

ISORAY (ISR)

Still Waiting for Revenue Growth to Materialize; Maintain Neutral.

Investment Rating Neutral
Prior Rating

Price Target N/A
Prior Target

Price (November 15, 2011) \$0.69
52 Week Range \$0.64 – \$1.73
Shares Outstanding 29.0 MM
Market Capitalization \$20.0 MM
Cash (pro forma) \$3.4 MM

Fiscal Year End June

Revenue (MM's):

	<u>Current</u>	<u>Prior</u>
2012E	\$7.0	\$7.9
2011A	\$5.2	
2010A	\$5.3	

EPS:

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

Quarterly EPS:

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

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Highlights

- FY1Q12 Results.** IsoRay reported revenues of \$1.3 million which were \$0.3 million below our estimate of \$1.6 million for the quarter. ISR attributes the lower-than-expected sales for the quarter to a reduction in prostate orders for the month of July. We believe ISR will need to step up non-prostate utilization of CS-131, which we believe the company aims to do with current marketing and R&D efforts, more quickly for us to have confidence the company's strategy for revenue growth works. We believe sales of CS-131 in prostate remain an important sales base for IsoRay, but as highlighted by this quarter's results, the rate of adoption of CS-131 in other cancer modalities will determine the extent of revenue growth we will see with this product as it is our belief revenues from prostate may have peaked. Additionally, gross margins declined to 6% (from 36% last quarter) due to supply at ISR's primary manufacturer (due to maintenance) and greater usage of (and higher costs stemming from) CS-131's secondary suppliers. We look to upcoming quarters to see the impact of ISR's strategy for revenue growth.
- IsoRay strategy for FY2012.** 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.
- 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. ISR expects GliaSite will be authorized by Washington state shortly which will allow ISR to begin taking GliaSite orders.
- Cash.** We believe IsoRay can fund operations through calendar year 2012 given its current cash position of \$3.4 million (\$2.1 million from recent sale of 2.5 million common shares) and current cash burn of approximately \$200,000–\$400,000 per quarter.
- 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-11A</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	\$1,213	\$1,566	\$1,880	\$2,302	\$6,962
Total Revenues	\$5,286	\$1,327	\$1,245	\$1,411	\$1,256	\$5,239	\$1,213	\$1,566	\$1,880	\$2,302	\$6,962
COGS	\$4,560	\$1,112	\$1,117	\$1,053	\$800	\$4,082	\$1,147	\$1,175	\$1,504	\$1,842	\$5,667
R&D	\$341	\$115	\$16	\$188	\$147	\$465	\$201	\$240	\$242	\$245	\$929
Sales & Marketing	\$1,954	\$373	\$336	\$235	\$288	\$1,232	\$314	\$318	\$321	\$324	\$1,277
G&A	\$2,440	\$596	\$561	\$628	\$638	\$2,423	\$653	\$659	\$659	\$659	\$2,631
Operating Expense	\$9,295	\$2,196	\$2,029	\$2,104	\$1,873	\$8,202	\$2,316	\$2,392	\$2,726	\$3,070	\$10,504
Operating Income/Loss	(\$4,009)	(\$868)	(\$785)	(\$693)	(\$617)	(\$2,963)	(\$1,102)	(\$825)	(\$847)	(\$768)	(\$3,542)
Other Income											
Interest income	\$11	-	\$1	\$1	\$2	\$3	\$0	\$1	\$2	\$2	\$5
Other	(\$36)	-	\$555	(\$338)	(\$100)	\$117	\$0	-	-	-	-
Net Non-Operating Income	(\$25)	-	\$556	(\$337)	(\$99)	\$121	\$0	\$1	\$2	\$2	\$5
Pretax Income	(\$4,034)	(\$868)	(\$228)	(\$1,030)	(\$715)	(\$2,842)	(\$1,102)	(\$824)	(\$845)	(\$766)	(\$3,537)
Taxes											
Income tax paid/(benefit)	-	-	-	-	-	-	-	-	-	-	-
Non-Operating income/(charge)	(\$11)		(\$3)	(\$3)	(\$5)	(\$11)	(\$3)				
Net Income/Loss	(\$4,044)	(\$868)	(\$231)	(\$1,033)	(\$721)	(\$2,853)	(\$1,105)	(\$824)	(\$845)	(\$766)	(\$3,537)
Earnings/ (Loss) Per Share	(\$0.18)	(\$0.04)	(\$0.01)	(\$0.04)	(\$0.03)	(\$0.11)	(\$0.04)	(\$0.03)	(\$0.03)	(\$0.03)	(\$0.12)
Shares Outstanding (MM)	22.96	23.05	25.07	26.01	26.40	25.13	26.49	28.99	30.09	30.19	28.94
Earnings Per Share (Fully Taxed)											
Earnings/ (Loss) Per Share (Diluted)	(0.14)	(0.03)	(0.01)	(0.03)	(0.02)	(0.09)	(0.03)	(0.02)	(0.02)	(0.02)	(0.10)
Fully Diluted Shares Out (MM)	28.86	28.95	30.97	31.91	33.32	31.29	33.41	35.91	37.01	37.11	35.86
NOL	(41,914)	(42,783)	(43,013)	(44,046)	(44,767)	(44,767)	(45,872)	(46,696)	(47,541)	(48,307)	(48,304)
Margin Analysis	2010A	1Q11E	2Q11E	3Q11E	4Q11E	2011E	1Q12E	2Q12E	3Q12E	4Q12E	2012E
Operating Margin	-76%	-65%	-63%	-49%	-49%	-57%	-91%	-53%	-45%	-33%	-51%
Gross Margin	14%	19%	10%	25%	36%	22%	6%	25%	20%	20%	19%
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 10/31/11)

Buy	79%	(30% are banking clients)
Neutral	21%	(13% are banking clients)
Sell	0%	(0% are banking clients)

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

Antares Pharma (AIS), Aradigm (ARDM), Biodel, 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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(RPRX), Nile Therapeutics (NLTX), MediciNova (MNOV) and Antares Pharma (AIS); Ladenburg Thalmann received compensation for investment banking services from Aradigm (ARDM), Repros Therapeutics (RPRX), Keryx Biopharmaceuticals (KERX) Nile Therapeutics (NLTX), MediciNova (MNOV) and Antares Pharma (AIS) in the last 12 months; Ladenburg Thalmann & Co. Inc. co-managed public offerings of securities for NLTX and KERX in the past 12 months, acted as lead placement agent (Registered Direct Offering) and Lead Manager in secondary offerings for Repros Therapeutics (RPRX), acted as sole placement agent for a secondary offering in Aradigm (ARDM), acted in an advisory capacity for Keryx Biopharmaceuticals (KERX) and Antares Pharma (AIS) and acted as Lead Manager in a securities offering for MediciNova (MNOV), and acted as a co placement agent in a private securities transaction for Nile Therapeutics, Inc. (NLTX) in the past 12 months; Ladenburg Thalmann & Co. Inc. expects to receive or intends to seek compensation for investment banking services during the next 3 months for all companies listed in The Universe. Among the companies listed in The Universe, the Analyst, or members of the Analyst’s household, own (long position) securities issued by ARDM.

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INVESTMENT RATING AND PRICE TARGET HISTORY



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