

ISORAY (ISR)

IsoRay FY2012 Strategy Articulated, Waiting to See Results on Execution; Maintain Neutral.

Investment Rating Neutral
Prior Rating

Price Target N/A
Prior Target

Price (October 3, 2011) \$0.98
52 Week Range \$0.77 – \$1.73
Shares Outstanding 26.0 MM
Market Capitalization \$25.5 MM
Cash (June 30, 2011) \$2.1 MM

Fiscal Year End June

Revenue (MM's):

	<u>Current</u>	<u>Prior</u>
2010A	\$5.3	
2011A	\$5.2	\$5.4
2012E	\$7.9	

EPS:

	<u>Current</u>	<u>Prior</u>	P/E
2010A	(\$0.18)		NA
2011A	(\$0.11)	(\$0.12)	NA
2012E	(\$0.10)		NA

Quarterly EPS:

	<u>Current</u>	<u>Prior</u>
2011A		
Sep	(\$0.04)	
Dec	(\$0.01)	
Mar	(\$0.04)	
Jun	(\$0.03)	(\$0.03)
2012E		
Sep	(\$0.03)	
Dec	(\$0.03)	
Mar	(\$0.02)	
Jun	(\$0.02)	

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Highlights

- **IsoRay strategy for FY2012 clearly articulated.** IsoRay will focus on 3 core marketing areas for 2012 to drive revenues: 1) increasing utilization of Proxcelan (CS-131) brachytherapy seed use in prostate cancer; 2) increase Proxcelan use in solid tumor (head and neck, lung, chest wall and colorectal cancer) indication; and 3) bring GliaSite radiation therapy system (FDA approved 510k in August 2011) to market. Additionally, management intends to continue clinical research activities to enhance the medical community's understanding of Proxcelan application beyond prostate cancer and increase awareness through additional publications and presentations at various medical conferences over FY2012.
- **IsoRay starts fiscal year 2012 with improvements in CS-131 seed revenues and product costs.** CS-131 product sales of \$1.3 million for FY4Q 2011 were shy of our estimate of \$1.4 million. We believe sales of CS-131 in prostate remain an important sales base for IsoRay, but believe rate of adoption of CS-131 in other cancer modalities will determine the extent of revenue growth we will see with this product as we believe revenues from prostate may have peaked. Cost of product sales were \$0.8 million which was below our estimate of \$1.1 million. We are glad to see management's steps in lowering seed production are improving gross margins and look forward to continued economies of scale in reduced labor costs. Additionally, CS-131 was granted a CE mark, opening up the EU market for CS-131. We look forward to analyzing the possibility for continued revenue growth throughout the upcoming quarters to better gauge this product's potential.
- **GliaSite approved in August 2011.** GliaSite is a balloon catheter device used in the brachytherapy treatment of brain cancer and has been FDA approved (2001) using Iotrex (liquid iodine). IsoRay received marketing approval for its modification of the GliaSite device from the FDA in August 2011 and will market it for use with Iotrex (worldwide licensing rights in brain cancer recently obtained). Additionally, IsoRay will seek FDA clearance for liquid CS-131 use in GliaSite.
- **Cash.** We believe IsoRay's management has taken great strides in the past year to preserve cash by minimizing expenditures and maximizing operational efficiencies resulting in a monthly cash burn of approximately \$0.2 million. IsoRay believes it can fund operations to mid-calendar year 2012 given its current cash position of \$2.1 million. Revenue growth could potentially mitigate IsoRay's cash needs, but we believe IsoRay could need to raise additional funds in the next six months and as such, the risk of dilution remains.
- **Until there is more visibility on IsoRay's ability to grow CS-131 seeds meaningfully (especially in non-prostate modalities) and more progress on the GliaSite launch, we continue to maintain our Neutral rating.** We are encouraged by the steps management is taking to increase Proxcelan visibility and the GliaSite approval, but believe we need more visibility and meaningful growth with both products to determine the sustainability of recent revenue growth. As such, we maintain our neutral rating.

