

BioCardia Inc. (BCDA-NASDAQ)

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DSMB Says OK to Continue – We Remain Neutral

BioCardia announces that the independent Data Safety Monitoring board (DSMB) has completed its prespecified data review for the Phase 3 CardiAMP Cell Therapy Heart Failure Trial. The DSMB based its review on all available data (N=97). Many of the patients have reached their one-year, and a few have reached their two-year, follow-up. The DSMB performed a risk-benefit assessment, indicated no safety concerns, and recommended that the study continue as designed. The ongoing CardiAMP Heart Failure Trial is expected to enroll 260 patients at up to 40 centers nationwide.

Investment Highlights:

BCDA-01: BioCardia cites this autologous cell therapy for the treatment of ischemic heart failure as the “top priority.” The CardiAMP Heart Failure Trial (BCDA-01) received a DSMB review on the available data for the 86 patients enrolled in the trial, which included 60 randomized patients who have reached their one-year follow-up. The DSMB performed a risk-benefit assessment, indicated no safety concerns, and recommended that the study continue as designed.

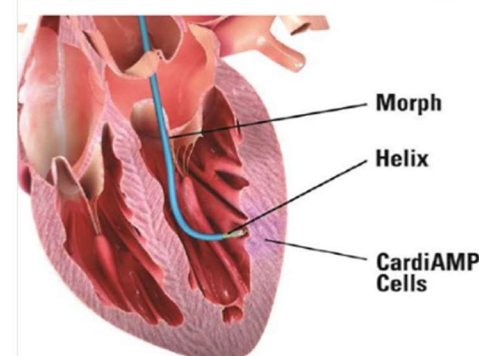
Milestones Expected:

- Q2 2021: Phase 3 pivotal trial prespecified independent DSMB Review of CardiAMP Heart Failure trial (BCDA-01) – completed.
- 1H 2021: Phase 3 pivotal trial first patient enrolled in CardiAMP Chronic Myocardial Ischemia Trial (BCDA-02).
- Roll in cohort safety data from BCDA-02, the CardiAMP autologous cell therapy under Phase 3 development for the treatment of chronic myocardial ischemia.
- Investigational New Drug (IND) acceptance of Phase 1/2 program of BCDA-03, allogeneic Neurokinin-1 receptor positive (NK1R+) Mesenchymal Stem Cells (MSC) for the treatment of ischemic heart failure intended initially for those patients excluded from BCDA-01.
- IND acceptance of Phase 1/2 program for BCDA-04. This is an allogeneic NK1R+ MSC Phase 1/2 program for the treatment of acute respiratory distress resulting from COVID-19.

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. In February, we revised our risk cut to projected revenues. In ischemia, we are at a 90% cut and for non-ischemic indications, we lowered our chances from 10% to just 1%, 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. We remain Neutral rated.

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

Current Price \$4.60
Price Target NA



Source: Biocardia

Stock Data			
52-Week Range	\$1.91	-	\$8.60
Shares Outstanding (mil.)	16.8		
Market Capitalization (mil.)	\$77		
Enterprise Value (mil.)	\$77		
Debt to Capital	0%		
Book Value/Share	\$2.62		
Price/Book	1.8		
Average Three Months Trading Volume (K)	101		
Insider Ownership	24.5%		
Institutional Ownership	23.6%		
Short interest (mil.)	2.7%		
Dividend / Yield	\$0.00/0.0%		



