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IsoRay, Inc. (NYSE/ISR)

November 11, 2021

Neutral-Rated – IsoRay: First Quarter 2022 Results Remain Gloomy.

IsoRay missed our already lowered estimate for revenue and expenses were higher than we anticipated. Revenues of \$2.5M vs. Expenses of \$4.8M translated into a loss of \$2.3M. Manufacturing costs remain high (>50%). Without a substantial rise in volumes we don't see gross margins rising and net margins are negative. The share count remains high (141M). The company does have a strong balance sheet of almost \$62M.

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Investment Highlights:

IsoRay fiscal year (Sept. 2022) results. Revenues were \$2.5M, down again from the prior quarter of \$2.7M, and again with more than half going to manufacturing. A substantial increase in volumes (in our opinion) is the only way to get competitive manufacturing margins. We noted G&A was higher at \$1.8M versus the prior period of \$1.3M. Cash is solid at \$62M. The key question remains, 'can IsoRay really build significant market share in the PC space'? The company has capital and has product, but thus far, it hasn't happened and we don't see the company as executing a turnaround. Sales and Marketing spending remains anemic at \$0.7M.

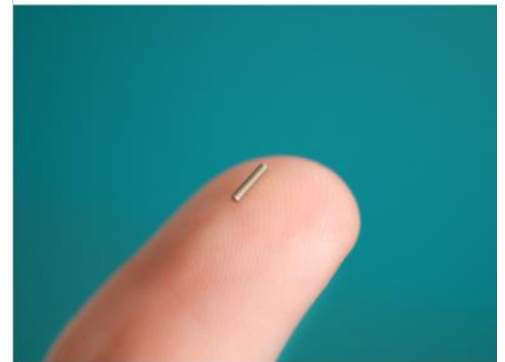
Cash on the balance sheet. IsoRay actually has some cash runway to continue to explore CS-131's potential.

Has the Treatment Paradigm Irreversibly Shifted Away from IsoRay? For the many years we have followed IsoRay, we have not seen the company break out in a meaningful way in terms of revenues or market share. It may be that the attributes of Cs-131 are outweighed by the complications associated with radiation versus other therapies available today. The treatment paradigm has shifted (biologics and other therapies), and at this point, we need to see revenues build for us to be more positive.

Valuation: We maintain our Neutral rating and previously removed our price target; with that said, our model is based on Cesium Blu in both prostate and non-prostate cancer markets; Adoption of Gamma Tile for brain cancer treatment should begin to increase over the next few years, generating more CS-131 seeds sales (to GT Medical). Still, we apply only a 10% probability of success for conservatism that our market share estimates will be fully realized. Using these metrics, we model the market potential and discount back using a 15% rate in our FCF, discounted EPS, and sum-of-the-parts models, which results in a fair value below \$1.00. These metrics are dependent on our clinical assumptions.

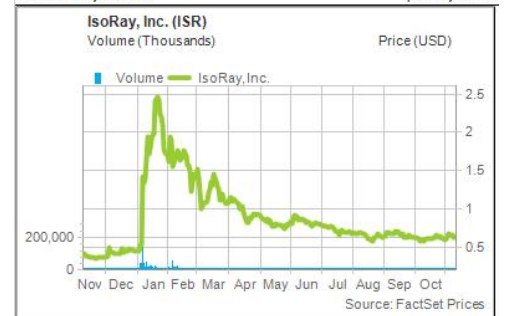
Risk Factors: Investment Risk, Market Share Risk, Regulatory Risk, Commercial Risk, and Financial Risk

Current Price	\$0.63
Price Target	NA



Source: IsoRay - CS-131 Seed

Stock Data			
52-Week Range	\$0.35	-	\$2.81
Shares Outstanding (mil.)	141.9		
Market Capitalization (mil.)	\$90		
Enterprise Value (mil.)	\$84		
Debt to Capital	0%		
Book Value/Share	\$0.19		
Price/Book	1.7		
Average Three Months Trading Volume (K)	447		
Insider Ownership	1.0%		
Institutional Ownership	12.6%		
Short interest (mil.)	1.0%		
Dividend / Yield	\$0.00/0.0%		



Risk Analysis:

Investment Risk: IsoRay is a small capital company, which can translate into high volatility and risk for investors. The company's revenues depend on one product with multiple applications. Prostate cancer treatment accounted for greater than three-fourths of product sales, and the prostate cancer market has been declining.

Market Share Risk. IsoRay faces well-entrenched competition within the brachytherapy marketplace as well as outside the marketplace from well-capitalized large pharma and biotechnology companies.

