

IsoRay, Inc.  
Form S-3  
December 10, 2010

As Filed with the Securities and Exchange Commission on December 10, 2010

Registration No. 333-

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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FORM S-3  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

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ISORAY, INC.  
(Exact name of registrant as specified in its charter)

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Minnesota  
(State or other jurisdiction  
of incorporation or organization)

41-1458152  
(I.R.S. Employer  
Identification No.)  
350 Hills Street, Suite 106  
Richland, WA 99354  
(509) 375-1202

(Address and Telephone Number of Principal Executive Offices and Principal Place of Business)

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Dwight Babcock, CEO  
350 Hills Street, Suite 106  
Richland, WA 99354  
(509) 375-1202

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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. (Check one):

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

#### CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be Registered (1)	Proposed maximum offering price per share (2)	Proposed maximum aggregate offering price (2)	Amount of registration fee
Common Stock (\$0.001 par value) (2)	226,344	\$ 1.29	\$ 291,983.76	\$ 20.82

(1) In accordance with Rule 416(a) under the Securities Act, the registrant is also registering hereunder an indeterminate number of shares that may be issued and resold resulting from stock splits, stock dividends or similar transactions.

(2) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(c) under the Securities Act based on the average of the high and low prices for the registrant's common stock as reported on the NYSE AMEX on December 6, 2010.

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IsoRay hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until IsoRay shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The registration statement, including the exhibits and the documents incorporated herein by reference, can be read on the Securities and Exchange Commission website are at the Securities and Exchange Commission offices mentioned under the heading "Where You Can Find More Information."

Until \_\_\_\_\_, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

## ABOUT THIS PROSPECTUS

You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front cover of this prospectus. You should not assume that the information incorporated by reference in this prospectus is accurate as of any date other than the date the respective information was filed with the Securities and Exchange Commission. Our business, financial condition, results of operations and prospects may have changed since those dates.

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission under which the selling shareholders may offer from time to time up to an aggregate of 226,344 shares of our common stock in one or more offerings. If required, each time a selling shareholder offers common stock, in addition to this prospectus, we will provide you with a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update, or change information contained in this prospectus. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus, the statements made in this prospectus will be deemed modified or superseded by those made in a prospectus supplement.

You should read carefully both this prospectus, any prospectus supplement, and the additional information described below under "Information Incorporated By Reference." This prospectus does not contain all the information provided in the registration statement we filed with the SEC. For further information about us or the securities offered hereby, you should refer to that registration statement, which you can obtain from the SEC as described below under "Where You Can Find More Information."

## PROSPECTUS SUMMARY

This summary highlights selected information appearing elsewhere or incorporated by reference in this prospectus and may not contain all of the information that is important to you. This prospectus includes or incorporates by reference information about the securities our selling shareholders are offering as well as information regarding our business and detailed financial data. After you read this summary, you should read this prospectus in its entirety, including the information incorporated by reference in this prospectus, especially the section entitled "Risk Factors." If you invest in our securities, you are assuming a high degree of risk.

Unless the context requires otherwise, in this prospectus, the terms "IsoRay," the "Company," "we," "us," "our" and similar terms refer to IsoRay, Inc. and its operating subsidiary IsoRay Medical, Inc., and, to the extent applicable, its non-operating subsidiary, IsoRay International LLC.

## BUSINESS OVERVIEW

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



IsoRay began production and sales of Proxcelan Cesium-131 brachytherapy seeds in October 2004 for the treatment of prostate cancer after clearance of its premarket notification (510(k)) by the Food and Drug Administration (FDA). In December 2007, IsoRay began selling its Proxcelan Cs-131 seeds for the treatment of ocular melanoma. In June 2009, the Company began selling its Proxcelan Cs-131 seeds for treatment of head and neck tumors, commencing with treatment of a tumor that could not be accessed by other treatment modalities. During the fiscal year ended June 30, 2010, the Company continued to expand the number of areas of the body in which the Proxcelan Cs-131 seeds were being utilized by adding lung cancer in August 2009, colorectal cancer in October 2009, and chest wall cancer in December 2009. The Company is continuing to expand the use of the Proxcelan Cs-131 seed for other cancer treatment applications using both existing delivery systems and researching delivery systems other than those historically used by the Company.

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

Brachytherapy seeds are small devices used in an interstitial radiation procedure. The procedure has become one of the primary treatments for prostate cancer. The brachytherapy procedure places radioactive seeds as close as possible to (in or near) the cancerous tumor (the word "brachytherapy" means close therapy). The seeds deliver therapeutic radiation thereby killing the cancerous tumor cells while minimizing exposure to adjacent healthy tissue. This procedure allows doctors to administer a higher dose of radiation directly to the tumor. Each seed contains a radioisotope sealed within a welded titanium capsule. When brachytherapy is the only treatment (monotherapy), approximately 70 to 120 seeds are permanently implanted in the prostate in an outpatient procedure lasting less than one hour. The number of seeds used varies based on the size of the prostate and the activity level specified by the physician. When brachytherapy is combined with external beam radiation or intensity modulated radiation therapy (dual therapy), then approximately 40 to 80 seeds are used in the procedure. The isotope decays over time and eventually the seeds become inert. The seeds may be used as a primary treatment or in conjunction with other treatment modalities, such as chemotherapy, or as treatment for residual disease after excision of primary tumors. The number of seeds for other treatment sites will vary from as few as 8 to 16 to as many as 117 to 123 depending on the type of cancer, the location of the tumor being treated and the type of therapy being utilized.

## Our Strategy

The key elements of IsoRay's strategy for fiscal year 2011 include:

§ 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.

Management plans to continue to build on an increasing number of studies related to Cs-131 therapy in the management of cancer that were published in the medical literature and presented at relevant oncology society meetings in 2010. The publication and presentation of speculative and real-world data contribute to the acceptability



of Cs-131 in the oncologic marketplace, and discussion in the medico-scientific community of established and novel Cs-131 applications is considered a prerequisite to expansion into untapped markets.

In calendar year 2010, eight presentations were made at the American Brachytherapy Society describing Cs-131 treatment of prostate, lung, and breast cancer. Five publications were abstracted to the MEDLINE database of citations of the medical literature that reported patients treated with Cs-131 for prostate cancer. Five additional publications mentioned Cs-131 as an accepted treatment for prostate cancer, and two publications specifically discussed the physics and dosimetric profile of Cs-131 for the treatment of prostate and eye cancers.

§ Continue to introduce the Proxcelan Cs-131 brachytherapy seed into the U.S. market for prostate cancer. Utilizing our direct sales organization, IsoRay intends to continue to seek to increase the number of centers making the use of Proxcelan Cs-131 seeds available to their patients in brachytherapy procedures for prostate cancer and by increasing the number of patients being treated at current centers using the Proxcelan Cs-131 seeds. IsoRay hopes to capture much of the incremental market growth if and when seed implant brachytherapy recovers market share from other treatments and to take market share from existing competitors.

§ Increase utilization of Cs-131 in treatment of other solid tumor applications such as head and neck, lung, chest wall, and colorectal cancers. IsoRay Medical has clearance from the FDA for its premarket notification, (510(k)) for Proxcelan™ brachytherapy seeds that are preloaded into bioabsorbable braided strands. This order cleared the product for commercial distribution for treatment of lung and head and neck tumors as well as tumors in other organs. IsoRay will continue to explore licenses or joint ventures with other companies to develop the appropriate technologies and therapeutic delivery systems for treatment of other solid tumors such as breast, liver, pancreas, and brain cancers.