Disclosures and Analyst Certifications can be found in Appendix A.

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Table 1: ISR– Quarterly Financial Model

Isoray
 Quarterly Sales and Financial Data
 (000s)
 June Fiscal Year

	<u>2010A</u>	<u>Sept-10A</u>	<u>Dec-10A</u>	<u>Mar-11A</u>	<u>Jun-11A</u>	<u>2011A</u>	<u>Sept-11E</u>	<u>Dec-11E</u>	<u>Mar-12E</u>	<u>Jun-12E</u>	<u>2012E</u>
Sales/Royalties											
Product Sales	\$5,286	\$1,327	\$1,245	\$1,411	\$1,256	\$5,239	\$1,576	\$1,773	\$2,127	\$2,403	\$7,880
Total Revenues	\$5,286	\$1,327	\$1,245	\$1,411	\$1,256	\$5,239	\$1,576	\$1,773	\$2,127	\$2,403	\$7,880
COGS	\$4,560	\$1,112	\$1,117	\$1,053	\$800	\$4,082	\$1,182	\$1,330	\$1,702	\$1,923	\$6,136
R&D	\$341	\$115	\$16	\$188	\$147	\$465	\$150	\$240	\$242	\$245	\$877
Sales & Marketing	\$1,954	\$373	\$336	\$235	\$288	\$1,232	\$291	\$294	\$297	\$300	\$1,181
G&A	\$2,440	\$596	\$561	\$628	\$638	\$2,423	\$659	\$666	\$666	\$666	\$2,656
Operating Expense	\$9,295	\$2,196	\$2,029	\$2,104	\$1,873	\$8,202	\$2,282	\$2,529	\$2,907	\$3,133	\$10,850
Operating Income/Loss	(\$4,009)	(\$868)	(\$785)	(\$693)	(\$617)	(\$2,963)	(\$706)	(\$756)	(\$779)	(\$729)	(\$2,970)
Other Income											
Interest income	\$11	-	\$1	\$1	\$2	\$3	\$1	\$1	\$2	\$2	\$6
Other	(\$36)	-	\$555	(\$338)	(\$100)	\$117	-	-	-	-	-
Net Non-Operating Income	(\$25)	-	\$556	(\$337)	(\$99)	\$121	\$1	\$1	\$2	\$2	\$6
Pretax Income	(\$4,034)	(\$868)	(\$228)	(\$1,030)	(\$715)	(\$2,842)	(\$705)	(\$755)	(\$777)	(\$727)	(\$2,964)
Taxes											
Income tax paid/(benefit)	-	-	-	-	-	-	-	-	-	-	-
Non-Operating income/(charge)	(\$11)		(\$3)	(\$3)	(\$5)	(\$11)					
Net Income/Loss	(\$4,044)	(\$868)	(\$231)	(\$1,033)	(\$721)	(\$2,853)	(\$705)	(\$755)	(\$777)	(\$727)	(\$2,964)
Earnings/ (Loss) Per Share	(\$0.18)	(\$0.04)	(\$0.01)	(\$0.04)	(\$0.03)	(\$0.11)	(\$0.03)	(\$0.03)	(\$0.02)	(\$0.02)	(\$0.10)
Shares Outstanding (MM)	22.96	23.05	25.07	26.01	26.40	25.13	26.50	26.60	31.70	31.80	29.15
Earnings Per Share (Fully Taxed)											
Earnings/ (Loss) Per Share (Diluted)	(0.14)	(0.03)	(0.01)	(0.03)	(0.02)	(0.09)	(0.02)	(0.02)	(0.02)	(0.02)	(0.08)
Fully Diluted Shares Out (MM)	28.86	28.95	30.97	31.91	32.30	31.03	32.40	32.50	37.60	37.70	35.05
NOL	(41,914)	(42,783)	(43,013)	(44,046)	(44,767)	(44,767)	(45,472)	(46,227)	(47,004)	(47,732)	(47,732)
Margin Analysis	2010A	1Q11E	2Q11E	3Q11E	4Q11E	2011E	1Q12E	2Q12E	3Q12E	4Q12E	2012E
Operating Margin	-76%	-65%	-63%	-49%	-49%	-57%	-45%	-43%	-37%	-30%	-38%
Gross Margin	14%	19%	10%	25%	36%	22%	33%	25%	20%	20%	22%
Net Margin	-	-	-	-	-	-	-	-	-	-	-
Tax Rate	-	-	-	-	-	-	-	-	-	-	-

