

## BioCardia Inc. (BCDA-NASDAQ)

September 17, 2019

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### BUY: Regenerative Medicine—The Best of Both Worlds

Head of Healthcare Research

646-465-6891

*BioCardia is a developing cell therapies in cardiovascular diseases. Through their two different cell therapy systems, CardiAMP (autologous) and CardiALLO, (allogeneic), BioCardia aims to improve the quality of life of patients suffering from ischemic heart failure and chronic myocardial ischemia with refractory angina.*

### Investment Highlights

**Heart Disease – Treating the Underlying Issue.** BioCardia strongly believes that stem cells have the power to change the course of cardiovascular disease. This may occur as a result of the trophic effects of these cells when administered directly into the local environment (heart muscle). The cells act like micro-drug factories secreting factors that help to reduce inflammation, reduce scarring and promote micro-angiogenesis (formation of new blood supply to the tissue). In doing such it is hoped in the case of an acute ischemic event, that the cells can help limit the initial damage and in the case of chronic disease may help to arrest the damage, even reverse it partially.

**Delivery Matters.** One of the characteristics that differentiates BioCardia from competitors in the field is the way the cells are delivered. The cells are administered directly to the patient's heart through the use of their Helix Biotherapeutic Delivery System and the Morph steerable guide. The end result is that more cells stay where they are needed versus other systems where the majority of cells are washed away in the dynamic blood flow associated with the heart.

**Roughly \$20B is spent per year for hospitalization costs.** Following an operation done on a patient's heart, on average, they are in the hospital for three to four nights spending at least \$10,000 a night. CardiAMP can allow the patient to be released the same day with anticipated savings for the system of up to \$40,000 of unwanted hospital costs.

**BioCardia is Assisted.** The company is conducting numerous clinical trials in heart disease and specifically heart ischemia. Focusing on heart failure consumes a significant amount of a company's resources. BioCardia gets an extra hand as the Centers for Medicare & Medicaid Services (CMS) has funded the ongoing Phase 3 trial of CardiAMP cell therapy system in ischemic heart failure.

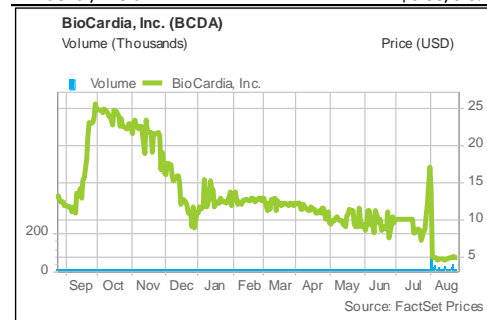
**Autologous vs. Allogeneic:** BioCardia is developing treatment using both autologous and allogeneic cells. BioCardia developed a diagnostic assay to determine which treatment is best suited for each patient. Autologous stem cell therapy is the company's leading product, CardiAMP, which is currently in a pivotal Phase 3 trial. Through CardiAMP, the patient's own bone marrow is extracted and is directly administered to the patient's heart to allow the most efficacy. If a patient's CD34 cell count does not reach the requirement for CardiAMP, BioCardia can offer CardiALLO. CardiALLO stands out as an allogeneic stem cell therapy that is based on donated marrow. CardiALLO is designed to be a fast follower behind CardiAMP.

Current Price \$4.84  
 Price Target \$24.00

Estimates	F2019E	F2020E	F2021E
<b>Expenses (\$000s)</b>	\$ 15,637	\$ 15,515	\$ 16,291
1Q March	\$ 3,903	\$ 3,641	\$ 3,823
2Q June	\$ 3,848	\$ 3,799	\$ 3,989
3Q September	\$ 3,866	\$ 3,959	\$ 4,157
4Q December	\$ 4,020	\$ 4,117	\$ 4,323
	<b>F2019E</b>	<b>F2020E</b>	<b>F2021E</b>
<b>EPS (diluted)</b>	\$ (1.57)	\$ (0.65)	\$ (0.34)
1Q March	\$ (0.08)	\$ (0.26)	\$ (0.10)
2Q June	\$ (0.77)	\$ (0.13)	\$ (0.08)
3Q September	\$ (0.43)	\$ (0.13)	\$ (0.08)
4Q December	\$ (0.28)	\$ (0.14)	\$ (0.09)

EBITDA/Share	(\$0.85)	(\$0.60)	(\$0.34)
EV/EBITDA (x)	0.0	0.0	0.0

<b>Stock Data</b>			
52-Week Range	\$4.32	-	\$32.22
Shares Outstanding (mil.)	6.7		
Market Capitalization (mil.)	\$33		
Enterprise Value (mil.)	\$32		
Debt to Capital	0%		
Book Value/Share	\$2.62		
Price/Book	1.8		
Average Three Months Trading Volume (K)	1		
Insider Ownership	63.0%		
Institutional Ownership	1.0%		
Short interest (mil.)	0.0%		
Dividend / Yield	\$0.00/0.0%		



Initiation - Sept. 17, 2019 - Buy - Price Target \$24.00

**Phase 3 Update: DSMB Say's No Safety Issues – Recommends that the trial should continue:** BioCardia announced that the independent Data Safety Monitoring board (DSMB) has completed its prespecified data review for the Phase 3 pivotal CardiAMP Heart Failure Trial, which included safety follow-up results on 35 patients and all additional data available on the 50 patients randomized in the trial as of the end of August. The DSMB indicated there were no safety concerns with the CardiAMP study results and recommended that the trial continue, as planned. The trial is an ongoing multi-center, double-blinded, randomized (3:2), sham-controlled pivotal CardiAMP Heart Failure Trial is expected to enroll 260 patients at up to 40 centers nationwide. The trial's primary efficacy endpoint is Six Minute Walk distance at 12 months' post-treatment, a measure of a patient's exercise capacity, and incorporates the impact of MACE and other clinically meaningful events. Secondary efficacy endpoints include quality of life as measured by the Minnesota Heart Failure Quality of Life self-assessment, and superiority relative to MACE and survival.

**Valuation:** Our product models run out to the year 2030. For CardiAMP and CardiALLO and all the related cardiac indications, each of which represent blockbuster markets, we haircut the revenues by 70% (assume only a 30% probability of success). 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 90% risk cut in our models. Our share count is projected for 2030 and assumes multiple raises. Our models are then equal weighted, averaged and rounded to the nearest whole number to derive our 12 months price target of \$24.00.

**Risks:** Partnership risks, Commercialization risks, Financial risks, Clinical and regulatory risks, and Legal and intellectual property risk.

**Exhibit 1. We view BioCardia as a unique company in the world of stem cells as the company has “The Best of Both Worlds”,** that is an Autologous and an Allogenic approach. A patient assay can determine if a patient's own cells are viable to treat disease and select which therapy is best, for each individual patient.

#### CardiAMP cell therapy system

- Regulated and manufactured as a device based procedure kit with anticipated low cost of goods and long shelf life
- For both leading indications, CardiAMP fits into standard interventional cardiology device channels

#### CardiALLO cell therapy system

- Commercial launch will leverage experience, training, and delivery systems. As an “off the shelf” cryopreserved cell therapy multiple doses per donor will be available. BioCardia has a unique approach which may address donor variability issues and international distribution
- Cardiology sales of these products are synergistic
- Direct sales force in U.S. selling into the cardiac catheterization suite and interventional cardiologist end users at 1200 hospitals in USA
- Co-exclusive partnering with large reference laboratory on cell proprietary potency assays



Source: BioCardia July Presentation.

