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**BioCardia Inc. (BCDA-NASDAQ) – Buy Rated;**  
**Reports Full Year Results – Heart Failure Trial**  
**Continues to Enroll (110 of 260) so far.**

March 30, 2022

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*BioCardia reported full year 2021 results, spending just \$12M last year and ending the period with \$13M in cash. Our model assumes the company raises capital. The focus of the earnings call was on the Phase 3 Heart Failure trial. Management has taken steps to support the enrollment (110 of the targeted 260 are enrolled). Management also touched on the strong basis for the trial which supports their optimistic view of success.*

**Investment Highlights:**

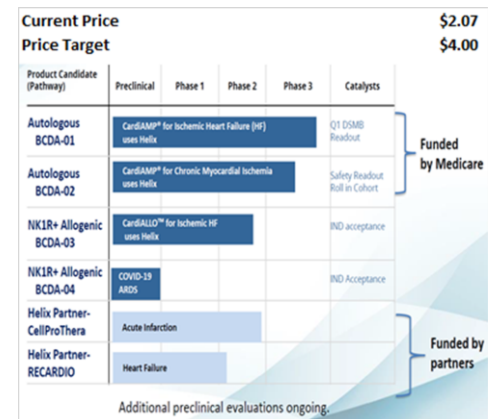
**BCDA-01:** The CardiAMP Heart Failure Trial (BCDA-01): The ongoing multi-center, double-blinded, randomized (3:2), controlled pivotal CardiAMP Heart Failure trial is expected to enroll 260 patients at up to 40 centers nationwide. The trial's primary endpoint is an outcomes composite score based on a three-tiered Finkelstein-Schoenfeld (FS) hierarchical analysis, an established outcomes design that has been used in other leading heart failure programs. We anticipate complete enrollment later this year with the top-line data next year. Good data would be transformative for the company and the heart failure space.

**Milestones Expected:**

- BCDA-01: Data Safety Monitoring Board review in the CardiAMP Cell Therapy Heart Failure Trial in Q3 2022.
- BCDA-02: CardiAMP Chronic Myocardial Ischemia Phase III pivotal trial roll-in cohort safety data in 2022.
- BCDA-03: IND acceptance of Phase I/II program of our allogeneic Neurokinin-1 Receptor Positive Mesenchymal Stem Cells (NK1R+ MSC) for the treatment of ischemic heart failure, intended initially for those patients excluded from BCDA-01 in Q4 2022.
- BCDA-04: IND acceptance of Phase I/II program for our allogeneic NK1R+ MSC Phase I/II program for the treatment of ARDS resulting from COVID-19 in Q2 2022.

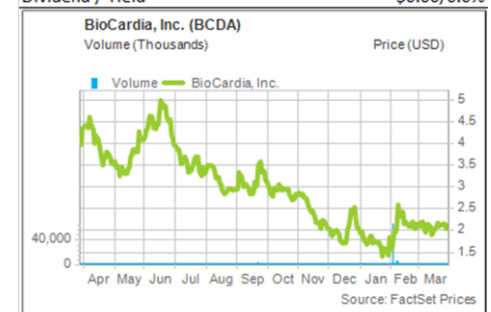
**Valuation:** Our product models run out to the year 2030. For CardiAMP and CardiALLO and all the related cardiac indications, each represents blockbuster markets. We adjusted our model for current and future dilution. Our risk cuts in our projected revenues are at 90% cut (or just a 10% probability of success), and for non-ischemic indications, just 1% probability of success, all but eliminating them from our future projections. In addition, in our free cash flow (FCFF), discounted EPS (EPS), and sum-of-the-parts (SOP) models, we apply a risk rate (r) of 30% on top of the revised risk cuts in our models. Our share count is projected for 2030 and assumes multiple raises. Our models are equal-weighted, averaged, and rounded to the nearest whole number to derive a fair value of \$4.0

**Risks:** Partnership risks, Commercialization risks, financial risks, Clinical and Regulatory risks, and Legal and Intellectual Property risks.



