

# **INSTITUTIONAL RESEARCH Regenerative Medicine UPDATE REPORT**

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

### March 7, 2022

Jason Kolbert

## Announces echocardiography data from the Phase III **CardiAMP Cell Therapy Heart Failure Trial at the** American College of Cardiology, but N=10?

Results from the 10-patient roll-in cohort of the clinical trial showed that myocardial wall motion in the 16 regions of the heart was more often characterized as normal after the study treatment at one year follow-up, and at two-year follow-up, as measured by the blinded echocardiography core lab at Yale University.

### **Investment Highlights:**

In the data series presented, just 13% of heart segments in the cohort were contracting normally before treatment versus 25% at 1 year (contracting normally), and at two years, 29% were contracting normally.

Our Takeaway – The data is encouraging, but N=10 is too small for us to draw any conclusion.

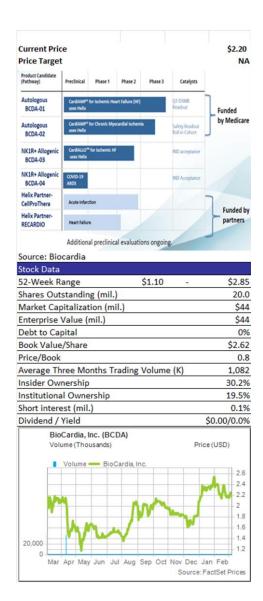
BCDA-01: The CardiAMP Heart Failure Trial (BCDA-01): The ongoing multi-center, double-blinded, randomized (3:2), controlled pivotal CardiAMP Heart Failure Trial is expected to enroll 260 patients at up to 40 centers nationwide. The trial's primary endpoint is an outcomes composite score based on a three-tiered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

BCDA-02: This is the CardiAMP Chronic Myocardial Ischemia Trial. It is a P3, multicenter, randomized, double-blinded, controlled study of up to 343 patients at up to 40 clinical sites. The trial is designed to provide the primary support for the safety and efficacy of the CardiAMP Cell Therapy System for the indication of chronic myocardial ischemia. This program benefits from the 2022 CMS reimbursement at up to \$20,000. The trial has been activated at two centers and the Company is working to activate additional centers.

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.

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#### **Exhibit 1. Income Statement**

Biocardia Inc: Income Statement (\$000) BCDA: YE December	2018A	2019A	2020A	2021A	1Q22A	2Q22A	3Q22A	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Net product revenue	282	300	23	1	IGEEA	LQLLA	JQLLA	TQLLL	LOLLL	20232	20242	20232	20202	20272	LOLOL	LULUL	20001
Collaboration agreement revenue	343	382	122	1,014													
BCDA-01 CardiaAMP Cell Therapy revenues US	010	002		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										-		-	4,502	68,679	93,131	94,717	96,330
BCDA-02 CardiaAMP Cell Therapy revenues EU											-	-	-	-	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	60	974	2	-	1.036	-	_	3.054	13.386	86.431	185.926	242,780	327.292
Product Sales & Royalties & Milestones	-	-	-	-	-	-	212	-	212	-	-	3,054	10,629	78,135	107,082	116,521	128,101
Expenses																	
Cost of goods sold	517	543	4	24			1	0	1	0	0	733	3,079	19,015	39,044	48,556	65,458
			3%	2%	30%	30%	30%	30%	0%	#DIV/0!	#DIV/0!	24%	23%	22%	21%	20%	20%
Research and Development	8,453	8,876	9,809	8,558	2,186	2,304	2,144	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	5,087	1,201	1,166	1,128	1,200	4,695	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	3,387	3,470	3,273	3,536	13,666	14,636	19,509	30,527	34,363	51,863	73,535	84,771	103,484
Operating income (Loss)	(14,102)	(14,593)	(15,529)	(12,630)	(3,327)	(2,496)	3,061	(3,536)	(12,630)	(14,636)	(19,509)	(27,473)	(20,976)	34,568	112,391	158,009	223,808
Interest expense				,	,			,	,	,	,	,	,				
Interest Income	118	23	21	9													
Other expense	(3)	(1)	504	(2)	2	1	3										
Total other income	115	(1)	504	(2)	2	1	3	-	-	-	-	-	-	-	-	-	-
Pretax Income	(13,987)	(14,571)	(15,004)	(12,623)	(3,325)	(2,497)	(3,057)	(3,536)	(12,630)	(14,636)	(19,509)	(27,473)	(20,976)	34,568	112,391	158,009	223,808
Income Tax Benefit (Provision)			-	-	,				-	-	-	-	-	8,296	31,469	47,403	76,095
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)	(3,325)	(2,497)	(3,057)	(3,536)	(12,630)	(14,636)	(19,509)	(27,473)	(20,976)	26,272	80,921	110,606	147,713
Deemed Dividend on Preferred Stock																	
GAAP-EPS	(0.37)	(0.92)	(1.48)	(0.75)	(0.19)	(0.14)	(0.11)	(0.13)	(0.57)	(0.54)	(0.71)	(1.00)	(0.76)	0.95	2.92	3.97	5.28
GAAP EPS (dil)	(0.37)	(2.13)	(1.55)	(0.29)	(0.07)	(0.08)	(0.05)	(0.06)	(0.26)	(0.26)	(0.34)	(0.48)	(0.36)	0.45	1.39	1.89	2.51
Weighted shares basic	38,285	15,761	10,118	16,917	17,066	17,651	27,110	27,137	22,241	27,205	27,314	27,423	27,533	27,644	27,754	27,866	27,977
Weighted shares dil	38,285	15,136	13,445	44,209	46,823	32,000	56,927	56,984	48,184	57,127	57,355	57,585	57,816	58,047	58,280	58,513	58,748

Source: Company Reports and Daw son James

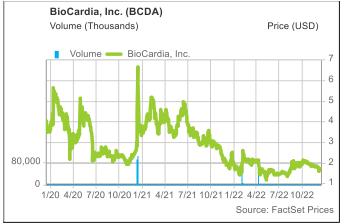
Source: Dawson James estimates, company reports



#### 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

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	Company Coverage		Investment Banking	
				% of
Ratings Distribution	# of Companies	% of Total	# of Companies	Totals
Market Outperform (Buy)	24	69%	1	3%
Market Perform (Neutral)	11	31%	2	6%
Market Underperform (Sell)	0	0%	0	0%
Total	35	100%	3	9%

Current as of 3-Mar-23

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