



**FOR IMMEDIATE RELEASE**

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## **ISORAY, INC. REPORTS IMPROVED PERFORMANCE IN FISCAL YEAR 2011**

*New Products and Sales Initiated in FY2011 Final Quarter Expected to Power Growth*

RICHLAND, Washington (September 28, 2011) – IsoRay Inc. (AMEX: ISR), a medical technology company and innovator in seed brachytherapy and medical radioisotope applications, announced its financial results for the year ended June 30, 2011.

Some of the highlights in the year ended June 30, 2011 include the Company's realization of a gross income rise of 59% over FY 2010, as that number grew from \$725,797 to \$1,157,417. The Company reduced its net loss by 30% from FY 2010's level of \$4,033,856 to \$2,842,213. The Company reduced operating loss for FY 2011 by 26%, showing an improvement of \$1,045,912 for a resulting net operating loss of \$2,962,988. The Company had cash and cash equivalents of \$2,112,254 as of June 30, 2011.

In fiscal year 2011, 92% of revenue was from the sales of Cesium-131 brachytherapy seeds (internal radiation therapy) for the treatment of prostate cancer, while the other 8% of revenue was generated by sales of seeds for the treatment of brain cancer, colorectal cancer, gynecological cancer, head and neck cancer, lung cancer, and ocular cancer. Case counts for FY 2011 were 102% of the cases in FY2010. Importantly, 9% of the cases for the year came from non-prostate cancer sites representing a 250% increase in non-prostate revenue growth over FY 2010.

IsoRay Chairman and CEO Dwight Babcock commented, "To date, we have been disappointed in how long it has taken to develop a broader implementation of our new products. The growth in sales and product adoption is slower in the medical device field than we had expected. We attribute that to the fact that the patients' experience and results need to be evaluated more thoroughly before physicians in community settings will embrace these new technologies. We are seeing a good deal of interest in our new products and expect that the positive feedback we have received will lead to increased revenue in the coming year. In the meantime, we have managed the Company with an eye toward our long term success."

In looking to the future, Babcock said, "I believe that current sales figures, while stable, should be enhanced as we advance our new marketing efforts focusing on Cesium-131's application to other cancer sites. I look with great anticipation toward expected future growth in revenue as a result of new product introductions as well." Babcock noted that IsoRay has strengthened its position as the brachytherapy isotope provider of choice because, unlike many of its competitors who are generally limited to prostate cancer, IsoRay continues to pursue the non-prostate market.

Major milestones achieved during the past fiscal year include:

- The Company completed a license agreement with Dr. Reddy's Laboratories (NYSE: RDY) for exclusive worldwide licensing rights to lotrex<sup>®</sup>, a liquid iodine radiation, for use in brain cancer treatment. lotrex<sup>®</sup> is a critical component in the GliaSite<sup>®</sup> radiation therapy system. The lotrex<sup>®</sup> licensing agreement was a crucial step in the process needed to allow IsoRay to achieve FDA clearance and address an immediate

market opportunity and patient needs, while the Company proceeds toward FDA clearance of its proprietary liquid Cesium-131 for use in the GliaSite® therapy system.

- The FDA cleared the Company's [GliaSite®](#) radiation therapy system, a balloon catheter device used in the treatment of brain cancer. The clearance was the major step required to return the GliaSite® radiation therapy system to the marketplace. The system's balloon catheter is a landmark technology that allows physicians to treat more brain cancer patients than ever before with internal radiation or [brachytherapy](#).
- The Company announced that a growing number of hospitals and medical treatment centers are adopting the Company's proprietary mesh Cesium-131 (Cs-131) brachytherapy seeds for use in conjunction with the da Vinci® Surgical System to treat early stage lung cancer patients.
- The Company announced a new dual therapy study using Cesium-131 brachytherapy and external beam radiation. Multiple sites have received Institutional Review Board (IRB) approval for the study, which is examining the efficacy of combining intensity modulated radiation (IMRT) with Cesium-131 to treat intermediate and high risk, early stage prostate cancer.
- The Company has launched its E-clinical data collection system for ease of data management. The online, real-time system provides an inexpensive vehicle to gather data from physicians allowing lead investigators to easily publish data on their successes.
- University of Kentucky Radiation Oncologist Dr. Marcus E. Randall performed the world's first Cesium-131 brachytherapy seed implant for gynecological cancer on a female patient whose cancer had reoccurred following previous radiation treatment.
- A multi-institutional lung study has launched examining the efficacy of brachytherapy over other techniques and treatments. New York Physician Dr. Bhupesh Parashar is leading the study which has expanded to include a growing number of institutions.
- IsoRay received its CE mark certification giving European approval to IsoRay's stranded and mesh seed (Cesium-131 seeds) configuration for cancer applications throughout the body including head and neck, lung, brain, colon, and prostate cancers.
- The Company won Seattle Business Magazine's Health Award for Outstanding Achievement in Medical Devices.
- IsoRay was selected, again, to the Washington State Deloitte Fast 500, which recognizes leading technology companies in regions around the world and includes both public and private companies.

