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Toll-Free: 561-391-5555 ♦ www.DawsonJames.com ♦ 1 North Federal Highway - Suite 500 ♦ Boca Raton, FL 33432

IsoRay, Inc. (NYSE/ISR)

November 22, 2019

BUY: Sequential Growth in the Quarter

IsoRay reported the first fiscal quarter (2020) with revenues of \$2.3M and gross profit of \$1M which translated into an operating loss of just \$0.8M. Sales were driven by increased penetration into the prostate brachytherapy marketplace.

Jason H. Kolbert
 Head of Healthcare Research
 646-465-6891
 jkolbert@dawsonjames.com

Investment Highlights:

The Power of Blu. The new initiative, “The Power of Blu,” seems to be working. This launch took place at the ABS 2019 conference (last June 2019). The campaign reintroduces IsoRay’s Cesium-131, now known as Cesium Blu. This name change embodies the companies continued growth and awareness of the power of Cesium as an alternative option in the oncology community.

Brachytherapy Back on the Throne. As we noted in our prior notes, towards the end of 2018, Alex Azar, the United States Secretary of Health and Human Services publicly stated that CMS, under Trump’s Administration’s advisement, plans on grouping radiation oncology therapy into the mandatory bundled payment model. This may be helping to drive market share back to prostate cancer - brachytherapy. Initiation of a capitated system (one fee for treatment) should drive hospitals to evaluate where they can achieve the best outcome for patients at the lowest cost. We believe, radiation therapy will be one of the answers. Recall that the cost of the Cs-131 seeds that IsoRay provides is covered outside the bundle.

New Branding - Blu Build. Earlier in 2019, Dr. David T. Marshall, a professor of Oncology and Urology at the Hollings Cancer Center, which is part of the University of South Carolina, performed the first prostate cancer surgery using the Blu Build real-time Cesium-131 brachytherapy delivery system. Dr. Marshall believes that the Blu Build technology can have a significant impact in the marketplace, stating, “No two patients are exactly alike. What Blu Build provides physicians is a real-time means to individually customize and deliver a precise placement of Cesium-131 brachytherapy seeds tailored to the patient’s anatomy and cancer as the physician is seeing it in the operating room at the time of surgery.” The main goal of the Blu Build model aligns perfectly with IsoRay’s mission statement, “IsoRay advances innovative radiotherapeutic technologies that focus on the patient.” The advantages of this system are all catered to the safety and efficacy of the patient. Cesium Blu introduces patients to a life of improved quality. It is able to directly target the tumor, minimizing damage to other tissue, as a result of the shorter half-life (Cesium-131) compared to the other radioisotopes on the market. With a competitive price and a customized procedure model, the stage is set for Blu Build to be an effective (efficacy & cost) treatment for not only prostate cancer, but also other hard to treat , in the brain, pelvis, gyn, head, neck, lung, colon, and rectal areas.

Current Price \$0.41
 Price Target \$1.00

Estimates	F2019E	F2020E	F2021E
Expenses (\$000s)	\$ 12,592	\$ 13,433	\$ 15,640
1Q July	\$ 3,080	\$ 3,151	\$ 3,910
2Q October	\$ 3,356	\$ 3,375	\$ 3,910
3Q January	\$ 3,088	\$ 3,438	\$ 3,910
4Q April	\$ 3,068	\$ 3,469	\$ 3,910
	F2019E	F2020E	F2021E
EPS (diluted)	\$ (0.08)	\$ (0.05)	\$ (0.01)
1Q July	\$ (0.02)	\$ (0.01)	\$ (0.00)
2Q October	\$ (0.02)	\$ (0.01)	\$ (0.00)
3Q January	\$ (0.02)	\$ (0.01)	\$ (0.00)
4Q April	\$ (0.02)	\$ (0.01)	\$ (0.00)

EBITDA/Share	(\$0.08)	(\$0.05)	(\$0.01)
EV/EBITDA (x)	0.0	0.0	0.0

Stock Data		
52-Week Range	\$0.27	\$0.50
Shares Outstanding (mil.)	67.4	
Market Capitalization (mil.)	\$28	
Enterprise Value (mil.)	\$21	
Debt to Capital	0%	
Book Value/Share	\$0.19	
Price/Book	3.6	
Average Three Months Trading Volume (K)	164	
Insider Ownership	0.9%	
Institutional Ownership	5.5%	
Short interest (mil.)	1.9%	
Dividend / Yield	\$0.00/0.0%	



Please find Important Disclosures beginning on Page 7.

