

INSTITUTIONAL RESEARCH

Medical Technology UPDATE REPORT

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IsoRay, Inc. (NYSE/ISR)

September 22, 2019

BUY: Reports 4th Quarter (Fiscal) Results

IsoRay reported the fourth fiscal quarter (June 2020) with revenues sequentially down to \$2.2M (was \$2.8M in the prior period), and gross profit of \$0.8M, which translated into an operating loss of \$1.1M, the highest in the year (annual loss of \$3.4M). Penetration into the PC Market appears to be slowing.

Investment Highlights:

IsoRay reported 4Q20 (fiscal year) results. Revenues were \$2.279M, down sequentially from \$2.880M in the prior period. Expenses of \$3.4M were up slightly vs. the prior quarter. This translated into a net loss of \$1.2M, or two cents a share. The company's cash balance was just \$2.39M, and we do expect to see a capital raise.

- Prostate brachytherapy represented 84% of total revenue for the period. The majority of non-prostate brachytherapy revenue in the quarter was comprised of sales to treat brain cancer, including sales of GammaTile Therapy. While this is still "tiny," it represents an area of significant potential growth.
- Net new physician customer count for the twelve months ended June 2020 increased 35% versus the prior year comparable period.
- ICD-10 Codes Received. This allows hospitals to bill for specific procedures involving certain cancers (lung, head and neck, pelvic, and others), set to take effect in October 2020.
- ROAPN Singled bundled payment, including brachytherapy. The implementation of this bundle "levels the playing field" for brachytherapy vs. other radiation modalities.

The Power of Blu. The new initiative, "The Power of Blu," remains underway. The launch was initiated in June 2019. The campaign reintroduces IsoRay's Cesium-131, now known as Cesium Blu. This name change embodies the company's continued growth and awareness of the power of Cesium as an alternative option in the oncology community.

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). 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 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

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Current Price						\$0.61
Price Target						\$1.00
Estimates		F2019A		F2020A		F2021E
Expenses (\$000s)	\$	12,592	\$	13,156	\$	15,767
1Q July	\$	3,080	\$	3,151	\$	3,942
2Q October	\$	3,356	\$	3,109	\$	3,942
3Q January	\$	3,088	\$	3,428	\$	3,942
4Q April	\$	3,068	\$	3,468	\$	3,942
		F2019A		F2020A		F2021E
EPS (diluted)	\$	(0.08)	\$	(0.05)	\$	(0.02)
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)	\$	(0.02)	\$	(0.00)
EBITDA/Share		(\$0.08)		(\$0.05)		(\$0.02)
EV/EBITDA (x)		0.0		0.0		0.0
Stock Data						
52-Week Range		\$0.29		-		\$1.06
Shares Outstanding (mil.)						68.9
Market Capitalization (mil	.)					\$42
Enterprise Value (mil.)						\$35
Debt to Capital						0%
Book Value/Share						\$0.19
Price/Book						6.7
Average Three Months Tra	din	g Volum	e (K)		576
Insider Ownership						1.4%
Institutional Ownership						10.4%
Short interest (mil.)						2.1%
Dividend / Yield				\$	0.0	00/0.0%
IsoRay, Inc. (ISR)						
Volume (Thousands)				Price	(U	SD)
■ Volume — IsoRa	y, Ind	D				1.1





Brachytherapy Back on the Throne. As we noted in our prior notes, Alex Azar, the United States Secretary of Health and Human Services publicly stated that CMS, under the Trump 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 can 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. Last year, 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 areas, in the brain, pelvis, gyn, head, neck, lung, colon, and rectal areas.

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 this past spring. It should help raise public awareness of brachytherapy and the revolutionary capability of Cesium-131. The goal of this program is to help train the next generation of brachy therapists 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.

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.

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Exhibit 1: 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 lodine-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 patients	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)	2018A	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
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 (Mengioma'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
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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; * Numbers are estimated for all years.