Source: Biocardia

Stock Data			
52-Week Range	\$1.25	-	\$5.10
Shares Outstanding (mil.)	16.9		
Market Capitalization (mil.)	\$35		
Enterprise Value (mil.)	\$34		
Debt to Capital	0%		
Book Value/Share	\$2.62		
Price/Book	0.8		
Average Three Months Trading Volume (K)	158		
Insider Ownership	25.0%		
Institutional Ownership	21.7%		
Short interest (mil.)	3.1%		
Dividend / Yield	\$0.00/0.0%		



**Exhibit 1. Product Pipeline**

Product Candidate (Pathway)	Preclinical	Phase 1	Phase 2	Phase 3	Catalysts	
<b>Autologous BCDA-01</b>	CardiAMP® for Ischemic Heart Failure (HF) uses Helix				Q1 DSMB Readout	} <b>Funded by Medicare</b>
<b>Autologous BCDA-02</b>	CardiAMP® for Chronic Myocardial Ischemia uses Helix				Safety Readout Roll in Cohort	
<b>NK1R+ Allogenic BCDA-03</b>	CardiALLO™ for Ischemic HF uses Helix				IND acceptance	
<b>NK1R+ Allogenic BCDA-04</b>	COVID-19 ARDS				IND Acceptance	} <b>Funded by partners</b>
<b>Helix Partner-CellProThera</b>	Acute Infarction					
<b>Helix Partner-RECARDIO</b>	Heart Failure					

Additional preclinical evaluations ongoing.

Source: BioCardia

**Exhibit 2. The Best of Both Worlds – Autologous and Allogenic Approaches to Heart Failure**

**CardiAMP cell therapy (BCDA-01, 02)**

- Regulated and manufactured as a procedure kit with anticipated low cost of goods and long shelf life
- For both leading indications, CardiAMP fits into standard interventional cardiology device channels
- Most components approved in EU and/or USA, but not for cardiovascular therapeutic usage



**CardiALLO cell therapy (BCDA-03)**

- Neurokinin 1 receptor positive for Substance P, the primary neuropeptide for pain
- Treats patients not possible to be treated with CardiAMP
- Potential orphan indication
- “Off the shelf” cell therapy
- Leverages delivery system



Source: BioCardia

**Product Modeling Assumptions**

1. We base our market share estimates for BioCardia's therapies on multiple assumptions around the product attributes associated with product delivery and outcomes. Given the blockbuster size of the U.S. and E.U. H.F. markets, the projected revenues become enormous quickly. However, the failure rate of therapeutics has also been high in the heart failure space. To balance these two factors, we apply between a 90% to 99% risk reduction (risk cut) to the net revenues in our models (U.S. & Europe) for the various indications and products.
2. We assume CardiAMP and CardiALLO will initially launch at \$50,000 per therapeutic course. Our projected market share grows over a six-year launch cycle, with CardiAMP at 20% of the total market in the year 2030, and CardiALLO achieves a 15% share of the total market by the year 2030.
3. Based on BioCardia's estimation of completing enrollment of the pivotal Phase 3 trial of BCDA-01 later this year and a standard FDA review time of 10 months suggests a launch in 2024/2025 is possible. We expect BCDA-02 to be a fast follower with approval and launch a year after BCDA-01, in 2026. We apply a 90% risk cut to our CardiAMP revenue model to adjust for the risk of approval.
4. We expect BCDA-03 (CardiALLO) to reach the market by 2027; however, we apply a therapeutic risk cut of 99% (or just a 1% probability of success) in our product model for conservatism.