#### IsoRay, Inc. and Subsidiaries Consolidated Statements of Operations

	Year ended June 30,	
	<u>2011</u>	<u>2010</u>
Product sales	\$ 5,238,973	\$ 5,286,084
Cost of product sales	<u>4,081,556</u>	<u>4,560,287</u>
Gross income	<u>1,157,417</u>	<u>725,797</u>
Operating expenses:		
Research and development expenses	981,186	340,959
Research and development reimbursement	(515,853)	-
Sales and marketing expenses	1,232,188	1,953,598

General and administrative expenses	<u>2,422,884</u>	<u>2,440,140</u>
Total operating expenses	<u>4,120,405</u>	<u>4,734,697</u>
Operating loss	<u>(2,962,988)</u>	<u>(4,008,900)</u>
Non-operating income (expense):		
Interest income	3,381	11,433
Gain on fair value of warrant liability	334,000	-
Financing and interest expense	<u>(216,606)</u>	<u>(36,389)</u>
Non-operating income (loss), net	<u>120,775</u>	<u>(24,596)</u>
Net loss	<u>(2,842,213)</u>	<u>(4,033,856)</u>
Preferred stock dividends	(10,632)	(10,632)
Net loss applicable to common shareholders	<u><u>\$(2,852,845)</u></u>	<u><u>\$(4,044,488)</u></u>
Basic and diluted loss per share	<u>\$ (0.11)</u>	<u>\$ (0.18)</u>
Weighted average shares used in computing net loss per share:		
Basic and diluted	<u>25,131,563</u>	<u>22,960,421</u>

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#### **About IsoRay, Inc.**

IsoRay, Inc., through its subsidiary, IsoRay Medical, Inc., is the exclusive producer of Cesium-131 internal radiation therapy, which is expanding brachytherapy options throughout the body. Learn more about this innovative Richland, Washington company and explore the many benefits and uses of Cesium-131 by visiting [www.isoray.com](http://www.isoray.com).

#### **Safe Harbor Statement**

Statements in this news release about IsoRay's future expectations, including: the advantages of our Cesium-131 seed, future demand for IsoRay's existing and planned products, whether revenue, cash flows and other financial metrics will improve in future periods, whether IsoRay will be able to continue to expand its base beyond prostate cancer, whether IsoRay's Cesium-131 seed will be used to treat additional cancers and malignant disease, whether IsoRay will be able to locate distributors in Europe and whether IsoRay will be able to generate sales in Europe, the advantages of the Gliasite delivery system, whether a liquid form of Cesium-131 will be developed that receives regulatory approval and can be used successfully with the Gliasite delivery system, whether the new data collection system will improve study enrollments and analysis, whether additional studies will be published with favorable outcomes from treatment with Cesium-131, and all other statements in this release, other than historical facts, are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 ("PSLRA"). This statement is included for the express purpose of availing IsoRay, Inc. of the protections of the safe harbor provisions of the PSLRA. It is important to note that actual results and ultimate corporate actions could differ materially from those in such forward-looking statements based on such factors as physician acceptance, training and use of IsoRay's products, changing levels of demand for IsoRay's current and proposed future products, IsoRay's ability to reduce or maintain expenses while increasing sales, whether later studies and protocols support the findings of the initial studies, success of future research and development activities, whether initial implants of Cesium-131 to treat non-prostate cancers result in favorable patient outcomes in both the short- and long-term, patient results achieved when Cesium-131 is used for the treatment of cancers and malignant diseases beyond prostate cancer, IsoRay's ability to successfully manufacture, market and sell its products, whether resources are available as needed to develop a liquid form of Cesium-131 and whether such liquid form receives and maintains all required regulatory approvals, whether any liquid form of Cesium-131 is able to be used successfully with the Gliasite delivery system, patient results achieved when Cesium-131 is used for the treatment of cancers and malignant diseases beyond prostate cancer whether with the Gliasite delivery system or in another delivery system, whether IsoRay will receive state regulatory approval to manufacture components of the Gliasite delivery system, whether IsoRay is able to locate suitable European distributors and enter into final agreements with them, IsoRay's ability to manufacture its products in sufficient quantities to meet demand within required delivery time periods while meeting its quality control standards, IsoRay's ability to enforce its intellectual property rights,

changes in reimbursement rates, changes in laws and regulations applicable to our product, and other risks detailed from time to time in IsoRay's reports filed with the SEC.