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UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

# FORM 8-K

## CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): May 16, 2011

## ISORAY, INC.

(Exact name of registrant as specified in its charter)

Minnesota  
(State or other jurisdiction  
of incorporation)

001-33407  
(Commission  
File Number)

41-1458152  
(IRS Employer  
Identification No.)

350 Hills Street, Suite 106, Richland, Washington 99354

(Address of principal executive offices) (Zip Code)

(509) 375-1202

(Registrant's telephone number)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act
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**Item 2.02. Results of Operations and Financial Condition**

On May 16, 2011, IsoRay, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2011, the text of which is attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K, including the exhibit, is furnished pursuant to Item 2.02 and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such filing.

In addition to historic information, this report, including the exhibit, contains forward-looking statements regarding events, performance and financial trends. Various factors could affect future results and could cause actual results to differ materially from those expressed in or implied by the forward-looking statements. Some of those factors are identified in the Company's periodic reports filed with the Securities and Exchange Commission, the most recent of which are the Company's Annual Report on Form 10-K for the year ended June 30, 2010 and the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2011.

**Item 9.01. Financial Statements and Exhibits**

**(d) Exhibits**

<u>Exhibit</u>	<u>Description</u>
99.1	Press release issued by IsoRay, Inc., dated May 16, 2011.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: May 16, 2011

IsoRay, Inc., a Minnesota corporation

By: /s/ Dwight Babcock  
Dwight Babcock, CEO

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**FOR IMMEDIATE RELEASE**

Contact: Sharon Schultz  
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## **ISORAY, INC. REPORTS GAINS IN THIRD QUARTER FISCAL YEAR 2011 RESULTS**

*17% Revenue Increase Fuels Significant Financial Improvement*

RICHLAND, Washington (May 16, 2011) – IsoRay Inc. (AMEX: ISR), announced financial results for the third fiscal quarter ended March 31, 2011 underscoring significant improvements in quarterly sales revenue growth both sequentially and in the prior year quarter. **Sales increased 17% in the period with the Company posting a 581% gain in gross profit compared to the prior year third quarter.**

**The growth in revenue was attributed to a 21% increase in patient cases over Q3 FY2010. Significantly, IsoRay's non-prostate cases represented 10% of overall sales. This rise reflects increasing adoption of the Company's breakthrough internal radiation therapy by medical practitioners and facilities across the country . IsoRay is the exclusive manufacturer of Cesium-131 used in internal radiation therapy ( brachytherapy ) for the treatment of lung, brain, colon, head and neck, ocular melanoma, and prostate cancer as well as other cancers throughout the body.**

**IsoRay Chairman and CEO Dwight Babcock, commenting on the quarter's improved performance said, "We are very pleased to have achieved these milestones including the second best quarterly revenues in the Company's history and the highest gross profit. The numbers reflect important gains for the Company and serve to endorse our ongoing strategy for expanding treatment applications beyond the prostate. We are particularly excited about the growth in sales of non-prostate treatment products. It is indicative of the Company's transformation from an exclusive prostate focus to a total body internal radiation therapy company. We are effectively opening new horizons for brachytherapy by making Cesium-131 available to address cancers in locations throughout the body in contrast to other internal radiation therapy alternatives. "**

**In other developments , 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. With this approval, IsoRay will now be seeking distributors throughout Europe.**

**Looking forward, IsoRay's GliaSite® radiation therapy system remains on target for the launch of its sales initiative in August 2011. GliaSite® therapy system is the world's only FDA-approved balloon catheter device used in the brachytherapy treatment of brain cancer . This innovative technology allows physicians to treat more brain cancer patients than ever before with internal radiation therapy (brachytherapy) with benefits over alternative radiation options while enhancing patient lifestyle.**

**Of the anticipated launch, CEO Babcock added, "We expect GliaSite sales to be an important factor in driving our cash flow." Along with building inventory for the product, he reported that the Company has completed the final testing and manufacture of Iotrex, a liquid iodine, which will initially be used in the GliaSite radiation therapy system. IsoRay is in the final stage of testing its GliaSite catheter system with Iotrex for submission of its 510K for GliaSite to the FDA. Use of Iotrex allows IsoRay to address imminent market opportunities both in the U.S. and Europe, while the Company seeks final approval for liquid Cesium-131 and its use in the GliaSite® therapy system.**

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**In another important development, IsoRay has just launched its real-time, E-clinical data collection system.** IsoRay will be using the E-clinical data system to provide patient data for various new studies providing an independent source for clinical analysis and publication. **The ease and accuracy of data submission offers physicians important benefits and features, while lowering the cost of acquiring empirical data. The online web data collection registry will immediately be used by physicians in the multi-institutional lung study examining the efficacy of brachytherapy over other techniques and treatments. Led by New York physician Dr. Bhupesh Parashar, the lung study has expanded with a growing number of institutions signing on to participate.**

IsoRay, Inc. and Subsidiaries  
Consolidated Statements of Operations  
(Unaudited)

	Three months ended March 31,		Nine months ended March 31,	
	2011	2010	2011	2010
Product sales	\$ 1,410,694	\$ 1,203,216	\$ 3,982,743	\$ 3,950,650
Cost of product sales	<u>1,053,268</u>	<u>1,150,730</u>	<u>3,281,800</u>	<u>3,411,012</u>
Gross profit	<u>357,426</u>	<u>52,486</u>	<u>700,943</u>	<u>539,638</u>
Operating expenses:				
Research and development expenses	244,184	98,964	374,317	226,974
Research and development reimbursement	(56,118)	-	(205,947)	-
Sales and marketing expenses	235,206	447,693	944,244	1,494,572
General and administrative expenses	<u>627,592</u>	<u>596,224</u>	<u>1,784,933</u>	<u>1,784,664</u>
Total operating expenses	<u>1,050,864</u>	<u>1,142,881</u>	<u>2,897,547</u>	<u>3,470,160</u>
Operating loss	<u>(693,438)</u>	<u>(1,090,395)</u>	<u>(2,196,604)</u>	<u>(2,930,522)</u>
Non-operating income (expense)				
Interest income	848	1,547	2,888	10,358
Gain / (loss) on fair value of warrant liability	(163,000)	-	257,000	-
Financing and interest expense	<u>(174,675)</u>	<u>(6,445)</u>	<u>(193,500)</u>	<u>(31,704)</u>
Non-operating income (expense), net	<u>(336,827)</u>	<u>(4,898)</u>	<u>66,388</u>	<u>(21,346)</u>
Net loss	(1,030,265)	(1,095,293)	(2,130,216)	(2,951,868)
Preferred stock dividends	<u>(2,658)</u>	<u>-</u>	<u>(7,974)</u>	<u>(36,679)</u>
Net loss applicable to common shareholders	<u>\$ (1,032,923)</u>	<u>\$ (1,095,293)</u>	<u>\$ (2,138,190)</u>	<u>\$ (2,988,547)</u>
Basic and diluted loss per share	<u>\$ (0.04)</u>	<u>\$ (0.05)</u>	<u>\$ (0.09)</u>	<u>\$ (0.13)</u>
Weighted average shares used in computing net loss per share: Basic and diluted	<u>26,008,878</u>	<u>22,942,458</u>	<u>24,709,541</u>	<u>22,942,458</u>

The accompanying notes are an integral part of these consolidated financial statements.

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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 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.

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