**Exhibit 3. Market Models:**

	2022	2023	2024	2025	2026	2027	2028	2029	2030
<b>BCDA-01 Heart Failure</b>									
U.S. Prevalance CHF	5,015,015	5,020,030	5,025,050	5,030,075	5,035,105	5,040,140	5,045,180	5,050,226	5,055,276
Market Size Growth (Annual)	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Candidates (Class II & III) for Therapy	501,502	502,003	502,505	503,008	503,511	504,014	504,518	505,023	505,528
Market Share Penetration				3.0%	6.0%	7.0%	8.0%	10.0%	14.0%
Number of Patients Procedures	0	0	0	15,090	30,211	35,281	40,361	50,502	70,774
Cost of Therapy \$	20,120	20,160	20,201	20,241	20,282	20,322	20,363	20,404	20,444
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	1%	1%	1%	1%	1%	1%	1%	1%	1%
U.S. Annual Sales (M) \$	-	-	-	3	6	7	8	10	14
<b>BCDA-01 Heart Failure</b>									
E.U. Prevalance CHF	9,027,027	9,036,054	9,045,090	9,054,135	9,063,189	9,072,253	9,081,325	9,090,406	9,099,496
Market Size Growth (Annual)	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Candidates (Class II & III) for Therapy	902,703	903,605	904,509	905,414	906,319	907,225	908,132	909,041	909,950
Market Share Penetration					1.0%	3.0%	5.0%	10.0%	12.0%
Number of Patients Procedures	0	0	0	0	9,063	27,217	45,407	90,904	109,194
Cost of Therapy \$	30,180	30,241	30,301	30,362	30,423	30,483	30,544	30,605	30,667
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	1%	1%	1%	1%	1%	1%	1%	1%	1%
E.U. Annual Sales (M) \$	-	-	-	-	3	8	14	28	33
<b>BCDA-02 Heart Failure</b>									
U.S. Prevalance CHF	5,228,392	5,306,818	5,386,420	5,467,216	5,549,225	5,632,463	5,716,950	5,802,704	5,889,745
Market Size Growth (Annual)	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%
Candidates (Chronic Myocardial Ischemia) for Therapy	209,136	212,273	215,457	218,689	221,969	225,299	228,678	232,108	235,590
Market Share Penetration	0.0%	0.0%	2.0%	5.0%	10.0%	15.0%	20.0%	20.0%	20.0%
Number of Patients Procedures	0	0	4,309	10,934	22,197	33,795	45,736	46,422	47,118
Cost of Therapy \$	20,120	20,160	20,201	20,241	20,282	20,322	20,363	20,404	20,444
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	10%	10%	10%	10%	10%	10%	10%	10%	10%
U.S. Annual Sales (M) \$	-	-	9	22	45	69	93	95	96
<b>BCDA-02 Heart Failure</b>									
E.U. Prevalance CHF	9,217,733	9,291,474	9,365,806	9,440,733	9,516,259	9,592,389	9,669,128	9,746,481	9,824,453
Market Size Growth (Annual)	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%
Candidates (Chronic Myocardial Ischemia) for Therapy	506,975	511,031	515,119	519,240	523,394	527,581	531,802	536,056	540,345
Market Share Penetration	0.0%	0.0%	0.0%	0.0%	2.0%	5.0%	10.0%	15.0%	16.0%
Number of Patients Procedures	0	0	0	0	10,468	26,379	53,180	80,408	86,455
Cost of Therapy \$	30,180	30,241	30,301	30,362	30,423	30,483	30,544	30,605	30,667
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	10%	10%	10%	10%	10%	10%	10%	10%	10%
U.S. Annual Sales (M) \$	-	-	-	-	32	80	162	246	265
<b>BCDA-03 Heart Failure</b>									
U.S. Prevalance CHF	5,015,015	5,020,030	5,025,050	5,030,075	5,035,105	5,040,140	5,045,180	5,050,226	5,055,276
Market Size Growth (Annual)	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Candidates (Class II & III) for Therapy	150,450	150,601	150,752	150,902	151,053	151,204	151,355	151,507	151,658
Market Share Penetration	0.0%	0.0%	0.0%	0.0%	0.0%	2.0%	5.0%	10.0%	15.0%
Number of Patients Procedures	0	0	0	0	0	3,024	7,568	15,151	22,749
Cost of Therapy \$	-	-	-	-	-	22,500	22,545	22,590	22,635
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	1%	1%	1%	1%	1%	1%	1%	1%	1%
U.S. Annual Sales (M) \$	-	-	-	-	-	1	2	3	5
<b>BCDA-03 Heart Failure</b>									
E.U. Prevalance CHF	9,027,027	9,036,054	9,045,090	9,054,135	9,063,189	9,072,253	9,081,325	9,090,406	9,099,496
Market Size Growth (Annual)	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Candidates (Class II & III) for Therapy	270,811	271,082	271,353	271,624	271,896	272,168	272,440	272,712	272,985
Market Share Penetration	0.0%	0.0%	0.0%	0.0%	0.0%	2.0%	5.0%	10.0%	15.0%
Number of Patients Procedures	0	0	0	0	0	5,443	13,622	27,271	40,948
Cost of Therapy \$	-	-	-	-	-	29,500	29,559	29,618	29,677
Price Growth	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Probability of Success	1%	1%	1%	1%	1%	1%	1%	1%	1%
U.S. Annual Sales (M) \$	-	-	-	-	-	2	4	8	12