## Company Overview

BioCardia is a clinical stage regenerative medicine company developing therapies for cardiovascular diseases. It is well known that the cardiovascular market has large unmet medical needs and BioCardia believes CardiAMP and CardiALLO are part of the solutions for patients following a heart attack and or diagnosed with chronic myocardial ischemic and or ischemic related cardiac disease. The company's lead program, CardiAMP, incorporates a proprietary molecular model in order to determine if a patient's own bone marrow qualifies as a candidate for this therapy. The company hopes with this therapy to improve the quality of life for patients following treatment for heart disease. CardiAMP was designed to be delivered in a 60-90 minute procedure. CardiALLO is an option for those patients who are not able to produce enough viable cells to manufacture CardiAMP. Both heart failure trials, BCDA-01 and BCDA-02 have been supported by CMS (Medicare) which has offset the financial burden for expensive HF trials.

## Exhibit 2. Upcoming Catalysts for BioCardia

Product	Indication	Event	Timeline	Impact
BCDA-01: CardiAMP Cell Therapy	Ischemic Heart Failure	Complete enrolling pivotal Phase 3 trial	2H20	++
BCDA-01: CardiAMP Cell Therapy	Ischemic Heart Failure	Complete Phase 3 and submit for US and EU approval	3Q21	+++
BCDA-01: CardiAMP Cell Therapy	Ischemic Heart Failure	Approval and Launch	2H22	+++
BCDA-02: CardiAMP Cell Therapy	Chronic Myocardial Ischemia	Complete enrollment for pivotal Phase 3	2H22	++
BCDA-02: CardiAMP Cell Therapy	Chronic Myocardial Ischemia	Complete Phase 3 and submit for US and EU approval	4Q23	+++
BCDA-02: CardiAMP Cell Therapy	Chronic Myocardial Ischemia	Approval and Launch	1Q24	+++
BCDA-03 CardALLO Cell Therapy	Ischemic Heart Failure	Seek Orphan Status	2021	+
BCDA-03 CardALLO Cell Therapy	Ischemic Heart Failure	Phase 1/2 Investigational New Drug approved	4Q19	+
BCDA-03 CardALLO Cell Therapy	Ischemic Heart Failure	Begin enrollment of Phase 1/2 Study	3Q20	+
BCDA-03 CardALLO Cell Therapy	Ischemic Heart Failure	Complete enrollment for Phase 1/2 trial	3Q22	++
BCDA-03 CardALLO Cell Therapy	Ischemic Heart Failure	Complete study and file for pivotal Phase 3 trial	3Q23	++
BCDA-03 CardALLO Cell Therapy	Ischemic Heart Failure	Begin enrollment of pivotal Phase 3 trial	4Q23	++
BCDA-03 CardALLO Cell Therapy	Ischemic Heart Failure	Complete enrollment of Phase 3 trial	2H25	+++
BCDA-03 CardALLO Cell Therapy	Ischemic Heart Failure	Complete Phase 3 and submit for US and EU approval	3Q26	+++
BCDA-03 CardALLO Cell Therapy	Ischemic Heart Failure	Approval and Launch	1Q27	+++

Stock Significance Scale: + of moderate importance; ++ higher level; +++ highly

Source: Dawson James estimates and BioCardia.

## Exhibit 3. Advanced clinical pipeline

Product Candidate (Pathway)	Preclinical	Phase 1	Phase 2	Phase 3	Approved
<b>BCDA-01</b>	CardiAMP: Ischemic Heart Failure			<ul style="list-style-type: none"> <li>Pivotal /Phase 3 has Medicare reimbursement</li> <li>Actively enrolling 24 US Sites</li> </ul>	
<b>BCDA-02</b>	CardiAMP: Chronic Myocardial Ischemia with Refractory Angina			<ul style="list-style-type: none"> <li>Pivotal/ Phase 3 has Medicare reimbursement</li> </ul>	
<b>BCDA-03</b>	CardiALLO: Ischemic Heart Failure			<ul style="list-style-type: none"> <li>Phase 1/2 IND acceptance anticipated Q4 2019</li> </ul>	
<b>Helix Partner-01</b> Cell Pro Thera	Acute Infarction			<ul style="list-style-type: none"> <li>Funded by Cell Pro Thera</li> </ul>	
<b>Helix Partner-02</b> University of Milan	Heart Failure			<ul style="list-style-type: none"> <li>Funded by University of Milan</li> </ul>	

Source: BioCardia July Presentation.

**Bull Case.** BioCardia's two regenerative stem cell therapies: CardiAMP and CardiALLO, represent the best of both worlds, an autologous model for those patients that can produce viable cells and an allogenic, off the shelf, alternative therapy for patients who fail to meet the requirements for autologous or in those scenarios where an acute therapy is immediately required. BioCardia also has a specialized delivery system, that separates its product from others in the cardiovascular, regenerative field. Delivery matters and too often we have seen in clinical trials the effect of potent cells diminished in the setting of cardiovascular disease, mainly because the cells are "swept away" with turbulent blood flow present in cardiac muscle. Delivering cells with BioCardia's unique "helix" catheter appears to be a factor in keeping the cells where they need to be, in order to see an effect on the vasculature, inflammation, and scarring present in the heart and its surrounding anatomy. Further we see BioCardia's dual approach (auto & allo) as allowing the company to tailor its cell therapy and in doing so, reach a wider segment of the market, with better outcomes. The lead program today is CardiAMP (BCDA-01) followed by CardiALLO. The goal is to treat ischemic heart failure with CardiALLO (BCDA-03) which is being developed as a "fast follower" to CardiAMP. CardiAMP is now in a Phase 3 (pivotal) study which is expected to complete enrollment by the second half of next year (2H20) with results six months after the last patient is treated. Based on this timeline, we could see approval and launch in 2022.

**Is there a basis to believe CardiAMP works?** In its Phase 2 trial, BCDA-01 demonstrated a significant improvement of patient cardiac function and quality of life. The need for a therapy (with no side-effects) that can be disease modifying is great. This compared to the current standard of care, which is typically either surgery, a catheter lab intervention, typically coupled with a hospital stay (costing thousands of dollars per day) with background of medications (poly-pharmacy), all designed to reduce stress on the heart but not really treating the heart itself, leaves room for improvement. Conservatively, we estimate BioCardia, once the therapy is commercialized, could realize significant revenues, given the number of patients and blockbuster size of the market. As mentioned, BioCardia also has a "fast follower" product, CardiAMP. CardiAMP is being investigated in chronic myocardial ischemia with refractory angina (BCDA-02). The idea being that these cells can elicit neo-angiogenesis and in doing so, alleviate ischemic stress. We expect the completion of enrollment for this pivotal Phase 3 trial in the second half of 2022, which could lead to an approval and launch in early 2024. CardiALLO is expected to begin enrollment for its Phase 2 trial late next year. Similarly to CardiAMP, CardiALLO has the potential to generate significant revenues given the size of the U.S. and European markets. A third generation therapy, CardiALLO (BCDA-03), is also being planned. Its also important to note that the current pivotal trial is being financially supported by CMS, which offsets the high cost associated with running large pivotal trials in the CV space. One would argue that an organization like CMS understands the big picture, that even slight positive disease modifying therapies can have a large financial impact on lowering the cost burdens to society associated with a large population effected by cardiac disease. In our model, we risk adjust our therapeutic assessment of the opportunity by multiplying our projected revenue estimated by just 10%. That is for every potential dollar in revenue, we are counting just \$0.10¢. Bulls will understand that on good pivotal data, the potential upside here is very large.

