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

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Reports 1Q22 Results: Closed with \$10M in Cash, Anticipates Cash Can Last to 1Q23

Enrollment in the CardiAMP Heart Failure Trial remains BioCardia's primary focus. The company has enrolled 111 patients out of 260. Breakthrough designation status has been granted by the FDA.

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 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.

Milestones Expected:

- BCDA-01: Data Safety Monitoring Board review in the CardiAMP Cell Therapy Heart Failure Trial in Q3-22.
- BCDA-02: CardiAMP Chronic Myocardial Ischemia Phase 3 pivotal trial (N=343) roll-in cohort safety data in 2022.
- BCDA-03: IND acceptance of Phase I/II program of our allogeneic Neurokinin-1 Receptor Positive Mesenchymal Stem Cells (NK1R+ MSC) for the treatment of ischemic heart failure, intended initially for those patients excluded from BCDA-01 in Q4-22.
- BCDA-04: Treatment of the first patient in the allogeneic NK1R+ MSC Phase 1/2 program for the treatment of ARDS resulting from COVID-19 in Q322.

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 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.



Source: Biocardia

Stock Data			
52-Week Range	\$1.10	-	\$5.10
Shares Outstanding (mil.)	16.9		
Market Capitalization (mil.)	\$25		
Enterprise Value (mil.)	\$25		
Debt to Capital	0%		
Book Value/Share	\$2.62		
Price/Book	0.6		
Average Three Months Trading Volume (K)	166		
Insider Ownership	26.1%		
Institutional Ownership	22.3%		
Short interest (mil.)	3.7%		
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	
Helix Partner-CellProThera	Acute Infarction					} Funded by partners
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. 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%	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. 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. 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

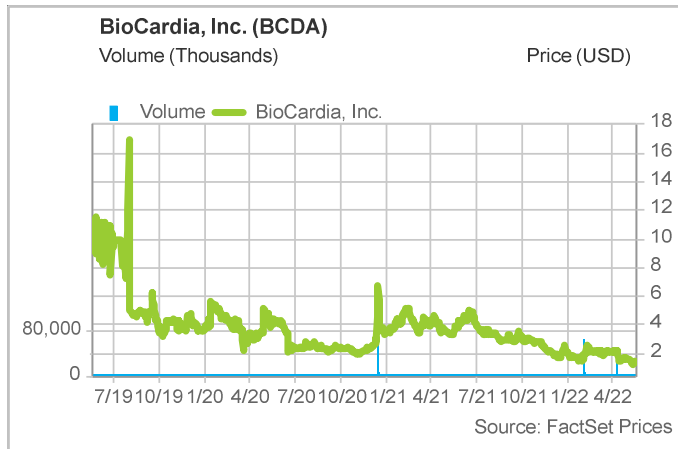
Biocardia Inc: Income Statement (\$000)																	
BCDA: YE December	2018A	2019A	2020A	2021A	1Q22A	2Q22E	3Q22E	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Net product revenue	282	300	23	1													
Collaboration agreement revenue	343	382	122	1,014													
BCDA-01 CardiaAMP 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	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	-	-	-	-	-	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	0	2,176	6,045	13,130	36,706	59,511	78,087	85,343
Research and Development	8,453	8,876	9,809	8,558	2,186	2,157	2,246	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	4,320	4,500	4,680	18,000	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	6,477	6,746	7,016	23,626	30,806	34,523	40,009	48,793	74,151	98,829	119,371	128,691
Operating income (Loss)	(14,102)	(14,593)	(15,529)	(12,630)	(3,327)	(6,477)	(6,746)	(7,016)	(23,626)	(30,806)	(25,818)	(14,822)	8,295	92,693	184,558	271,065	298,025
Interest expense																	
Interest Income	118	23	21	9													
Other expense	(3)	(1)	504	(2)	2												
Total other income	115	(1)	504	(2)	2	-	-	-	-	-	-	-	-	-	-	-	-
Pretax Income	(13,987)	(14,571)	(15,004)	(12,623)	(3,325)	(6,477)	(6,746)	(7,016)	(23,626)	(30,806)	(25,818)	(14,822)	8,295	92,693	184,558	271,065	298,025
Income Tax Benefit (Provision)						(648)	(675)	(702)	(2,024)	(5,545)	(5,164)	(3,557)	1,991	22,246	51,676	81,320	101,328
Tax Rate	0%	0%	0%	0%	10%	10%	10%	10%	9%	18%	20%	24%	24%	24%	28%	30%	34%
GAAP Net Income (loss)	(13,987)	(14,571)	(15,004)	(12,623)	(3,325)	(5,829)	(6,072)	(6,315)	(21,602)	(25,261)	(20,655)	(11,265)	6,305	70,446	132,882	189,746	196,696
Deemed Dividend on Preferred Stock																	
GAAP-EPS	(0.37)	(0.92)	(1.48)	(0.75)	(0.19)	(0.22)	(0.22)	(0.23)	(0.88)	(0.93)	(0.76)	(0.41)	0.23	2.55	4.79	6.81	7.03
GAAP EPS (dil)	(0.37)	(2.13)	(1.55)	(0.29)	(0.07)	(0.10)	(0.11)	(0.11)	(0.40)	(0.44)	(0.36)	(0.20)	0.11	1.21	2.28	3.24	3.35
Weighted shares basic	38,285	15,761	10,118	16,917	17,066	27,083	27,110	27,137	24,599	27,205	27,314	27,424	27,533	27,644	27,754	27,866	27,977
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

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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 16-May-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	31	72%	4	13%
Market Perform (Neutral)	12	28%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	43	100%	4	9%

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