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Toll-Free: 866-928-0928 ♦ www.DawsonJames.com ♦ 101 North Federal Highway - Suite 600 ♦ Boca Raton, FL 33432

BioCardia Inc. (BCDA-NASDAQ) – Buy Rated;

February 14, 2022

DSMB Say's Keep Going – Phase 3 HF Trial

Jason Kolbert
Senior Analyst

BioCardia announces that the independent Data Safety Monitoring board (DSMB) has completed its prespecified review for the ongoing Phase 3 Pivotal CardiAMP trial. Thus far data for n=108 patients enrolled with an additional six crossover patient procedures in the trial to date has been reviewed. The DSMB performed a risk-benefit assessment, indicated no significant safety concerns, and recommended that the study continue as designed.

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. The FS procedure is a ranked analysis that compares occurrence of cardiovascular and other health-related events, along with functional capacity measures, through one year in patients receiving the study treatment to patients in the control arm who don't receive the study treatment. We anticipate complete enrollment later this year with the top-line data next year. Good data is transformative for the company and the heart failure space.

Business Development too. BioCardia has an innovative catheter. We are hopeful to see active business development deals that could bring in non-dilutive capital as the company's clinical data matures.

Milestones Expected:

- BCDA-02: CardiAMP Chronic Myocardial Ischemia Phase 3 pivotal trial - roll-in cohort safety data.
- BCDA-03: IND acceptance of Phase 1/2 program for the allogeneic Neurokinin-1 receptor-positive (NK1R+) Mesenchymal Stem Cells (MSC) to treat ischemic heart failure, intended initially for those patients excluded from BCDA-01.
- BCDA-04: IND acceptance of Phase 1/2 program for the allogeneic NK1R+ MSC Phase I/II program to treat ARDS resulting from COVID-19.

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 - \$5.18
Shares Outstanding (mil.)	16.9
Market Capitalization (mil.)	\$41
Enterprise Value (mil.)	\$41
Debt to Capital	0%
Book Value/Share	\$2.62
Price/Book	0.9
Average Three Months Trading Volume (K)	34
Insider Ownership	25.0%
Institutional Ownership	19.6%
Short interest (mil.)	1.2%
Dividend / Yield	\$0.00/0.0%

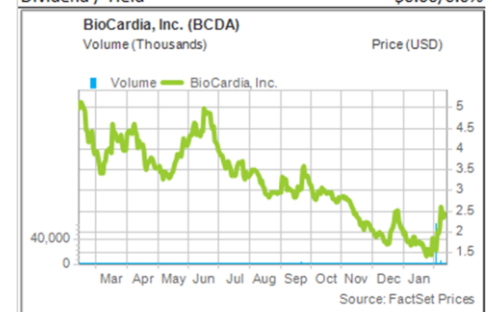


Exhibit 1. Product Pipeline

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

BCDA-01 Heart Failure	2022	2023	2024	2025	2026	2027	2028	2029	2030
U.S. Prevalence 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
BCDA-01 Heart Failure	2022	2023	2024	2025	2026	2027	2028	2029	2030
E.U. Prevalence 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
BCDA-02 Heart Failure	2022	2023	2024	2025	2026	2027	2028	2029	2030
U.S. Prevalence 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
BCDA-02 Heart Failure	2022	2023	2024	2025	2026	2027	2028	2029	2030
E.U. Prevalence 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
BCDA-03 Heart Failure	2022	2023	2024	2025	2026	2027	2028	2029	2030
U.S. Prevalence 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
BCDA-03 Heart Failure	2022	2023	2024	2025	2026	2027	2028	2029	2030
E.U. Prevalence 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. Valuation Models. Our valuation is based on our projected revenues in our product models. These are then reduced by 99%, a risk rate cut, or a 1-10% probability of success factor. This suggests we are leaving upside in our estimates on good data. We apply assumptions for FDA product approvals, launch dates, and product attributes to estimate revenues. These estimates feed into our income statement through the year 2030. Our price target is derived from an equal-weighted average of free cash flow (FCFF), discounted EPS (EPS), and sum-of-the-parts (SOP) models. For companies that are well established with mature products and revenues, we typically discount at a 10% rate; for companies in the early stages of product commercialization, we typically use a higher rate, 15%. For BioCardia, we use a 30% risk rate as the company is not yet profitable. This risk rate is in addition to the therapeutic cut (90% to 99%) in our product models. The result of this methodology is a price target of \$4.00 per share.

