

ISORAY (ISR)

Revenues Trend Up, Costs Trend Down - FY 3Q 2011 Results Indicate Improvements Across the Board; Maintaining Neutral Rating.

Investment Rating Neutral
Prior Rating

Price Target N/A
Prior Target

Price (May 16, 2011) \$0.97
52 Week Range \$0.85 – \$1.73
Shares Outstanding 26.0 MM
Market Capitalization \$25.22 MM
Cash (March 31, 2011) \$2.7 MM

Fiscal Year End June

Revenue (MM's):

| | Current | Prior |
|-------|---------|-------|
| 2011E | \$5.4 | \$5.1 |
| 2010A | \$5.3 | |
| 2009A | \$5.4 | |

EPS:

| | Current | Prior | P/E |
|-------|----------|----------|-----|
| 2011E | (\$0.12) | (\$0.11) | NA |
| 2010A | (\$0.18) | | NA |
| 2009A | (\$0.27) | | NA |

Quarterly EPS:

| | Current | Prior |
|---------|----------|----------|
| 2011E | | |
| Sep (A) | (\$0.04) | |
| Dec (A) | (\$0.01) | |
| Mar (A) | (\$0.04) | |
| Jun | (\$0.03) | (\$0.04) |
| 2010A | | |
| Sep | (\$0.04) | |
| Dec | (\$0.04) | |
| Mar | (\$0.05) | |
| Jun | (\$0.05) | |

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Highlights

- IsoRay starts calendar year 2011 with improvements in CS-131 seed revenues and product costs.** CS-131 product sales of \$1.4 million were above our estimate of \$1.2 million. We believe sales of CS-131 in prostate remain an important sales base for IsoRay (\$1.3 million this quarter), 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 have peaked. Cost of product sales were \$1.1 million which was slightly below our estimate of \$1.2 million. However, we believe ISR has made strides to reduce their cost of product sales (better production margins through lower labor costs and increased physician orders for CS-131 seed pre-loading by ISR vs. 3rd party contractor loading services). While the true impact of ISR's lower cost of CS-131 seed production is unknown until economies of scale are more visible, we believe management is taking the right steps to improve their gross margins. Additionally, CS-131 was granted a CE mark, opening up the EU market for CS-131. We are encouraged by the growth of CS-131 revenues in the non-prostate indication this quarter (non-prostate revenues of \$0.2 million represented 10% of overall revenues this quarter), a 50% increase over non-prostate sales of \$0.15 million in the quarter ended December 31, 2010. Revenue growth was attributed to a 21% increase in patient cases in FY 3Q 2011. We are encouraged by this trend and we look forward to analyzing potentially continued revenue growth throughout the upcoming quarters to better gauge this product's potential.
- GliaSite update.** The GliaSite catheter system is in its final testing stage and ISR plans to submit its 510K to the FDA upon completion. GliaSite is a balloon catheter device used in the brachytherapy treatment of brain cancer and has been FDA approved (2001) using Iotrex (liquid iodine). Until FDA approval of liquid CS-131 and its use in GliaSite is granted, ISR plans to market Iotrex for use with GliaSite. We believe there could be a niche for GliaSite in the treatment of brain cancer and await updates on its upcoming launch.
- Cash.** We believe IsoRay's management has taken great strides in the past year to preserve cash by minimizing expenditures and maximizing operational efficiencies for a monthly cash burn of approximately \$0.2 million. As such, IsoRay believes it can fund operations for the next 12 months given its current cash position of \$2.7 million at March 31, 2011. Revenue growth could potentially mitigate IsoRay's cash needs, but we believe IsoRay could need to raise additional funds in the next twelve months and as such, risk of dilution remains. ISR was granted a R&D award by the IRS for the Company's 2010 tax year (ending June 30, 2011) and a grant award of \$321,000 is expected in July 2011 which would further extend ISR's cash resources.
- 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 this quarter's results but believe we need more time to determine whether meaningful growth in this area is maintained. We remain on the sidelines until there is more visibility on the resumption and continuation of top-line revenue growth and on the progress with GliaSite which the Company indicates is on target for launch in August 2011.