§ Return Gliasite® radiation therapy system to market in the United States and European Union (EU). In June of 2010, the Company acquired exclusive worldwide distribution rights to the Gliasite® radiation therapy system, the only FDA-cleared balloon catheter device used in the treatment of brain cancer from Hologic, Inc. The product possesses an established reimbursement rate for both in-patient and out-patient settings. The Company intends to return the product to market in a configuration equivalent to the original FDA-cleared device. The Company is working to obtain the rights to license or acquire the Iotrex solution (Iodine-125) manufactured for use in the Gliasite® radiation therapy system. The Company has developed a liquid Cesium-131 solution for use in the Gliasite® radiation therapy system as either a substitute for the Iotrex or as an alternative treatment option for physicians to utilize in the system.

§ Continue to develop data on Cs-131 for treatment of ocular melanoma. The Company's first sale for ocular melanoma occurred in late 2007 and periodic sales have occurred since then. IsoRay is sponsoring a prospective review of the patients treated with Cs-131 to date. Although the ocular melanoma market is not a large one, this application of Cs-131 continues to demonstrate the potential viability for other solid tumors.

• Introduce Proxcelan Cesium-131 brachytherapy seeds to the Canadian and European Union (EU) markets. Health Canada's Therapeutic Products Directorate has approved IsoRay's Class 3 Medical Device License Applications for Model CS-1 Proxcelan™ (Cesium-131) brachytherapy seeds and the Proxcelan™ Sterile Implant Devices containing Model CS-1 Seeds. This allows IsoRay to market its brachytherapy seeds and related preloaded brachytherapy seeds throughout Canada. In November 2009, the Company entered into a distribution agreement with Inter V Medical of Montreal, Quebec, Canada for exclusive rights to sell the Proxcelan Cs-131 brachytherapy seed in Canada. Approval to market Cesium-131 seeds in Russia was also obtained in 2009; and the Company has an exclusive distribution agreement in place with a Russian distributor, UralDial LLC, to distribute Proxcelan Cs-131 brachytherapy seeds in Russia, however, the economic downturn in Russia has slowed the Company's market penetration efforts. The Company is focusing on the Canadian and European Union (EU) markets until the Russian market recovers.



§ Maintain ISO 13485 certification. 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, the European Union (EU) and Russia. The Company completed its registrations of Proxcelan Cs-131 brachytherapy seeds in Canada and Russia during fiscal year 2009.

## OUR CORPORATE INFORMATION

Our principal executive offices are located at 350 Hills Street, Suite 106, Richland, Washington 99354, and our telephone number is (509) 375-1202. We maintain an Internet website at [www.isoray.com](http://www.isoray.com). We have not incorporated by reference into this prospectus the information in, or that can be accessed through, our website, and you should not consider it to be a part of this prospectus.

Although our predecessor operating company was organized in 1998, IsoRay, Inc. was incorporated in 1983 in Minnesota and operated under the name Century Park Pictures Corporation until the merger with IsoRay Medical, Inc. on July 28, 2005.

## THE OFFERING

This prospectus relates to the resale by the selling shareholders identified in this prospectus of up to 226,344 shares of common stock. Such shares were issued to the selling shareholders in various transactions as described under the section entitled "Selling Security Holders" beginning on page 17 of this prospectus. All of the shares, when sold, will be sold by the selling shareholders. The selling shareholders may sell their shares from time to time at market prices prevailing at the time of sale, at prices related to the prevailing market price, or at negotiated prices. We will not receive any proceeds from the sale of shares by the selling shareholders, but we will incur expenses, including legal and accounting fees.

## RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks listed below and other information included and incorporated by reference in this prospectus. There may also be risks of which we are currently unaware, or that we currently regard as immaterial based on the information available to us that later prove to be material. If any of these risks occur, our business, operating results and financial condition could be seriously harmed, the trading price of our common stock could decline, and you could lose some or all of your investment.

### Risks Related to this Offering

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

The Price Of Our Common Stock May Be Adversely Affected By The Future Issuance And Sale Of Shares Of Our Common Stock Or Other Equity Securities, Including Pursuant To The Sales Agreement, Or By Our Announcement That Such Issuances And Sales May Occur. We cannot predict the size of future issuances or sales of our common stock or other equity securities, including those made pursuant to this offering, those made pursuant to the Company's November 22, 2010 securities purchase agreement with an investor who purchased 2.25 million shares and warrants to purchase up to 4,041,667 shares of common stock, those made pursuant to the Company's Sales Agreement with C.K. Cooper & Company, Inc., future acquisitions or capital raising activities, or the effect, if any, that such issuances or sales may have on the market price of our common stock. The issuance and sale of substantial amounts of common stock or other equity securities, including the sales pursuant to this offering, or announcement that such issuances and sales may occur, could adversely affect the market price of our common stock.

Our Reduced Stock Price May Adversely Affect Our Liquidity. Our common stock has been trading at less than \$1.00 per share periodically in the last year. Many market makers are reluctant to make a market in stock with a trading price of less than \$1.00 per share. To the extent that we have fewer market makers for our common stock, our volume and liquidity will likely decline, which could further depress our stock price.

Future Sales By Shareholders, Or The Perception That Such Sales May Occur, May Depress The Price Of Our Common Stock. The sale or availability for sale of substantial amounts of our shares in the public market, including shares issuable upon conversion of outstanding preferred stock or exercise of common stock warrants and options, or the perception that such sales could occur, could adversely affect the market price of our common stock and also could impair our ability to raise capital through future offerings of our shares. As of November 30, 2010, we had 25,804,325 outstanding shares of common stock, and the following additional shares were reserved for issuance: 2,151,372 shares upon exercise of outstanding options, 7,006,091 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, including the maximum number of warrants issuable in our November 2010 offering, there would be approximately an additional 9,217,000 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.

Failure to Comply with NYSE Amex Listing Standards And Any Resulting Delisting Could Adversely Affect The Market For Our Common Stock. Our common stock is presently listed on the NYSE Amex. The NYSE Amex will consider delisting a company's securities if, among other things, the company fails to maintain minimum shareholder's equity or the company has sustained losses which are so substantial in relation to its overall operations or its existing financial resources, or its financial condition has become so impaired that it appears questionable, in the opinion of the NYSE Amex, as to whether such issuer will be able to continue operations and/or meet its obligations as they mature. As of the quarter ended September 30, 2010, IsoRay fell below the minimum shareholder's equity requirement of \$6 million needed to maintain its listing. Management increased its shareholder's equity above \$6 million via its November 2010 offering and believes that the purchase of the \$2.25 million of common stock by the investor will be sufficient to maintain the required minimum shareholder's equity through fiscal 2011. There can be no assurance that we will be able to continue to raise sufficient capital to maintain our listing on the NYSE Amex. In the event that our common stock is delisted from the NYSE Amex, trading, if any, in the common stock would be conducted in the over-the-counter market. As a result, our shareholders would likely find it more difficult to dispose of, or to obtain

accurate quotations as to the market value of, our common stock.