A Key Collaboration Opportunity. IsoRay Inc. has established an important connection with the Texas Oncology group, an independent oncology practice with over 210 locations in Texas and around 460 working physicians. This new training collaboration was announced on April 16, 2019, and will aid in public awareness of brachytherapy and the revolutionary capability of Cesium-131. The goal of this program is to help train the next generation of brachytherapists using several different approaches like case observations, practice on artificial prostates, physics planning, and real-time procedure methodology. These video tutorials can all be accessed through their webinar.

Valuation: We model Cesium Blu in both prostate and non-prostate cancer markets; however, we see the real driver as the prostate cancer marketplace. 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), but 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 to arrive at a \$1.00 price target. These metrics are dependent on our clinical assumptions.

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

Modeling Assumptions:

1. We assume continued growth of the patient incidence and prevalence of prostate cancer. We also assume that brachytherapy can become a larger part of the over-all prostate cancer therapy marketplace. We currently assume brachytherapy is under 10% and over the next decade and rise to 17%. Within the brachytherapy marketplace, Cs-131 has just a 5% market share. We assume that share can rise by 23% over the next decade.
2. Pricing. We assume on average \$70 per seed and 50 seeds per case in PC. Please see the market model below for our assumptions in non-prostate indications.
3. For IsoRay, and a result of the complexities of Isotope management, there may be a significant reduction in the cost of manufacturing associated with the volume.
4. GammaTile. We model the recurrent brain cancers marketplace (300,000 cases per year) and assume the market is based on the 75% of patients who may undergo tumor resection. At just 3% market share, \$150 per seed and 65 seeds on average, the market becomes significant at \$86M annually. We apply just a 10% probability that the full commercial opportunity can be realized based on GT Medical's ability to invest the needed capital to aggressively change the current treatment paradigm.

Exhibit 11: Cs-131 Models in Prostate, Other and GammaTile.

CS-131 sales (\$000)	2018A	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Prostate Cancer	260,840	266,057	271,378	276,806	282,342	287,989	293,748	299,623	305,616	311,728	317,963	324,322	330,808
% Patients electing monotherapeutic brachytherapy	9.3%	9.4%	9.6%	9.8%	10.0%	12.0%	13.0%	14.0%	15.0%	16.0%	17.0%	17.0%	17.2%
Number of patients for brachytherapy	24,258	25,009	26,052	27,127	28,234	34,559	38,187	41,947	45,842	49,876	54,054	55,135	56,899
Market share	5.0%	6.0%	8.0%	10.0%	12.0%	14.0%	16.0%	18.0%	20.0%	22.0%	22.5%	22.7%	22.8%
Patients electing CS-131 (Over Iodine-125 or Palladium-103)	1,213	1,501	2,084	2,713	3,388	4,838	6,110	7,551	9,168	10,973	12,162	12,516	12,973
Price per seed	70	70	70	70	70	70	70	70	70	70	70	70	70
Seeds per patient	50	50	50	50	50	50	50	50	50	50	50	50	50
CS-131 sales (Prostate cancer) (\$000)	\$4,245	\$5,252	\$7,295	\$9,494	\$11,858	\$16,934	\$21,385	\$26,427	\$32,090	\$38,405	\$42,567	\$43,805	\$45,405
	505713%												
Non-prostate cancers (Head & Neck), Gyn., Lung Cancer	254,000	259,080	264,262	269,547	274,938	280,437	286,045	291,766	297,601	303,554	309,625	312,721	315,848
% Patients receiving brachytherapy (monotherapy or combination)	10.0%	12.0%	13.00%	14.00%	15.00%	16.00%	17.00%	18.00%	19.00%	20.00%	21.00%	22.00%	23.00%
Number of patients for brachytherapy	25,400	31,090	34,354	37,737	41,241	44,870	48,628	52,518	56,544	60,711	65,021	68,799	72,645
Market share	0.3%	0.5%	0.8%	1.0%	1.5%	2.0%	2.5%	3.0%	3.5%	4.0%	4.5%	4.9%	4.9%
Patients receiving CS-131 brachytherapy	76	155	258	377	619	897	1,216	1,576	1,979	2,428	2,926	3,371	3,560
Price per seed	115	115	115	115	115	115	115	115	115	115	115	115	115
Seeds per patient	65	65	65	65	65	65	65	65	65	65	65	65	65
CS-131 sales (Non-prostate cancer) (\$000)	\$570	\$1,162	\$1,926	\$2,821	\$4,624	\$6,708	\$9,087	\$11,777	\$14,793	\$18,153	\$21,871	\$25,199	\$26,608
GammaTile (\$000)													
Brain cancer (cs/yr) - Candidates (new and recurrent)	300,000	306,000	312,120	318,362	324,730	331,224	337,849	344,606	351,498	358,528	365,698	373,012	380,473
% Patients undergoing surgical resection	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%
Patients requiring treatment of tumor bed following resection	225,000	229,500	234,090	238,772	243,547	248,418	253,387	258,454	263,623	268,896	274,274	279,759	285,354
Market share	0.0%	0.1%	0.5%	1.0%	1.3%	1.5%	1.8%	2.0%	2.3%	2.5%	2.8%	3.1%	3.1%
Patients receiving wafer	0	230	1,170	2,388	3,044	3,726	4,434	5,169	5,932	6,722	7,543	8,673	8,846
Price per seed	\$150	\$150	\$150	\$150	\$150	\$150	\$150	\$150	\$150	\$150	\$150	\$150	\$150
Seeds per patients	65	65	65	65	65	65	65	65	65	65	65	65	65
Probability Factor	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
Wafer sales (Meningioma's) (\$000)	\$0	\$224	\$1,141	\$2,328	\$2,968	\$3,633	\$4,323	\$5,040	\$5,783	\$6,554	\$7,354	\$8,456	\$8,625
Probability adjusted sales (\$000)	\$0	\$224	\$1,141	\$2,328	\$2,968	\$3,633	\$4,323	\$5,040	\$5,783	\$6,554	\$7,354	\$8,456	\$8,625
Combined Revenues	\$4,815	\$6,638	\$10,362	\$14,643	\$19,451	\$27,275	\$34,796	\$43,244	\$52,666	\$63,112	\$71,793	\$77,459	\$80,638

