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IsoRay, Inc. (NYSE/ISR)

March 31, 2021

Neutral-Rated – IsoRay – Feels Like Déjà Vu – We Remain Neutral

IsoRay, for years, made little progress in terms of building market share and instead distracted folks with streams of never-ending investigator lead studies. New management promised to change all that; thus, we are disappointed to see the company falling back into promoting investigator-led studies again.

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Investment \:

IsoRay recently reported 2Q21 (fiscal year) results. Revenues were \$2.36M, with approximately half (again) going to manufacturing and related costs. Combined with expenses, this translated into a loss of \$807K. The company reported \$9.6M in cash at 2Q21 (fiscal year), but the company did turn around and raise capital, \$51M for 36M shares, which can be added to the 2Q share count of 83M. So, the good news is IsoRay has cash; the bad news is the cost is dilution, so much so that we believe profitability with CS-131 is now out of reach for the company.

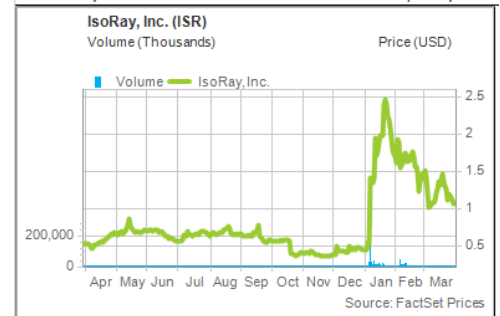
The Study: IsoRay press released a small prospective series of patients with recurrent head and neck (H&N) cancers treated with surgical resection and Cesium-131 brachytherapy. The study found potential benefits that support further research into combination therapy with Cesium-131 brachytherapy and surgical resection.

So, what does it mean? IsoRay actually has some cash runway to continue to explore CS-131's potential, but publishing these ad-hoc studies reminds us of IsoRay's old management. The fundamentals attributed to this therapy have not changed. 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. 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				\$1.08
Price Target				NA
Estimates	F2019A	F2020A	F2021E	
Expenses (\$000s)	\$ 12,592	\$ 13,571	\$ 13,743	
1Q July	\$ 3,080	\$ 3,151	\$ 3,098	
2Q October	\$ 3,356	\$ 3,109	\$ 3,232	
3Q January	\$ 3,088	\$ 3,916	\$ 3,706	
4Q April	\$ 3,068	\$ 3,395	\$ 3,706	
	F2019A	F2020A	F2021E	
EPS (diluted)	\$ (0.08)	\$ (0.05)	\$ (0.05)	
1Q July	\$ (0.02)	\$ (0.01)	\$ (0.01)	
2Q October	\$ (0.02)	\$ (0.01)	\$ (0.01)	
3Q January	\$ (0.02)	\$ (0.02)	\$ (0.01)	
4Q April	\$ (0.02)	\$ (0.01)	\$ (0.01)	
EBITDA/Share	(\$0.08)	(\$0.05)	(\$0.05)	
EV/EBITDA (x)	0.0	0.0	0.0	
Stock Data				
52-Week Range	\$0.35	-	\$2.81	
Shares Outstanding (mil.)				141.2
Market Capitalization (mil.)				\$152
Enterprise Value (mil.)				\$146
Debt to Capital				0%
Book Value/Share				\$0.19
Price/Book				6.7
Average Three Months Trading Volume (K)				544
Insider Ownership				1.0%
Institutional Ownership				6.4%
Short interest (mil.)				2.0%
Dividend / Yield				\$0.00/0.0%



VALUATION

We see IsoRay as an established company that has an approved product that is being commercialized. Revenue today is small at just \$10M annually and has struggled to grow at any significant rate. We have been “liberal” with a 15% risk rate. Typically for early stage companies with no approved products that possess a lot of clinical risks, we use a 30% risk rate, and for established companies with more predictable revenues and typically cash flow positive, we apply a 10% risk rate. We model the company's revenues (and expenses) out to 2030. We consider the need to raise capital, and as such, we use a future projected share count. We then apply these metrics to our free cash flow to the firm (FCFF), discounted earnings (dEPS) and the sum of the parts (SOP) models, which are equal weighted, averaged and rounded to the nearest whole number. The current valuation suggests a fair value below \$1.00. As such, we are Neutral rated.