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**We Do Not Expect To Pay Any Dividends For The Foreseeable Future.** We do not anticipate paying any dividends to our shareholders for the foreseeable future except for dividends on the Series B Preferred Stock which we intend to pay on or before December 31, 2010 if required to comply with the Form S-3 eligibility requirements. 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.

**Purchasers Of The Shares Will Incur Immediate Dilution.** Purchasers of shares of common stock in this offering will experience immediate and substantial dilution because the purchase price of the common stock will likely be higher than the net tangible book value per share of the outstanding common stock immediately after this offering. In addition, purchasers will experience dilution, which may be substantial, when we issue additional shares of common stock that we are permitted or required to issue under options, warrants, our stock option plans or other employee or director compensation plans.

#### Risks Related To Our Business

**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, the European Union (EU) 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; the ability of physicians to properly utilize the device and avoid excessive levels of radiation to patients, and the ability to use this product to treat multiple types of cancers in various organs. Because of our reliance on this product as the 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 Primarily One Type Of Cancer.** Currently, the Proxcelan Cs-131 seed is used almost exclusively for the treatment of prostate cancer (over ninety-six percent of our sales). We are just beginning to treat other types of cancer including lung cancer (approximately 3% of our sales) and ocular melanoma, head and neck, colorectal and chest wall that together constitute less than one percent of our sales. Management believes the Proxcelan Cs-131 seed will continue to be used to treat other types of cancers as the Company identifies existing delivery systems that it can be utilized or develops new delivery methods for the product, however these delivery systems may not prove as effective as anticipated. Management believes that clinical data gathered by select groups of physicians under treatment protocols specific to other organs will be needed prior to widespread acceptance of our product for treating other cancer sites. If our current and future products do not become accepted in treating cancers of other sites, our sales will depend solely on treatment of prostate cancer, a market with increasing competition and ongoing loss of market share by all brachytherapy products.

**We Have Ongoing Cash Requirements.** IsoRay has generated material operating losses since inception. We expect to continue to experience significant net operating losses. Due to recent capital investments and substantial cost reductions, management believes cash and cash equivalents on hand will be sufficient to meet our anticipated cash requirements for operations, debt service, and capital expenditure requirements through December 31,

2011. Management now estimates that operational cashflow breakeven will be achieved at approximately \$700,000 in monthly revenue. However, there is no assurance as to when break-even will occur. If we are unable to generate profits and unable to obtain additional financing to meet our working capital requirements, we may have to 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 2010, approximately sixty-eight percent (68%) of our Cs-131 was supplied through UralDial from reactors located in Russia. 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 increase from current pricing. Our current contract with UralDial terminates on December 31, 2010 and is in the process of being renegotiated. Management will seek to negotiate favorable pricing but there is no assurance as to the outcome of these negotiations.

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 can be subject to unanticipated shutdowns. Failure to obtain deliveries of Cs-131 from multiple sources could have a material adverse effect on seed production and there may be a delay before we could locate alternative suppliers beyond the 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.

**Unfavorable Industry Trends in the Prostate Market.** Several factors occurred in fiscal 2009 that caused our revenues to significantly decline and these factors continued into fiscal 2010 and fiscal 2011 contributing to our failure to improve sales in the prostate market. Beginning in the fall of 2008, U.S. consumers significantly curtailed all spending (even for life saving medical procedures) which impacted the brachytherapy industry as a whole. In February of 2009 noted urologists announced at a medical conference that prostate specific antigen (PSA) testing was not as necessary as previously believed. Their statements were widely publicized. Management continues to believe that many people have been influenced by these statements to cut back on PSA testing thereby decreasing in the short term the number of prostate procedures performed.

In 2010, the American Cancer Society revised their advice regarding PSA testing. In March 2010, the American Cancer Society warned that regular testing for prostate cancer is of questionable value and can do men more harm than good. The ACS suggested that an initial discussion about screening should take place at age 50 for men who are at average risk of prostate cancer and are expected to live at least 10 more years. For men at high risk of developing prostate cancer, the discussion should take place starting at age 45 for men at high risk of developing prostate cancer, this includes African American men and men who have a first-degree relative (father, brother or son) diagnosed with prostate cancer at an early age (younger than age 65). For men at even higher risk such as those with several first-degree relatives who had prostate cancer at an early age, this discussion should take place at age 40. After this discussion, those men who want to be screened should be tested with the prostate specific antigen (PSA) blood test. The digital rectal exam (DRE) may also be done as a part of screening but is no longer recommended.

Also the emergence of IMRT as the preferred treatment alternative as a result of a much higher reimbursement rate to physicians compared to brachytherapy treatments has resulted in declining market share for brachytherapy treatment. In fiscal 2011, each of these factors continued to impact the performance of the Company in the prostate market and the industry as a whole and there is no assurance that they will not continue to impact sales of the Company in the prostate market through fiscal 2011.

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 contract with UralDial and through reactor irradiation of natural barium and subsequent separation of Cs-131 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 and at a reasonable price.

IsoRay entered into an exclusive agreement (through December 31, 2010) with UralDial in Russia to provide Cs-131 in quantities sufficient to supply a significant percentage of future demand for this isotope. 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 UralDial agreement provides 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 Cs-131 would be reduced significantly unless the Company has a source of enriched barium for utilization in domestic reactors.

We Have Entered Into An Agreement With A Single Distributor For Our Cesium-131 From Russia. In December 2009, the Company entered into a new agreement with UralDial to purchase Cs-131 directly from UralDial through December 31, 2010 instead of directly from Institute of Nuclear Materials (INM) and Research Institute of Atomic Reactors (RIAR) as the Company had done prior to the original agreement with UralDial in December 2008. As a result, the Company continues to rely on UralDial to obtain Cs-131 from Russian sources. UralDial has agreed to maintain at least two Russian sources of its Cs-131 and through the UralDial agreement we have obtained set pricing for our Russian Cs-131 through the end of 2010. There can be no guarantee that UralDial will always be able to supply us with sufficient Cs-131 or will renew our existing contract on favorable terms in December 2010, which could be due in part to risks associated with foreign operations and beyond our and UralDial's control. If we were unable to obtain supplies of isotopes from Russia in the future, our overall supply of Cs-131 would be reduced significantly unless we have 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 at fixed rates that cover the cost of stranded and loose seeds. Clinics and physicians performing procedures in a free standing center are reimbursed at the actual cost of the seeds. It is expected that CMS will continue to reimburse providers using this same methodology in 2011.

In 2003, IsoRay applied to the CMS and received a reimbursement code for our Cs-131 seed. On July 1, 2007, CMS revised the coding system for brachytherapy seeds and separated the single code into two codes – one code for loose seeds and a second code for stranded seeds. This methodology was applied to all companies manufacturing brachytherapy seeds. Reimbursement amounts are reviewed and revised annually based upon information submitted to CMS on claims by providers. Although no changes are anticipated for 2011, adjustments can be made to reimbursement amounts or coverage policies, which could result in changes to reimbursement for brachytherapy services. These changes can positively or negatively affect market demand for our products. We monitor these changes and provide comments, as permitted, when changes are proposed, prior to implementation.

