's former Chairman and CEO, had personally guaranteed \$20,000 of the BFEDD loan, which was funded in December 2004. In exchange for his personal guaranty, Mr. Girard received 5,728 shares of common stock. As a condition of his resignation in February 2008, the Company prepaid \$20,000 on the BFEDD loan and obtained Mr. Girard's release and Mr. Girard in turn surrendered the 5,728 shares to the Company. As part of his settlement, Mr. Girard also surrendered 30,072 shares of common stock he had received in 2004 for personally guaranteeing a portion of a line of credit for the Company.

Mr. Girard and David Swanberg, the Company's former Executive VP – Operations, personally guaranteed a portion of the HAEIFC loan. As part of their resignations, the Company obtained their releases from these personal guarantees by prepaying \$60,000 and \$40,000, respectively.

Mr. Stephen Boatwright, a former Company director, has been actively involved in providing various legal services to the Company and IsoRay Medical, Inc. through the law firm of Keller Rohrback, PLC. During the fiscal years ended June 30, 2008 and 2007, the Company paid Keller Rohrback, PLC approximately \$426,000 and \$459,000, respectively, for legal services. In addition, the Company had accrued at June 30, 2008 approximately \$10,000 in legal fees to be paid.

Patent and Know-How Royalty License Agreement

Effective August 1, 1998, Pacific Management Associates Corporation (PMAC) transferred its entire right, title and interest in an exclusive license agreement with Donald Lawrence to IsoRay, LLC (a predecessor company) in exchange for a membership interest. The terms of the license agreement require the payment of a royalty based on the Net Factory Sales Price, as defined in the agreement, of licensed product sales. Because the licensor's patent application was ultimately abandoned, only a 1% "know-how" royalty based on Net Factory Sales Price, as defined, remains applicable. To date, management believes that there have been no product sales incorporating the "know-how" and that therefore no royalty is due pursuant to the terms of the agreement. Management believes that ultimately no royalties should be paid under this agreement as there is no intent to use this "know-how" in the future.

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

Director Independence

Using the standards of the American Stock Exchange, the Company's Board has determined that Mr. Kauffman, Mr. LaVoy, and Mr. Smith each qualify under such standards as an independent director. Mr. Kauffman, Mr. LaVoy and Mr. Smith each meet the American Stock Exchange listing standards for independence both as a director and as a member of the Audit Committee, and Mr. Kauffman and Mr. Smith each meet the American Stock Exchange listing standards for independence both as a director and as a member of the Compensation Committee. No other directors are independent under these standards. The Company did not consider any relationship or transaction between itself and these independent directors not already disclosed in this report in making this determination.

Table of Contents**ITEM 14 – PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The Company paid or accrued the following fees in each of the prior two fiscal years to its principal accountant, DeCoria, Maichel & Teague, P.S.:

	Year ended June 30, 2008	Year ended June 30, 2007
1. Audit fees	\$ 42,107	\$ 41,016
2. Audit-related fees	–	1,800
3. Tax fees	7,750	4,250
4. All other fees	–	–
Totals	\$ 49,857	\$ 47,066

Audit fees include fees for the audit of our annual financial statements, reviews of our quarterly financial statements, and related consents for documents filed with the SEC. Audit-related fees include fees related to work on common stock offering memorandums. Tax fees include fees for the preparation of our federal and state income tax returns.

As part of its responsibility for oversight of the independent registered public accountants, the Audit Committee has established a pre-approval policy for engaging audit and permitted non-audit services provided by our independent registered public accountants, DeCoria, Maichel & Teague, P.S. In accordance with this policy, each type of audit, audit-related, tax and other permitted service to be provided by the independent auditors is specifically described and each such service, together with a fee level or budgeted amount for such service, is pre-approved by the Audit Committee. The Audit Committee has delegated authority to its Chairman to pre-approve additional non-audit services (provided such services are not prohibited by applicable law) up to a pre-established aggregate dollar limit. All services pre-approved by the Chairman of the Audit Committee must be presented at the next Audit Committee meeting for review and ratification. All of the services provided by DeCoria, Maichel & Teague, P.S. described above were approved by our Audit Committee.

The Company's principal accountant, DeCoria, Maichel & Teague P.S., did not engage any other persons or firms other than the principal accountant's full-time, permanent employees.