Regulatory Risk: Barium is the main raw material used to make Cesium-131. IsoRay relies heavily on the production of Barium. The main supplier of Cesium-131 is in Russia, so the majority of the production of Cesium is dependent on U.S. - Russian relations. The manufacturing facilities all need to pass certain standards of operation in order to be functionally running.

Commercial Risk: End consumers may believe that there is a lack of product doses for Cesium 131, and radiation therapy represents a complication for some providers.

Financial Risk: IsoRay is likely to have additional capital raises before the company can be self-sustaining.

Exhibit 4. Income Statement

IsoRay™ Medical, Inc.: Income Statement (\$000)	6.2017	6.2018	6.2019	6.2020	July-Sept	Oct-Dec	Jan-Mar	Apr-Jun	6.2021	July-Sept	Oct-Dec	Jan-Mar	Apr-Jun	6.2022	6.2023	6.2024	6.2025	6.2026	6.2027	6.2028	6.2029	6.2030*
IsoRay™ Medical, Inc.: YE Jun 30	2017A	2018A	2019A	2020A	1Q21A	2Q21A	3Q21A	4Q21A	2021A	1Q22A	2Q22E	3Q22E	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Cs-131 Prostate Cancer	4,761	5,369	5,252	6,927	1,930	1,909	2,000	2,160	7,999	2,364	2,470	2,470	2,470	9,882	14,515	18,712	23,490	28,881	34,914	41,621	43,419	45,206
Cs-131 Seeds (non-prostate - non-brain)		506	1,162	1,703	300	300	450	400	1,450	100	370	370	370	1,479	1,509	1,539	1,570	1,601	1,633	1,666	1,699	1,733
Gamma Tile			224	1,050	154	150	150	150	604	100	594	594	594	2,375	3,028	3,706	4,410	5,141	5,899	6,685	7,501	8,625
Total Product Sales	4,761	5,923	7,314	9,680	2,384	2,359	2,600	2,710	10,053	2,564	3,434	3,434	3,434	13,736	19,051	23,956	29,470	35,622	42,445	49,972	52,619	55,564
Expenses																						
Cost of product sales (prostate)	3,923	3,790	3,808	4,733	1,100	2,321	1,038	1,254	5,713	1,435	1,922	1,922	1,922	7,201	7,049	8,624	10,314	12,112	14,431	16,991	17,364	18,336
COGS % of revenue	82%	68%	64%	49%	57%	57%	40%	40%	57%	56%	56%	56%	56%	52%	37%	36%	35%	34%	34%	34%	33%	33%
Cost of product sales (non-prostate)	-	291	459	311	38	200	110	348	348	100	193	193	193	771	907	1,049	1,196	1,348	1,506	1,670	1,840	2,072
COGS % of revenue (non-prostate)	-	5%	28%	20%	25%	20%	20%	20%	20%	100%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Sales and marketing expenses	2,310	2,660	2,679	2,976	581	581	659	1,821	1,821	761	464	464	464	1,857	1,895	1,932	1,971	2,011	2,051	2,092	2,134	2,176
S&M % of revenue	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
General and administrative expenses	3,918	4,165	4,172	4,571	1,067	619	1,185	1,312	4,183	1,840	1,067	1,067	1,067	4,267	4,352	4,439	4,528	4,618	4,711	4,805	4,901	4,999
G&A % of revenue	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Research and development	965	1,746	1,474	1,126	312	292	362	468	1,434	702	376	376	376	1,506	1,581	1,613	1,629	1,645	1,661	1,678	1,695	1,712
R&D % of revenue	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Stk Optn's Non-GAAP Adj	(48)			(73)																		
Total Expenses	11,068	12,652	12,592	13,571	3,098	3,232	3,366	3,803	13,499	4,838	4,022	4,022	4,022	15,601	15,784	17,657	19,638	21,734	24,361	27,236	27,934	29,295
Operating income (Loss)	(6,307)	(6,729)	(5,278)	(3,891)	(714)	(873)	(766)	(1,093)	(3,446)	(2,274)	(588)	(588)	(588)	(1,866)	3,267	6,299	9,832	13,888	18,085	22,737	24,685	26,269
Interest income	117	29		30	1	5	21	32	59	31												
Change in fair value of warrant derivative liability	27																					
Financing and interest expense	-																					
Total other income	144	29	-	30	1	5	21	32	59	31	-	-	-	-	-	-	-	-	-	-	-	-
Pre-tax Income	(6,163)	(6,700)	(5,278)	(3,861)	(713)	(868)	(745)	(1,061)	(3,387)	(2,243)	(588)	(588)	(588)	(1,866)	3,267	6,299	9,832	13,888	18,085	22,737	24,685	26,269
Income Tax Benefit (Provision)	-	-	-	(11)	(3)	(61)	(52)	(74)	(190)	(53)	(53)	(53)	(53)	(159)	359	882	1,573	2,361	3,255	4,320	6,194	7,648
Tax Rate	0%	0%	0%	0%	7%	7%	7%	7%	6%	9%	9%	9%	9%	9%	11%	14%	16%	17%	18%	19%	25%	29%
GAAP Net Income (loss)	(6,166)	(6,711)	(5,278)	(3,872)	(716)	(807)	(693)	(987)	(3,197)	(2,243)	(535)	(535)	(535)	(1,707)	2,908	5,417	8,259	11,527	14,829	18,417	18,491	18,621
Preferred stock dividends	(11)	(11.00)																				
GAAP-EPS	(0.11)	(0.12)	(0.08)	(0.05)	(0.01)	(0.01)	(0.01)	(0.01)	(0.03)	(0.02)	(0.00)	(0.00)	(0.00)	(0.03)	0.02	0.04	0.06	0.08	0.10	0.13	0.13	0.13
Non GAAP EPS (dil)	(0.11)	(0.12)	(0.08)	(0.05)	(0.01)	(0.01)	(0.01)	(0.01)	(0.03)	(0.02)	(0.00)	(0.00)	(0.00)	(0.03)	0.02	0.04	0.06	0.08	0.10	0.13	0.13	0.13
Wgtd Avg Shrs (Bas) - '000s	55,016	55,159	67,042	72,057	85,980	119,047	122,566	141,673	117,317	141,915	142,057	142,199	142,341	142,128	142,697	143,269	143,843	144,419	144,998	145,579	146,162	146,747
Wgtd Avg Shrs (Dil) - '000s	55,016	55,159	67,042	74,341	95,124	119,047	122,566	141,673	119,602	141,915	142,057	142,199	142,341	142,128	142,697	143,269	143,843	144,419	144,998	145,579	146,162	146,747