In July 2010, CMS published proposed changes for both reimbursement programs for government fiscal year 2011. No changes in reimbursement have been proposed by CMS for 2011. If the proposed changes are finalized, as expected in November 2010, there will be no changes in CMS reimbursement for 2011 but there is no assurance this will occur and is subject to revision annually.



Historically, private insurers have followed Medicare guidelines in establishing reimbursement rates. However, third-party payers are increasingly challenging the pricing of certain medical services or devices, and we cannot be sure that they will reimburse our customers at levels sufficient for us to maintain favorable sales and price levels for our products. There is no uniform policy on reimbursement among third-party payers, and we can provide no assurance that our products will continue to qualify for reimbursement from all third-party payers or that reimbursement rates will not be reduced. A reduction in or elimination of third-party reimbursement for treatments using our products would likely have a material adverse effect on our revenues.

Furthermore, any federal and state efforts to reform government and private healthcare insurance programs, such as those passed by the federal government in 2010, could significantly affect the purchase of healthcare services and products in general and demand for our products in particular. Medicare is the payer in approximately 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 purchasing decisions;
- § research and development and manufacturing expenses;
- § patient outcomes from our therapy;
- § physician acceptance of our products;
- § government or private healthcare reimbursement policies;
- § healthcare reform;
- § our manufacturing performance and capacity;
- § incidents, if any, that could cause temporary shutdown of our manufacturing facility;
- § the amount and timing of sales orders;
- § rate and success of future product approvals;
- § timing of FDA clearance, if any, of competitive products and the rate of market penetration of competing products;
- § seasonality of purchasing behavior in our market;
- § overall economic conditions; and
- § the successful introduction or market penetration of alternative therapies.

We Have Limited Data on the Clinical Performance of Cs-131. As of June 30, 2010, the Proxcelan Cs-131 seed had been implanted in over 5,000 patients and research papers are being published on the use of the Proxcelan seed. While there is less historical statistical data for the Proxcelan seed than is available for I-125 and Pd-103 seeds during the fiscal year ended June 30, 2010, the Company reached a key milestone by collecting the first 5 year outcome data for patients that received treatment with the Proxcelan seed. In addition, during 2010 there were nine reports of the Proxcelan seed being used in the treatment of prostate and ocular melanoma published in peer-reviewed literature. There were eight presentations made at the 2010 meeting of the American Brachytherapy Society covering the application of the Proxcelan seed in prostate, lung and breast cancers. 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, more quickly than the resolution of 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.

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





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

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.

**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, the European Union (EU) 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; time-sensitive delivery requirements due to the short half-life of our product; language barriers and other difficulties in providing long-distance customer service; potentially increase time to collect accounts receivable; significant currency fluctuations, which could cause third-party distributors to reduce the number of products they purchase from us because the cost of our products to them could fluctuate relative to the price they can charge their customers; reduced protection of intellectual property rights in some foreign countries; and the possibility that contractual provisions governed by foreign laws would be interpreted differently than intended in the event of a contract dispute. Any future foreign sales of our products could also be adversely affected by export license requirements, the imposition of governmental controls, political and economic instability, trade restrictions, changes in tariffs, and difficulties in staffing and managing foreign operations. Many of these factors may also affect our ability to import Cs-131 from Russia under our contract with UralDial.

**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.

## Risks Related to Our Stock and Reporting Requirements

**If We Are Unable To Successfully Address The Material Weakness In Our Internal Controls, Our Ability To Report Our Financial Results On A Timely And Accurate Basis May Be Adversely Affected.** Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our reputation and operating results could be harmed. We have in the past discovered, and may in the future discover, areas of our internal controls that need improvement. In its assessment of the effectiveness in internal control over financial reporting as of June 30, 2010 and as of September 30, 2010, the Company determined that there were deficiencies that constituted a material weakness. Specifically, the Company did not maintain a sufficient complement of personnel with the appropriate level of knowledge, experience and training to analyze, review and monitor the accounting of complex financial transactions. As a result, the Company did not prepare adequate contemporaneous documentation that would provide a sufficient basis for an effective evaluation and review of the accounting for complex transactions that are significant or non-routine. This material weakness resulted in errors in the preliminary June 30, 2010 consolidated financial statements and more than a remote likelihood that a material misstatement of the Company's annual or interim financial statements would not be prevented or detected. The Company is in the process of developing and implementing a remediation plan to address the material weakness described above, along with the deficiencies also identified in the assessment, which are described in our Annual Report on Form 10-K filed with the SEC on September 28, 2010. Specifically, in April 2010, an additional accounting position at the Company's operating subsidiary was filled with a Certified Public Accountant to address issues with segregation of duties (however, the Company no longer employed this additional accountant as of November 29, 2010 but is actively seeking a replacement as of the date of this filing), and the Company is assessing additional steps that may be taken in fiscal year 2011 to improve internal controls. We cannot be certain that these measures will ensure that we implement and maintain adequate controls over our financial processes and reporting in the future and had not improved the process as of September 30, 2010. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

**Our Reporting Obligations As A Public Company Are Costly.** Operating a public company involves substantial costs to comply with reporting obligations under federal securities laws that have continued to increase as provisions of the Sarbanes Oxley Act of 2002 have been implemented. As a smaller reporting company, the Company incurred costs to implement additional provisions of the Sarbanes Oxley Act during fiscal year 2010 in particular related to the implementation of Section 404(b). These Section 404(b) reporting obligations were permanently exempted through legislation passed in July 2010 and this exemption retrospectively applied to the year ended June 30, 2010 for companies classified as smaller reporting companies.

**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. We amended our shareholder rights plan to permit the issuance of the common stock and warrants to the investor in our November 2010 offering and therefore this investor may acquire up to 25% of our outstanding common stock. 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.

## NOTE REGARDING FORWARD-LOOKING STATEMENTS

All statements contained in this prospectus and the documents incorporated by reference herein, other than statements of historical facts, that address future activities, events or developments are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, which we refer to as the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. These statements often contain the words "may," "will," "believe," "expect," "anticipate," "intends," "estimate," "forecast," "project," and similar expressions, although not all forward-looking statements contain these words. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including statements relating but not limited to:

- projections of earnings, revenues or other financial items;
- plans and objectives of management for future operations;
- proposed new products or services;
- future operations, plans, regulatory filings or approvals;
- proposed new products or services, any statements regarding pending or future mergers or acquisitions; and
- future economic conditions or performance, and any statement 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 that may cause actual results to differ materially.

You should not place undue reliance on our forward-looking statements because the matters they describe are subject to known and unknown risks, uncertainties and other unpredictable factors, many of which are beyond our control. Our forward-looking statements are based on the information currently available to us and speak only as of the date of this prospectus, or, in the case of forward-looking statements incorporated by reference, as of the date of the filing that includes the statement. New risks and uncertainties arise from time to time, and it is impossible for us to predict these matters or how they may affect us. Over time, our actual results, performance or achievements will likely differ from the anticipated results, performance or achievements that are expressed or implied by our forward-looking statements, and such difference might be significant and materially adverse to our security holders. We do not undertake and specifically decline any obligation to update any forward-looking statements or to publicly announce the results of any revisions to any statements to reflect new information or future events or developments.