Average	\$	4
Price Target	\$	3
Year		2022

DCF Valuation Using FCF (mln):

units (000)	2019A	2020A	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(14,571)	(15,004)	(14,243)	(28,238)	(32,688)	(27,794)	(16,896)	6,117	90,405	182,157	268,544	295,377
Tax Rate	0%	0%	0%	10%	18%	20%	24%	24%	24%	28%	30%	34%
EBIT(1-t)	(14,571)	(15,004)	(14,243)	(25,414)	(26,804)	(22,235)	(12,841)	4,649	68,708	131,153	187,981	194,949
CapEx												
Depreciation	78	498	135	-	-	-	-	-	-	-	-	-
Change in NWC												
FCF	(14,493)	(14,506)	(14,108)	(25,414)	(26,804)	(22,235)	(12,841)	4,649	68,708	131,153	187,981	194,949
PV of FCF	(11,149)	(8,583)	(6,421)	(8,898)	(7,219)	(4,607)	(2,046)	570	18,505	27,172	29,958	23,899
Discount Rate	30%											
Long Term Growth Rate	1%											
Terminal Cash Flow	678,960											
Terminal Value YE2030	83,233											
NPV	160,566											
NPV-Debt	1,016											
Shares out (thousands)	48,418											2030E
NPV Per Share	\$ 3											

Source: Dawson James estimates.

Current Year	2022
Year of EPS	2030
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 4.03
NPV	\$ 5.00

Source: Dawson James estimates.

		Discount Rate and Earnings Multiple Varies, Year is Constant					
		2030 EPS					
Earnings Multiple		5%	10%	15%	20%	25%	30%
		0		\$0.00	\$0.00	\$0.00	\$0.00
5		\$14.00	\$9.00	\$7.00	\$5.00	\$3.00	\$ 2.00
10		\$27.00	\$19.00	\$13.00	\$9.00	\$7.00	\$ 5.00
15		\$41.00	\$28.00	\$20.00	\$14.00	\$10.00	\$ 7.00
20		\$55.00	\$38.00	\$26.00	\$19.00	\$14.00	\$ 10.00
25		\$68.00	\$47.00	\$33.00	\$23.00	\$17.00	\$ 12.00
30		\$82.00	\$56.00	\$39.00	\$28.00	\$20.00	\$ 15.00
35		\$95.00	\$66.00	\$46.00	\$33.00	\$24.00	\$ 17.00

BioCardia	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales MMs	Term Val
BCDA-01 CardiAMP cell therapy US	1%	30%	3	10%	\$1,447	\$4,989
NPV						\$1.88
BCDA-01 CardiAMP cell therapy US	1%	30%	3	10%	\$3,349	\$11,547
NPV						\$4.34
BCDA-02 CardiALLO cell therapy US	1%	30%	4	5%	\$963	\$3,322
NPV						\$0.48
BCDA-02 CardiALLO cell therapy EU	1%	30%	4	5%	\$2,651	\$9,142
NPV						\$1.32
BCDA-03 CardiALLO cell therapy US	1%	50%	5	5%	\$515	\$1,051
NPV						\$0.06
BCDA-02 CardiALLO cell therapy EU	1%	50%	5	5%	\$1,215	\$2,480
NPV						\$0.13
Net Margin						40%
MM Shrs OS (2030E)						48
Total						\$4

Source: Dawson James estimates.

