

CytoSorbents Corporation (NASDAQ/CTSO)

February 19, 2020

BUY: Cytosorb For Coronavirus – It Makes Good Cents

Cytosorbents and China Medical System Holdings Limited (CMS-HKG:0867, not rated), an established specialty pharma company with a focus on sales and marketing in China and Asia, entered into an agreement to bring CytoSorb to mainland China to treat critically-ill patients with COVID-19 (2019-nCoV). In our opinion, this could jumpstart Cytosorb's presence in China and Asia.

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Current Price \$5.40
 Price Target \$15.00

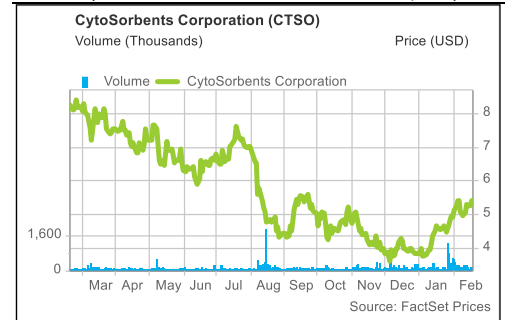
Investment Highlights

ARDS and the Cytokine Storm Can kill you. As we wrote in our Feb.11th note for Athersys (ATHX-Buy Rated), Acute Respiratory Distress Syndrome, or ARDS, occurs when fluid builds up in the tiny, elastic air sacs (alveoli) in your lungs. Severe pneumonia and the new Coronavirus too can result in an infection in the lobes of the lungs, triggering an inflammatory cascade that causes death. Cytosorb can mechanically assist in slowing down the storm (vs. Athersys Multistem which uses cell therapy to slow down – normalize immune system modulation). The two together could curb the mortality rate associated with this virus and what's very positive for both companies is that the therapy is agnostic of the cause, i.e., It's not viral-specific, so it should work on all patients (flu and or Coronavirus).

Adapted from the press release: *"The clinical features of the COVID-19 coronavirus and its causal relationship to the "cytokine storm" create a potential role for CytoSorb in treating patients suffering from severe coronavirus infection. "CytoSorb, the Wuhan Coronavirus, and Cytokine Storm." This was highlighted in a recent publication in Lancet Respiratory Medicine by Drs. Claudio Ronco, Paolo Navalesi, and Jean Louis Vincent entitled, "Coronavirus epidemic: preparing for extracorporeal organ support in intensive care." Notably, the authors state, "A sepsis-like syndrome might occur frequently due to the virus itself or to a superimposed bacterial infection and in this case, since pharmacological approaches have shown poor results, new extracorporeal organ support therapies including haemoadsorption and haemoperfusion, with new sorbent cartridges designed to remove cytokines and other circulating mediators, should be considered." These publications provide the rationale to potentially use CytoSorb, the first specifically-approved extracorporeal cytokine adsorber in the European Union, in this setting. CytoSorb is distributed in 58 countries worldwide, and is available in Hong Kong, Vietnam, Malaysia, Germany, United Kingdom, Italy France, Spain, Belgium, United Arab Emirates, India, Russia, Finland, Sri Lanka, and Australia where patients infected with the virus have been reported".*

Bottom line: We have not factored in China to our model, so any sales to China represent upside. We can recall other products and companies such as Sciclone (SCLN-no private), which has an immune modulator product that was utilized during the SARS outbreak in China and became a significant product afterward. **Cytosorb could build an important foothold in China as awareness grows of the technology and its ease of use and its ability to treat any virus related severe complication independent of the specific pathogen.**