We have identified some of the important factors that could cause future events to differ from our current expectations and they are described in this prospectus under the caption "Risk Factors" as well as in our most recent Annual Report on Form 10-K, including without limitation under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in other documents that we may file with the SEC, all of which you should review carefully. Please consider our forward-looking statements in light of those risks as you read this prospectus.

## INDUSTRY AND MARKET DATA

This prospectus contains and incorporates by reference market data, industry statistics and other data that have been obtained from, or compiled from, information made available by third parties. Although we believe these third-party sources are reliable, we have not independently verified the information. Except as may otherwise be noted, none of the sources cited in this prospectus has consented to the inclusion of any data from its reports, nor have we sought their consent. In addition, some data are based on our good faith estimates. Such estimates are derived from publicly available information released by independent industry analysts and third-party sources, as well as our own management's experience in the industry, and are based on assumptions made by us based on such data and our knowledge of such industry and markets, which we believe to be reasonable. However, none of our estimates have been verified by any independent source. See "Special Note Regarding Forward-Looking Statements" above.

## USE OF PROCEEDS

The proceeds from the resale of the shares of common stock under this prospectus are solely for the account of the selling shareholders identified in this prospectus. We will not receive any proceeds from the sale of shares under this prospectus, but we will incur expenses, including legal and accounting fees.

## SELLING SECURITY HOLDERS

This prospectus covers the resale of 226,344 shares of common stock held by existing shareholders who have registration rights, and their trustees, pledgees, donees or successors. The shares to be offered by the selling shareholders are "restricted" securities under applicable federal and state securities laws and are being registered under the Securities Act to give the selling shareholders the opportunity to sell these shares publicly. The registration of these shares does not require that any of the shares be offered or sold by the selling shareholders. The selling shareholders may from time to time offer and sell all or a portion of their shares indicated below in privately negotiated transactions or on the NYSE AMEX or any other market on which our common stock may subsequently be listed.

Such shares were issued to the selling shareholders in various transactions as described below.

All of the shares of common stock registered for resale in this prospectus were issued in exchange for warrants at an exercise price of \$0.95 per share during October 2010. This exercise price reflects a temporary reduction in the exercise price of these warrants. The information that follows describes the original terms of the warrants, which were all issued in private placement transactions.

209,427 shares of common stock registered for resale in this prospectus were issued to certain of the selling shareholders upon exercise of warrants originally issued pursuant to a private placement memorandum between December 2005 and February 2006 at an exercise price of \$6.00 per share.

6,917 shares of common stock registered for resale in this prospectus were issued to certain of the selling shareholders upon exercise of warrants originally issued pursuant to a private placement memorandum in February 2006 at an exercise price of \$6.50 per share.

10,000 shares of common stock registered for resale in this prospectus were issued to certain of the selling shareholders upon exercise of warrants originally issued in a private placement transaction that closed on March 22, 2007 at an exercise price of \$5.00 per share.

The following table sets forth certain information regarding the selling shareholders and the shares of common stock beneficially owned by them, which information is available to us as of November 30, 2010. The selling shareholders may offer the shares under this prospectus from time to time and may elect to sell some, all or none of the shares set forth next to their name. As a result, we cannot estimate the number of shares of common stock that a selling shareholder will beneficially own after termination of sales under this prospectus. However, for the purposes of the table below, we have assumed that, after completion of the offering, none of the shares covered by this prospectus will be held by the selling shareholders. In addition, a selling shareholder may have sold, transferred or otherwise disposed of all or a portion of that holder's shares of common stock since the date on which they provided information for this table. We have not made independent inquiries about this. We are relying on written commitments from the selling shareholders to notify us of any changes in their beneficial ownership after the date they originally provided this information. See section entitled "Plan of Distribution" beginning on page 22.



Selling Shareholder	# of Shares Beneficially Owned Before Offering(1)	# of Shares Offered	# of Shares Beneficially Owned After Offering(1)(2)	% of Shares Beneficially Owned After Offering(1)(2)
John P. Boesel, III	4,037	4,037	0	*
Wayne T. Clasen	60,000	30,000	30,000	*
Gene P. Clasen	5,000	5,000	0	*
Sherry A. Clasen and Gene P. Clasen	25,000	25,000	0	*
Ira J. Gaines	10,000	10,000	0	*
Eugene Raymond	1,890	1,890	0	*
Eugene A. Raymond and Marilyn K. Raymond	10,000	5,000	5,000	*
Donald D. Montgomery	10,000	5,000	5,000	*
William R. Bell	5,000	5,000	0	*
Duane Ferguson and Barbara J. Ferguson	47,500	23,750	23,750	*
5901 Properties LLC	13,334	6,667	6,667	*
John A. Winterton	15,000	10,000	5,000	*
Swanson Living Trust	10,000	10,000	0	*
J. Richard Hunt and Shirley M. Hunt	10,000	5,000	5,000	*
Jill E. Factor Revocable Trust, Jill E. Factor TTEE, Arnold Factor CO-TTEE, UAD Dec 10, 2002	10,000	10,000	0	*
Mangus Family Partners	10,000	5,000	5,000	*
Seamark Fund, LP	60,000	10,000	50,000	*
Norbert F. Hansen	10,000	5,000	5,000	*
William G. and Janet L. Muldoon	25,000	25,000	0	*
Jerry L. Russell	25,000	12,500	12,500	*
Vince Palasota	25,000	12,500	12,500	*

\* Less than 1%.

(1) Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the shares indicated in the table. Percentage ownership calculations are based on 25,804,325 shares outstanding as of November 30, 2010.

(2) Assumes that the selling shareholders dispose of all of the shares of common stock covered by this prospectus and do not acquire beneficial ownership of any additional shares. The registration of these shares does not necessarily mean that the selling shareholders will sell all or any portion of the shares covered by this prospectus.

#### GENERAL DESCRIPTION OF SECURITIES

Our selling shareholders, directly or through agents, dealers or underwriters designated from time to time, may offer, and sell, together or separately, in one or more offerings, up to 226,344 shares of our common stock, par value \$0.001 per share.

## DESCRIPTION OF CAPITAL STOCK

The following is a summary description of the rights of our common stock and related provisions of our amended Articles of Incorporation and our Bylaws. The following description of our capital stock is intended as a summary only and is qualified in its entirety by reference to our amended Articles of Incorporation and our Bylaws, which are filed as exhibits to the registration statement of which this prospectus forms a part, and to the applicable provisions of Minnesota law.

### Common Stock

Our common shares are listed on the NYSE Amex under the symbol "ISR". As of November 30, 2010, 25,804,325 shares of common stock were issued and outstanding.

The Company's Articles of Incorporation provide that the Company has the authority to issue 200 million shares of capital stock, which are currently divided into two classes as follows: 194 million shares of common stock, par value of \$0.001 per share; and 6 million shares of preferred stock, also with a par value of \$0.001 per share.

The holders of our common stock have no preemptive or other subscription rights, and there are no conversion rights or redemption or sinking fund provisions with respect to such shares. All of the outstanding shares of our common stock are, and the shares of our common stock when issued will be, fully paid and nonassessable.

**Voting.** Holders of the common stock are entitled to one vote per share on all matters to be voted on by the Company's shareholders. The Company's bylaws provide that a majority of the outstanding shares of the corporation entitled to vote constitute a quorum at a meeting of the shareholders.