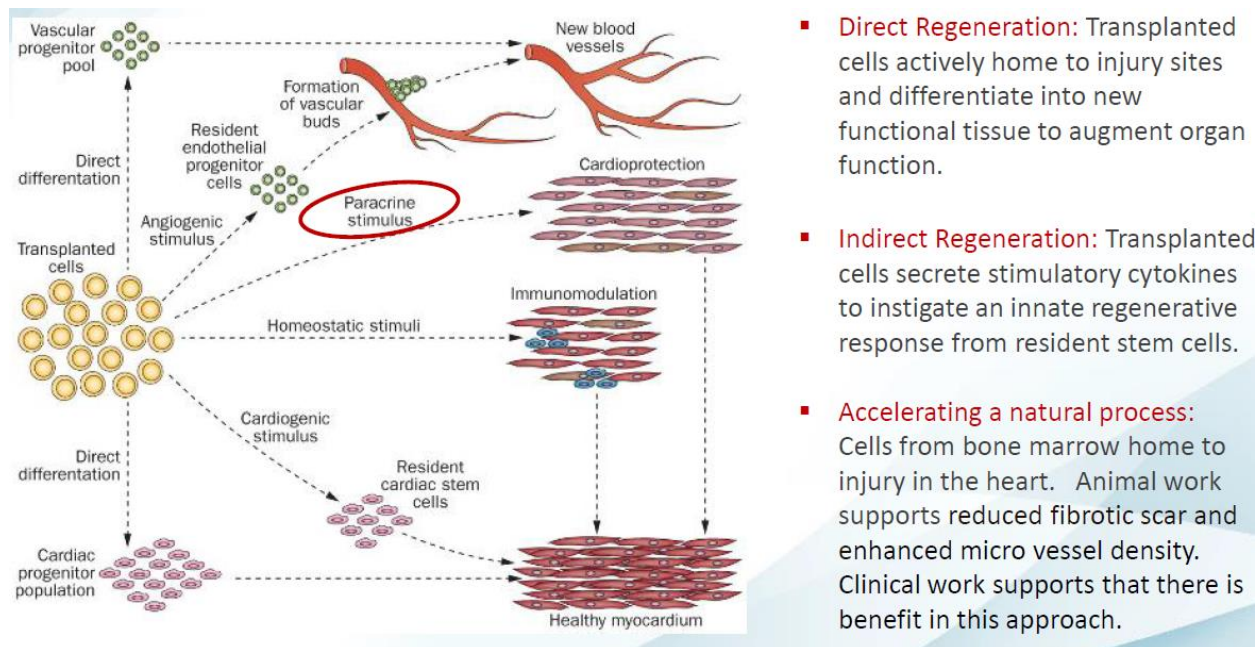
**Bear Case.** Stem cell therapy for heart failure sounds great but the reality is that we have not seen any products meet the test of pivotal trials. Other companies, such as Mesoblast (MESO: Not rated), Caladrius (CLBS: Buy Rated) are currently in pivotal trials in heart failure. Success or failure there may be viewed as a surrogate for BioCardia. While other companies, Athersys (ATHX: Buy Rated) and Cytori (CYTX: not rated), have shown promise, neither continued their program, probably as a result of limited resources and the high cost and complex trial requirements in heart. There are questions about how cells are delivered, how many cells remain in the target area, and how effective the cells really are at modifying the disease process. Cardiovascular disease itself has multiple associated comorbidities. As a result, large clinical trials are required just to zero out the variables. Enrollment is tricky too. Establishing clear criteria that work across multiple sites, in multiple geographies, can be a challenge. The odds are against drug development before the trial even begins. Compounding this is the fact that bears are skeptical on cell therapy in general and specifically for heart failure. As this is new ground, bears will argue that odds favor failure versus success based on the fact that Phase 2 proof of concept studies are just not as predictive in heart failure as they might be in other indications.

**Our Take.** CardiAMP is currently in a Phase 3 trial for heart failure, in 24 sites. The trial is supported by National Medicare reimbursement, which is cost off-setting for BioCardia. A pivotal trial in refractory angina is ready to begin enrolling patients. CardiALLO represents an allogenic fast follower to CardiAMP and may be able to leverage much of the data from that trial. One of the historical reasons for failure in this space likely relates to how cells have been delivered in the past. Principally injected in the infarct related artery or delivered in proximity to identified areas of ischemia. BioCardia's novel helix catheter appears to solve much of the historic deliver problems seen with past therapies. We add all this up and consider BioCardia with a market cap of just \$33M, and recently raised capital (\$8.7M) which now funds the company through the next major inflection points, and we conclude that the risk/reward ratio is compelling.

**Finances:** BioCardia raised capital in August, adding \$9.5M to the balance sheet (last reported cash of \$2.8 million in March). We have assumed multiple raises in our model, so our price target is based on a fully diluted out-year share forecast.

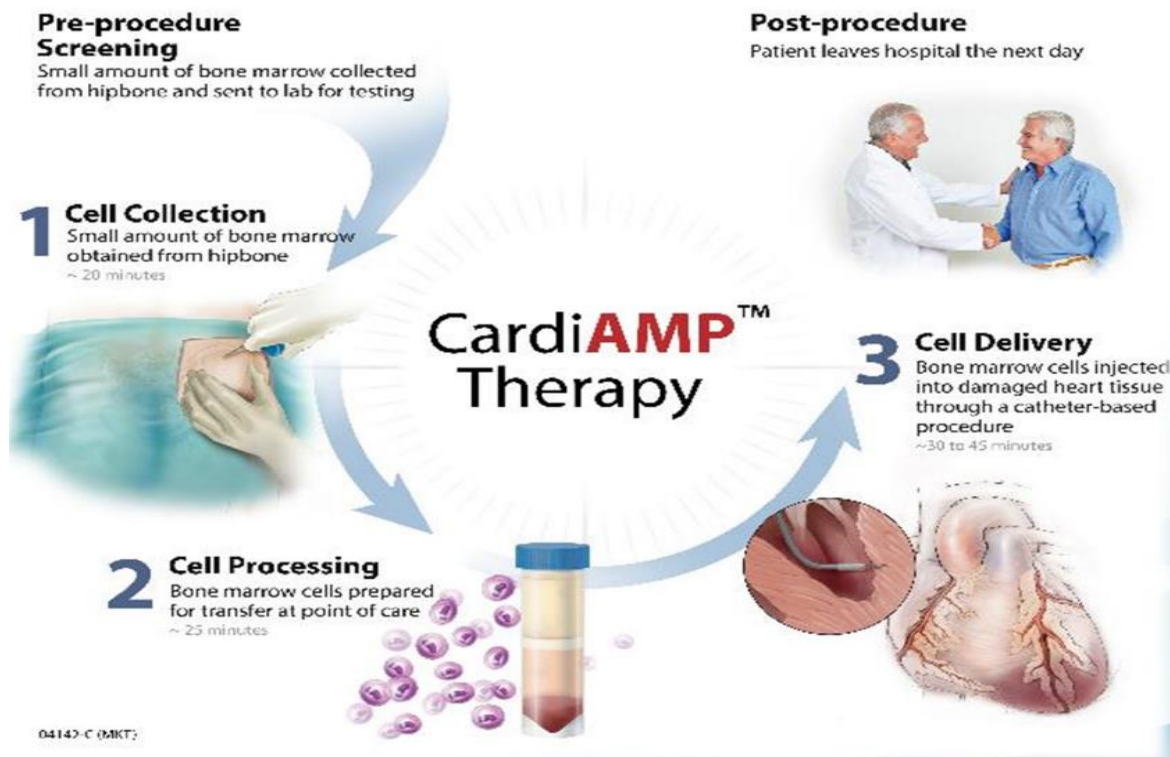


**Exhibit 4. Mechanistic basis for regeneration.** Transplanted cells are hypothesized to benefit the heart through direct and indirect pathways.



