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IsoRay, Inc. (NYSE/ISR)

November 12, 2020

Neutral Rated – IsoRay – Quarter’s Performance is Flat

IsoRay reported its Fiscal 1Q21 (June year-end) quarter and the numbers were basically flat from the prior period. IsoRay has failed to demonstrate a break-out in terms of revenues or market share in the Prostate Cancer seed therapy marketplace, which really is the core element of our thesis. We have yet to see GammaTile (brain) launch in any meaningful way.

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Investment Highlights:

IsoRay recently reported 1Q21 (fiscal year) results. Revenues were \$2.384M with about half of that amount going to Cost of Goods Sold. Combined with expenses, this translated into a loss of \$714k. IsoRay did raise capital in October (approximately \$9.5M) for 18M shares and another 9M warrants. The company reported \$1.93M in cash at 1Q21 (fiscal year).

So, what does it mean? IsoRay actually has some cash runway to continue to explore CS-131’s potential. The fundamentals attributed to this therapy have not changed; however, in the many years we have followed IsoRay, we have just 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.

From the Press Release:

- Prostate brachytherapy represented 79% of total revenue for the first quarter of fiscal 2021 compared to 90% in the prior year comparable period.
- Non-prostate brachytherapy revenue increased 104% versus the prior year comparable period. The majority of non-prostate brachytherapy revenue in the quarter was comprised of sales to treat brain cancer, including sales of GammaTile Therapy.
- Net new physician customer count for the twelve-month period ended September 30, 2020 increased 11% versus the prior year comparable period.
- ROAPN – Singled bundled payment, including brachytherapy. The implementation of this bundle “levels the playing field” for brachytherapy vs. other radiation modalities.

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 GammaTile for brain cancer treatment should begin to increase over the next few years, generating more Cs-131 seeds sales (to GT Medical). Still, for conservatism, we apply only a 10% probability of success 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	\$0.42		
Price Target	NA		
Estimates	F2019A	F2020A	F2021E
Expenses (\$000s)	\$ 12,592	\$ 13,571	\$ 14,217
1Q July	\$ 3,080	\$ 3,151	\$ 3,098
2Q October	\$ 3,356	\$ 3,109	\$ 3,706
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	\$0.31	-	\$1.06
Shares Outstanding (mil.)	87.2		
Market Capitalization (mil.)	\$37		
Enterprise Value (mil.)	\$31		
Debt to Capital	0%		
Book Value/Share	\$0.19		
Price/Book	6.7		
Average Three Months Trading Volume (K)	89		
Insider Ownership	1.3%		
Institutional Ownership	8.2%		
Short interest (mil.)	1.1%		
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 which 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) model, which are equal weighted, averaged and rounded to the nearest whole number. The current valuation suggests a fair value (*price target*) below \$1.00. As such, we are Neutral rated.

Exhibit 2. FCFF Model

Average	\$	0.5
Price Target	\$	0.5
Year		2020

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)	(4,483)	(141)	3,455	6,650	10,355	14,593	18,945	21,885	23,567	24,538
Tax Rate	0%	0%	0%	6%	9%	11%	14%	16%	17%	18%	19%	25%	29%
EBIT(1-t)	(6,700)	(5,278)	(3,850)	(4,216)	(128)	3,075	5,719	8,698	12,113	15,535	17,727	17,651	17,393
CapEx	-	-	-	-	-	-	-	-	-	-	-	-	-
Depreciation	-	-	-	-	-	-	-	-	-	-	-	-	-
Change in NWC	-	-	-	-	-	-	-	-	-	-	-	-	-
FCF	(6,700)	(5,278)	(3,850)	(4,216)	(128)	3,075	5,719	8,698	12,113	15,535	17,727	17,651	17,393
PV of FCF	(8,861)	(6,070)	(3,850)	(3,666)	(97)	2,022	3,270	4,324	5,237	5,840	5,795	5,017	4,299.28
Discount Rate	15%												
Long Term Growth Rate	1%												
Terminal Cash Flow	125,478												
Terminal Value YE2030	31,016												
NPV	53,138												
NPV-Debt	-												
Shares out (thousands)	98,757	2030E											
NPV Per Share	\$	0.5											

Source: Dawson James estimates, company reports.

Exhibit 3. Discounted EPS Model

Current Year	2020
Year of EPS	2030
Earnings Multiple	10
Discount Factor	15%
Selected Year EPS	\$ 0.18
NPV	\$ 0.44

		Discount Rate and Earnings Multiple Varies, Year is Constant					
		2030 EPS					
		5%	10%	15%	20%	25%	30%
Earnings Multiple	2	\$0.32	\$0.20	\$0.13	\$0.09	\$0.06	\$ 0.04
	5	\$0.81	\$0.51	\$0.33	\$0.21	\$0.14	\$ 0.10
	10	\$1.62	\$1.02	\$0.65	\$0.43	\$0.28	\$ 0.19
	15	\$2.43	\$1.53	\$0.98	\$0.64	\$0.43	\$ 0.29
	20	\$3.24	\$2.04	\$1.31	\$0.85	\$0.57	\$ 0.38
	25	\$4.05	\$2.54	\$1.63	\$1.07	\$0.71	\$ 0.48
	30	\$4.86	\$3.05	\$1.96	\$1.28	\$0.85	\$ 0.57
	35	\$5.67	\$3.56	\$2.28	\$1.49	\$0.99	\$ 0.67