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VALUATION

We see IsoRay as an established company that has commercialized an approved product that has strong product attributes. Revenue today is small at just \$10M 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 2. FCFF Model

PV of FCF

	Price Target \$	1.3												
	Year	2020												
DCF Valuation Using FCF (mln):														
units ('000)			2018A	2019A	2020A	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
EBIT			(6,700)	(5,278)	(3,446)	(1,124)	1,253	5,803	10,088	15,070	20,789	26,673	31,312	34,750
Tax Rate			0%	0%	0%	7%	9%	11%	14%	16%	17%	18%	19%	25%
EBIT(1-t)			(6,700)	(5,278)	(3,438)	(1,045)	1,140	5,164	8,676	12,659	17,255	21,872	25,363	25,978
CapEx			-	-	-	-	-	-	-	-	-	-	-	-
Depreciation			-	-	-	-	-	-	-	-	-	-	-	-
Change in NWC														
FCF			(6,700)	(5,278)	(3,438)	(1,045)	1,140	5,164	8,676	12,659	17,255	21,872	25,363	25,978

(3,438)

 Discount Rate
 15%

 Long Term Growth Rate
 1%

 Terminal Cash Flow
 185,555

 Terminal Value YE2030
 45,866

 NPV
 88,677

 NPV-Debt

 Shares out (thousands)
 70,746

 NPV PS Share
 \$ 1.3

(8,861)

(6,070)

2030E

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	\$ 0.37
NPV	\$ 0.91

		Discount R	ate and Earnin	gs Multiple Va 2030 E		Constant	
		5%	10%	15%	20%	25%	30%
Earnings							
Multiple	2	\$0.44	\$0.26	\$0.16	\$0.10	\$0.06 \$	0.04
	5	\$1.09	\$0.65	\$0.40	\$0.25	\$0.16 \$	0.10
	10	\$2.18	\$1.31	\$0.80	\$0.50	\$0.32 \$	0.21
	15	\$3.27	\$1.96	\$1.20	\$0.75	\$0.48 \$	0.31
	20	\$4.36	\$2.61	\$1.60	\$1.00	\$0.64 \$	0.42
	25	\$5.44	\$3.26	\$2.00	\$1.25	\$0.80 \$	0.52
	30	\$6.53	\$3.92	\$2.40	\$1.50	\$0.96 \$	0.62
	35	\$7.62	\$4.57	\$2.80	\$1.75	\$1.12 \$	0.73

25,721

6,357.72

7,385

8,223

8,291

Source: Dawson James estimates

Exhibit 4. Sum of the Parts Model

IsoRay, Inc.	LT Gr	Discount Rate `	∕rs. to Peak Mkt	% Success	Peak Sales MM's	NPV
CS-131 (Prostate cancer)	1%	15%	5	100%	\$45	\$324
NPV						\$0.68
CS-131 (non-prostate cancer)	1%	15%	5	100%	\$27	\$190
NPV					ľ	\$0.40
GammaTile	1%	30%	3	50%	\$86	\$297
NPV						\$0.29
Net Margin						30%
MM Shrs OS (2028E)						71
Total						\$1.4

Source: Dawson James estimates

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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.