ITEM 15 – EXHIBITS AND REPORTS ON FORM 8-K

(except as otherwise indicated, all exhibits were previously filed)

Exhibit #	Description
2.1	Merger Agreement dated as of May 27, 2005, by and among Century Park Pictures Corporation, Century Park Transitory Subsidiary, Inc., certain shareholders and IsoRay Medical, Inc. incorporated by reference to the Form 8-K filed on August 3, 2005.
2.2	Certificate of Merger, filed with the Delaware Secretary of State on July 28, 2005 incorporated by reference to the Form 8-K filed on August 3, 2005.
3.1	Articles of Incorporation and By-Laws are incorporated by reference to the Exhibits to the Company's Registration Statement of September 15, 1983.
3.2	Certificate of Designation of Rights, Preferences and Privileges of Series A and B Convertible Preferred Stock, filed with the Minnesota Secretary of State on June 29, 2005 incorporated by reference to the Form

Edgar Filing: IsoRay, Inc. - Form 10-K

8-K filed on August 3, 2005.

- 3.3 Restated and Amended Articles of Incorporation incorporated by reference to the Form 10-KSB filed on October 11, 2005.
- 3.4 Text of Amendments to the Amended and Restated By-Laws of the Company, incorporated by reference to the Form 8-K filed on February 7, 2007.
- 3.5 Amended and Restated By-Laws of the Company dated as of January 8, 2008, incorporated by reference to the Form 8-K filed on January 14, 2008.
- 4.2 Intentionally Omitted
- 4.3 Intentionally Omitted

Table of Contents

- 4.4 Intentionally Omitted
- 4.5 Intentionally Omitted
- 4.6 Intentionally Omitted
- 4.7 Amended and Restated 2005 Stock Option Plan incorporated by reference to the Form S-8 filed on August 19, 2005.
- 4.8 Amended and Restated 2005 Employee Stock Option Plan incorporated by reference to the Form S-8 filed on August 19, 2005.
- 4.9 Form of Registration Right Agreement among IsoRay Medical, Inc., Meyers Associates, L.P. and the other signatories thereto, dated October 15, 2004, incorporated by reference to the Form SB-2 filed on November 10, 2005.
- 4.10 Form of Registration Rights Agreement among IsoRay, Inc., Meyers Associates, L.P. and the other signatories thereto, dated February 1, 2006, incorporated by reference to the Form SB-2/A1 filed on March 24, 2006.
- 4.11 Form of IsoRay, Inc. Common Stock Purchase Warrant, incorporated by reference to the Form SB-2/A1 filed on March 24, 2006.
- 4.12 2006 Director Stock Option Plan, incorporated by reference to the Form S-8 filed on August 18, 2006.
- 4.13 Form of Registration Rights Agreement among IsoRay, Inc. and the other signatories thereto, dated August 9, 2006, incorporated by reference to the Form 8-K filed on August 18, 2006.
- 4.14 Form of IsoRay, Inc. Common Stock Purchase Warrant, dated August 9, 2006, incorporated by reference to the Form 8-K filed on August 18, 2006.
- 4.15 Form of Registration Rights Agreement among IsoRay, Inc., Meyers Associates, L.P. and the other signatories thereto, dated October 17, 2005, incorporated by reference to the Form SB-2 filed on October 16, 2006.
- 4.16 Amended and Restated 2006 Director Stock Option Plan, incorporated by reference to the Form S-8/A1 filed on December 18, 2006.
- 4.17 Amended and Restated 2005 Stock Option Plan, incorporated by reference to the Form S-8/A1 filed on December 18, 2006.
- 4.18 Intentionally omitted.
- 4.19 Rights Agreement, dated as of February 1, 2007, between the Computershare Trust Company N.A., as Rights Agent, incorporated by reference to Exhibit 1 to the Company's Registration Statement on Form 8-A filed on February 7, 2007.
- 4.20 Certificate of Designation of Rights, Preferences and Privileges of Series C Junior Participating Preferred Stock, incorporated by reference to Exhibit 1 to the Company's Registration Statement on Form 8-A filed February 7, 2007.
- 4.21 2008 Employee Stock Option Plan, incorporated by reference to the Form S-8 filed on January 14, 2008.
- 10.2 Universal License Agreement, dated November 26, 1997 between Donald C. Lawrence and William J. Stokes of Pacific Management Associates Corporation, incorporated by reference to the Form SB-2 filed on November 10, 2005.
- 10.3 Royalty Agreement of Invention and Patent Application, dated July 12, 1999 between Lane A. Bray and IsoRay LLC, incorporated by reference to the Form SB-2 filed on November 10, 2005.
- 10.4 Intentionally Omitted
- 10.5 Section 510(k) Clearance from the Food and Drug Administration to market Lawrence CSERION Model CS-1, dated March 28, 2003, incorporated by reference to the Form SB-2 filed on November 10, 2005.
- 10.6 Battelle Project No. 45836 dated June 20, 2003, incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.
- 10.7 Intentionally Omitted
- 10.8 Work for Others Agreement No. 45658, R2, dated April 27, 2004 between Battelle Memorial Institute, Pacific Northwest Division and IsoRay Products LLC, incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.