Estimates	F2019E	F2020E	F2021E
Expenses (\$000s)	\$ 42,188	\$ 45,867	\$ 55,937
1Q March	\$ 9,475	\$ 10,549	\$ 12,865
2Q June	\$ 9,862	\$ 11,008	\$ 13,425
3Q September	\$ 11,723	\$ 11,925	\$ 14,544
4Q December	\$ 11,129	\$ 12,384	\$ 15,103
	F2019E	F2020E	F2021E
EPS (diluted)	\$ (0.62)	\$ (0.30)	\$ 0.15
1Q March	\$ (0.15)	\$ (0.07)	\$ 0.03
2Q June	\$ (0.11)	\$ (0.07)	\$ 0.04
3Q September	\$ (0.21)	\$ (0.08)	\$ 0.04
4Q December	\$ (0.14)	\$ (0.08)	\$ 0.04
EBITDA/Share	(\$0.55)	(\$0.32)	\$0.16
EV/EBITDA (x)	0.0	0.0	0.0
Stock Data			
52-Week Range	\$3.49	-	\$8.61
Shares Outstanding (mil.)	32.4		
Market Capitalization (mil.)	\$175		
Enterprise Value (mil.)	\$155		
Debt to Capital	0%		
Book Value/Share	\$0.35		
Price/Book	15.2		
Average Three Months Trading Volume (K)	141		
Insider Ownership	5.4%		
Institutional Ownership	27.8%		
Short interest (mil.)	8.3%		
Dividend / Yield	\$0.00/0.0%		



Multiple Catalysts Ahead:

- The “**Remove Endocarditis**” trial in Germany. The trial has now enrolled 250 patients (and plans to add another 15 to account for any drop-outs). We should see data this year.
- Advancement of the **U.S. pivotal REFRESH 2-AKI** trial. An interim analysis is planned at N=200, estimated to occur by 1H20.
- **UK TISORB study** (company-sponsored) is evaluating the use of Cytosorb to remove anti-platelet drugs (ticagrelor) in emergency cardiac surgery patients. We note this is a global \$20B market.
- **HemoDefend IDE.**, We need to check on the status suffice to say we believe a 2020 approval is possible as this is expected to be a DeNovo 510-K (two-site, n=20 person trial), to support the filing.
- HemoDefend background. Recall that there has been ongoing controversy on whether there is a difference between "old" blood and "new" blood or blood that has been stored for some time in a refrigerated compartment versus blood that has been freshly donated by a person. Although current studies show contradicting results (independent studies were highly varied in approach), it is undisputed that biological changes occur during RBC storage, although unknown if they are beneficial/harmless or detrimental changes. Whether or not aged blood is bad, HemoDefend is still advantageous when storing donated blood. Not only will it keep donated blood fresh and extend the shelf-life of blood, but it will also remove the many contaminants that may be present in donated blood, or from the changes, RBCs undergo while in storage. This is to minimize the current 1-5% risk chance patients have of developing a transfusion reaction, which could be as mild as a fever to as severe as death.
- The HemoDefend technology can be implemented in two ways; as an in-line filter between the blood bag and the patient during transfusion, or in an approach called “Beads in a Bag.” Beads in a Bag is CytoSorbents’ innovative, patent-pending technology that will purify blood during the entire refrigerated storage period. CytoSorbents’ biocompatible beads are perfect for this use for several reasons: the beads can have extended contact with blood without causing damage to the RBCs, they are neutrally buoyant and will suspend in blood so that the blood storage bag does not need to be mixed, and during transfusion, an integrated filter will keep the beads in the bag. HemoDefend won’t require any extra machine, electricity, energy source, or any other manipulation to be used, so it won’t cost much to possibly save a life.

Valuation. We use a series of therapeutic models across the various indications and geographies and project product revenues for the company out to the year 2030. In our U.S. therapeutic models, we apply a 30% risk cut (70% success probability) that both U.S. approvals and our market share forecasts can be realized. For us, valuation becomes an interesting question when we discuss the appropriate “r” risk-rate to use in our three model metrics, free cash flow to the firm (FCFF), Discounted EPS and Sum-Of-The-Parts (SOP) models, which are equal-weighted, averaged and rounded to the nearest whole number. Typically for early-stage companies with no revenues, we use 30%, and for companies with established products and revenues, we use a lower 15%. Cytosorbents arguably is somewhere in the middle, as products are approved and selling in Europe but not yet in the U.S. If we select a conservative 30%, we drive a \$9.00 price target. If we select a more aggressive 15%, we arrive at a \$28.00 target. If we select a mid-point (22.5%), we derive a \$15.00 target. Given their unique position of approval in Europe, established proof of concept, and a product that works, we select the mid-point of 22.5% and set our target for CytoSorbents at \$15.00.

Risk. Market risks, Regulatory risks, Financial risks and Commercialization risks.

