



Statistics	AMEX:	ISR	Market capitalization:	\$ 7 million
	Recent price (01/02/09):	0.29	Shares outstanding (11/03/08):	23.0 million
	52-week price range:	\$ 2.34 – .15	Fiscal year ends:	June 30
	Average daily volume:	29,000	Next earnings due:	Jan 2009

## Analyst Coverage

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## Business Summary

IsoRay, Inc. engages in the development, manufacture, and sale of brachytherapy seeds for the treatment of prostate cancer and other malignant diseases in the United States, Europe and Russia. Brachytherapy seeds are rice-sized radioactive capsules that are implanted near or directly on tumor tissue. Proxcelan™ (Cesium-131), the Company's newly branded isotope, is the first major advancement in brachytherapy in over twenty years. Completed and ongoing clinical studies validate its superior performance to Iodine-125 and Palladium-103, two commodity isotopes that have dominated the brachytherapy market since its inception.

The Company believes that Cs-131 is far less likely to cause collateral damage to surrounding tissue than its peers because it has a higher average energy, a key factor in how uniformly the radiation dose can be delivered throughout the prostate. Early studies demonstrate Cs-131 implants are able to deliver the required dose while maintaining good homogeneity across the gland itself, thus reducing unnecessary dosage to critical structures such as the urethra and rectum. It also has a shorter half-life than its peers, which limits the amount of seed implants as well as the duration and severity of typical side effects associated with brachytherapy. Cs-131 delivers 90 percent of the radiation within 33 days, compared to Palladium-103 (58 days) and Iodine-125 (204 days).

Cs-131 received FDA 510(k) clearance in 2003 for treatment of malignant disease of the head and neck, brain, breast, prostate and other organs. IsoRay continues to conduct post-market clinical trials for Proxycelan because its clearance was based on its similarity to other products on the market, not specific clinical trials. The Company believes that ongoing clinical trials will continue to validate its superior performance and help to discover new potential applications for its isotope.

To date there have been roughly 2,000 Cs-131 implants performed without a tumor related fatality or reported incidence of permanent incontinence. IsoRay also intends to develop the isotope for the post-surgical brachytherapy market, which includes seed treatment for breast and eye cancer. IsoRay believes that ocular melanoma presents a future application of its technology.

## Outlook

The Frost Sullivan research service projects that the implantable prostate seeds market is expected to grow to \$300.2 M in revenue by 2010, which represents a CAGR of 11.1 percent. As Proxcelan is still a new technology, it currently owns a small fraction of this market. The Company expects that favorable clinical trial results will continue to validate the superiority of its product. There is a growing body of evidence that shows use of Proxcelan produces fewer side effects to urinary and sexual functions, the two key quality of life issues most affected by prostate seed therapy.

Cs-131 is well-positioned to take advantage of two critical industry trends within the radiation-oncology community. The first catalyst is scientific as recent radiobiological data suggest the rate of replication for malignant prostate tissue may be faster than previously thought, thus increasing the importance placed on speed in dosage administration. The shorter half-life of Cs-131 plays well into this trend. The second catalyst is economic as the maximum potential profit on a per patient basis is achieved by combining 3-D image external beam radiation with brachytherapy or surgery. During combination therapy, physicians prefer high energy isotopes with a short half-life as the first strike against rapidly dividing cancerous cells, then follow up with longer term use of IMRT to combat slower dividing cells. IsoRay has developed an experienced sales team, critical industry alliances, and an efficient manufacturing process to gain market share for Proxcelan in the brachytherapy market.

First quarter ended: September 30, 2008 (In US \$; 000s omitted, except EPS)	Three Months Ended	
	<u>9/30/08</u>	<u>9/30/07</u>
Total revenue:	\$ 1,520	\$ 1,856
Net (loss) income:	(1,794)	(2,159)
Net income per share (basic and diluted):	(0.08)	(0.09)
Weighted average shares used in computing net loss per share (basic and diluted):	22,942,088	23,001,041

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## Recent Developments

- **November 24, 2008**... IsoRay announced that its operating subsidiary has hired Anthony G. Pasqualone as Vice President of business Development in charge of Sales.
- **November 13, 2008**... IsoRay announced its financial results for the first quarter ended September 30, 2008. IsoRay Chairman and Interim CEO Dwight Babcock said sales revenue for the quarter decreased by 18 percent to approximately \$1,519,583 as compared to approximately \$1,855,719 in the year-earlier period. However, medical centers ordering the Company's Proxcelan™ seeds remained steady at 47 compared to the 49 centers that ordered in the first quarter of fiscal 2008. Net loss decreased from approximately \$2,159,401 or \$0.09 loss per share in fiscal year 2008's first quarter, to approximately \$1,793,596 or \$0.08 loss per share in the quarter ended September 30, 2008. The decreased loss was mainly due to reduced material and production costs and reduced operating expenses as ISR has worked to streamline its operations and become more efficient.
- **August 20, 2008**... IsoRay announced its financial results for the fourth quarter and year ended June 30, 2008. All of the Company's revenues were generated through sales of Proxcelan™ Cesium-131 seeds for the treatment of prostate cancer. Since the first patient implant in October 2004 over 2,800 prostate cancer patients have been treated with Cesium-131. For fiscal year 2008, sales revenue increased by 25% to \$7,158,690 over fiscal year 2007. Net loss for fiscal year 2008 decreased 11% to \$8,557,507. Sales revenue increased 7% to \$1,760,985 for the fourth quarter ending June 30, 2008 compared to the prior quarter ended June 30, 2007. Gross margin for the fourth quarter was \$381,139, an improvement of 5,270% over the gross loss of \$7,372 for the prior year fourth quarter and increased 279% from the gross margin of \$100,661 for the previous quarter. Net loss for the quarter ended June 30, 2008 was \$1,441,439 which represents an improvement of 47% and 34% over the net loss for the quarters ended June 30, 2007 and March 31, 2008, respectively.
- **July 24, 2008**... IsoRay announced completion of a baseline inspection by the Food and Drug Administration (FDA) for all its Quality Systems. IsoRay underwent its first inspection by the FDA from July 14 - 18. The inspection covered the manufacturing and quality systems at its Richland facility. At the end of the inspection no report of deviations from GP or list of observations (form FDA 483) was issued to IsoRay.

## Financial Highlights

<u>Fiscal year: June 30</u>	<u>2008</u>	<u>2007</u>	<u>2006</u>
<i>(in US; 000s omitted, except EPS)</i>			
Total revenues:	\$7,159	\$5,738	1,994
Operating (loss) income:	(8,803)	(9,700)	(7,195)
Net (loss) income:	(8,557)	(9,605)	(8,218)
Net income (loss) per share (basic and diluted):	(0.37)	(0.54)	(0.68)
Weighted average shares used in computing net loss per share (basic and diluted):	23,063,282	17,827,522	12,051,964

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ISR chart provided by Edgar®Online

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