Exhibit 1. FCFF Model

Average	\$	0.4
Price Target	\$	0.4
Year		2021

DCF Valuation Using FCF (mln):

units ('000)	2018A	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(6,700)	(5,278)	(3,861)	(4,100)	(1,590)	1,671	4,668	8,162	12,180	16,339	20,953	22,860	24,405
Tax Rate	0%	0%	0%	6%	9%	11%	14%	16%	17%	18%	19%	25%	29%
EBIT(1-t)	(6,700)	(5,278)	(3,850)	(3,860)	(1,447)	1,487	4,014	6,856	10,109	13,398	16,972	17,123	17,298
CapEx	-	-	-	-	-	-	-	-	-	-	-	-	-
Depreciation	-	-	-	-	-	-	-	-	-	-	-	-	-
Change in NWC	-	-	-	-	-	-	-	-	-	-	-	-	-
FCF	(6,700)	(5,278)	(3,850)	(3,860)	(1,447)	1,487	4,014	6,856	10,109	13,398	16,972	17,123	17,298
PV of FCF	(10,190)	(6,980)	(4,428)	(3,860)	(1,258)	1,124	2,639	3,920	5,026	5,792	6,380	5,597	4,917.24
Discount Rate	15%												
Long Term Growth Rate	1%												
Terminal Cash Flow	124,794												
Terminal Value YE2030	35,474												
NPV	65,754												
NPV-Debt	-												
Shares out (thousands)	160,771	2030E											
NPV Per Share	\$	0.4											

Source: Dawson James estimates, company reports.

Exhibit 2. Discounted EPS Model

Current Year	2021
Year of EPS	2030
Earnings Multiple	10
Discount Factor	15%
Selected Year EPS	\$ 0.11
NPV	\$ 0.31

		Discount Rate and Earnings Multiple Varies, Year is Constant					
		2030 EPS					
Earnings Multiple		5%	10%	15%	20%	25%	30%
		2		\$0.25	\$0.16	\$0.10	\$0.07
5		\$0.62	\$0.39	\$0.25	\$0.16	\$0.11	\$ 0.07
10		\$1.24	\$0.78	\$0.50	\$0.33	\$0.22	\$ 0.15
15		\$1.86	\$1.17	\$0.75	\$0.49	\$0.33	\$ 0.22
20		\$2.48	\$1.56	\$1.00	\$0.65	\$0.43	\$ 0.29
25		\$3.10	\$1.95	\$1.25	\$0.82	\$0.54	\$ 0.37
30		\$3.72	\$2.34	\$1.50	\$0.98	\$0.65	\$ 0.44
35		\$4.34	\$2.73	\$1.75	\$1.14	\$0.76	\$ 0.51

Source: Dawson James estimates

Exhibit 3. Sum of the Parts Model

IsoRay, Inc.	LT Gr	Discount Rate	Yrs. to Peak Mkt	% Success	Peak Sales MMs	NPV
CS-131 (Prostate cancer)	1%	15%	6	100%	\$45	\$323
NPV						\$0.26
CS-131 (non-prostate cancer)	1%	15%	6	100%	\$1	\$10
NPV						\$0.01
GammaTile	1%	30%	3	50%	\$86	\$297
NPV						\$0.13
Net Margin						30%
MM Shrs OS (2028E)						161
Total						\$0.4