**Dividends.** The Company's Board of Directors, in its sole discretion, may declare and pay dividends on the common stock, payable in cash or other consideration, out of funds legally available, if all dividends due on the preferred stock have been declared and paid. The Company has not paid any cash dividends on its common stock and does not plan to pay any cash dividends on its common stock for the foreseeable future.

**Liquidation, Subdivision, or Combination.** In the event of any liquidation, dissolution or winding up of the Company or upon the distribution of its assets, all assets and funds remaining after payment in full of the Company's debts and liabilities, and after the payment to holders of any then outstanding preferred stock of the full preferential amounts to which they were entitled, would be divided and distributed among holders of the common stock.

**Anti-Takeover Effects Of Provisions Of The Articles Of Incorporation.** The authorized but unissued shares of our common and preferred stock are available for future issuance without our shareholders' approval. These additional shares may be utilized for a variety of corporate purposes including but not limited to future public or direct offerings to raise additional capital, corporate acquisitions and employee incentive plans. The issuance of such shares may also be used to deter a potential takeover of IsoRay that may otherwise be beneficial to shareholders by diluting the shares held by a potential suitor or issuing shares to a shareholder that will vote in accordance with IsoRay's Board of Directors' desires. A takeover may be beneficial to shareholders because, among other reasons, a potential suitor may offer shareholders a premium for their shares of stock compared to the then-existing market price.

On February 1, 2007, the Board of Directors of IsoRay, Inc. declared a dividend of one preferred share purchase right (a "Right") for each outstanding Common Share of the par value of \$.001 per share (the "Common Shares") of the Company. The dividend is payable on February 16, 2007 (the "Record Date") to shareholders of record on that date.



Each Right entitles the registered holder to purchase from the Company one one-hundredth of a Series C Junior Participating Preferred Share of the par value of \$.001 per share (the "Preferred Shares") of the Company at a price of \$25 per one one-hundredth of a Preferred Share (the "Purchase Price"), subject to adjustment. The description and terms of the Rights are set forth in a Rights Agreement (the "Rights Agreement"), dated as of February 1, 2007, between the Company and Computershare Trust Company N.A., as Rights Agent (the "Rights Agent").

Initially, the Rights will attach to all certificates representing Common Shares then outstanding and no separate Right Certificates will be distributed. The Rights will separate from the Common Shares and a Distribution Date for the Rights will occur upon the earlier of:

- (i) the close of business on the fifteenth day following a public announcement that a person or group of affiliated or associated persons has become an "Acquiring Person" (i.e., has become, subject to certain exceptions, the beneficial owner of 15% or more of the voting power of the outstanding shares of voting capital stock of the Company in the election of directors), or
- (ii) the close of business on the fifteenth day following the first public announcement relating to a tender offer or exchange offer the consummation of which would result in a person or group of affiliated or associated persons becoming, subject to certain exceptions, the beneficial owner of 15% or more of the voting power of the outstanding shares of voting capital stock of the Company in the election of directors (or such later date as may be determined by the Board of Directors of the Company prior to a person or group of affiliated or associated persons becoming an Acquiring Person).

Until the Distribution Date,

- (i) the Rights will be evidenced by the Common Share certificates and will be transferred with and only with the Common Shares,
- (ii) new Common Share certificates issued after the Record Date upon transfer or new issuance of the Common Shares will contain a notation incorporating the Rights Agreement by reference, and
- (iii) the surrender for transfer of any Common Share certificate, even without such notation or a copy of this Summary of Rights attached thereto, will also constitute the transfer of the Rights associated with the Common Shares represented by such certificate.

As promptly as practicable following the Distribution Date, separate certificates evidencing the Rights ("Right Certificates") will be mailed to holders of record of the Common Shares as of the close of business on the Distribution Date and such separate Right Certificates alone will evidence the Rights.

The Rights are not exercisable until the Distribution Date. The Rights will expire on February 16, 2017, unless extended or earlier redeemed or exchanged by the Company as described below.

The Purchase Price payable, and the number of Preferred Shares or other securities or property issuable, upon exercise of the Rights are subject to adjustment from time to time to prevent dilution:

- (i) in the event of a stock dividend on, or a subdivision, combination or reclassification of, the Preferred Shares,
- (ii) upon the grant to holders of the Preferred Shares of certain rights, options or warrants to subscribe for or purchase Preferred Shares or convertible securities at less than the then current market price of the Preferred Shares, or

(iii) upon the distribution to holders of the Preferred Shares of evidences of indebtedness or assets (excluding regular periodic cash dividends or dividends payable in Preferred Shares) or of subscription rights or warrants (other than those described in clause (ii) hereof).

The number of Preferred Shares issuable upon the exercise of a Right is also subject to adjustment in the event of a dividend on Common Shares payable in Common Shares, or a subdivision, combination or consolidation of the Common Shares.

With certain exceptions, no adjustment in the Purchase Price will be required until cumulative adjustments require an adjustment of at least 1% in the Purchase Price. No fractional Preferred Shares will be issued (other than fractional shares which are integral multiples of one one-hundredth (subject to adjustment) of a Preferred Share, which may, at the election of the Company, be evidenced by depositary receipts) if in lieu thereof a payment in cash is made based on the closing price (pro-rated for the fraction) of the Preferred Shares on the last trading date prior to the date of exercise.

In the event that any person or group of affiliated or associated persons becomes an Acquiring Person, proper provision shall be made so that each holder of a Right, other than Rights that are or were beneficially owned by the Acquiring Person (which will thereafter be void), will thereafter have the right to receive upon exercise thereof at the then current exercise price of the Right that number of Common Shares having a market value of two times the exercise price of the Right, subject to certain possible adjustments.

In the event that, after the Distribution Date or within 15 days prior thereto, the Company is acquired in certain mergers or other business combination transactions or 50% or more of the assets or earning power of the Company and its subsidiaries (taken as a whole) are sold after the Distribution Date or within 15 days prior thereto, each holder of a Right (other than Rights which have become void under the terms of the Rights Agreement) will thereafter have the right to receive, upon exercise thereof at the then current exercise price of the Right, that number of common shares of the acquiring company (or, in certain cases, one of its affiliates) having a market value of two times the exercise price of the Right.

In certain events specified in the Rights Agreement, the Company is permitted to temporarily suspend the exercisability of the Rights.

At any time after a person or group of affiliated or associated persons becomes an Acquiring Person (subject to certain exceptions) and prior to the acquisition by a person or group of affiliated or associated persons of 50% or more of the voting power of the outstanding shares of voting capital stock of the Company in the election of directors, the Board of Directors of the Company may exchange all or part of the Rights (other than Rights which have become void under the terms of the Rights Agreement) for Common Shares or equivalent securities at an exchange ratio per Right equal to the result obtained by dividing the exercise price of a Right by the current per share market price of the Common Shares, subject to adjustment.

At any time prior to such time as a person or group of affiliated or associated persons becomes an Acquiring Person, the Board of Directors of the Company may redeem the Rights in whole, but not in part, at a price of \$.001 per Right, subject to adjustment (the "Redemption Price"), payable in cash. The period of time during which the Rights may be redeemed may be extended by the Board of Directors of the Company if no person has become an Acquiring Person. The redemption of the Rights may be made effective at such time, on such basis and with such conditions as the Board of Directors in its sole discretion may establish. The Board of Directors and the Company shall not have any liability to any person as a result of the redemption or exchange of the Rights pursuant to the provisions of the Rights Agreement.

