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## BioCardia Inc. (BCDA-NASDAQ) – Neutral Rated

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### DSMB Recommends Trial be Paused...

BioCardia announced that the Data Safety Monitoring Board (DSMB) has completed its prespecified data review for the ongoing Phase III pivotal CardiAMP Cell Therapy Heart Failure Trial and has recommended that the trial be paused. BioCardia is pausing the trial pending the one-year follow-up outcomes analysis for patients that have been treated and those that have been enrolled but not yet treated.

#### Investment Highlights:

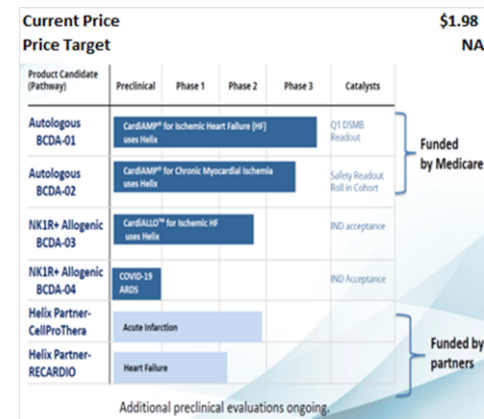
##### The DSMB recommendation stated:

- "Based on an analysis of the trial data, the primary FS composite endpoint assessment and a supplemental analysis presented on 7/19/23, unrelated to any emergent safety events, **the DSMB recommends pausing new patient enrollment and any potential crossover patient procedures pending an outcomes analysis of patients currently completing the one-year follow-up as well as the patients completing their imminently scheduled treatment.**
- The DSMB recommends notifying currently enrolled patients completing their treatment sequence that the trial will be paused following their scheduled treatment to assess intermediate study results.
- The DSMB recommends the blind not be broken at this time to protect the integrity of the outcomes yet to be collected and to ensure that the study may be restarted without compromise after completion of the one-year data analysis."

**According to the Company:** "The blinded data report available to the company groups together all patients, including treated and control patients. That blinded data shows that the aggregate survival rate at follow-up is greater than that observed in recent similar large pivotal trials in patients with heart failure with reduced ejection fraction. The blinded data also shows improved health outcomes in aggregate for patients followed-up through all key visit dates through 12-months such as measured by the six-minute walk test, patient classification per the New York Heart Association system, quality of life measured using the Minnesota Living with Heart Failure questionnaire, and heart function as measured by the left ventricular ejection fraction. The blinded data does not disclose the difference in outcomes between the treated group and the control group of patients."

**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	\$1.33 - \$2.92
Shares Outstanding (mil.)	20.4
Market Capitalization (mil.)	\$40
Enterprise Value (mil.)	\$40
Debt to Capital	0%
Book Value/Share	\$2.62
Price/Book	0.8
Average Three Months Trading Volume (K)	4
Insider Ownership	38.4%
Institutional Ownership	15.9%
Short interest (mil.)	1.0%
Dividend / Yield	\$0.00/0.0%