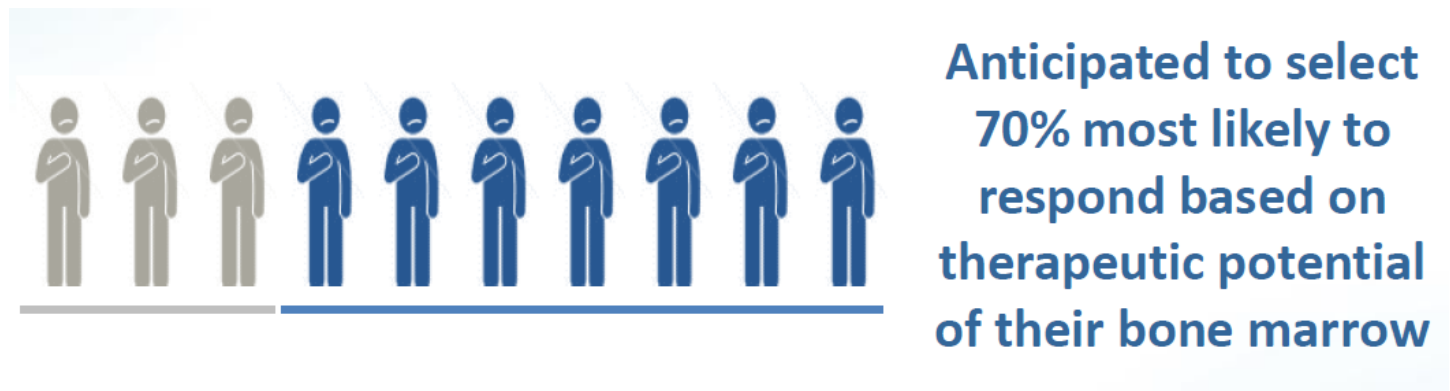
Source: BioCardia July Presentation.

**Exhibit 5. Investigational CardiAMP (Autologous Model) cell therapy system,** from collection and screening to delivery with a specialized catheter.



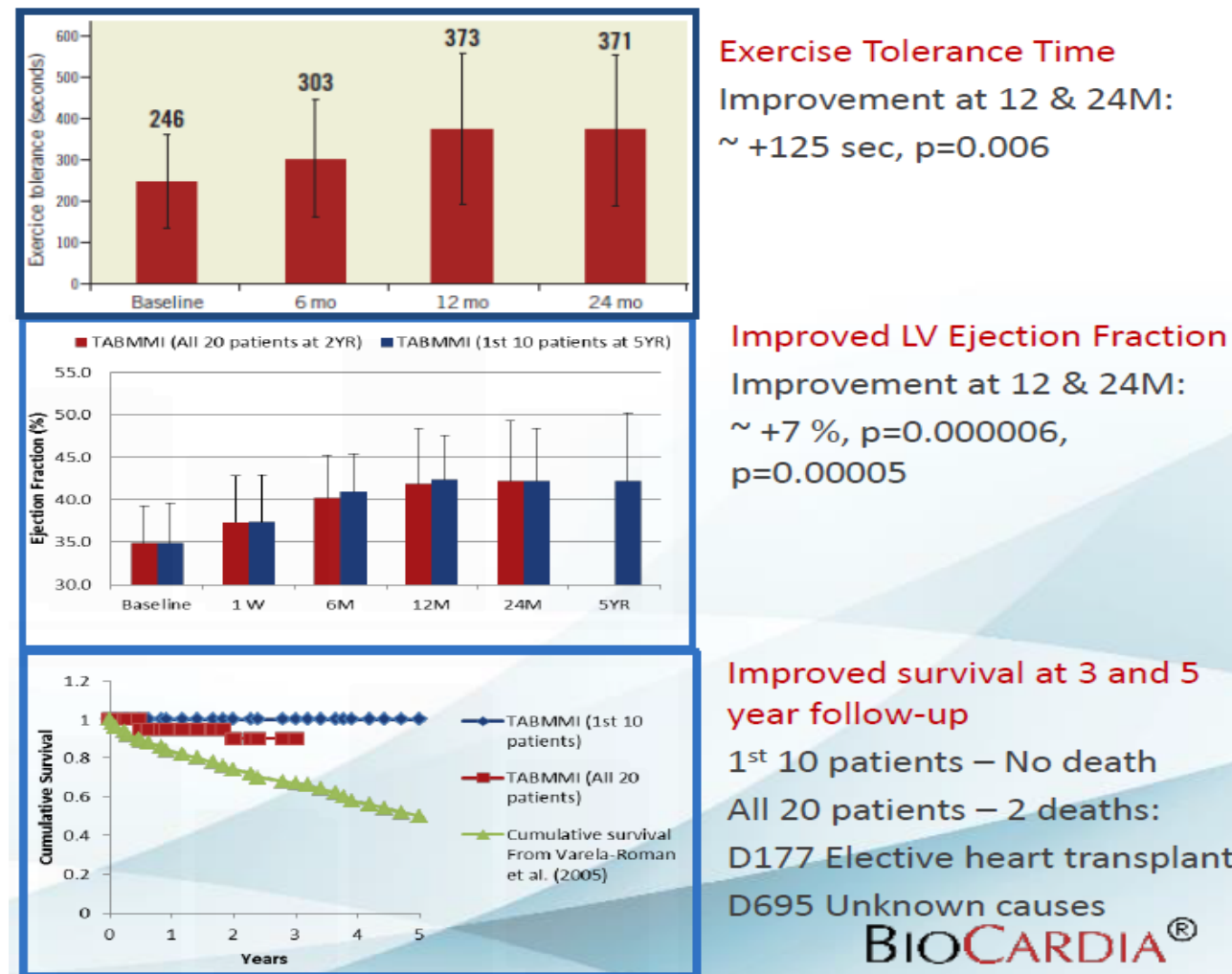
Source: BioCardia July Presentation.

