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BioCardia Inc. (BCDA-NASDAQ) – Neutral Rated

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“The 250-patient randomized controlled study is unlikely to meet its primary three-tiered FS efficacy endpoint”

BioCardia press release states: “Based on these measures at one-year follow-up, the 250-patient randomized controlled study is unlikely to meet its primary three-tiered FS efficacy endpoint, as seen from the initial 102 randomized patient set assessed at 12-month follow-up (110 patients had been randomized and eight of them had not completed their 12-month follow-up visit at the time of the analysis).”

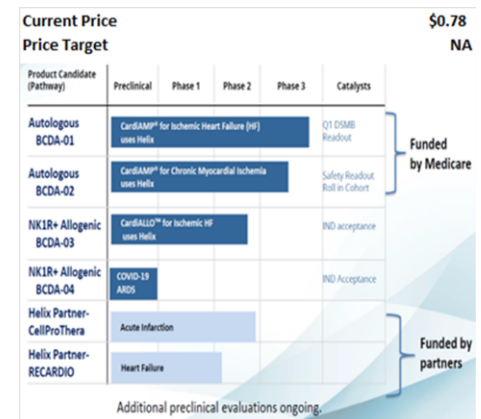
Investment Highlights:

The DSMB recommendation stated:

- For the first-tier, all cause death, including cardiac death equivalents such as heart transplant or left ventricular assist device placement at 12 months there were 5.6% of CardiAMP treatment patients versus 5.3% for the control group ($p = 0.42$). All available follow-up in the patients followed up to 24 months showed a separation between groups with 8.3% all cause death including cardiac death equivalents in the treatment group versus 13.2% in the control group ($p = 0.94$), corresponding to a 37% relative risk reduction for Tier 1 events for the treated patients compared to control patients on guideline directed medical therapy (GDMT).
- For the second-tier, non-fatal major adverse cardiac events (MACCE), excluding those deemed procedure-related occurring within the first seven days and defined as heart failure hospitalization, stroke and myocardial infarction, 16.7% of treatment group had MACCE compared to 15.8% of the control group ($p=0.82$). All available follow-up data for patients followed up to 24 months showed a separation between groups, with 16.7% MACCE rate in the treatment group versus 23.6% in the control group ($p=.76$). This corresponds to an 18% relative risk reduction for MACCE over GDMT.
- For the third-tier of change in Six Minute Walk Test (6MWT) distance from baseline to 12 months, both CardiAMP treatment patients and control patients experienced a clinically meaningful improvement at 12 months which was not statistically different. The treated group median 6MWT at 12M increased 36.1 with a standard deviation of ± 70.8 meters, and the control group median 6MWT increased at 12M by 33.4 meters ± 74.8 meters ($p = 0.6$). Results at 24 months also showed improvements in both groups with the treatment group median improving 1.8 ± 76.1 meters and the control group median improving 17.4 ± 95.7 meters ($p=0.33$). The improvement in 6MWT at 12M for the control group was greater than was expected in this population.

Valuation: We model to 2030 with probability of success factors in our models. 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%. Our models are equal-weighted, averaged, and rounded to the nearest whole number to derive a fair-value target.

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



Source: Biocardia

Stock Data			
52-Week Range	\$0.76	-	\$2.92
Shares Outstanding (mil.)	21.6		
Market Capitalization (mil.)	\$17		
Enterprise Value (mil.)	\$16		
Debt to Capital	0%		
Book Value/Share	\$2.62		
Price/Book	0.3		
Average Three Months Trading Volume (K)	11		
Insider Ownership	41.6%		
Institutional Ownership	14.0%		
Short interest (mil.)	0.9%		
Dividend / Yield	\$0.00/0.0%		