Source: Corporate reports and Ladenburg Thalmann estimates

Source: Company Reports, Ladenburg Thalmann & Company Estimates

APPENDIX A: IMPORTANT RESEARCH DISCLOSURES

ANALYST CERTIFICATION

I, Matt Kaplan, attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

The research analyst(s) primarily responsible for the preparation of this research report have received compensation based upon various factors, including the firm's total revenues, a portion of which is generated by investment banking activities.

For details on IsoRay please contact Matt Kaplan.

COMPANY BACKGROUND

IsoRay is a medical device company with a marketed, revenue-generating, radioactive device used for cancer treatment. Cesium-131 (brand name Proxcelan) is a radioactive seed used in brachytherapy procedures primarily for prostate cancer and is approved in indications beyond prostate cancer. The Company plans to launch GliaSite in fiscal 3Q 2011. For additional information on our analysis of IsoRay please contact Matt Kaplan.

VALUATION METHODOLOGY

We value the Company based on a revenue multiple-model based on forward revenues. Our price target is currently removed as we believe there is significant risk to our forward revenue projections.

RISKS

On top of normal economic and market risk factors that impact most all equities, IsoRay is uniquely subject to risks typical for to small-cap biotech companies: The products the Company has on the market may not generate significant revenues or may run into FDA regulatory issues, and the products the Company is developing may not work, may prove to be unsafe, may never win approval and may never generate meaningful revenues. Changing medical practices, a changing reimbursement environment and/or products introduced by others could shrink the market for the Company's products. The Company may not be able to enforce its own patents or may find itself infringing on patents held by others.

Being a micro-cap company, the company is specifically exposed to risks inherent with the following characteristics: Its revenues are dependent on one product; Although cleared to treat any malignant tissue, the Company's sole product is currently used to treat two types of cancer; The Company relies heavily on a limited number of suppliers; it is possible that other treatments may be deemed superior to brachytherapy.

For a full review of ISR specific risk factors investors should refer to the Company's most recent forms 10K and 10Q on file with the SEC.

STOCK RATING DEFINITIONS

Buy: The stock's return is expected to exceed 15% over the next twelve months.

Neutral: The stock's return is expected to be plus or minus 15% over the next twelve months.

Sell: The stock's return is expected to be negative 15% or more over the next twelve months.

Investment Ratings are determined by the ranges described above at the time of initiation of coverage, a change in risk, or a change in target price. At other times, the expected returns may fall outside of these ranges because of price movement and/or volatility. Such interim deviations from specified ranges will be permitted but will become subject to review.

RATINGS DISPERSION AND BANKING RELATIONSHIPS (as of 9/30/11)

Buy	77%	(33% are banking clients)
Neutral	23%	(12% are banking clients)
Sell	0%	(0% are banking clients)

BIOTECHNOLOGY & HEALTHCARE SECTOR STOCKS UNDER AUTHOR ANALYST COVERAGE ("The Universe")

Antares Pharma (AIS), Aradigm (ARDM), Biondi, Inc. (BIOD), BioDelivery Sciences International (BDSI), Cornerstone Therapeutics (CRTX), Flamel Technologies S.A. (FLML), IsoRay (ISR), Keryx Biopharmaceuticals (KERX), MAP Pharmaceuticals (MAPP), MediciNova (MNOV), Nile Therapeutics (NLTX), Osteologix (OLGX), Repros Therapeutics (RPRX) and United Therapeutics (UTHR), XOMA Ltd (XOMA).

COMPANY SPECIFIC DISCLOSURES:

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INVESTMENT RATING AND PRICE TARGET HISTORY



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