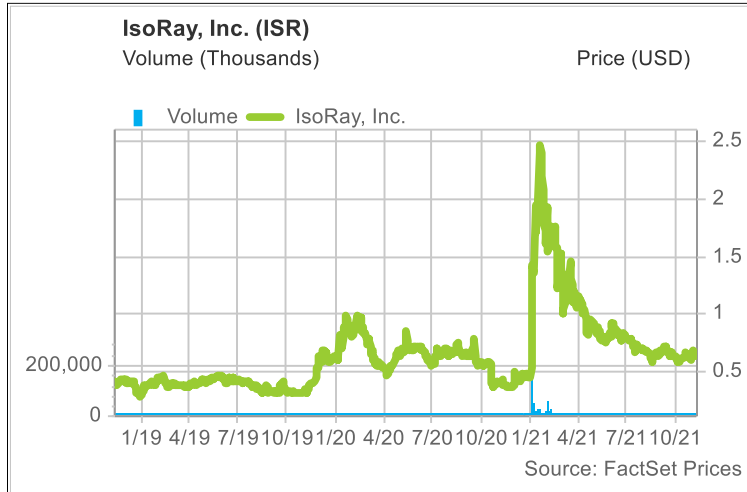
Source: Dawson James estimates and Company Reports

Companies mentioned in this report

GT Medical (private)

Important Disclosures:

Price Chart:



Price target and rating changes over the past three years:

- Initiated – Buy – July 1, 2019 – Price Target \$1.00
- Update – Buy – September 26, 2019 – Price Target \$1.00
- Update – Buy – November 22, 2019 – Price Target \$1.00
- Update – Buy – February 5, 2020 – Price Target \$1.00
- Update – Buy – May 13, 2020 – Price Target \$1.00
- Update – Buy – September 22, 2020 – Price Target \$1.00
- Rating Change – Neutral – October 20, 2020 – Price Target NA
- Update – Neutral – November 12, 2020 – Price Target NA
- Update – Neutral – March 31, 2021 – Price Target NA
- Update – Neutral – September 22, 2021 – Price Target NA
- Update – Neutral – September 22, 2021 – Price Target NA
- Update – Neutral – November 11, 2021 – Price Target NA

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- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months;
- 3) **Sell:** The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

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Current as of 10/15/21	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Ratings Distribution				
Market Outperform (Buy)	25	69%	4	16%
Market Perform (Neutral)	11	31%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	36	100%	4	11%

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