

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

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Jason Kolbert

Managing Director & Senior Analyst
jkolbert@dawsonjames.com

New data from the CardiAMP Cell Therapy HF Trial

BioCardia, Inc. announced plans to review the two-year roll-in cohort results from the CardiAMP Cell Therapy for Heart Failure Trial at this year's HFSA annual meeting, October 3rd, 2022.

Investment Highlights:

The data from the CardiAMP Cell Therapy Heart Failure trial is planned to be released today with anticipated details for a conference call with trial clinical leadership and management to follow. The planned conference call is expected to review the data presented at the Heart Failure Society of America meeting, detail the status of the trial, and discuss efforts being taken to implement an adaptive statistical analysis plan as recommended by the recent independent Data Safety Monitoring Board (DSMB) review.

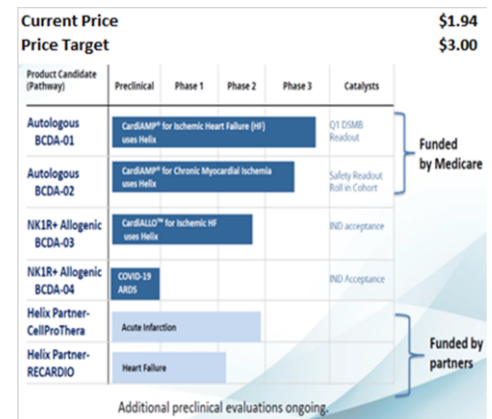
BCDA-01: The CardiAMP Heart Failure Trial (BCDA-01): The ongoing multi-center, double-blinded, randomized (3:2), controlled pivotal CardiAMP Heart Failure Trial is expected to enroll 260 patients at up to 40 centers nationwide. The trial's primary endpoint is an outcomes composite score based on a three-tiered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

What did the DSMB say? The DSMB based their review on available data for all participating patients enrolled, including 101 patients at or past the 12-month primary endpoint. The DSMB performed a risk-benefit assessment, indicated no significant safety concerns, and recommended that the study continue as designed. The DSMB also recommended that BioCardia consider implementing an adaptive statistical analysis plan which could enable an early readout for study treatment efficacy.

2nd Quarter Results: BioCardia spent \$2.5M in the quarter and closed the period with \$8.6M in cash. We do anticipate the company is likely to raise capital.

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 a 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 \$3.0.

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



Current Price				\$1.94		
Price Target				\$3.00		
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 AIO5				IND Acceptance	
Helix Partner-CellProThera	Acute Infarction					
Helix Partner-RECARDIO	Heart Failure					
Additional preclinical evaluations ongoing.						
Source: Biocardia						
Stock Data						
52-Week Range	\$1.10 -		\$3.09			
Shares Outstanding (mil.)	17.8					
Market Capitalization (mil.)	\$34					
Enterprise Value (mil.)	\$34					
Debt to Capital	0%					
Book Value/Share	\$2.62					
Price/Book	0.7					
Average Three Months Trading Volume (K)	18					
Insider Ownership	24.0%					
Institutional Ownership	17.9%					
Short interest (mil.)	0.5%					
Dividend / Yield	\$0.00/0.0%					

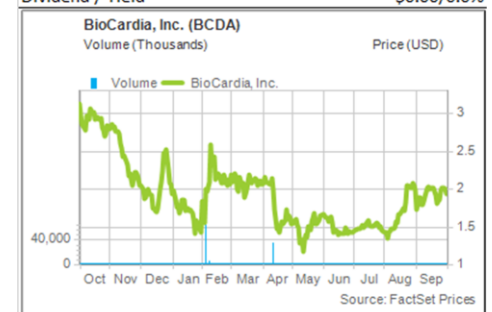


Exhibit 1. Product Pipeline

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	
NK1R+ Allogenic BCDA-04	COVID-19 ARDS				IND Acceptance	} Funded by partners
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:

	2022	2023	2024	2025	2026	2027	2028	2029	2030
BCDA-01 Heart Failure									
U.S. Prevalance 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 E.U.									
U.S. Prevalance 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									
U.S. Prevalance 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 E.U.									
U.S. Prevalance CHF	9,217,733	9,291,474	9,366,806	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									
U.S. Prevalance 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 E.U.									
U.S. Prevalance 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. Income Statement