Modeling Assumptions

- 1. We assume continued steady growth for CytoSorb in the current key EU direct sales countries of Germany, Austria, and Switzerland.
2. We assume a selling price per cartridge of \$1,000 for direct sales and \$600 for distribution sales. We estimate that each patient will require an average of five units (CytoSorb cartridges) for sepsis treatment and three units for cardiac treatment.
3. We conservatively assume that CytoSorb can achieve a ten percent market share of the market in Germany, Austria and Switzerland, and 3% of the market in the rest of the EU by 2030.
4. Our model includes CytoSorb revenues in the U.S. for cardiac surgery and sepsis beginning in 2021 upon commercialization. To these revenues, we apply a 70% probability of success (or 30% risk cut).

Exhibit 1. CytoSorb sepsis EU direct sales (Germany, Austria, and Switzerland)

Table with 13 columns (2018E-2030E) and rows for EU population, Germany population, Austria population, Switzerland population, Critical care population, Percent of patients with access to hospitals with CytoSorb, Total patients, Market penetration, Total addressable patients, Estimated units per patient, Total filler needed, Cost of therapy, Change in price, Revenue ('000), Risk factor, and Total revenue ('000).

Source: Dawson James estimates

Exhibit 2. CytoSorb sepsis EU sales by distributorship (excluding Germany, Austria, and Switzerland)

Table with 13 columns (2018E-2030E) and rows for EU population, Germany population, Austria population, Switzerland population, Critical care population, Percent of patients with access to hospitals with CytoSorb, Total patients, Market penetration, Total addressable patients, Estimated units per patient, Total filler needed, Cost of therapy, Change in price, Revenue ('000), Risk factor, and Total revenue ('000).

Source: Dawson James estimates

Exhibit 3. CytoSorb U.S. sales for cardiac surgery

Table with 13 columns (2018E-2030E) and rows for US population, Cardiac surgery, Market penetration, Total addressable patients, Estimated units per patient, Total filler needed, Cost of therapy, Change in price, Revenue ('000), Risk factor, and Total revenue ('000).

Source: Dawson James estimates

Exhibit 4. CytoSorb EU sales for cardiac surgery

Table with 13 columns (2018E-2030E) and rows for Cardiac surgery, Market penetration, Total addressable patients, Estimated units per patient, Total filler needed, Cost of therapy, Change in price, Revenue ('000), Risk factor, and Total revenue ('000).

Source: Dawson James estimates

Exhibit 5. CytoSorb U.S. sales for sepsis

Table with 13 columns (2018E-2030E) and rows for US population, Severe sepsis patients, Market penetration, Total addressable patients, Estimated units per patient, Total filler needed, Cost of therapy, Change in price, Revenue ('000), Risk factor, and Total revenue ('000).

Source: Dawson James estimates

Valuation. We use a series of therapeutic models across the various indications and geographies and project product revenues for the company out to the year 2030. In our U.S. therapeutic models, we apply a 30% risk cut (70% success probability) that both U.S. approvals and our market share forecasts can be realized. For us, valuation becomes an interesting question when we discuss the appropriate "r" risk-rate to use in our three model metrics, free cash flow to the firm (FCFF), Discounted EPS and Sum-Of-The-Parts (SOP) models, which are equal-weighted, averaged and rounded to the nearest whole number. Typically for early-stage companies with no revenues, we use 30%, and for companies with established products and revenues, we use a lower 15%. Cytosorbents arguably is somewhere in the middle, as products are approved and selling in Europe but not yet in the U.S. If we select a conservative 30%, we drive a \$9.00 price target. If we select a more aggressive 15%, we arrive at a \$28.00 target. If we select a mid-point (22.5%), we derive a \$15.00 target. Given their unique position of approval in Europe, established proof of concept, and a product that works, we select the mid-point of 22.5% and set our target for CytoSorbents at \$15.00.