Exhibit 5. Income Statement

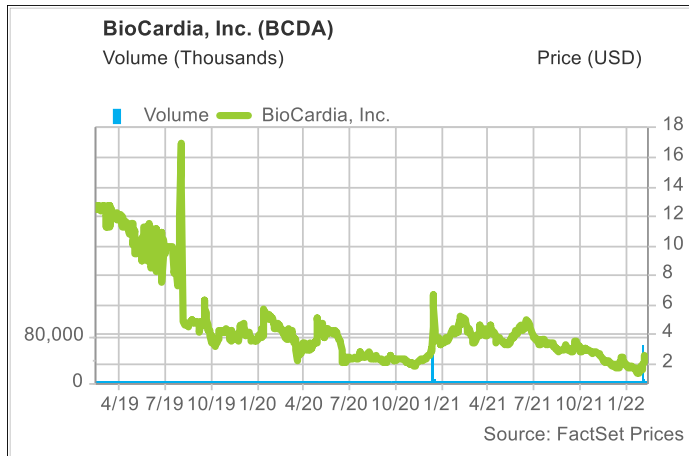
BioCardia Inc: Income Statement (\$000)																	
BCDA: YE December	2018A	2019A	2020A	1Q21A	2Q21A	3Q21A	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Net product revenue	282	300	23		9	1	7	24									
Collaboration agreement revenue	343	382	122	46	60	820	35	128									
BCDA-01 CardiaAMP Cell Therapy revenues US		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	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															1,706	3,423	5,149
BCDA-03 CardALLO Cell Therapy revenues EU															1,606	4,027	8,077
Total Product Sales	625	599	145	46	69	821	41	152	-	-	8,705	25,187	57,088	166,844	283,387	390,436	426,716
Product Sales & Royalties & Milestones	-	-	-	-	-	-	-	-	-	-	8,705	25,187	51,146	78,135	107,082	116,521	128,101
Expenses																	
Cost of goods sold	517	543	4	0			12	12	0	0	2,176	6,045	13,130	36,706	59,511	78,087	85,343
			3%	30%	30%	30%	30%	8%	#DIV/0!	#DIV/0!	25%	24%	23%	22%	21%	20%	20%
Research and Development	8,453	8,876	9,809	1,841	2,362	2,240	2,678	10,299	10,814	11,355	11,923	12,519	13,145	13,802	14,492	15,217	15,978
Selling, general and administrative	5,757	6,045	5,861	1,177	1,196	1,289	1,600	6,154	18,000	22,000	23,100	24,255	25,468	26,741	28,078	29,482	30,956
Total expenses	14,727	15,192	15,674	3,018	3,558	3,529	4,290	14,395	28,238	32,688	36,499	42,083	50,971	76,438	101,230	121,892	131,339
Operating income (Loss)	(14,102)	(14,593)	(15,529)	(2,972)	(3,489)	(2,708)	(4,249)	(14,243)	(28,238)	(32,688)	(27,794)	(16,896)	6,117	90,405	182,157	268,544	295,377
Interest expense																	
Interest Income	118	23	21	4	2	2											
Other expense	(3)	(1)	504	(1)													
Total other income	115	(1)	504	(1)	-	-	-	-	-	-	-	-	-	-	-	-	-
Pretax Income	(13,987)	(14,571)	(15,004)	(2,969)	(3,487)	(2,706)	(4,249)	(14,243)	(28,238)	(32,688)	(27,794)	(16,896)	6,117	90,405	182,157	268,544	295,377
Income Tax Benefit (Provision)									(2,824)	(5,884)	(5,559)	(4,055)	1,468	21,697	51,004	80,563	100,428
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	10%	18%	20%	24%	24%	24%	28%	30%	34%
GAAP Net Income (loss)	(13,987)	(14,571)	(15,004)	(2,969)	(3,487)	(2,706)	(4,249)	(14,243)	(25,414)	(26,804)	(22,235)	(12,841)	4,649	68,708	131,153	187,981	194,949
Deemed Dividend on Preferred Stock																	
GAAP-EPS	(0.37)	(0.92)	(1.48)	(0.18)	(0.20)	(0.16)	(0.25)	(0.84)	(1.48)	(1.56)	(1.29)	(0.74)	0.27	3.93	7.48	10.67	11.03
GAAP EPS (dil)	(0.37)	(2.13)	(1.55)	(0.08)	(0.07)	(0.06)	(0.09)	(0.30)	(0.54)	(0.57)	(0.47)	(0.27)	0.10	1.44	2.73	3.90	4.03
Weighted shares basic	38,285	15,761	10,118	16,569	17,047	17,066	17,083	16,941	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	46,894	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

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- 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... 8-Feb-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	31	76%	6	19%
Market Perform (Neutral)	10	24%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	41	100%	6	15%

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