Source: Dawson James

VALUATION

We see IsoRay as an established company that has commercialized an approved product that has strong product attributes. Revenue today are small at just \$6M annually, but we believe these revenues, with our modest assumptions, can grow over the coming decade. For these reasons, we apply 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. This method results in a \$1.00 price target for IsoRay.

Exhibit 12. FCFF Model

IsoRay Medical, Inc.

Average	\$	1.1
Price Target	\$	1.1
Year		2019

DCF Valuation Using FCF (mln):

units ('000)	2018A	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(6,700)	(5,612)	(3,497)	(1,044)	1,323	5,861	10,148	15,135	20,860	26,751	31,396	34,840	36,467
Tax Rate	0%	0%	4%	7%	9%	11%	14%	16%	17%	18%	19%	25%	29%
EBIT(1-t)	(6,700)	(5,612)	(3,357)	(971)	1,204	5,216	8,727	12,713	17,314	21,936	25,430	26,046	25,789
CapEx	-	-	-	-	-	-	-	-	-	-	-	-	-
Depreciation	-	-	-	-	-	-	-	-	-	-	-	-	-
Change in NWC	-	-	-	-	-	-	-	-	-	-	-	-	-
FCF	(6,700)	(5,612)	(3,357)	(971)	1,204	5,216	8,727	12,713	17,314	21,936	25,430	26,046	25,789
PV of FCF	(7,705)	(5,612)	(2,919)	(734)	792	2,982	4,339	5,496	6,509	7,171	7,229	6,438	5,543.20
Discount Rate	15%												
Long Term Growth Rate	1%												
Terminal Cash Flow	186,050												
Terminal Value YE2030	39,990												
NPV	77,224												
NPV-Debt	-												
Shares out (thousands)	70,325											2030E	
NPV Per Share	\$ 1.1												

Source: Dawson James

Exhibit 13. Discounted EPS Model

Current Year	2019
Year of EPS	2030
Earnings Multiple	10
Discount Factor	15%
Selected Year EPS	\$ 0.37
NPV	\$ 0.80

		Discount Rate and Earnings Multiple Varies, Year is Constant					
		2030 EPS					
Earnings Multiple		5%	10%	15%	20%	25%	30%
		2		\$0.43	\$0.26	\$0.16	\$0.10
5		\$1.09	\$0.65	\$0.40	\$0.25	\$0.16	\$ 0.10
10		\$2.17	\$1.30	\$0.80	\$0.50	\$0.32	\$ 0.21
15		\$3.26	\$1.95	\$1.20	\$0.75	\$0.48	\$ 0.31
20		\$4.35	\$2.61	\$1.60	\$1.00	\$0.64	\$ 0.41
25		\$5.43	\$3.26	\$2.00	\$1.25	\$0.80	\$ 0.52
30		\$6.52	\$3.91	\$2.40	\$1.50	\$0.96	\$ 0.62
35		\$7.61	\$4.56	\$2.80	\$1.75	\$1.12	\$ 0.73