Exhibit 6. FCFF Model

Average \$	15
Price Target \$	17
Year	2020

DCF Valuation Using FCF (min):

units ('000)	2018A	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(17,830)	(17,612)	(10,524)	5,367	32,536	74,957	139,901	238,510	295,964	330,995	355,282	380,125	376,677
Tax Rate	0%	5%	8%	10%	12%	15%	18%	21%	24%	28%	33%	33%	33%
EBIT (1-t)	(17,830)	(16,731)	(9,682)	4,831	28,632	63,714	114,719	188,423	224,932	238,317	238,039	254,683	252,373
CapEx	(493)	(543)	(597)	(657)	(722)	(794)	(874)	(961)	(1,057)	(1,163)	(1,279)	(1,407)	(1,548)
Depreciation	391	414	-	-	-	-	-	-	-	-	-	-	-
Change in NWC													
FCF	(17,932)	(16,860)	(10,279)	4,174	27,910	62,919	113,845	187,462	223,875	237,154	236,759	253,276	250,825
PV of FCF	(26,910)	(20,653)	(10,279)	3,407	18,599	34,228	50,556	67,957	66,250	57,290	46,689	40,773	32,962
Discount Rate	22.5%												
Long Term Growth Rate	1%												
Terminal Cash Flow	1,178,296												
Terminal Value YE2030	154,844												
NPV	563,275												
NPV-Debt													
Shares out ('000)	33,804	2030E											
NPV Per Share	17												

Source: Dawson James estimates

Exhibit 7. Discounted EPS Model

Current Year	2020
Year of EPS	2030
Earnings Multiple	15
Discount Factor	22.5%
Selected Year EPS	7.47
NPV	14.72

Source: Dawson James estimates

Discount Rate and Earnings Multiple Varies, Year is Constant							
	14.72	5%	10%	15%	20%	25%	30%
Earnings Multiple	0	0.00	0.00	0.00	0.00	0.00	0.00
	5	22.92	14.39	9.23	6.03	4.01	2.71
	10	45.83	28.78	18.45	12.06	8.02	5.42
	15	68.75	43.18	27.68	18.09	12.02	8.12
	20	91.67	57.57	36.91	24.12	16.03	10.83
	25	114.58	71.96	46.14	30.14	20.04	13.54
	30	137.50	86.35	55.36	36.17	24.05	16.25
	35	160.42	100.74	64.59	42.20	28.06	18.95

Source: Dawson James estimates

Exhibit 8. Sum of the Parts Model

CytoSorbents	LT Gr	Discount Rate	Yrs to Mkt	% Success	Peak Sales (MMs)	Term Val
CytoSorb - Sepsis Direct Sales (EU)	1%	22.5%	0	70%	\$113	\$526
NPV						\$5
CytoSorb - Sepsis Distributor (EU)	1%	22.5%	0	70%	\$88	\$408
NPV						\$4
CytoSorb (Cardiac surgery US)	1%	22.5%	2	50%	\$68	\$318
NPV						\$1.41
CytoSorb (Cardiac surgery EU)	1%	22.5%	0	70%	\$17	\$79
NPV						\$0.7
CytoSorb (Sepsis US)	1%	22.5%	4	50%	\$271	\$1,262
NPV						\$3.7
Net Margin						45%
MM Shrs OS (2030E)						34
Total						\$15

Source: Dawson James estimates

Risk Analysis

Market Share Risk: CytoSorbents' potential inability to further grow product sales in the EU will hinder its profitability as more capital is invested in clinical trials to bring CytoSorb to the U.S. market. The company's product represents a new treatment for critical care patients that may take longer for adoption than predicted.

Regulatory Risk: There may be certain regulatory risks related to CytoSorb approval in the U.S.

Commercial Risk: There is no guarantee that the company will be able to develop and expand sales operations to offset research and development costs. Delays in U.S. commercialization will be negatively reflected in its valuation.

Financial Risk: The company should be expected to raise capital in the near term. We assume a raise and dilution, but there is no guarantee that market conditions will be favorable.