Exhibit 1. Income Statement

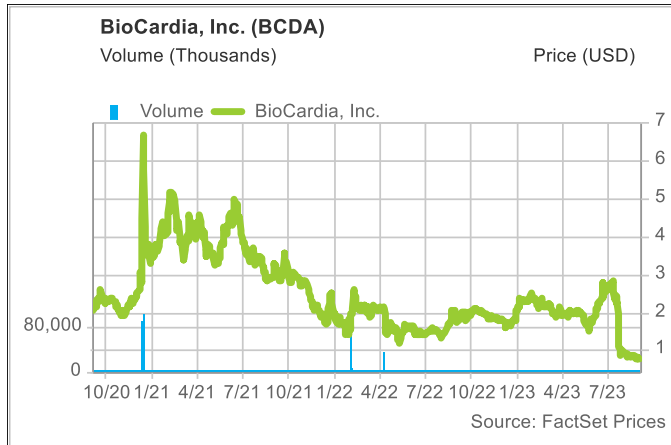
Biocardia Inc: Income Statement (\$000)																	
BCDA: YE December	2018A	2019A	2020A	2021A	2022A	1Q23A	2Q23A	3Q23E	4Q23E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Net product revenue	282	300	23	1													
Collaboration agreement revenue	343	382	122	1,014													
BCDA-01 CardiaAMP Cell Therapy revenues US		0	0	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	2,757	8,297	13,869	27,822	33,486
BCDA-02 CardiaAMP Cell Therapy revenues US						0	0	0	0	-	-	-	4,502	68,679	93,131	94,717	96,330
BCDA-02 CardiaAMP Cell Therapy revenues EU						0	0	0	0	-	-	-	-	-	64,974	98,437	165,706
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
Total Product Sales	625	599	145	1,015	1,352	-	-	-	-	-	-	3,054	13,386	86,431	185,926	242,780	327,292
Product Sales & Royalties & Milestones	-	-	-	-	212	64	43	-	-	107	-	3,054	10,629	78,135	107,082	116,521	128,101
Expenses																	
Cost of goods sold	517	543	4	24		0	0	0	0	0	0	733	3,079	19,015	39,044	48,556	65,458
			3%	2%	0%	25%	25%	25%	25%	#DIV/0!	#DIV/0!	24%	23%	22%	21%	20%	20%
Research and Development	8,453	8,876	9,809	8,558	8,834	2,384	2,314	2,319	2,412	9,276	9,739	10,226	10,738	11,275	11,838	12,430	13,052
				4%													
Selling, general and administrative	5,757	6,045	5,861	5,087	4,419	1,190	1,181	1,375	1,430	5,500	10,000	20,000	21,000	22,050	23,153	24,310	25,526
Total expenses	14,727	15,192	15,674	13,645	13,253	3,574	3,495	3,694	3,842	14,605	19,345	30,355	34,182	51,673	73,335	84,562	103,264
Operating income (Loss)	(14,102)	(14,593)	(15,529)	(12,630)	(11,901)	(3,574)	(3,452)	(3,694)	(3,842)	(14,605)	(19,345)	(27,301)	(20,796)	34,758	112,590	158,218	224,028
Interest expense																	
Interest Income	118	23	21	9													
Other expense	(3)	(1)	504	(2)	6	9	28										
Total other income	115	(1)	504	(2)	6	9	28	-	-	-	-	-	-	-	-	-	-
Pretax Income	(13,987)	(14,571)	(15,004)	(12,623)	(11,907)	(3,501)	(3,424)	(3,694)	(3,842)	(14,605)	(19,345)	(27,301)	(20,796)	34,758	112,590	158,218	224,028
Income Tax Benefit (Provision)														8,342	31,525	47,466	76,170
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	24%	28%	30%	34%
GAAP Net Income (loss)	(13,987)	(14,571)	(15,004)	(12,623)	(11,907)	(3,501)	(3,424)	(3,694)	(3,842)	(14,605)	(19,345)	(27,301)	(20,796)	26,416	81,065	110,753	147,859
Deemed Dividend on Preferred Stock																	
GAAP-EPS	(0.37)	(0.92)	(1.48)	(0.75)	(0.67)	(0.17)	(0.17)	(0.13)	(0.14)	(0.61)	(0.70)	(0.98)	(0.74)	0.94	2.87	3.90	5.19
GAAP EPS (dil)	(0.37)	(2.13)	(1.55)	(0.29)	(0.33)	(0.09)	(0.09)	(0.06)	(0.07)	(0.30)	(0.34)	(0.47)	(0.36)	0.46	1.39	1.89	2.52
Weighted shares basic	38,285	15,761	10,118	16,917	17,721	20,177	20,384	27,718	27,746	24,006	27,815	27,927	28,038	28,151	28,264	28,377	28,490
Weighted shares dil	38,285	15,136	13,445	44,209	36,000	40,000	40,000	57,155	57,212	48,592	57,355	57,585	57,816	58,047	58,280	58,513	58,748

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
- Update Price Target Change – Buy – April 19, 2022 – Price Target \$3.0
- Update – Buy – May 18, 2022 – Price Target \$3.0
- Update – Buy – August 31, 2022 – Price Target \$3.0
- Update – Buy – October 3, 2022 – Price Target \$3.0
- Rating Change – Buy to Neutral – November 10, 2022 – Price Target \$NA
- Update – Neutral – December 16, 2022 – Price Target \$NA
- Update – Neutral – March 7, 2023 – Price Target \$NA
- Update – Neutral – April 21, 2023 – Price Target \$NA
- Update – Neutral – June 8, 2023 – Price Target \$NA
- Update – Neutral – June 22, 2023 – Price Target \$NA
- Update – Neutral – July 24, 2023 – Price Target \$NA
- Update – Neutral – August 17, 2023 – Price Target \$NA
- Update – Neutral – September 5, 2023 – Price Target \$NA

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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.

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Current as of 22-Aug-23

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	23	65.70%	3	8.60%
Market Perform (Neutral)	12	34.30%	3	8.60%
Market Underperform (Sell)	0	0%	0	0.00%
Total	35	100%	6	17.20%

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