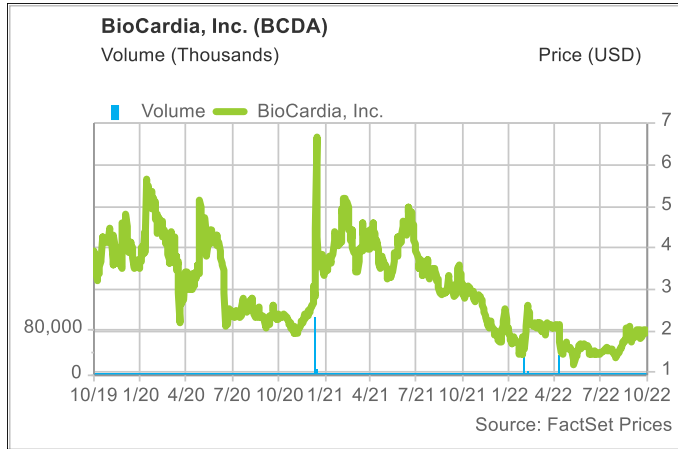
BioCardia Inc: Income Statement (\$000)																	
BCDA: YE December	2018A	2019A	2020A	2021A	1Q22A	2Q22A	3Q22E	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Net product revenue	282	300	23	1													
Collaboration agreement revenue	343	382	122	1,014													
BCDA-01 CardiaAMP 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											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														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	-	-	-	-	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	24			0	0	0	0	2,176	6,045	13,130	36,706	59,511	78,087	85,343
			3%	2%	30%	30%	30%	30%			25%	24%	23%	22%	21%	20%	20%
Research and Development	8,453	8,876	9,809	8,558	2,186	2,304	2,500	2,500	6,367	7,004	7,354	7,722	8,108	8,513	8,939	9,386	9,855
Selling, general and administrative	5,757	6,045	5,861	5,087	1,201	1,166	2,000	2,000		22,000	23,100	24,255	25,468	26,741	28,078	29,482	30,956
Total expenses	14,727	15,192	15,674	13,645	3,387	3,470	4,500	4,500	15,857	28,424	32,021	37,382	46,034	71,255	95,788	116,178	125,338
Operating income (Loss)	(14,102)	(14,593)	(15,529)	(12,630)	(3,327)	(2,496)	(4,500)	(4,500)	(15,857)	(28,424)	(23,316)	(12,195)	11,054	95,589	187,599	274,259	301,378
Interest expense																	
Interest Income	118	23	21	9													
Other expense	(3)	(1)	504	(2)	2	(1)											
Total other income	115	(1)	504	(2)	2	(1)	-	-	-	-	-	-	-	-	-	-	-
Pretax Income	(13,987)	(14,571)	(15,004)	(12,623)	(3,325)	(2,497)	(4,500)	(4,500)	(15,857)	(28,424)	(23,316)	(12,195)	11,054	95,589	187,599	274,259	301,378
Income Tax Benefit (Provision)											(4,663)	(2,927)	2,653	22,941	52,528	82,278	102,468
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	20%	24%	24%	24%	28%	30%	34%
GAAP Net Income (loss)	(13,987)	(14,571)	(15,004)	(12,623)	(3,325)	(2,497)	(4,500)	(4,500)	(15,857)	(28,424)	(18,653)	(9,268)	8,401	72,648	135,071	191,981	198,909
Deemed Dividend on Preferred Stock																	
GAAP-EPS	(0.37)	(0.92)	(1.48)	(0.75)	(0.19)	(0.14)	(0.25)	(0.25)	(0.91)	(1.60)	(1.05)	(0.52)	0.47	4.03	7.47	10.57	10.91
GAAP EPS (dil)	(0.37)	(2.13)	(1.55)	(0.29)	(0.07)	(0.04)	(0.08)	(0.08)	(0.29)	(0.50)	(0.33)	(0.16)	0.15	1.25	2.32	3.28	3.39
Weighted shares basic	38,285	15,761	10,118	16,917	17,066	17,651	17,669	17,686	17,518	17,731	17,802	17,873	17,945	18,016	18,089	18,161	18,234
Weighted shares dil	38,285	15,136	13,445	44,209	46,823	56,870	56,927	56,984	54,401	57,127	57,356	57,585	57,816	58,048	58,280	58,514	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

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- 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 20-Sep-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	25	83%	3	12%
Market Perform (Neutral)	4	13%	1	25%
Market Underperform (Sell)	1	3%	0	0%
Total	30	100%	4	13%

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