- 10.9 Development Loan Agreement for \$230,000, dated September 15, 2004 between Benton-Franklin Economic Development District and IsoRay Medical, Inc., incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.

Table of Contents

- 10.10 Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Sealed Source, dated September 17, 2004, incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.
- 10.11 CRADA PNNL/245, "Y-90 Process Testing for IsoRay", dated December 22, 2004 between Pacific Northwest National Laboratory and IsoRay Medical Inc., including Amendment No. 1, incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.
- 10.12 Intentionally Omitted
- 10.13 Amendment 1 to Agreement 45658, dated February 23, 2005 between Battelle Memorial Institute Pacific Northwest Division and IsoRay Medical, Inc., incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.
- 10.14 Equipment Lease Agreement dated April 14, 2005 between IsoRay Medical, Inc. and Nationwide Funding, LLC, incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.
- 10.15 Intentionally Omitted
- 10.16 Master Lease Agreement Number 5209, dated May 7, 2005 between VenCore Solutions LLC and IsoRay Medical, Inc., incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.
- 10.17 Contract #840/08624332/04031 dated August 25, 2005 between IsoRay, Inc. and the Federal State Unitary Enterprise << Institute of Nuclear Materials >>, Russia, incorporated by reference to the Form SB-2 filed on November 10, 2005.
- 10.18 State of Washington Radioactive Materials License dated October 6, 2005, incorporated by reference to the Form SB-2 filed on November 10, 2005.
- 10.19 Express Pricing Agreement Number 219889, dated October 5, 2005 between FedEx and IsoRay Medical, Inc., incorporated by reference to the Form 10-QSB filed on November 21, 2005.
- 10.20 Intentionally Omitted
- 10.21 Contract Modification Quality Class G, dated October 25, 2005 to Contract Number X40224 between Energy Northwest and IsoRay, Inc., incorporated by reference to the Form 10-QSB filed on November 21, 2005.
- 10.22 Agreement dated August 9, 2005 between the Curators of the University of Missouri and IsoRay Medical, Inc., incorporated by reference to the Form SB-2/A2 filed on April 27, 2006 (confidential treatment requested).
- 10.23 Intentionally Omitted
- 10.24 Intentionally Omitted
- 10.25 Economic Development Agreement, dated December 14, 2005, by and between IsoRay, Inc. and the Pocatello Development Authority, incorporated by reference to the Form 8-K filed on December 20, 2005.
- 10.26 License Agreement, dated February 2, 2006, by and between IsoRay Medical, Inc. and IBt SA, incorporated by reference to the Form 8-K filed on March 24, 2006 (confidential treatment requested).
- 10.27 Intentionally Omitted.
- 10.28 Service Agreement between IsoRay, Inc. and Advanced Care Medical, Inc., dated March 1, 2006, incorporated by reference to the Form SB-2/A2 filed on April 27, 2006.
- 10.29 Intentionally Omitted.
- 10.30 Intentionally Omitted.
- 10.31 Loan Agreement, dated June 15, 2006, by and between IsoRay Medical, Inc. and the Hanford Area Economic Investment Fund Committee, incorporated by reference to the Form 8-K filed on June 21, 2006.
- 10.32 Commercial Security Agreement, dated June 15, 2006, by and between IsoRay Medical, Inc. and the Hanford Area Economic Investment Fund Committee, incorporated by reference to the Form 8-K filed on June 21, 2006.
- 10.33 Common Stock and Warrant Purchase Agreement among IsoRay, Inc. and the other signatories thereto, dated August 9, 2006, incorporated by reference to the Form 8-K filed on August 18, 2006.