Exhibit 9. Income Statement

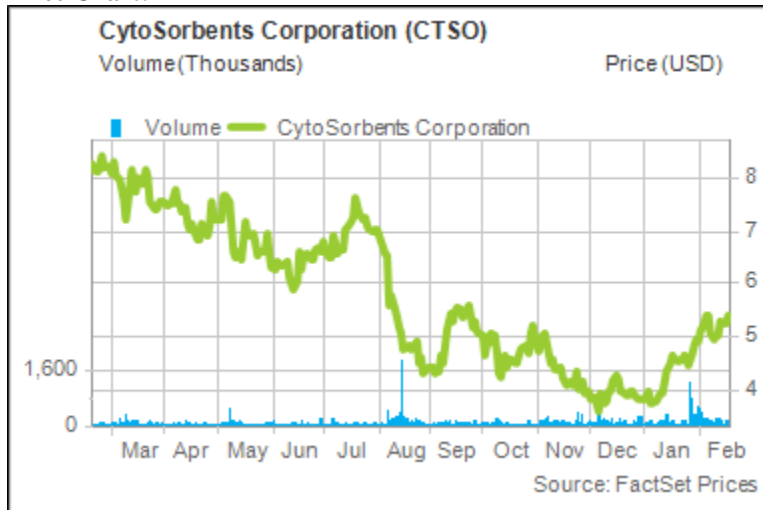
CTSO: Income Statement (\$000)																					
.. YE December 31	2018A	1Q19A	2Q19A	3Q19A	4Q19E	2019E	1Q20E	2Q20E	3Q20E	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue:																					
CytoSorb Direct Sales (Germany, Austria, Switzerland)	20,143	4,576	5,850	5,728	6,200	22,148	5,196	5,422	5,874	6,100	22,591	40,239	54,439	69,046	84,070	99,520	115,405	131,735	148,520	150,699	150,699
CytoSorb Distributor (Rest of EU)							2,208	2,304	2,497	2,593	9,602	13,336	21,587	27,297	41,422	55,871	70,651	85,766	86,763	87,771	87,771
CytoSorb (Cardiac surgery EU)							690	720	780	810	3,000	6,866	9,218	11,604	14,022	16,474	16,589	16,705	16,822	16,940	16,940
CytoSorb (Cardiac surgery US)							-	-	-	-	-	5,345	10,776	16,294	21,899	27,593	66,755	67,290	67,829	68,373	68,373
CytoSorb (sepsis US)							-	-	-	-	-	8,773	17,846	45,376	92,302	187,755	200,508	223,353	246,919	271,225	271,225
VetResQ						300	35	36	39	41	150	158	165	174	182	191					
Other Sales	109																				
Total Product Sales	20,252	4,576	5,850	5,728	6,200	22,354	8,129	8,482	9,189	9,543	35,343	74,717	114,031	169,790	253,897	387,404	469,908	524,849	566,853	595,008	595,008
Royalty (HemoDefend US)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Grant revenue	2,252	615	382	367	-	1,364	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	22,504	5,191	6,232	6,095	6,200	23,718	8,129	8,482	9,189	9,543	35,343	74,717	114,031	169,790	253,897	387,404	469,908	524,849	566,853	595,008	595,008
Expenses:																					
Costs of Goods Sold	7,489	1,738	1,834	1,696	1,550	6,818	1,626	1,696	1,838	1,909	7,069	14,943	22,806	33,958	50,779	77,481	93,982	104,970	113,371	119,002	119,002
%COGS	37%	38%	29%	25%	25%	25%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Research and Development	7,723	2,418	2,930	3,185	2,839	10,513	2,660	2,775	3,007	3,122	11,564	12,721	13,993	15,392	16,931	18,624	20,487	22,536	24,789	27,268	29,995
%R&D	38%	53%	50%	56%	46%	47%	33%	33%	33%	33%	33%	17%	12%	9%	7%	5%	4%	4%	4%	5%	5%
Selling, General and Administrative	20,874	4,758	4,506	6,108	6,200	21,571	5,706	5,954	6,450	6,698	24,807	28,528	31,381	32,009	32,649	33,302	33,968	34,647	35,340	36,047	36,768
%SG&A	103%	104%	77%	107%	100%	96%	70%	70%	70%	70%	70%	38%	28%	19%	13%	9%	7%	7%	6%	6%	6%
Legal, financial and other counseling	2,002	561	592	733	541	2,427	558	582	631	655	2,427	2,427	2,427	2,427	2,427	2,427	2,427	2,427	2,427	2,427	2,427
Total Expenses	38,088	9,475	9,862	11,723	11,129	41,330	10,549	11,008	11,925	12,384	45,867	58,619	70,607	83,786	102,786	131,834	150,863	164,579	175,927	184,743	188,191
Operating Income (Loss)	(15,584)	(4,284)	(3,630)	(5,628)	(4,929)	(17,612)	(2,420)	(2,526)	(2,736)	(2,841)	(10,524)	16,098	43,424	86,005	151,111	255,570	319,045	360,270	390,926	410,264	406,817
Interest income (expense), net	(1,461)	(205)	(214)	(302)	(4,929)	(17,612)	(2,420)	(2,526)	(2,736)	(2,841)	(10,524)	16,098	43,424	86,005	151,111	255,570	319,045	360,270	390,926	410,264	406,817
Gain (loss) on foreign currency transactions	(785)	(393)	297	(956)																	
Change in warrant liability																					
Other income (expense), net																					
Total Other Income	(2,246)	(598)	83	(1,258)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pretax Income	(17,830)	(4,882)	(3,547)	(6,886)	(4,929)	(17,612)	(2,420)	(2,526)	(2,736)	(2,841)	(10,524)	16,098	43,424	86,005	151,111	255,570	319,045	360,270	390,926	410,264	406,817
Income Tax Benefit (Provision)	-	-	-	-	(246)	(881)	(194)	(202)	(219)	(227)	(842)	1,610	5,211	12,901	27,200	53,670	76,571	100,876	129,006	135,387	134,249
Tax Rate	0%	0%	5%	5%	5%	5%	8%	8%	8%	8%	8%	10%	12%	15%	18%	21%	24%	28%	33%	33%	33%
GAAP Net Income (Loss)	(17,830)	(4,882)	(3,547)	(6,886)	(4,682)	(16,731)	(2,227)	(2,324)	(2,517)	(2,614)	(9,682)	14,488	38,213	73,104	123,911	201,901	242,474	269,394	261,921	274,877	272,567
GAAP-EPS	(0.58)	(0.15)	(0.11)	(0.21)	(0.14)	(0.52)	(0.07)	(0.07)	(0.08)	(0.08)	(0.30)	0.44	1.17	2.22	3.75	6.09	7.29	7.77	7.81	8.16	8.06
GAAP-EPS (Dil)	(0.58)	(0.15)	(0.11)	(0.21)	(0.14)	(0.52)	(0.07)	(0.07)	(0.08)	(0.08)	(0.30)	0.44	1.17	2.22	3.75	6.09	7.29	7.77	7.81	8.16	8.06
Wgt'd Avg Shrs (Bas) - '000s	30,719	31,931	32,267	32,366	32,398	32,240	32,430	32,463	32,495	32,528	32,479	32,609	32,740	32,871	33,003	33,135	33,268	33,401	33,535	33,669	33,804
Wgt'd Avg Shrs (Dil) - '000s	30,719	31,931	32,267	32,366	32,398	32,240	32,430	32,463	32,495	32,528	32,479	32,609	32,740	32,871	33,003	33,135	33,268	33,401	33,535	33,669	33,804