Source: Dawson James

Exhibit 14. 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%	5	100%	\$45	\$324
NPV						\$0.69
CS-131 (non-prostate cancer)	1%	15%	5	100%	\$27	\$190
NPV						\$0.40
GammaTile	1%	30%	3	50%	\$86	\$297
NPV						\$0.29
Net Margin						30%
MM Shrs OS (2028E)						70
Total						\$1.4

Source: Dawson James

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 15. Income Statement

IsoRay™ Medical, Inc.: Income Statement (\$000)	6.2017	6.2018	July-Sept	Oct-Dec	Jan-Mar	Apr-Jun	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.: YTD Jun 30	2017A	2018A	1C19A	2C19A	3C19A	4C19A	2019A	1Q20E	2Q20E	3Q20E	4Q20E	2020E	1Q21E	2Q21E	3Q21E	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	
Cs-131 Prostate Cancer	4,761	5,369	1,268	1,260	1,366	1,550	5,252	1,678	1,751	1,897	1,970	7,295	2,374	2,374	2,374	2,374	9,494	11,858	16,934	21,385	26,427	32,090	38,405	42,567	43,905	45,405	
Cs-131 Seeds (non-prostate - non-brain)		506	267	279	302	314	1,162	481	481	481	481	1,926	705	705	705	705	2,821	4,624	6,708	9,087	11,777	14,793	18,153	21,871	25,199	26,608	
Gamma Tile			51	54	58	60	224	285	285	285	285	1,141	582	582	582	582	2,328	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	1,562	1,904	1,924	1,924	7,314	2,445	2,518	2,663	2,736	10,362	3,661	3,661	3,661	3,661	14,643	19,451	27,275	34,796	43,244	52,666	63,112	71,793	77,459	80,638	
Expenses																											
Cost of product sales (prostate)	3,923	3,790	938	1,000	900	970	3,808	1,100	1,133	1,199	1,231	4,663	1,464	1,464	1,464	1,464	5,857	7,586	10,092	12,526	15,135	17,907	21,458	24,410	25,562	26,611	
COGS % of revenue	82%	68%	60%	79%	66%	50%	64%	45%	45%	45%	45%	45%	40%	40%	40%	40%	40%	39%	37%	36%	35%	34%	34%	34%	34%	33%	
Cost of product sales (non-prostate)	-	291	100	139	145	75	459	153	153	153	153	613	257	257	257	257	1,030	1,518	2,068	2,682	3,363	4,115	4,941	5,845	6,731	7,047	
COGS % of revenue	20%	5%	8%	42%	40%	20%	28%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	
Sales and marketing expenses	2,310	2,860	649	702	645	683	2,679	683	683	683	683	2,733	697	697	697	697	2,787	2,843	2,900	2,958	3,017	3,077	3,139	3,202	3,266	3,331	
S&M % of revenue																											
General and administrative expenses	3,918	4,165	973	1,101	1,099	999	4,172	1,064	1,064	1,064	1,064	4,255	1,085	1,085	1,085	1,085	4,341	4,427	4,516	4,606	4,698	4,792	4,888	4,986	5,086	5,187	
G&A % of revenue																											
Research and development	965	1,746	420	414	299	341	1,474	387	387	387	387	1,548	406	406	406	406	1,625	1,706	1,792	1,827	1,846	1,864	1,883	1,902	1,921	1,940	
R&D % of revenue																											
(48)																											
Total Expenses	11,068	12,652	3,080	3,356	3,088	3,068	12,592	3,387	3,420	3,486	3,519	13,812	3,910	3,910	3,910	3,910	15,640	18,081	21,367	24,600	28,060	31,756	36,309	40,344	42,565	44,116	
Operating Income (Loss)	(6,307)	(6,729)	(1,518)	(1,429)	(1,163)	(1,144)	(5,278)	(943)	(903)	(822)	(782)	(3,450)	(249)	(249)	(249)	(249)	(997)	1,370	5,908	10,195	15,184	20,911	26,802	31,449	34,895	36,523	
Interest income	117	29	10	15	34	49	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Change in fair value of warrant derivative liability	27	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Financing and interest expense	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Total other income	144	29	10	15	36	49	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Pre-tax Income	(6,163)	(6,700)	(1,509)	(1,414)	(1,127)	(1,095)	(5,278)	(943)	(903)	(822)	(782)	(3,450)	(249)	(249)	(249)	(249)	(997)	1,370	5,908	10,195	15,184	20,911	26,802	31,449	34,895	36,523	
Income Tax/Benefit (Provision)	-	-	-	-	-	-	-	(38)	(36)	(33)	(31)	(138)	(17)	(17)	(17)	(17)	(70)	123	850	1,427	2,420	3,555	4,824	5,975	8,808	10,694	
Tax Rate	0%	-	-	-	-	-	-	4%	4%	4%	4%	4%	7%	7%	7%	7%	7%	9%	11%	14%	16%	17%	18%	19%	25%	29%	
GAAP Net Income (loss)	(6,166)	(6,711)	(1,511)	(1,416)	(1,130)	(1,098)	(5,278)	(905)	(867)	(790)	(751)	(3,312)	(232)	(232)	(232)	(232)	(927)	1,246	5,258	8,768	12,755	17,356	21,978	25,474	26,087	25,829	
Preferred stock dividends	(11)	(11,000)	-	-	-	3,000	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
GAAP-EPS	(0.11)	(0.12)	(0.02)	(0.02)	(0.02)	(0.02)	(0.08)	(0.01)	(0.01)	(0.01)	(0.01)	(0.05)	(0.00)	(0.00)	(0.00)	(0.00)	(0.01)	0.02	0.08	0.13	0.19	0.25	0.32	0.37	0.38	0.37	
Non GAAP EPS (dil)	(0.11)	(0.12)	(0.02)	(0.02)	(0.02)	(0.02)	(0.08)	(0.01)	(0.01)	(0.01)	(0.01)	(0.05)	(0.00)	(0.00)	(0.00)	(0.00)	(0.01)	0.02	0.08	0.13	0.19	0.25	0.32	0.37	0.38	0.37	
Wght Avg Shrs (Bas) - '000s	55,016	55,159	66,147	67,331	67,333	67,357	67,042	67,424	67,492	67,559	67,627	67,526	67,694	67,762	67,830	67,898	67,796	68,068	68,340	68,614	68,889	69,165	69,442	69,720	70,000	70,280	
Wght Avg Shrs (Dil) - '000s	55,016	55,159	66,147	67,331	67,333	67,357	67,042	67,424	67,492	67,559	67,627	67,526	67,694	67,762	67,830	67,898	67,796	68,068	68,340	68,614	68,889	69,165	69,442	69,720	70,000	70,280	