Table of Contents

- 10.34 Intentionally Omitted.
- 10.35 Form of Officer and Director Indemnification Agreement, incorporated by reference to the Form SB-2 Post Effective Amendment No. 2 filed on October 13, 2006.
- 10.36 Contract No. 840/20553876/11806-32, dated October 6, 2006, by and between IsoRay Medical, Inc. and FSUE “SSC-Research Institute of Atomic Reactors,” incorporated by reference to the Form 8-K filed on November 6, 2006 (confidential treatment requested for redacted portions).
- 10.37 Agreement for Exclusive Right to Buy, dated October 6, 2006, by and between IsoRay Medical, Inc. and FSUE “SSC-Research Institute of Atomic Reactors,” incorporated by reference to the Form 8-K filed on November 6, 2006 (confidential treatment requested for redacted portions).
- 10.38 Form of Securities Purchase Agreement by and among IsoRay, Inc. and the Buyers dated March 22, 2007, incorporated by reference to the Form 8-K filed on March 23, 2007.
- 10.39 Form of Common Stock Purchase Warrant dated March 21, 2007, incorporated by reference to the Form 8-K filed on March 23, 2007.
- 10.40 Placement Agent Agreement by and between the Company and Punk, Ziegel & Company, L.P. dated March 14, 2007, incorporated by reference to the Form 8-K filed on March 23, 2007.
- 10.41 Placement Agent Agreement by and between the Company and Maxim Group LLC dated February 2, 2006, incorporated by reference to the Form 8-K filed on March 23, 2007.
- 10.42 Intentionally Omitted.
- 10.43 Intentionally Omitted.
- 10.44 Intentionally Omitted.
- 10.45 Lease Agreement, dated effective as of September 1, 2007, by and between IsoRay, Inc. and Perma-Fix Northwest Richland, Inc., incorporated by reference to the Form 8-K filed on October 16, 2007.
- 10.46 Amendment No. 1 to License Agreement, dated October 12, 2007, by and between IsoRay Medical, Inc. and IBt, SA, incorporated by reference to the Form 8-K filed on October 17, 2007.
- 10.47 Loan Covenant Waiver Letter dated August 18, 2008 from the Benton-Franklin Economic Development District, filed herewith.
- 10.48 Loan Covenant Waiver Letter dated August 26, 2008 from the Hanford Area Economic Investment Fund Committee, filed herewith.
- 21.1 Subsidiaries of the Company, filed herewith.
- 23.1 Consent of DeCoria, Maichel & Teague, P.S., filed herewith.
- 31.1 Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 - Chief Executive Officer, filed herewith.
- 31.2 Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 - Chief Financial Officer, filed herewith.
- 32.1 Certifications Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, filed herewith.

Reports on Form 8-K

On May 13, 2008, the Company filed a Current Report on Form 8-K announcing its financial results for the third quarter of fiscal year 2008.

On August 20, 2008, the Company filed a Current Report on Form 8-K announcing its financial results for the fourth quarter of fiscal year 2008.

Table of Contents

IsoRay, Inc.
Index to Financial Statements

	Page
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
Financial Statements:	
<u>Consolidated Balance Sheets as of June 30, 2008 and 2007</u>	F-3
<u>Consolidated Statements of Operations for the years ended June 30, 2008 and 2007</u>	F-4
<u>Consolidated Statement of Changes in Shareholders' Equity for the years ended June 30, 2008 and 2007</u>	F-5
<u>Consolidated Statements of Cash Flows for the years ended June 30, 2008 and 2007</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7

F-1

Table of Contents

Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders
IsoRay, Inc.
Richland, Washington

We have audited the accompanying consolidated balance sheets of IsoRay, Inc. and Subsidiaries (“the Company”) (see Note 1) as of June 30, 2008 and 2007, and the related consolidated statements of operations, changes in shareholders’ equity and cash flows for the years then ended. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion the financial statements referred to above present fairly, in all material respects, the consolidated financial position of IsoRay, Inc. and Subsidiaries as of June 30, 2008 and 2007, and the consolidated results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ DeCoria, Maichel & Teague, P.S.

Spokane, Washington
September 29, 2008

F-2

Table of Contents**IsoRay, Inc. and Subsidiaries
Consolidated Balance Sheets**

	2008	June 30,	2007
ASSETS			
Current assets:			
Cash and cash equivalents	\$ 4,820,033	\$	9,355,730
Short-term investments	3,726,000		9,942,840
Accounts receivable, net of allowance for doubtful accounts of \$33,031 and \$99,789, respectively	1,016,495		1,092,925
Inventory	899,964		880,834
Prepaid expenses and other current assets	267,001		458,123
Total current assets	10,729,493		21,730,452
Fixed assets, net of accumulated depreciation and amortization	6,040,641		3,665,551
Deferred financing costs, net of accumulated amortization	65,221		95,725
Licenses, net of accumulated amortization	455,646		262,074
Restricted cash	175,852		—
Other assets, net of accumulated amortization	345,040		322,360
Total assets	\$ 17,811,893	\$	26,076,162