Exhibit 1. Income Statement

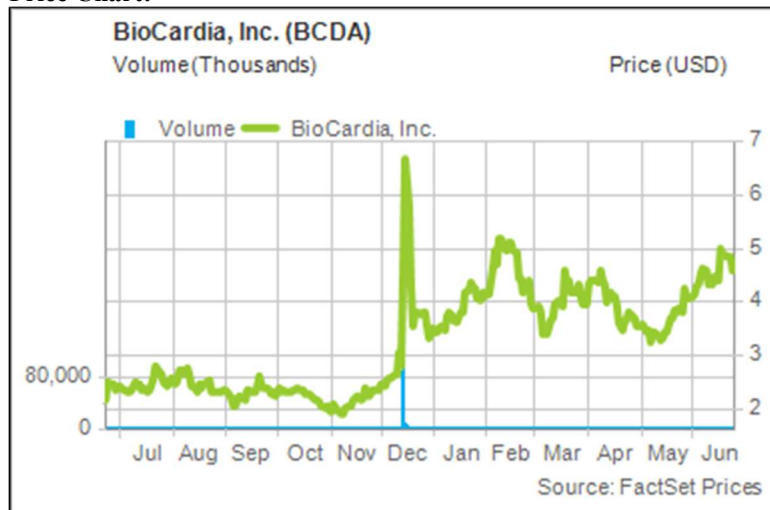
Biocardia Inc: Income Statement (\$000)																	
BCDA: YE December	2018A	2019A	2020A	1Q21A	2Q21E	3Q21E	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Net product revenue	282	300	23		6	6	7	24									
Collaboration agreement revenue	343	382	122	46	31	33	35	128									
BCDA-01 CardiaAMP Cell Therapy revenues US		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	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	46	37	40	41	152	-	-	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	0	11	12	12	35	0	0	2,176	6,045	13,130	36,706	59,511	78,087	85,343
			3%	30%	30%	30%	30%	23%			25%	24%	23%	22%	21%	20%	20%
Research and Development	8,453	8,876	9,809	1,841	2,472	2,575	2,678	10,299	10,814	11,355	11,923	12,519	13,145	13,802	14,492	15,217	15,978
Selling, general and administrative	5,757	6,045	5,861	1,177	1,477	1,539	1,600	6,154	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	3,018	3,960	4,125	4,290	15,393	28,238	32,688	36,499	42,083	50,971	76,438	101,230	121,892	131,339
Operating income (Loss)	(14,102)	(14,593)	(15,529)	(2,972)	(3,923)	(4,086)	(4,249)	(15,241)	(28,238)	(32,688)	(27,794)	(16,896)	6,117	90,405	182,157	268,544	295,377
Interest expense																	
Interest Income	118	23	21	4													
Other expense	(3)	(1)	504	(1)													
Total other income	115	(1)	504	(1)	-	-	-	-	-	-	-	-	-	-	-	-	-
Pretax Income	(13,987)	(14,571)	(15,004)	(2,969)	(3,923)	(4,086)	(4,249)	(15,241)	(28,238)	(32,688)	(27,794)	(16,896)	6,117	90,405	182,157	268,544	295,377
Income Tax Benefit (Provision)									(2,824)	(5,884)	(5,559)	(4,055)	1,468	21,697	51,004	80,563	100,428
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	10%	18%	20%	24%	24%	24%	28%	30%	34%
GAAP Net Income (loss)	(13,987)	(14,571)	(15,004)	(2,969)	(3,923)	(4,086)	(4,249)	(15,241)	(25,414)	(28,804)	(22,235)	(12,841)	4,649	68,708	131,153	187,981	194,949
Deemed Dividend on Preferred Stock																	
GAAP-EPS	(0.37)	(0.92)	(1.48)	(0.18)	(0.18)	(0.19)	(0.20)	(0.75)	(1.17)	(1.23)	(1.02)	(0.59)	0.21	3.11	5.91	8.43	8.71
GAAP EPS (dil)	(0.37)	(2.13)	(1.55)	(0.08)	(0.08)	(0.09)	(0.09)	(0.34)	(0.54)	(0.57)	(0.47)	(0.27)	0.10	1.44	2.73	3.90	4.03
Weighted shares basic	38,285	15,761	10,118	16,569	21,586	21,607	21,629	20,348	21,683	21,770	21,857	21,945	22,033	22,121	22,210	22,299	22,388
Weighted shares dil	38,285	15,136	13,445	36,647	46,683	46,730	46,777	44,209	46,894	47,082	47,270	47,460	47,650	47,841	48,032	48,225	48,418

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

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Ratings Definitions:

- 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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As of: 21-Jun-21

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	24	71%	4	17%
Market Perform (Neutral)	10	29%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	34	100%	4	12%

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