The terms of the Rights may be amended by the Board of Directors of the Company, subject to certain limitations after such time as a person or group of affiliated or associated persons becomes an Acquiring Person, without the consent of the holders of the Rights, including an amendment prior to the date a person or group of affiliated or associated persons becomes an Acquiring Person to lower the 15% threshold for exercisability of the Rights to not less

than the greater of (i) the sum of .001% and the largest percentage of the outstanding shares of voting capital stock of the Company with voting power in the election of directors then known by the Company to be beneficially owned by any person or group of affiliated or associated persons (subject to certain exceptions) or (ii) 10%. On November 22, 2010, the Board amended the Rights Agreement to exclude the investor who purchased common stock and warrants in our November 2010 offering and its Affiliates and Associates from being considered an Acquiring Person unless and until this investor together with its Affiliates and Associates has become the Beneficial Owner of in excess of 25% of the voting power of the Voting Capital Stock then outstanding.

Until a Right is exercised, the holder thereof, as such, will have no rights as a shareholder of the Company, including, without limitation, the right to vote or to receive dividends.

The foregoing description of the Rights Agreement is qualified in its entirety by reference to the full text of the Rights Agreement.

Transfer Agent and Registrar. The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent's address is 350 Indiana Street, Golden, CO 80401, and its telephone number is (303) 262-0600.

#### PLAN OF DISTRIBUTION

We are registering an aggregate of 226,344 shares of common stock issued to the selling shareholders to permit the resale of such shares of common stock by the holders thereof from time to time after the date of this prospectus. Unless the context otherwise requires, as used in this prospectus, "selling shareholders" includes the selling shareholders named in the table on page 18 and donees, pledgees, transferees or other successors-in-interest selling shares received from selling shareholders as a gift, pledge or other transfer after the date of this prospectus. Upon being notified by a selling shareholder that a donee, pledgee, transferee or other successor-in-interest intends to sell more than 500 shares, we will, to the extent required, promptly file a supplement to this prospectus to name specifically such person as a selling shareholder.

We will not receive any of the proceeds from the sale by the selling shareholders of the shares of common stock. We will bear all fees and expenses incident to our obligation to register the shares of common stock.

The selling shareholders may sell all or a portion of the shares of common stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of common stock are sold through underwriters or broker-dealers, the selling shareholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of common stock may be sold on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale, in the over-the-counter market or in transactions otherwise than on these exchanges or systems or in the over-the-counter market and in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions. The selling shareholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- broker-dealers may agree with the selling shareholders to sell a specified number of such shares at a stipulated price per share;





- through the writing or settlement of options or other hedging transactions, whether such options are listed on an options exchange or otherwise;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling shareholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, as permitted by that rule, or Section 4(1) under the Securities Act, if available, rather than under this prospectus, provided that they meet the criteria and conform to the requirements of those provisions.

Broker-dealers engaged by the selling shareholders may arrange for other broker-dealers to participate in sales. If the selling shareholders effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling shareholders or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal. Such commissions will be in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction will not be in excess of a customary brokerage commission in compliance with the Financial Industry Regulatory Authority or FINRA, Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with sales of the shares of common stock or otherwise, the selling shareholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the shares of common stock in the course of hedging in positions they assume. The selling shareholders may also sell shares of common stock short and if such short sale shall take place after the date that this registration statement is declared effective by the SEC, the selling shareholders may deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling shareholders may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares, to the extent permitted by applicable law. The selling shareholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). Notwithstanding the foregoing, the selling shareholders have been advised that they may not use shares registered on this registration statement to cover short sales of our common stock made prior to the date the registration statement, of which this prospectus forms a part, has been declared effective by the SEC.

The selling shareholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act, amending, if necessary, the list of selling shareholders to include the pledgee, transferee or other successors in interest as selling shareholders under this prospectus. The selling shareholders also may transfer and donate the shares of common stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling shareholders and any broker-dealer or agents participating in the distribution of the shares of common stock may be deemed to be “underwriters” within the meaning of Section 2(11) of the Securities Act in connection with such sales. In such event, any commissions paid, or any discounts or concessions allowed to, any such broker-dealer

or agent and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. selling shareholders who are “underwriters” within the meaning of Section 2(11) of the Securities Act will be subject to the applicable prospectus delivery requirements of the Securities Act including Rule 172 thereunder and may be subject to certain statutory liabilities of, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

Each selling shareholder, other than Mr. Boesel, has informed the Company that it is not a registered broker-dealer and does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the common stock. Upon the Company being notified in writing by a selling shareholder that any material arrangement has been entered into with a broker-dealer for the sale of common stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such selling shareholder and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such the shares of common stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction. In no event shall any broker-dealer receive fees, commissions and markups, which, in the aggregate, would exceed eight percent (8.0%).

Under the securities laws of some states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of common stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any selling shareholder will sell any or all of the shares of common stock registered pursuant to the registration statement, of which this prospectus forms a part.

Each selling shareholder and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, to the extent applicable, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of common stock by the selling shareholder and any other participating person. To the extent applicable, Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

We will pay all expenses of the registration of the shares of common stock pursuant to the registration rights agreement, including, without limitation, SEC filing fees and expenses of compliance with state securities or “blue sky” laws; provided, however, that each selling shareholder will pay all underwriting discounts and selling commissions, if any and any related legal expenses incurred by it.

Once sold under the registration statement, of which this prospectus forms a part, the shares of common stock will be freely tradeable under the Securities Act in the hands of persons other than our affiliates.

#### LEGAL MATTERS

The validity of the issuance of the securities offered by this prospectus will be passed upon for us by Keller Rohrback, PLC, Phoenix, Arizona.

## EXPERTS

DeCoria, Maichel & Teague, P.S., independent registered public accounting firm, has audited our consolidated balance sheets as of June 30, 2010 and June 30, 2009, and related consolidated statements of operations, shareholders' equity and cash flows for the years ended June 30, 2010 and 2009, included in our Annual Report on Form 10-K for the fiscal year ended June 30, 2010, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on DeCoria, Maichel & Teague, P.S.'s report, given on the authority of said firm as experts in accounting and auditing.

## INTERESTS OF NAMED EXPERTS AND COUNSEL

Certain members of Keller Rohrback, PLC hold common stock of the Company, which in the aggregate equal less than one-quarter of a percent (0.25%) of the total issued and outstanding shares of our common stock.

## MATERIAL CHANGES

None.

## WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed a registration statement on Form S-3 with the SEC relating to the common stock offered by this prospectus. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules thereto. We have omitted parts of the registration statement, as permitted by the rules and regulations of the SEC. Statements contained in this prospectus as to the contents of any contract or other document referred to are not necessarily complete and in each instance reference is made to the copy of such contract or other document filed as an exhibit to the registration statement, each such statement being qualified in all respects by such reference. For further information with respect to us and the common stock, offered hereby, reference is made to such registration statement, exhibits and schedules.