Source: Dawson James Estimates

**Exhibit 4. Income Statement**

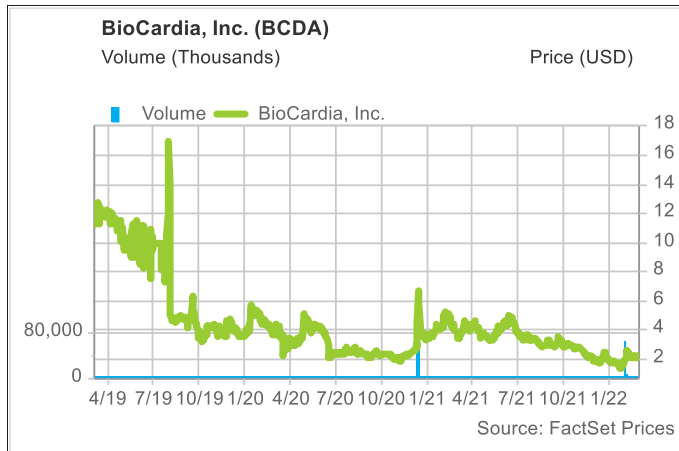
BioCardia Inc: Income Statement (\$000)																					
BCDA- YE December	2018A	2019A	2020A	1Q21A	2Q21A	3Q21A	4Q21A	2021A	1Q22E	2Q22E	3Q22E	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Net product revenue	282	300	23		9	1	-9	1													
Collaboration agreement revenue	343	382	122	46	60	820	88	1,014													
BCDA-01 CardiaAMP Cell Therapy revenues US								0	0	0	0	0	0	0	0	3,054	6,127	7,170	8,219	10,304	14,469
BCDA-01 CardiaAMP Cell Therapy revenues EU			0						0	0	0	0	0	0	0	0	2,757	8,297	13,869	27,822	33,486
BCDA-02 CardiaAMP Cell Therapy revenues US															8,705	22,133	45,019	68,679	93,131	94,717	96,330
BCDA-02 CardiaAMP Cell Therapy revenues EU																	3,185	80,412	162,435	246,094	265,129
BCDA-03 CardALLO Cell Therapy revenues US																		680	1,706	3,423	5,149
BCDA-03 CardALLO Cell Therapy revenues EU																		1,606	4,027	8,077	12,152
<b>Total Product Sales</b>	<b>625</b>	<b>599</b>	<b>145</b>	<b>46</b>	<b>69</b>	<b>821</b>	<b>79</b>	<b>1,015</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>8,705</b>	<b>25,187</b>	<b>57,088</b>	<b>166,844</b>	<b>283,387</b>	<b>390,436</b>	<b>426,716</b>
<b>Product Sales &amp; Royalties &amp; Milestones</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>8,705</b>	<b>25,187</b>	<b>51,146</b>	<b>78,135</b>	<b>107,082</b>	<b>116,521</b>	<b>128,101</b>
<b>Expenses</b>																					
Cost of goods sold	517	543	4	0	30%	30%	24	24	0	0	0	0	0	0	2,176	6,045	13,130	36,706	59,511	78,087	85,343
Research and Development	8,453	8,876	9,809	1,841	2,362	2,240	2,115	8,558	2,067	2,157	2,246	2,336	8,986	9,435	9,907	10,402	10,922	11,469	12,042	12,644	13,276
Selling, general and administrative	5,757	6,045	5,861	1,177	1,196	1,289	1,425	5,087	4,140	4,320	4,500	4,680	18,000	22,000	23,100	24,255	25,468	26,741	28,078	29,482	30,956
<b>Total expenses</b>	<b>14,727</b>	<b>15,192</b>	<b>15,674</b>	<b>3,018</b>	<b>3,558</b>	<b>3,529</b>	<b>3,540</b>	<b>13,645</b>	<b>6,207</b>	<b>6,477</b>	<b>6,746</b>	<b>7,016</b>	<b>26,446</b>	<b>30,806</b>	<b>34,523</b>	<b>40,009</b>	<b>48,793</b>	<b>74,151</b>	<b>98,829</b>	<b>119,371</b>	<b>128,691</b>
Operating income (Loss)	(14,102)	(14,593)	(15,529)	(2,972)	(3,489)	(2,708)	(3,461)	(12,630)	(6,207)	(6,477)	(6,746)	(7,016)	(26,446)	(30,806)	(25,818)	(14,822)	8,295	92,693	184,558	271,065	298,025
Interest expense																					
Interest Income	118	23	21	4	2	2	1	9													
Other expense	(3)	(1)	504	(1)			(1)	(2)													
<b>Total other income</b>	<b>115</b>	<b>(1)</b>	<b>504</b>	<b>(1)</b>	<b>-</b>	<b>-</b>	<b>(1)</b>	<b>(2)</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Pretax Income</b>	<b>(13,987)</b>	<b>(14,571)</b>	<b>(15,004)</b>	<b>(2,969)</b>	<b>(3,487)</b>	<b>(2,706)</b>	<b>(3,461)</b>	<b>(12,623)</b>	<b>(6,207)</b>	<b>(6,477)</b>	<b>(6,746)</b>	<b>(7,016)</b>	<b>(26,446)</b>	<b>(30,806)</b>	<b>(25,818)</b>	<b>(14,822)</b>	<b>8,295</b>	<b>92,693</b>	<b>184,558</b>	<b>271,065</b>	<b>298,025</b>
Income Tax Benefit (Provision)									(621)	(648)	(675)	(702)	(2,645)	(5,545)	(5,164)	(3,557)	1,991	22,246	51,676	81,320	101,328
<b>Tax Rate</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>10%</b>	<b>10%</b>	<b>10%</b>	<b>10%</b>	<b>10%</b>	<b>18%</b>	<b>20%</b>	<b>24%</b>	<b>24%</b>	<b>24%</b>	<b>28%</b>	<b>30%</b>	<b>34%</b>
<b>GAAP Net Income (loss)</b>	<b>(13,987)</b>	<b>(14,571)</b>	<b>(15,004)</b>	<b>(2,969)</b>	<b>(3,487)</b>	<b>(2,706)</b>	<b>(3,461)</b>	<b>(12,623)</b>	<b>(5,586)</b>	<b>(5,829)</b>	<b>(6,072)</b>	<b>(6,315)</b>	<b>(23,802)</b>	<b>(25,261)</b>	<b>(20,655)</b>	<b>(11,265)</b>	<b>6,305</b>	<b>70,446</b>	<b>132,882</b>	<b>189,746</b>	<b>196,696</b>
Deemed Dividend on Preferred Stock																					
<b>GAAP-EPS</b>	<b>(0.37)</b>	<b>(0.92)</b>	<b>(1.48)</b>	<b>(0.18)</b>	<b>(0.20)</b>	<b>(0.16)</b>	<b>(0.20)</b>	<b>(0.75)</b>	<b>(0.33)</b>	<b>(0.34)</b>	<b>(0.35)</b>	<b>(0.37)</b>	<b>(1.39)</b>	<b>(1.47)</b>	<b>(1.20)</b>	<b>(0.65)</b>	<b>0.36</b>	<b>4.03</b>	<b>7.58</b>	<b>10.77</b>	<b>11.12</b>
GAAP EPS (dil)	(0.37)	(2.13)	(1.55)	(0.08)	(0.07)	(0.06)	(0.07)	(0.29)	(0.12)	(0.12)	(0.13)	(0.13)	(0.51)	(0.54)	(0.44)	(0.24)	0.13	1.47	2.77	3.93	4.06
Weighted shares basic	38,285	15,761	10,118	16,569	17,047	17,066	17,083	16,917	17,100	17,117	17,134	17,152	17,126	17,194	17,263	17,332	17,402	17,472	17,542	17,612	17,682
Weighted shares dil	38,285	15,136	13,445	36,647	46,683	46,730	46,777	44,209	46,823	46,870	46,917	46,964	46,894	47,082	47,270	47,460	47,650	47,841	48,032	48,225	48,418