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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	1Q21E	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	1,544	6,671	2,374	2,374	2,374	2,374	9,494	11,858	16,934	21,385	26,427	32,090	38,405	42,567	43,805	45,405
Cs-131 Seeds (non-prostate - non-brain)		506	1,162	482	421	500	450	1,853	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			224	286	285	300	285	1,156	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	7.314	2,315	2,206	2.880	2,279	9,680	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																						
Exponed																						
Cost of product sales (prostate)	3,923	3,790	3,808	1,000	1,000	1,100	1,150	4,250	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%	64%	43%	43%	43%	43%	44%	40%	40%	40%	40%	40%	39%	37%	36%	35%	34%	34%	34%	33%	33%
Cost of product sales (non-prostate)	-	291	459	79	95	74	58	306	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%	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	2,660	2,679	815	666	805	690	2,976	759	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	1,097	1,071	1,155	1,248	4,571	1,166	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																						
Research and development	965	1,746	1,474	233	277	294	322	1,126	296	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																						
	(48)																					
	(- /																					
Stk Optn's																						
Non-GAAP, Adj				(73)				(73)														
Total Expenses	11,068	12,652	12,592	3,151	3,109	3,428	3,468	13,156	3,942	3,942	3,942	3,942	15,767	18,198	21,472	24,707	28,174	31,877	36,438	40,481	42,709	44,268
Operating income (Loss)	(6,307)	(6,729)	(5,278)	(836)	(903)	(548)	(1,189)	(3,476)	(281)	(281)	(281)	(281)	(1,124)	1,253	5,803	10,088	15,070	20,789	26,673	31,312	34,750	36,370
, , ,	, , ,	, , ,	, , ,				, ,	, , ,				` '										
Interest income	117	29		20	6	3	1	30														
Change in fair value of warrant derivative liability	27	20		20	Ü	Ü	.	00														
Financing and interest expense																						
Thanong and moreot expense																						
Total other income	144	29	-	20	6	3	1	30	-		-	-	-	-	-	-	-	-	-	-	-	-
Pretax Income	(6,163)	(6,700)	(5,278)	(816)	(897)	(545)	(1,188)	(3,446)	(281)	(281)	(281)	(281)	(1,124)	1,253	5,803	10,088	15,070	20,789	26,673	31,312	34,750	36,370
Income Tax Benefit (Provision)	-		-	` '	(2)	(3)	(3)	(8)	(20)	(20)	(20)	(20)	(79)	113	638	1,412	2,411	3,534	4,801	5,949	8,772	10,649
Tax Rate	0%			4%	4%	4%	4%	0%	7%	7%	7%	7%	7%	9%	11%	14%	16%	17%	18%	19%	25%	29%
GAAP Net Income (loss)	(6,166)	(6,711)	(5,278)	(816)	(899)	(548)	(1,191)	(3,454)	(261)	(261)	(261)	(261)	(1,045)	1,140	5,164	8,676	12,659	17,255	21,872	25,363	25,978	25,721
Preferred stock dividends	(11)	(11.00)		(3.00)																		
	, ,																					
GAAP-EPS	(0.11)	(0.12)	(0.08)	(0.01)	(0.01)	(0.01)	(0.02)	(0.05)	(0.00)	(0.00)	(0.00)	(0.00)	(0.02)	0.02	0.08	0.13	0.18	0.25	0.31	0.36	0.37	0.37
Non GAAP EPS (dil)	(0.11)	(0.12)	(0.08)	(0.01)	(0.01)	(0.01)	(0.02)	(0.05)	(0.00)	(0.00)	(0.00)	(0.00)	(0.02)	0.02	0.08	0.13	0.18	0.25	0.31	0.36	0.37	0.37
Wgtd Avg Shrs (Bas) - '000s	55,016	55,159	67,042	67,388	67,388	67,558	68,075	67,602	68,143	68,211	68,279	68,348	68,245	68,519	68,793	69,069	69,346	69,623	69,902	70,182	70,463	70,746
Wgtd Avg Shrs (Dil) - '000s	55,016	55,159	67,042	67,388	67,388	67,558	68,075	67,602	68,143	68,211	68,279	68,348	68,245	68,519	68,793	69,069	69,346	69,623	69,902	70,182	70,463	70,746

Source: Dawson James estimates and Company Reports

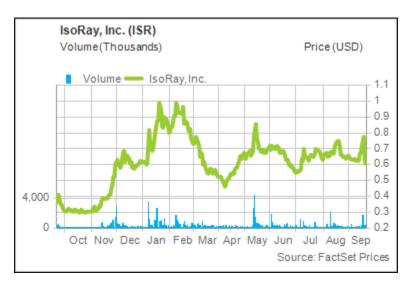


Companies mentioned in this report

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

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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;
- Neutral: The analyst believes the price of the stock is fairly valued for the next 12-18 months:
- 3) **Sel**l: 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.

	Company Co	verage	Investment Banking			
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals		
Market Outperform (Buy)	23	85%	4	17%		
Market Perform (Neutral)	4	15%	1	25%		
Market Underperform (Sell)	0	0%	0	0%		
Total	27	100%	5	19%		

Analyst Certification:

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