Source: Dawson James estimates

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	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	3Q21E	4Q21E	2021E	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	2,000	7,839	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	300	300	1,200	1,224	1,248	1,273	1,299	1,325	1,351	1,378	1,406	1,434
Gamma Tile			224	1,050	154	150	150	150	604	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	2,450	2,450	9,643	13,481	18,791	23,691	29,199	35,346	42,164	49,685	52,326	55,265
Expenses																		
Cost of product sales (prostate)	3,923	3,790	3,808	4,733	1,100	2,321	1,396	1,396	6,214	5,257	6,953	8,529	10,220	12,018	14,336	16,893	17,267	18,238
COGS % of revenue	82%	68%	64%	49%	57%	57%	57%	57%	64%	39%	37%	36%	35%	34%	34%	34%	33%	33%
Cost of product sales (non-prostate)	-	291	459	311	38	90	90	90	361	720	855	996	1,142	1,293	1,450	1,613	1,781	2,012
COGS % of revenue	20%	5%	28%	20%	25%	20%	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	759	759	759	3,036	3,096	3,158	3,221	3,286	3,351	3,418	3,487	3,557	3,628
S&M % of revenue																		
General and administrative expenses	3,918	4,165	4,172	4,571	1,067	619	1,166	1,166	4,662	4,756	4,851	4,948	5,047	5,148	5,251	5,356	5,463	5,572
G&A % of revenue																		
Research and development	965	1,746	1,474	1,126	312	292	296	296	1,182	1,241	1,303	1,330	1,343	1,356	1,370	1,384	1,397	1,411
R&D % of revenue																		
	(48)			(73)														
Sk Optn's Non-GAAP, Adj																		
Total Expenses	11,068	12,652	12,592	13,571	3,098	3,232	3,706	3,706	13,743	15,070	17,120	19,023	21,037	23,166	25,825	28,732	29,466	30,860
Operating income (Loss)	(6,307)	(6,729)	(5,278)	(3,891)	(714)	(873)	(1,256)	(1,256)	(4,100)	(1,590)	1,671	4,668	8,162	12,180	16,339	20,953	22,860	24,405
Interest income	117	29		30	1	5												
Change in fair value of warrant derivative liability	27																	
Financing and interest expense	-																	
Total other income	144	29	-	30	1	5	-	-	-	-	-	-	-	-	-	-	-	-
Pretax Income	(6,163)	(6,700)	(5,278)	(3,861)	(713)	(868)	(1,256)	(1,256)	(4,100)	(1,590)	1,671	4,668	8,162	12,180	16,339	20,953	22,860	24,405
Income Tax Benefit (Provision)	-	-	-	(11)	(3)	(61)	(88)	(88)	(240)	(143)	184	653	1,306	2,071	2,941	3,981	5,737	7,107
Tax Rate	0%			0%	7%	7%	7%	7%	6%	9%	11%	14%	16%	17%	18%	19%	25%	29%
GAAP Net Income (loss)	(6,166)	(6,711)	(5,278)	(3,872)	(716)	(807)	(1,168)	(1,168)	(3,860)	(1,447)	1,487	4,014	6,856	10,109	13,398	16,972	17,123	17,298
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)	(0.01)	0.01	0.03	0.04	0.06	0.08	0.11	0.11	0.11
Non GAAP EPS (dil)	(0.11)	(0.12)	(0.08)	(0.05)	(0.01)	(0.01)	(0.01)	(0.01)	(0.03)	(0.01)	0.01	0.03	0.04	0.06	0.08	0.11	0.11	0.11
Wgtd Avg Shrs (Bas) - '000s	55,016	55,159	67,042	72,057	85,980	119,047	155,166	155,321	128,879	155,710	156,334	156,960	157,589	158,220	158,854	159,490	160,129	160,771
Wgtd Avg Shrs (Dil) - '000s	55,016	55,159	67,042	74,341	95,124	119,047	155,166	155,321	131,164	155,710	156,334	156,960	157,589	158,220	158,854	159,490	160,129	160,771

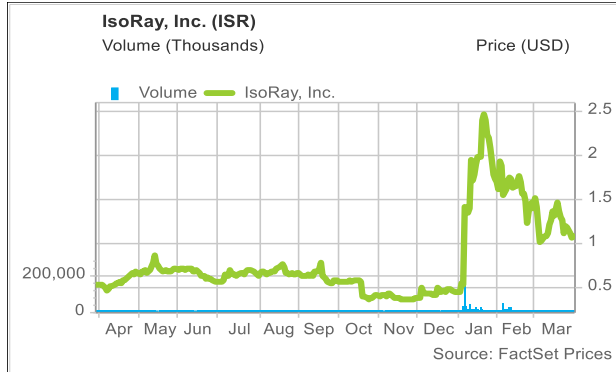
Source: Dawson James estimates and Company Reports

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

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	# of Companies	% of Total	# of Companies	% of Totals
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Market Perform (Neutral)	9	31%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	29	100%	6	21%

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