Source: Dawson James estimates, company reports

Companies mentioned in this report:

**Important Disclosures:**

**Price Chart:**



Price target and ratings changes over the past three years:

- Initiated – Buy – September 17, 2019 – Price Target \$24.00
- Update – Buy – November 20, 2019 – Price Target \$24.00
- Update – Buy – February 18, 2020 – Price Target \$24.00
- Update – Buy – May 5, 2020 – Price Target \$24.00
- Update – Buy – July 7, 2020 – Price Target \$24.00
- Update – Buy – August 13, 2020 – Price Target \$24.00
- Update – Buy – October 9, 2020 – Price Target \$24.00
- Price Target Change – Buy – November 11, 2020 – Price Target \$14.00
- Price Target Change – Buy – March 2, 2021 – Price Target \$5.00
- Rating Change – Buy to Neutral – April 15, 2021 – Price Target NA
- Update - Neutral – June 24, 2021 – Price Target NA
- Update - Neutral – December 14, 2021 – Price Target NA
- Rating Change – Buy – January 24, 2022 – Price Target \$4.0
- Update – Buy – February 3, 2022 – Price Target \$4.0
- Update – Buy – February 14, 2022 – Price Target \$4.0
- Update – Buy – March 3, 2022 – Price Target \$4.0
- Update – Buy – March 30, 2022 – Price Target \$4.0

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**Ratings 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.

Current as of... 15-Mar-22

	<b>Company Coverage</b>		<b>Investment Banking</b>	
<b>Ratings Distribution</b>	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	31	74%	4	13%
Market Perform (Neutral)	11	26%	0	0%
Market Underperform (Sell)	0	0%	0	0%
<b>Total</b>	<b>42</b>	<b>100%</b>	<b>4</b>	<b>10%</b>

**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.