

# INSTITUTIONAL RESEARCH

# Regenerative Medicine UPDATE REPORT

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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) – Neutral Rated

August 17, 2023

Jason Kolbert

Post DSMB Pausing Trial: Reports 2<sup>nd</sup> Qtr. Loss of \$3.4M We Expect the Company to Raise Capital Again, soon

BioCardia reported 2<sup>nd</sup> Quarter results, reporting a \$3.4M loss. From the SEC filing (as the company doesn't list cash remaining in its press release) we see that the company now has \$4.3M in cash and equivalents remaining at the end of June. This suggests the company will need to raise capital soon. Given the fact that last month the DSMB concluded that the trial was unlikely to meet its primary FS composite endpoint, the stock is now pushing new lows.

# **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.

Managing Director & Senior Analyst jkolbert@dawsonjames.com



Jource, Diocardia		
Stock Data		
52-Week Range	\$0.85	- \$2.92
Shares Outstanding (mil.)		21.6
Market Capitalization (mil	l.)	\$19
Enterprise Value (mil.)		\$18
Debt to Capital		0%
Book Value/Share		\$2.62
Price/Book		0.3
Average Three Months Tra	8	
Insider Ownership		42.1%
Institutional Ownership		13.9%
Short interest (mil.)		0.1%
Dividend / Yield		\$0.00/0.0%
BioCardia, Inc. (BCD)	A)	





## **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)	ľ	- [	-	-	-	-	-	-	- '	- 1	-	-	-	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

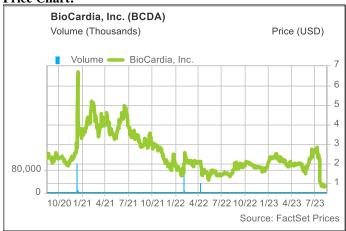
Source: Dawson James estimates, company reports



## Companies mentioned in this report:

#### **Important Disclosures:**





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

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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;
- 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 3-Aug-23

	Company		Investment	
	Coverage		Banking	
				% of
Ratings Distribution	# of Companies	% of Total	# of Companies	Totals
Market Outperform (Buy)	24	69%	3	8.60%
Market Perform (Neutral)	11	31%	3	8.60%
Market Underperform (Sell)	0	0%	0	0.00%
Total	35	100%	6	17.20%

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