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>2009A</u> | <u>Sept-09A</u> | <u>Dec-09A</u> | <u>Mar-10A</u> | <u>Jun-10A</u> | <u>2010A</u> | <u>Sept-10A</u> | <u>Dec-10A</u> | <u>Mar-11A</u> | <u>Jun-11E</u> | <u>2011E</u> |
|---|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|
| Sales/Royalties | | | | | | | | | | | |
| Product Sales | \$5,418 | \$1,379 | \$1,368 | \$1,203 | \$1,335 | \$5,286 | \$1,327 | \$1,245 | \$1,411 | \$1,397 | \$5,379 |
| Total Revenues | \$5,418 | \$1,379 | \$1,368 | \$1,203 | \$1,335 | \$5,286 | \$1,327 | \$1,245 | \$1,411 | \$1,397 | \$5,379 |
| COGS | \$5,771 | \$1,160 | \$1,100 | \$1,151 | \$1,149 | \$4,560 | \$1,112 | \$1,117 | \$1,053 | \$1,106 | \$4,388 |
| R&D | \$959 | \$69 | \$59 | \$99 | \$114 | \$341 | \$115 | \$16 | \$188 | \$190 | \$508 |
| Sales & Marketing | \$2,366 | \$443 | \$604 | \$448 | \$459 | \$1,954 | \$373 | \$336 | \$235 | \$238 | \$1,182 |
| G&A | \$2,793 | \$602 | \$550 | \$596 | \$691 | \$2,440 | \$596 | \$561 | \$628 | \$628 | \$2,413 |
| Operating Expense | \$11,888 | \$2,274 | \$2,313 | \$2,294 | \$2,414 | \$9,295 | \$2,196 | \$2,029 | \$2,104 | \$2,161 | \$8,490 |
| Operating Income/Loss | (\$6,471) | (\$895) | (\$945) | (\$1,090) | (\$1,079) | (\$4,009) | (\$868) | (\$785) | (\$693) | (\$764) | (\$3,111) |
| Other Income | | | | | | | | | | | |
| Interest income | \$111 | \$6 | \$3 | \$0 | \$3 | \$11 | - | \$1 | \$1 | - | \$2 |
| Other | \$199 | (\$17) | \$8 | (\$60) | \$33 | (\$36) | - | \$555 | (\$338) | - | - |
| Net Non-Operating Income | \$310 | (\$11) | \$11 | (\$60) | \$36 | (\$25) | - | \$556 | (\$337) | - | \$2 |
| Pretax Income | (\$6,161) | (\$907) | (\$934) | (\$1,150) | (\$1,043) | (\$4,034) | (\$868) | (\$228) | (\$1,030) | (\$764) | (\$2,891) |
| Taxes | | | | | | | | | | | |
| Income tax paid/(benefit) | - | - | - | - | - | - | - | - | - | - | - |
| Non-Operating income/(charge) | | | | | | | | | | | |
| | - | - | - | - | (\$11) | (\$11) | | (\$3) | (\$3) | (\$3) | |
| Net Income/Loss | (\$6,161) | (\$907) | (\$934) | (\$1,150) | (\$1,054) | (\$4,044) | (\$868) | (\$231) | (\$1,033) | (\$767) | (\$2,891) |
| Earnings/ (Loss) Per Share | (\$0.27) | (\$0.04) | (\$0.04) | (\$0.05) | (\$0.05) | (\$0.18) | (\$0.04) | (\$0.01) | (\$0.04) | (\$0.03) | (\$0.12) |
| Shares Outstanding (MM) | 22.94 | 22.94 | 22.94 | 22.94 | 23.02 | 22.96 | 23.05 | 25.07 | 26.01 | 26.11 | 25.06 |
| Earnings Per Share (Fully Taxed) | | | | | | | | | | | |
| Earnings/ (Loss) Per Share (Diluted) | (0.21) | (0.03) | (0.03) | (0.04) | (0.04) | (0.14) | (0.03) | (0.01) | (0.03) | (0.02) | (0.09) |
| Fully Diluted Shares Out (MM) | 28.84 | 28.84 | 28.84 | 28.84 | 28.92 | 28.86 | 28.95 | 30.97 | 31.91 | 32.01 | 30.96 |
| NOL | (37,870) | (38,776) | (39,710) | (40,861) | (41,914) | (41,914) | (42,783) | (43,013) | (44,046) | (44,813) | (44,806) |
| Margin Analysis | <u>2009A</u> | <u>1Q10A</u> | <u>2Q10A</u> | <u>3Q10A</u> | <u>4Q10A</u> | <u>2010A</u> | <u>1Q11E</u> | <u>2Q11E</u> | <u>3Q11E</u> | <u>4Q11E</u> | <u>2011E</u> |
| Operating Margin | -119% | -65% | -69% | -91% | -81% | -76% | -65% | -63% | -49% | -55% | -58% |
| Gross Margin | -7% | 19% | 20% | 4% | 14% | 14% | 19% | 10% | 25% | 21% | 18% |
| Net Margin | - | - | - | - | - | - | - | - | - | - | - |
| Tax Rate | - | - | - | - | - | - | - | - | - | - | - |

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 4/30/11)

| | | |
|---------|-----|---------------------------|
| Buy | 72% | (37% are banking clients) |
| Neutral | 28% | (18% 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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Thalmann received compensation for investment banking services from BioDelivery Sciences Intl. (BDSI), Aradigm (ARDM), Repros Therapeutics (RPRX), Keryx Biopharmaceuticals (KERX) Nile Therapeutics (NLTX) and MediciNova (MNOV) in the last 12 months; Ladenburg Thalmann & Co. Inc. co-managed public offerings of securities for ARDM, 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 BioDelivery Sciences Intl. (BDSI) and Keryx Biopharmaceuticals (KERX) and Antares Pharma (AIS) and acted as Lead Manager in a securities offering for MediciNova (MNOV) 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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