

BioCardia Inc. (BCDA-NASDAQ) – Neutral Rated

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Reports 3rd Quarter: Burning \$3M/QTR with \$6.6M Left on the Balance Sheet - Lowering to Neutral

BioCardia announced 3rd Quarter results. The company spent \$3M in cash and ended operations with just \$6M on the balance sheet. While it's important to note that the company's trials are in part supported by non-dilutive funding (CMS) we still expect the company will raise capital soon, and as a result, we are lowering our rating from Buy to Neutral.

Investment Highlights:

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.

DSMB Update: The DSMB also recommended that the Company consider implementing an adaptive statistical analysis plan, which could enable an early readout for study treatment efficacy. Efforts are underway to have an adaptive statistical analysis plan in place by the next DSMB review anticipated in March 2023.

BCDA-02: This is the CardiAMP Chronic Myocardial Ischemia Trial. It is a P3, multi-center, 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: 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 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	\$1.10 - \$2.85
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)	46
Insider Ownership	15.7%
Institutional Ownership	17.6%
Short interest (mil.)	0.2%
Dividend / Yield	\$0.00/0.0%

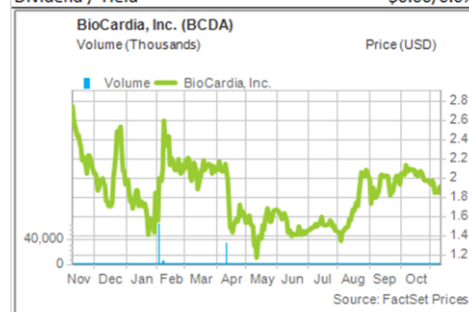


Exhibit 1. Product Pipeline

Three Platforms, Four Clinical Stage Product Candidates for Cardiovascular and Pulmonary Diseases

Platform	Product Candidate	Preclinical Recent Significant Events	Phase 1	Phase 2	Phase 3	Anticipated Catalysts
Autologous MNC	BCDA-01	CardiAMP® for Ischemic Heart Failure (HFrEF) Q1 2022 FDA Breakthrough Designation, Q2 2022 CMS Code, Q4 2022 HFSA Data 100% Survival at Two Years				<ul style="list-style-type: none"> Regulatory submission Japan Q4 '22 DSMB Q1 '23
	BCDA-02	CardiAMP® for Chronic Myocardial Ischemia Q4 2021 First Patient Treated; Q2 2022 CMS Code				<ul style="list-style-type: none"> Q4 '22 Roll In Safety Readout
Allogeneic NK1R+ MSC	BCDA-03	CardiALLO™ for Ischemic HFrEF Q3 2022 Animal Studies for new CMC Completed				<ul style="list-style-type: none"> Q4 '22 IND acceptance
	BCDA-04	COVID-19 ARDS Q2 2022 IND Approved				<ul style="list-style-type: none"> Q4 '22 First Patient
Helix Biotherapeutic Delivery	BCDA-01, 02, 03 & Partners	Approved in Europe; Investigational USA Q3 2022 BlueRock Agreement				<ul style="list-style-type: none"> Revenues, growth of previously inked deals

Notes:

MNC = Mononuclear Cells

NK1R+ MSC = Neurokinin 1 Receptor Positive Mesenchymal Stem Cells

05295-V (MKT) Corporate Presentation 2022 Q4

Source: BioCardia

BIOCARDIA®
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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 10 to 20% of the total market in the year 2030, and CardiALLO achieving 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 2025/2026 is possible. We expect BCDA-02 to be a fast follower with approval and launch a year after BCDA-01, in 2026-7. 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:

BCDA-01 Heart Failure										
U.S. Prevalance CHF	2022	2023	2024	2025	2026	2027	2028	2029	2030	
Market Size Growth (Annual)	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	
Candidates (Class II & III) for Therapy	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	
Market Share Penetration	501,502	502,003	502,505	503,008	503,511	504,014	504,518	505,023	505,528	
Number of Patients Procedures				3.0%	6.0%	7.0%	8.0%	10.0%	14.0%	
Cost of Therapy	0	0	0	15,090	30,211	35,281	40,361	50,502	70,774	
Price Growth	\$ 20,120	\$ 20,160	\$ 20,201	\$ 20,241	\$ 20,282	\$ 20,322	\$ 20,363	\$ 20,404	\$ 20,444	
Probability of Success	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	
U.S. Annual Sales (M)	1%	1%	1%	1%	1%	1%	1%	1%	1%	
	\$ -	\$ -	\$ -	\$ 3	\$ 6	\$ 7	\$ 8	\$ 10	\$ 14	
BCDA-01 Heart Failure										
E.U. Prevalance CHF	2022	2023	2024	2025	2026	2027	2028	2029	2030	
Market Size Growth (Annual)	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	
Candidates (Class II & III) for Therapy	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	
Market Share Penetration	902,703	903,605	904,509	905,414	906,319	907,225	908,132	909,041	909,950	
Number of Patients Procedures				1.0%	3.0%	5.0%	10.0%	12.0%		
Cost of Therapy	0	0	0	0	9,063	27,217	45,407	90,904	109,194	
Price Growth	\$ 30,180	\$ 30,241	\$ 30,301	\$ 30,362	\$ 30,423	\$ 30,483	\$ 30,544	\$ 30,605	\$ 30,667	
Probability of Success	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	
E.U. Annual Sales (M)	1%	1%	1%	1%	1%	1%	1%	1%	1%	
	\$ -	\$ -	\$ -	\$ -	\$ 3	\$ 8	\$ 14	\$ 28	\$ 33	
BCDA-02 Heart Failure										
U.S. Prevalance CHF	2022	2023	2024	2025	2026	2027	2028	2029	2030	
Market Size Growth (Annual)	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	
Candidates (Chronic Myocardial Ischemia) for Therapy	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	
Market Share Penetration	209,136	212,273	215,457	218,689	221,969	225,299	228,678	232,108	235,590	
Number of Patients Procedures					1.0%	15.0%	20.0%	20.0%	20.0%	
Cost of Therapy	0	0	0	0	2,220	33,795	45,736	46,422	47,118	
Price Growth	\$ 20,120	\$ 20,160	\$ 20,201	\$ 20,241	\$ 20,282	\$ 20,322	\$ 20,363	\$ 20,404	\$ 20,444	
Probability of Success	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	
U.S. Annual Sales (M)	10%	10%	10%	10%	10%	10%	10%	10%	10%	
	\$ -	\$ -	\$ -	\$ -	\$ 5	\$ 69	\$ 93	\$ 95	\$ 96	
BCDA-02 Heart Failure										
E.U. Prevalance CHF	2022	2023	2024	2025	2026	2027	2028	2029	2030	
Market Size Growth (Annual)	9,217,733	9,291,474	9,365,806	9,440,733	9,516,259	9,592,389	9,669,128	9,746,481	9,824,453	
Candidates (Chronic Myocardial Ischemia) for Therapy	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	
Market Share Penetration	506,975	511,031	515,119	519,240	523,394	527,581	531,802	536,056	540,345	
Number of Patients Procedures					0.0%	0.0%	4.0%	6.0%	10.0%	
Cost of Therapy	0	0	0	0	0	0	21,272	32,163	54,034	
Price Growth	\$ 30,180	\$ 30,241	\$ 30,301	\$ 30,362	\$ 30,423	\$ 30,483	\$ 30,544	\$ 30,605	\$ 30,667	
Probability of Success	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	
U.S. Annual Sales (M)	10%	10%	10%	10%	10%	10%	10%	10%	10%	
	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 65	\$ 98	\$ 166	
BCDA-03 Heart Failure										
U.S. Prevalance CHF	2022	2023	2024	2025	2026	2027	2028	2029	2030	
Market Size Growth (Annual)	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	
Candidates (Class II & III) for Therapy	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	
Market Share Penetration	150,450	150,601	150,752	150,902	151,053	151,204	151,355	151,507	151,658	
Number of Patients Procedures					0.0%	2.0%	5.0%	10.0%	15.0%	
Cost of Therapy	0	0	0	0	0	3,024	7,568	15,151	22,749	
Price Growth	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 22,500	\$ 22,545	\$ 22,590	\$ 22,635	
Probability of Success	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	
U.S. Annual Sales (M)	1%	1%	1%	1%	1%	1%	1%	1%	1%	
	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 1	\$ 2	\$ 3	\$ 5	
BCDA-03 Heart Failure										
E.U. Prevalance CHF	2022	2023	2024	2025	2026	2027	2028	2029	2030	
Market Size Growth (Annual)	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	
Candidates (Class II & III) for Therapy	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	
Market Share Penetration	270,811	271,082	271,353	271,624	271,896	272,168	272,440	272,712	272,985	
Number of Patients Procedures					0.0%	2.0%	5.0%	10.0%	15.0%	
Cost of Therapy	0	0	0	0	0	5,443	13,622	27,271	40,948	
Price Growth	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 29,500	\$ 29,559	\$ 29,618	\$ 29,677	
Probability of Success	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	
U.S. Annual Sales (M)	1%	1%	1%	1%	1%	1%	1%	1%	1%	
	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 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	3Q22A	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										-	-	-	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

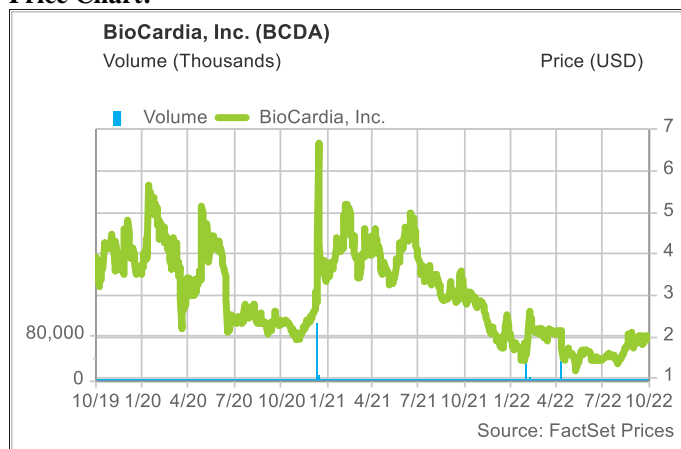
Source: Company Reports and Dawson James

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

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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;
- 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 10-Nov-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	23	77%	3	13%
Market Perform (Neutral)	6	20%	1	17%
Market Underperform (Sell)	1	3%	0	0%
Total	30	100%	4	13%

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