**Exhibit 6. Investigational CardiAMP cell therapy system pre-procedure screening selects patients likely to respond to CardiAMP.**



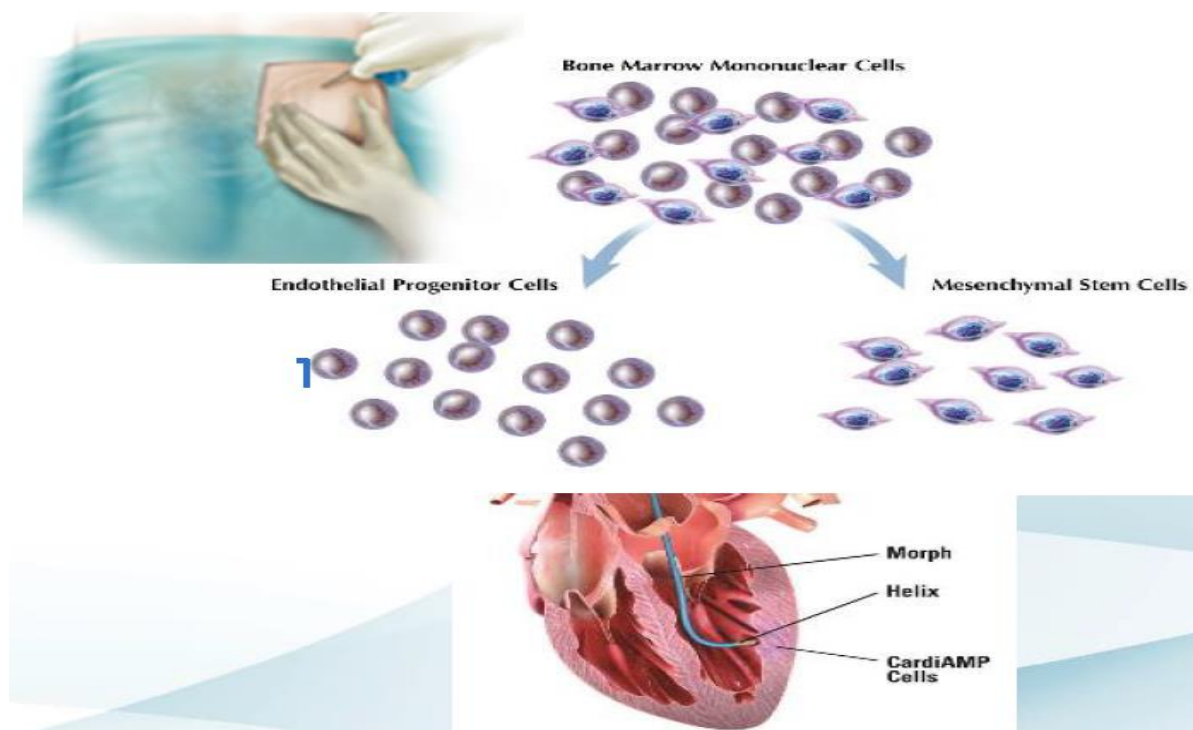
Source: BioCardia July Presentation.

**Exhibit 7. On All Key Metrics (used for approval by regulators), CardiAMP has Shown Improvement.**



Source: BioCardia July Presentation.

**Exhibit 8. Transendocardial Autologous Cells in Heart Failure Trial (TAC-HFT)**



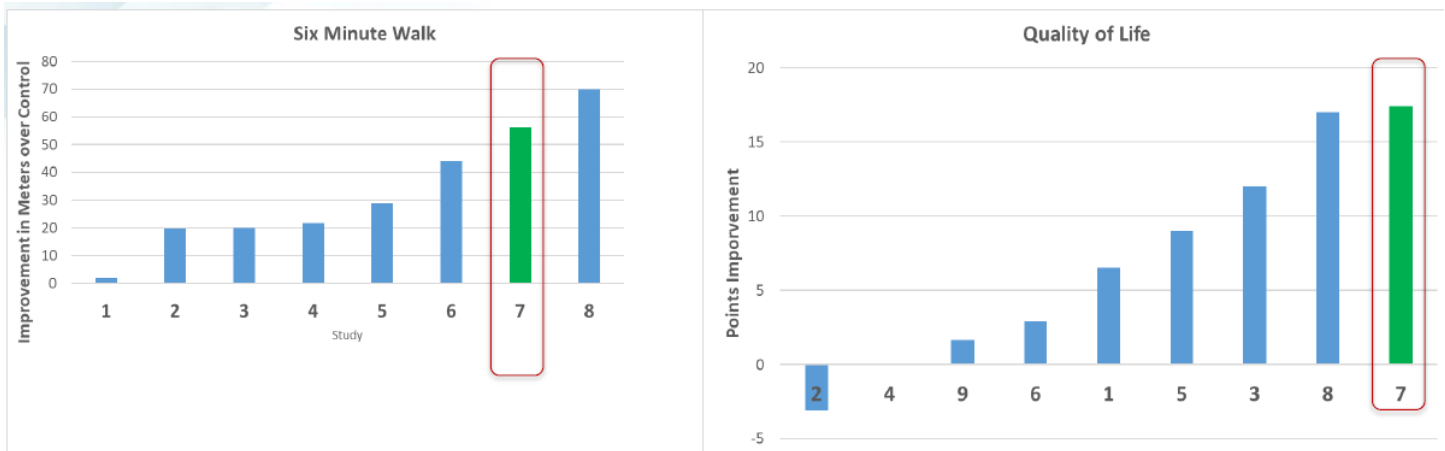
Source: BioCardia July Presentation.

**Exhibit 9. Phase 2 Placebo Controlled Randomized Trial Results: Improvement Shown in Key Metrics.**

Secondary Efficacy Endpoints	Active (Mean)	Placebo (Mean)	Treat. Difference	Favors CardiAMP Therapy	P-value
6 minute walk (meters) N=28, Mean $\pm$ St Dev	+14.3 $\pm$ 59.6	-42.0 $\pm$ 18.1	+56.3	✓	0.049
MLHF quality of life (pts) N= 29, Mean $\pm$ St Dev	-7.7 $\pm$ 17.8	+9.7 $\pm$ 24.8	-17.4	✓	0.038
Maximum Oxygen Use (mL/kg·min)	+0.16	-0.870	+1.03	✓	0.321 NS*
NY Heart Association Class	-0.42	-0.25	-0.17	✓	0.638 NS
LV End Systolic Volume (ml)	+3.2	+47.2	-44	✓	0.129 NS
LV End Diastolic Volume (ml)	+4.5	+51.2	-46.7	✓	0.149 NS
LV Ejection Fraction (%)	+0.97	-2.38	+3.35	✓	0.252 NS

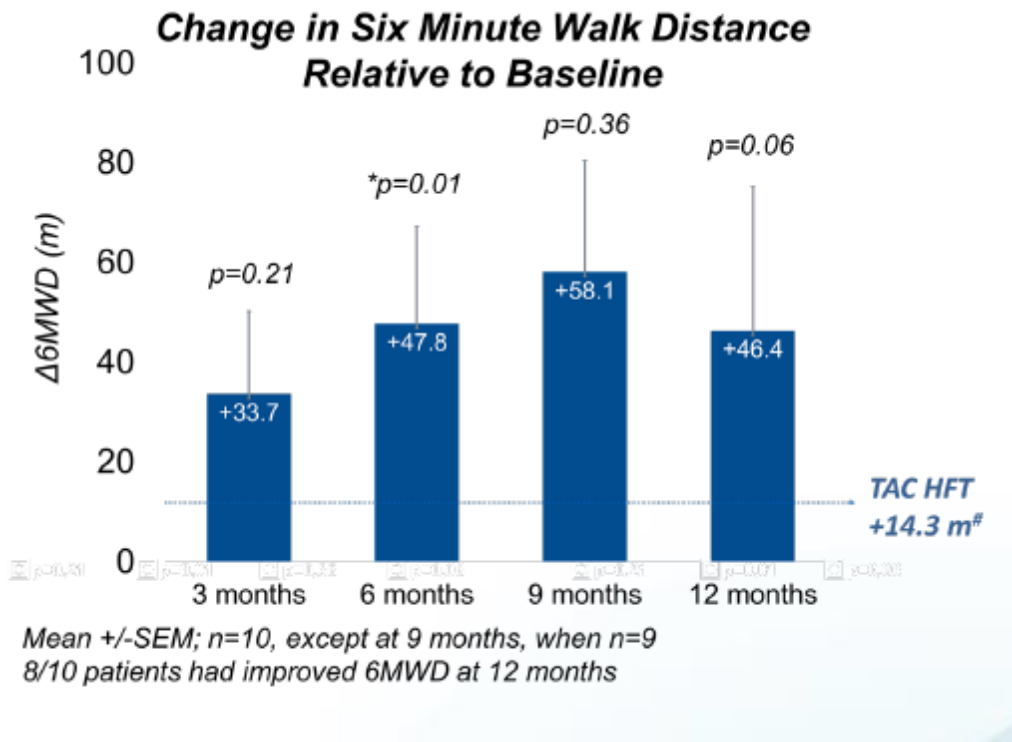
Source: BioCardia July Presentation.