We are subject to the information and periodic reporting requirements of the Exchange Act, and in accordance therewith file periodic reports, current reports, proxy statements and other information with the SEC. Such periodic reports, current reports, proxy statements, other information and a copy of this registration statement on Form S-3 may be inspected by anyone without charge and copies of these materials may be obtained upon the payment of the fees prescribed by the SEC, at the Public Reference Room maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. This registration statement on Form S-3 and the periodic reports, current reports, proxy statements and other information filed by us are also available through the Internet web site maintained by the SEC at the following address: <http://www.sec.gov>.

## INCORPORATION BY REFERENCE

The SEC allows us to "incorporate by reference" into this prospectus the information we file with it. This means that we can disclose important information to you by referring you to those documents. The information we incorporate by reference is considered to be a part of this prospectus, and later information we file with the SEC will automatically update and supersede this information. The following documents filed with the SEC (in each case, under our Commission File No. 001-33407) are incorporated by reference in this prospectus:

- (a) Our Annual Report on Form 10-K for the fiscal year ended June 30, 2010 (filed September 28, 2010), which contains audited financial statements for our latest fiscal year for which such statements have been filed.
- (b) Our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2010 (filed November 15, 2010).
- (c) Our Current Reports on Form 8-K filed on July 30, 2010 and November 22, 2010, and our amended Current Report on Form 8-K/A filed on November 24, 2010.
- (d) The description of our common stock contained in our Registration Statement on Form 8-A, filed with the Commission on April 12, 2007, including any amendments or reports filed for the purpose of updating such description.

We are also incorporating by reference any future filings we make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act until this offering is completed, including those made between the date of filing of the initial registration statement and prior to effectiveness of the registration statement, except for information furnished under Item 2.02 or Item 7.01 of our Current Reports on Form 8-K which is not deemed to be filed and not incorporated by reference herein.

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed to be modified or superseded to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference in this prospectus modifies or supersedes that statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We will provide, without charge, to each person to whom a copy of this prospectus has been delivered, upon written or oral request of such person, a copy of any or all of the documents incorporated by reference herein (other than certain exhibits to such documents not specifically incorporated by reference). Requests for such copies should be directed to: IsoRay, Inc., 350 Hills Street, Suite 106, Richland, Washington 99354, telephone number (509) 375-1202, Attention: Brien Ragle, Controller.

#### COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

The Company's Articles of Incorporation provide to directors and officers indemnification to the full extent provided by law, and provide that, to the extent permitted by Minnesota law, a director will not be personally liable for monetary damages to the Company or its shareholders for breach of his or her fiduciary duty as a director, except for liability for certain actions that may not be limited under Minnesota law. On July 1, 2006, the Company first entered into Indemnification Agreements with each of its directors and executive officers, and the Company has and intends to continue to enter into substantially identical agreements with any officers and directors who take office after July 1, 2006. The purpose of the Indemnification Agreements is to provide all officers and directors with indemnification to the fullest extent permitted under the Minnesota Business Corporations Act.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.



PART II  
INFORMATION NOT REQUIRED IN PROSPECTUS

## Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth the estimated costs and expenses payable by the registrant in connection with the offering of the securities being registered. We will pay all expenses of the offering. All of such expenses are estimates, other than the filing fees payable to the SEC.

SEC registration fees	\$ 22
Printing fees and expenses	\$ 500
Legal fees and expenses	\$ 10,000
Accounting fees and expenses	\$ 2,000
Miscellaneous expenses	\$ 0
Total	\$ 12,522

## Item 15. Indemnification of Directors and Officers.

The Company's Articles of Incorporation provide to directors and officers indemnification to the full extent provided by law, and provide that, to the extent permitted by Minnesota law, a director will not be personally liable for monetary damages to the Company or its shareholders for breach of his or her fiduciary duty as a director, except for liability for certain actions that may not be limited under Minnesota law. On July 1, 2006, the Company first entered into Indemnification Agreements with each of its directors and executive officers, and the Company has and intends to continue to enter into substantially identical agreements with any officers and directors who take office after July 1, 2006. The purpose of the Indemnification Agreements is to provide all officers and directors with indemnification to the fullest extent permitted under the Minnesota Business Corporations Act.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

## Item 16. Exhibits.

Exhibit Number	Description
3.3	Restated and Amended Articles of Incorporation incorporated by reference to the Form 10-KSB filed on October 11, 2005.
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.
4.19	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



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- 5.1 February 7, 2007.  
Opinion of Keller Rohrback, PLC.  
23.1 Consent of Keller Rohrback, PLC (included in its opinion filed as Exhibit  
5.1 hereto).  
23.2 Consent of DeCoria, Maichel & Teague, P.S., independent registered  
public accounting firm.  
24.1 Power of Attorney (included on signature page).

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Item 17. Undertakings.

a. The undersigned registrant hereby undertakes:

1. To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

i. To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

ii. To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

iii. To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

Provided however, that: Paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

2. That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

3. To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

b. That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

1. If the Registrant is relying on Rule 430B: Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

2. If the Registrant is relying on Rule 430B: Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.
3. If the Registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
- c. That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities: The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
- i. Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
  - ii. Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
  - iii. The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
  - iv. Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

d. The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

e. Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

f. The undersigned registrant hereby undertakes that:

1. For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933 shall be deemed to be part of this registration statement as of the time it was declared effective.
2. For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Richland, State of Washington, on December 8, 2010.

ISORAY, INC.

By: /s/ Dwight Babcock  
Dwight Babcock,  
Chief Executive  
Officer

## POWER OF ATTORNEY

We, the undersigned directors and officers of IsoRay, Inc., do hereby constitute and appoint Dwight Babcock and Robert Kauffman, or either of them, our true and lawful attorneys and agents, to do any and all acts and things in our name and behalf in our capacities as directors and officers and to execute any and all instruments for us and in our names in the capacities indicated below, which said attorneys and agents, or either of them, may deem necessary or advisable to enable said corporation to comply with the Securities Act of 1933, as amended, and any rules, regulations, and requirements of the Securities and Exchange Commission, in connection with this registration statement, including specifically, but without limitation, power and authority to sign for us or any of us in our names and in the capacities indicated below, any and all amendments (including post-effective amendments) to this registration statement, or any related registration statement that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended; and we do hereby ratify and confirm all that the said attorneys and agents, or either of them, shall do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed below by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Dwight Babcock Dwight Babcock	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	December 8, 2010
/s/ Brien Ragle Brien Ragle	Controller (Principal Financial and Accounting Officer)	December 8, 2010
/s/ Robert Kauffman Robert Kauffman	Vice Chairman of the Board of Directors	December 8, 2010
/s/ Thomas LaVoy Thomas LaVoy	Director	December 8, 2010
/s/ Albert Smith Albert Smith	Director	December 8, 2010

EXHIBIT INDEX

Exhibit Number	Description
3.3	Restated and Amended Articles of Incorporation incorporated by reference to the Form 10-KSB filed on October 11, 2005.
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.
4.19	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.
5.1	Opinion of Keller Rohrback, PLC.
23.1	Consent of Keller Rohrback, PLC (included in its opinion filed as Exhibit 5.1 hereto).
23.2	Consent of DeCoria, Maichel & Teague, P.S., independent registered public accounting firm.
24.1	Power of Attorney (included on signature page).