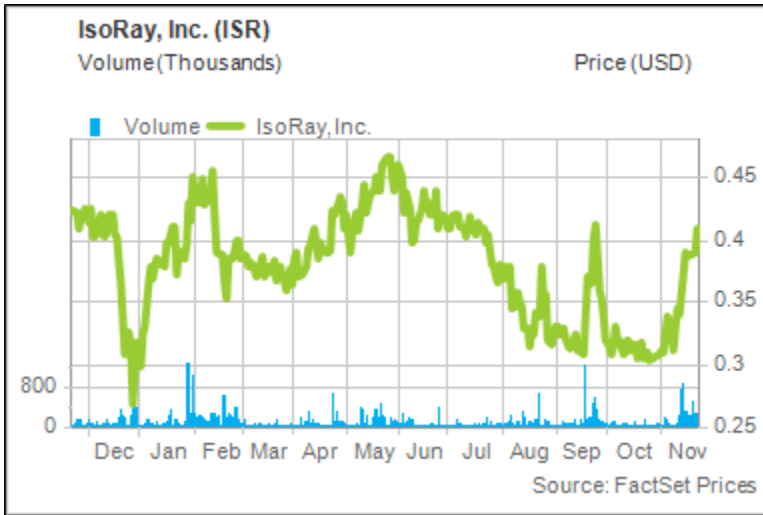
Source: Dawson James and Company Reports

Companies mentioned in this report

GT Medical (private)
Centers for Medicare and Medicaid Services (Federal Agency)

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

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Rating Definitions:

- 1) **Buy:** The analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 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.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	23	88%	2	9%
Market Perform (Neutral)	3	12%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	26	100%	2	8%

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