**Exhibit 10. Phase 2 Efficacy Results in Six Minute Walk Relative to Other (Entresto) CRT and Heart Failure Therapies.**



Source: BioCardia July Presentation.

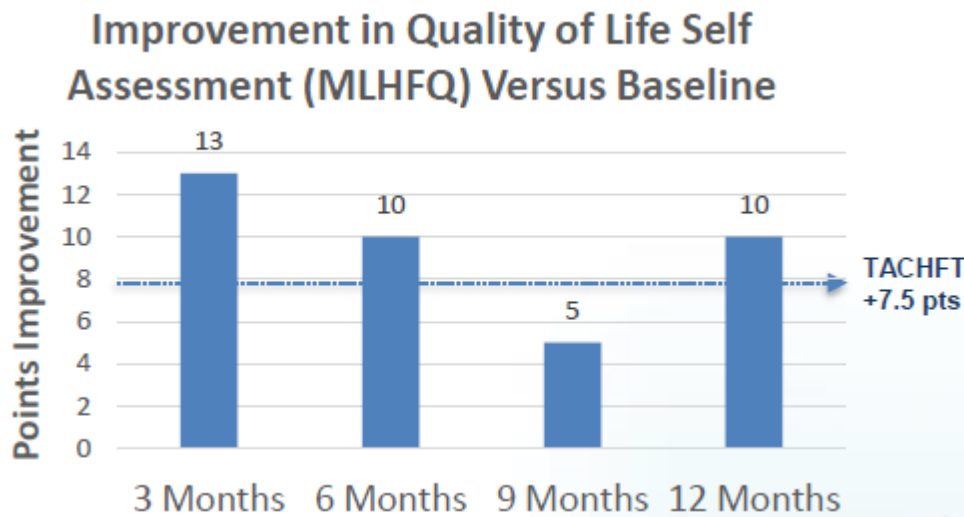
**Exhibit 11. Phase 3 : Change in Six Minute Walk Distance (relative to base line).** Data Safety Monitoring Board (DSMB) pre-specified interim analysis of safety outcomes for the first 10 patients treated in the Phase 3 trial of its investigational CardiAMP cell therapy product no significant safety concerns with the CardiAMP study results and recommended that the trial continue, as planned.



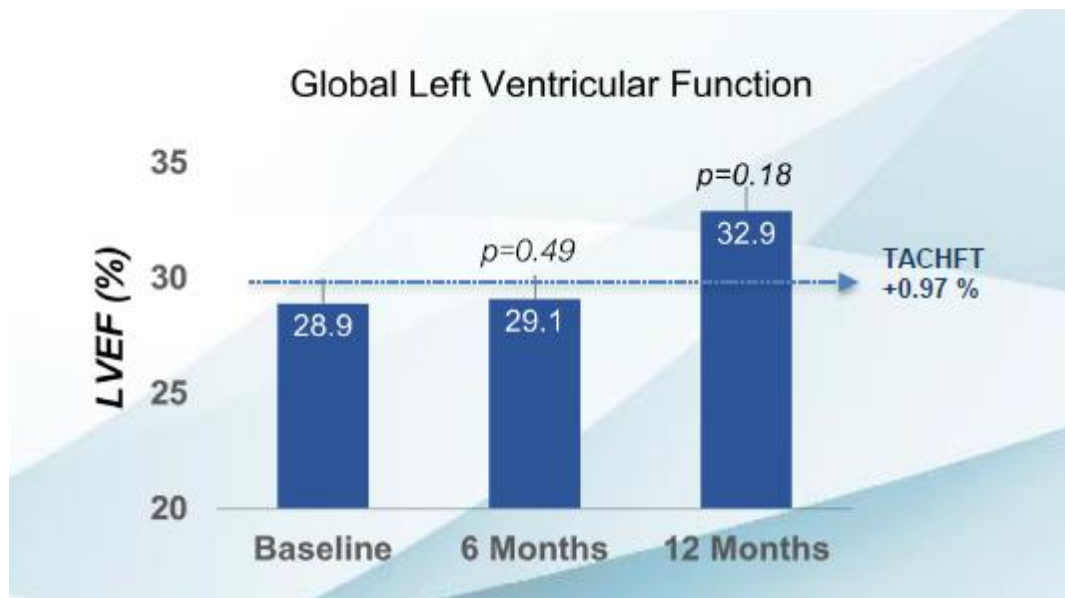
Source: BioCardia July Presentation.



**Exhibit 12. Phase 3 : QOL Measures.** Results from CardiAMP-HF Study Roll-In Phase: 12-month follow-up results compared to baseline (shown as mean  $\pm$  sem). N=10 for baseline, 3 months, and 6 months; N=9 for 9 months where one patient was hospitalized, N = 10 for 12 months. Results compared to improvements in Phase 2 TAC-HFT Study.



Source: BioCardia July Presentation.



Source: BioCardia July Presentation.

**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 EU HF markets we apply a 70% risk reduction to the net revenues, suggesting on success there is a lot of upside in our estimates.
2. We assume CardiAMP and CardiALLO will initially launch at \$50,000 per operation. Our projected market share grows over the six-year launch cycle, with CardiAMP consuming up to 25% of the total market in the year 2028 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 in 2H20, we assume standard FDA review time of 10 months with the launch in 1Q22. We expect BCDA-02 to be a fast follower with approval and launch a year after BCDA-01, in 1Q23. To adjust for the risk of approval, we apply a 70% risk cut to our CardiAMP revenue model.
4. We expect that BCDA-03 (CardiALLO) could reach the market by 2027, however, for conservatism, we apply a therapeutic risk cut of 70% in our product model. This suggests that clinical progress could make our numbers too conservative.