**Exhibit 1. Income Statement**

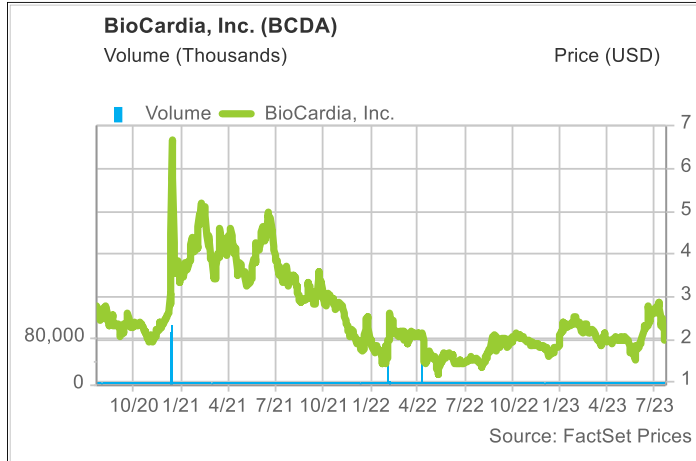
BioCardia Inc: Income Statement (\$000)																	
BCDA: YE December	2018A	2019A	2020A	2021A	2022A	1Q23A	2Q23E	3Q23E	4Q23E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Net product revenue	282	300	23	1													
Collaboration agreement revenue	343	382	122	1,014													
BCDA-01 CardiaAMP 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
<b>Total Product Sales</b>	<b>625</b>	<b>599</b>	<b>145</b>	<b>1,015</b>	<b>1,352</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>3,054</b>	<b>13,386</b>	<b>86,431</b>	<b>185,926</b>	<b>242,780</b>	<b>327,292</b>
<b>Product Sales &amp; Royalties &amp; Milestones</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>212</b>	<b>64</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>64</b>	<b>-</b>	<b>3,054</b>	<b>10,629</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	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	2,226	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	1,320	1,375	1,430	5,500	10,000	20,000	21,000	22,050	23,153	24,310	25,526
<b>Total expenses</b>	<b>14,727</b>	<b>15,192</b>	<b>15,674</b>	<b>13,645</b>	<b>13,253</b>	<b>3,574</b>	<b>3,546</b>	<b>3,694</b>	<b>3,842</b>	<b>14,656</b>	<b>19,345</b>	<b>30,355</b>	<b>34,182</b>	<b>51,673</b>	<b>73,335</b>	<b>84,562</b>	<b>103,264</b>
Operating income (Loss)	(14,102)	(14,593)	(15,529)	(12,630)	(11,901)	(3,574)	(3,546)	(3,694)	(3,842)	(14,656)	(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	-	-	-	-	-	-	-	-	-	-	-
<b>Total other income</b>	<b>115</b>	<b>(1)</b>	<b>504</b>	<b>(2)</b>	<b>6</b>	<b>9</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>(12,623)</b>	<b>(11,907)</b>	<b>(3,501)</b>	<b>(3,546)</b>	<b>(3,694)</b>	<b>(3,842)</b>	<b>(14,656)</b>	<b>(19,345)</b>	<b>(27,301)</b>	<b>(20,796)</b>	<b>34,758</b>	<b>112,590</b>	<b>158,218</b>	<b>224,028</b>
Income Tax Benefit (Provision)														8,342	31,525	47,466	76,170
<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>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</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>(12,623)</b>	<b>(11,907)</b>	<b>(3,501)</b>	<b>(3,546)</b>	<b>(3,694)</b>	<b>(3,842)</b>	<b>(14,656)</b>	<b>(19,345)</b>	<b>(27,301)</b>	<b>(20,796)</b>	<b>26,416</b>	<b>81,065</b>	<b>110,753</b>	<b>147,859</b>
Deemed Dividend on Preferred Stock																	
<b>GAAP-EPS</b>	<b>(0.37)</b>	<b>(0.92)</b>	<b>(1.48)</b>	<b>(0.75)</b>	<b>(0.67)</b>	<b>(0.17)</b>	<b>(0.13)</b>	<b>(0.14)</b>	<b>(0.14)</b>	<b>(0.58)</b>	<b>(0.71)</b>	<b>(1.00)</b>	<b>(0.76)</b>	<b>0.96</b>	<b>2.92</b>	<b>3.97</b>	<b>5.29</b>
GAAP EPS (dil)	(0.37)	(2.13)	(1.55)	(0.29)	(0.33)	(0.09)	(0.06)	(0.06)	(0.07)	(0.28)	(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	27,191	27,218	27,245	25,458	27,314	27,423	27,533	27,643	27,754	27,865	27,977
Weighted shares dil	38,285	15,136	13,445	44,209	36,000	40,000	57,098	57,155	57,212	52,866	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

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Current as of 17-Jul-23

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	25	69%	2	5.50%
Market Perform (Neutral)	11	31%	2	5.50%
Market Underperform (Sell)	0	0%	0	0.00%
Total	36	100%	4	11.00%

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