Source: Dawson James estimates

Exhibit 4. 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	\$324
NPV						\$0.43
CS-131 (non-prostate cancer)	1%	15%	6	100%	\$1	\$10
NPV						\$0.01
GammaTile	1%	30%	3	50%	\$86	\$297
NPV						\$0.21
Net Margin						30%
MM Shrs OS (2028E)						99
Total						\$0.6

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 5. Income Statement

IsoRay™ Medical, Inc.: Income Statement (\$000)	6.2017	6.2018	6.2019	July-Sept	Oct-Dec	Jan-Mar	Apr-Jun	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	1Q20A	2Q20A	3Q20A	4Q20A	2020A	1Q21A	2Q21E	3Q21E	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Cs-131 Prostate Cancer	4,761	5,369	5,252	1,547	1,500	2,080	1,800	6,927	1,930	2,000	2,000	2,000	7,930	11,858	16,934	21,385	26,427	32,090	38,405	42,567	43,805	45,405
Cs-131 Seeds (non-prostate - non-brain)		506	1,162	482	421	500	300	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	286	285	300	179	1,050	154	150	150	150	604	2,968	3,633	4,323	5,040	5,783	6,554	7,354	8,456	8,625
Total Product Sales	4,761	5,923	7,314	2,315	2,206	2,880	2,279	9,680	2,384	2,450	2,450	2,450	9,734	16,051	21,815	26,982	32,766	39,198	46,311	51,300	53,666	55,464
Expenses																						
Cost of product sales (prostate)	3,923	3,790	3,808	1,000	1,000	1,600	1,133	4,733	1,100	1,396	1,396	1,396	5,289	6,260	8,072	9,713	11,468	13,327	15,746	17,442	17,710	18,303
COGS % of revenue	82%	68%	64%	43%	43%	56%	56%	49%	57%	57%	57%	57%	54%	39%	37%	36%	35%	34%	34%	34%	33%	33%
Cost of product sales (non-prostate)	-	291	459	79	95	62	75	311	38	90	90	90	361	838	976	1,119	1,268	1,422	1,581	1,746	1,972	2,012
COGS % of revenue	-	5%	28%	20%	20%	12%	20%	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	815	666	805	690	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	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	1,097	1,071	1,155	1,248	4,571	1,067	1,166	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	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	233	277	294	322	1,126	312	296	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	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				(73)				(73)														
Non-GAAP Adj																						
Total Expenses	11,068	12,652	12,592	3,151	3,109	3,916	3,395	13,571	3,098	3,706	3,706	3,706	14,217	16,191	18,360	20,331	22,411	24,604	27,366	29,414	30,099	30,926
Operating income (Loss)	(6,307)	(6,729)	(5,278)	(836)	(903)	(1,036)	(1,116)	(3,891)	(714)	(1,256)	(1,256)	(1,256)	(4,483)	(1,411)	3,455	6,650	10,355	14,593	18,945	21,885	23,567	24,538
Interest income	117	29		20	6	3	1	30	1													
Change in fair value of warrant derivative liability	27																					
Financing and interest expense	-																					
Total other income	144	29	-	20	6	3	1	30	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Pre-tax Income	(6,163)	(6,700)	(5,278)	(816)	(897)	(1,033)	(1,115)	(3,861)	(713)	(1,256)	(1,256)	(1,256)	(4,483)	(1,411)	3,455	6,650	10,355	14,593	18,945	21,885	23,567	24,538
Income Tax Benefit (Provision)	-	-	-	(2)	(3)	(6)	(6)	(11)	(3)	(8)	(8)	(8)	(267)	(13)	380	931	1,657	2,481	3,410	4,158	5,916	7,145
Tax Rate	0%	0%	0%	4%	4%	4%	4%	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)	(816)	(899)	(1,036)	(1,109)	(3,872)	(716)	(1,168)	(1,168)	(1,168)	(4,216)	(128)	3,075	5,719	8,698	12,113	15,535	17,727	17,651	17,393
Preferred stock dividends	(11)	(11.00)																				
GAAP-EPS	(0.11)	(0.12)	(0.08)	(0.01)	(0.01)	(0.02)	(0.01)	(0.05)	(0.01)	(0.01)	(0.01)	(0.01)	(0.05)	(0.00)	0.04	0.07	0.10	0.14	0.18	0.20	0.20	0.20
Non GAAP EPS (dil)	(0.11)	(0.12)	(0.08)	(0.01)	(0.01)	(0.02)	(0.01)	(0.05)	(0.01)	(0.01)	(0.01)	(0.01)	(0.05)	(0.00)	0.03	0.06	0.09	0.12	0.16	0.18	0.18	0.18
Wghtd Avg Shrs (Bas) - '000s	55,016	55,159	67,042	67,388	67,388	67,558	85,895	72,057	68,898	86,066	86,152	86,238	81,839	86,454	86,800	87,148	87,497	87,848	88,200	88,553	88,908	89,264
Wghtd Avg Shrs (Dil) - '000s	55,016	55,159	67,042	67,388	67,388	67,558	95,029	74,341	68,898	95,219	95,314	95,410	88,710	95,648	96,031	96,416	96,802	97,190	97,580	97,970	98,363	98,757

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

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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	22	81%	4	18%
Market Perform (Neutral)	5	19%	1	20%
Market Underperform (Sell)	0	0%	0	0%
Total	27	100%	5	19%

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