**Exhibit 13. Market Models:**

<b>BCDA-01 Heart Failure</b>												
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
U.S. Prevalence CHF	5,000,000	5,005,000	5,010,005	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%	0.1%	0.1%	0.1%
Candidates (Class II & III) for Therapy	500,000	500,500	501,001	501,502	502,003	502,505	503,008	503,511	504,014	504,518	505,023	505,528
Market Share Penetration	0.0%	0.0%	0.0%	2.0%	5.0%	10.0%	15.0%	20.0%	20.0%	25.0%	25.0%	25.0%
Number of Patients Procedures	0	0	0	10,030	25,100	50,251	75,451	100,702	100,803	126,130	126,256	126,382
Cost of Therapy	\$ 20,000	\$ 20,040	\$ 20,080	\$ 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%	0.2%	0.2%	0.2%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
U.S. Annual Sales (M)	\$ -	\$ -	\$ -	\$ 61	\$ 152	\$ 305	\$ 458	\$ 613	\$ 615	\$ 771	\$ 773	\$ 775
<b>BCDA-01 Heart Failure</b>												
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
E.U. Prevalence CHF	9,000,000	9,009,000	9,018,009	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%	0.1%	0.1%	0.1%
Candidates (Class II & III) for Therapy	900,000	900,900	901,801	902,703	903,605	904,509	905,414	906,319	907,225	908,132	909,041	909,950
Market Share Penetration	0.0%	0.0%	0.0%	0	0	0	2.0%	6.0%	10.0%	15.0%	20.0%	20.0%
Number of Patients Procedures	0	0	0	0	0	0	18,108	54,379	90,723	136,220	181,808	181,990
Cost of Therapy	\$ 30,000	\$ 30,060	\$ 30,120	\$ 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%	0.2%	0.2%	0.2%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
U.S. Annual Sales (M)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 165	\$ 496	\$ 830	\$ 1,248	\$ 1,669	\$ 1,674
<b>BCDA-02 Heart Failure</b>												
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
U.S. Prevalence CHF	5,000,000	5,075,000	5,151,125	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%	1.5%	1.5%	1.5%
Candidates (Chronic Myocardial Ischemia) for Therapy	200,000	203,000	206,045	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%	0.0%	0.0%	2.0%	5.0%	10.0%	15.0%	20.0%	25.0%	25.0%	25.0%
Number of Patients Procedures	0	0	0	0	4,245	10,773	21,869	33,295	45,060	57,169	68,027	78,897
Cost of Therapy	\$ 20,000	\$ 20,040	\$ 20,080	\$ 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%	0.2%	0.2%	0.2%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
U.S. Annual Sales (M)	\$ -	\$ -	\$ -	\$ -	\$ 26	\$ 65	\$ 133	\$ 203	\$ 275	\$ 349	\$ 355	\$ 361
<b>BCDA-02 Heart Failure</b>												
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
E.U. Prevalence CHF	9,000,000	9,072,000	9,144,576	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
Market Size Growth (Annual)	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%	0.8%
Candidates (Chronic Myocardial Ischemia) for Therapy	495,000	498,960	502,952	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%	0	0	2.0%	6.0%	10.0%	15.0%	20.0%	20.0%
Number of Patients Procedures	0	0	0	0	0	0	10,385	31,404	52,758	79,770	107,211	108,069
Cost of Therapy	\$ 30,000	\$ 30,060	\$ 30,120	\$ 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%	0.2%	0.2%	0.2%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
U.S. Annual Sales (M)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 95	\$ 287	\$ 482	\$ 731	\$ 984	\$ 994
<b>BCDA-03 Heart Failure</b>												
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
U.S. Prevalence CHF	5,000,000	5,005,000	5,010,005	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%	0.1%	0.1%	0.1%
Candidates (Class II & III) for Therapy	150,000	150,150	150,300	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%	0.0%	0.0%	0.0%	2.0%	5.0%	10.0%	15.0%
Number of Patients Procedures	0	0	0	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%	0.2%	0.2%	0.2%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
U.S. Annual Sales (M)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 20	\$ 51	\$ 103	\$ 154
<b>BCDA-03 Heart Failure</b>												
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
E.U. Prevalence CHF	9,000,000	9,009,000	9,018,009	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%	0.1%	0.1%	0.1%
Candidates (Class II & III) for Therapy	270,000	270,270	270,540	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%	0.0%	0.0%	0.0%	2.0%	5.0%	10.0%	15.0%
Number of Patients Procedures	0	0	0	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%	0.2%	0.2%	0.2%
Probability of Success	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
U.S. Annual Sales (M)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 48	\$ 121	\$ 242	\$ 365

Source: Dawson James Estimates

**Valuation.** We value BioCardia based on the revenues in our product models, which are reduced by 70% rate cut or a 30% probability of success. This suggests we are leaving a lot of upside in our estimates on good data. We apply assumptions for FDA product approvals, launch dates, and product attributes to estimate revenues. These estimates feed into our income statement through the year 2030. Our price target is derived from an equal-weighted average of free cash flow (FCFF), discounted EPS (EPS), and sum-of-the-parts (SOP) models. For companies that are well established with mature products and revenues, we typically discount at a 10% rate, for companies in the early stages of product commercialization we typically use a higher rate, 15%. For BioCardia, we use a 30% risk rate as the company is not yet profitable. This risk rate is in addition to the therapeutic cut (70%) in our product models. The result of this methodology is a price target of \$24.00 per share.

#### Exhibit 14. Discounted Free Cash Flow Model

Average \$ 24

Price Target \$ 23  
Year 2019

##### DCF Valuation Using FCF (mln):

units ('000)	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(15,110)	(14,975)	(15,724)	14,670	100,982	243,623	610,948	994,814	1,731,539	2,543,011	3,258,277	3,413,956
Tax Rate	0%	0%	0%	10%	18%	20%	24%	24%	24%	28%	30%	34%
EBIT(1-t)	(15,110)	(14,975)	(15,724)	13,203	82,805	194,898	464,321	756,059	1,315,969	1,830,968	2,280,794	2,253,211
CapEx												
Depreciation	101	-	-	-	-	-	-	-	-	-	-	-
Change in NWC												
FCF	(15,009)	(14,975)	(15,724)	13,203	82,805	194,898	464,321	756,059	1,315,969	1,830,968	2,280,794	2,253,211
PV of FCF	(5,255)	(4,033)	(3,258)	2,104	10,151	18,379	33,681	42,187	161,324	172,660	165,445	125,726
Discount Rate	30%											
Long Term Growth Rate	1%											
Terminal Cash Flow	7,847,389											
Terminal Value YE2030	437,873											
NPV	1,156,983											
NPV-Debt	1,016											
Shares out (thousands)	50,677	2030E										
NPV Per Share	\$ 23											

Source: Dawson James estimates.

Source: Dawson James

#### Exhibit 15. EPS Model

Current Year	2019
Year of EPS	2030
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 44.46
NPV	\$ 25.00

Source: Dawson James estimates.

Discount Rate and Earnings Multiple Varies, Year is Constant							
Earnings Multiple	2030 EPS						
		5%	10%	15%	20%	25%	30%
	0	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$ -
	5	\$42.00	\$25.00	\$16.00	\$10.00	\$6.00	\$ 4.00
	10	\$84.00	\$51.00	\$31.00	\$19.00	\$12.00	\$ 8.00
	15	\$127.00	\$76.00	\$47.00	\$29.00	\$19.00	\$ 12.00
	20	\$169.00	\$101.00	\$62.00	\$39.00	\$25.00	\$ 16.00
	25	\$211.00	\$126.00	\$78.00	\$49.00	\$31.00	\$ 20.00
	30	\$253.00	\$152.00	\$93.00	\$58.00	\$37.00	\$ 24.00
	35	\$295.00	\$177.00	\$109.00	\$68.00	\$43.00	\$ 28.00

Source: Dawson James

#### Exhibit 16. Sum-of-the-Parts Model

BioCardia	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales MMs	Term Val
BCDA-01 CardiAMP cell therapy US	1%	30%	3	30%	\$2,584	\$8,910
NPV						\$9.60
BCDA-01 CardiAMP cell therapy US	1%	30%	3	30%	\$5,581	\$19,245
NPV						\$20.74
BCDA-02 CardiALLO cell therapy US	1%	30%	4	30%	\$1,204	\$4,152
NPV						\$3.44
BCDA-02 CardiALLO cell therapy EU	1%	30%	4	30%	\$3,314	\$11,428
NPV						\$9.47
BCDA-03 CardiALLO cell therapy US	1%	50%	5	30%	\$515	\$1,051
NPV						\$0.33
BCDA-02 CardiALLO cell therapy EU	1%	50%	5	30%	\$1,215	\$2,480
NPV						\$0.77
Net Margin						40%
MM Shrs OS (2030E)						51
Total						\$24

Source: Dawson James

**Risk Analysis**

In addition to the typical risks associated with development stage specialty pharmaceutical companies, potential risks specific to BioCardia are as follows:

**Partnership risk.** The company is also expected to make agreements with partners for additional products, but there can be no assurances that the company will be able to secure favorable partnerships.