Source: Dawson James estimates

Important Disclosures:

Companies mentioned in this report include:
China Medical System Holdings Limited (CMS-HKG:0867, Not Rated),
Atherys (ATHX) Buy rated

Price Chart:



Price target and rating changes over the past three years:

- Initiated – Buy – July 11, 2019 – Price Target \$15.00
- Update – Buy – August 12, 2019 – Price Target \$15.00
- Update – Buy – August 15, 2019 – Price Target \$15.00
- Update – Buy – August 19, 2019 – Price Target \$15.00
- Update – Buy – November 6, 2019 – Price Target \$15.00
- Update – Buy – February 19, 2020 – Price Target \$15.00

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Information about valuation methods and risks can be found in the “STOCK VALUATION” and “RISK ANALYSIS” sections of this report.

The securities of the company discussed in this report may be unsuitable for investors depending on their specific investment objectives and financial position. This report is offered for informational purposes only and does not constitute an offer or solicitation to buy or sell any securities discussed herein in any jurisdiction where such would be prohibited. Additional information is available upon request.

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%	3	13%
Market Perform (Neutral)	3	12%	1	33%
Market Underperform (Sell)	0	0%	0	0%
Total	26	100%	4	15%

Analyst Certification:

The analyst(s) whose name appears on this research report certifies that 1) all of the views expressed in this report accurately reflect his (their) personal views about any and all of the subject securities or issuers discussed; and 2) no part of the research analyst’s compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst in this research report; and 3) all Dawson James employees, including the analyst(s) responsible for preparing this research report, may be eligible to receive non-product or service-specific monetary bonus compensation that is based upon various factors, including total revenues of Dawson James and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.