**Commercial risk.** There are no assurances that the company will be able to achieve significant sales, market share, or become profitable.

**Clinical and regulatory risk.** Lead products need to complete clinical trials. It is difficult to complete enrollment which could lead to a delay of the trial. Trials may not produce the results expected from previous research or be sufficient for regulatory approval.

**Financial risk.** The company may need to raise capital in the marketplace, and there can be no assurances that the company will be able to successfully raise capital and or do so, at favorable terms.

**Legal and intellectual property risk.** The company may have to defend its patents and technical know-how, and there can be no assurances that the patents will not be infringed or will be held as valid if challenged, and or that the company may infringe on third parties' patents.



## Exhibit 17. Income Statement

Biocardia Inc: Income Statement (\$000)																	
BCDA: YE December	2018A	1Q19A	2Q19A	3Q19E	4Q19E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Net product revenue	282	76	62	75	78	300	315	331									
Collaboration agreement revenue	343	140	24	25	25	214	225	236									
BCDA-01 CardiaAMP Cell Therapy revenues US						0	0	0	60,542	151,809	304,530	458,166	612,723	614,562	770,509	772,822	775,142
BCDA-01 CardiaAMP Cell Therapy revenues EU									0	0	0	164,940	496,305	829,659	1,248,224	1,669,295	1,674,306
BCDA-02 CardiaAMP Cell Therapy revenues US										25,677	65,286	132,796	202,586	274,714	349,241	355,188	361,237
BCDA-02 CardiaAMP Cell Therapy revenues EU										-	-	94,590	28,661	482,474	730,959	984,374	994,234
BCDA-03 CardALLO Cell Therapy revenues US													-	20,413	51,185	102,677	154,477
BCDA-03 CardALLO Cell Therapy revenues EU													-	48,174	120,796	242,317	364,566
<b>Total Product Sales</b>	<b>625</b>	<b>216</b>	<b>86</b>	<b>100</b>	<b>103</b>	<b>505</b>	<b>540</b>	<b>567</b>	<b>60,542</b>	<b>177,486</b>	<b>369,816</b>	<b>850,492</b>	<b>1,340,275</b>	<b>2,269,995</b>	<b>3,270,913</b>	<b>4,126,672</b>	<b>4,323,962</b>
<b>Product Sales &amp; Royalties &amp; Milestones</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>60,542</b>	<b>177,486</b>	<b>369,816</b>	<b>590,962</b>	<b>815,308</b>	<b>957,862</b>	<b>1,291,730</b>	<b>1,473,003</b>	<b>1,655,422</b>
<b>Expenses</b>																	
Cost of goods sold	517	106	191	136	141	543	162	170	18,163	44,372	92,454	204,118	308,263	499,399	686,892	825,334	864,792
							30%	30%	30%	25%	25%	24%	23%	22%	21%	20%	20%
Research and Development	8,453	2,166	2,219	2,219	2,308	8,876	9,319	9,785	10,275	10,788	11,328	11,894	12,489	13,113	13,769	14,457	15,180
Selling, general and administrative	5,757	1,631	1,438	1,511	1,572	6,045	6,347	6,664	18,000	22,000	23,100	24,255	25,468	26,741	28,078	29,482	30,956
<b>Total expenses</b>	<b>14,727</b>	<b>3,903</b>	<b>3,848</b>	<b>3,866</b>	<b>4,020</b>	<b>15,637</b>	<b>15,515</b>	<b>16,291</b>	<b>45,872</b>	<b>76,504</b>	<b>126,193</b>	<b>239,544</b>	<b>345,461</b>	<b>538,456</b>	<b>727,902</b>	<b>868,395</b>	<b>910,006</b>
Operating income (Loss)	(14,102)	(3,687)	(3,762)	(3,766)	(3,917)	(15,132)	(14,975)	(15,724)	14,670	100,982	243,623	610,948	994,814	1,731,539	2,543,011	3,258,277	3,413,956
Interest expense																	
Interest Income	118	23	23	23	23	23											
Other expense	(3)	(1)	(1)	(1)	(1)	(1)											
<b>Total other income</b>	<b>115</b>	<b>22</b>	<b>(1)</b>	<b>(1)</b>	<b>(1)</b>	<b>(1)</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Pretax Income</b>	<b>(13,987)</b>	<b>(3,665)</b>	<b>(3,740)</b>	<b>(3,744)</b>	<b>(3,895)</b>	<b>(15,110)</b>	<b>(14,975)</b>	<b>(15,724)</b>	<b>14,670</b>	<b>100,982</b>	<b>243,623</b>	<b>610,948</b>	<b>994,814</b>	<b>1,731,539</b>	<b>2,543,011</b>	<b>3,258,277</b>	<b>3,413,956</b>
Income Tax Benefit (Provision)									1,467	18,177	48,725	146,628	238,755	415,569	712,043	977,483	1,160,745
<b>Tax Rate</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<b>10%</b>	<b>18%</b>	<b>20%</b>	<b>24%</b>	<b>24%</b>	<b>24%</b>	<b>28%</b>	<b>30%</b>	<b>34%</b>
<b>GAAP Net Income (loss)</b>	<b>(13,987)</b>	<b>(3,665)</b>	<b>(3,740)</b>	<b>(3,744)</b>	<b>(3,895)</b>	<b>(15,110)</b>	<b>(14,975)</b>	<b>(15,724)</b>	<b>13,203</b>	<b>82,805</b>	<b>194,898</b>	<b>464,321</b>	<b>756,059</b>	<b>1,315,969</b>	<b>1,830,968</b>	<b>2,280,794</b>	<b>2,253,211</b>
Deemed Dividend on Preferred Stock																	
<b>GAAP-EPS</b>	<b>(0.37)</b>	<b>(0.08)</b>	<b>(0.77)</b>	<b>(0.56)</b>	<b>(0.42)</b>	<b>(0.94)</b>	<b>(1.03)</b>	<b>(0.63)</b>	<b>0.50</b>	<b>3.12</b>	<b>7.32</b>	<b>17.37</b>	<b>28.17</b>	<b>48.84</b>	<b>67.68</b>	<b>83.97</b>	<b>82.62</b>
GAAP EPS (dil)	(0.37)	(0.08)	(0.77)	(0.43)	(0.28)	(0.85)	(0.60)	(0.34)	0.27	1.68	3.94	9.35	15.16	26.28	36.42	45.19	44.46
Weighted shares basic	38,285	43,629	4,848	6,700	9,207	16,096	14,485	25,060	26,414	26,519	26,626	26,732	26,839	26,947	27,055	27,163	27,272
Weighted shares dil	38,285	43,629	4,848	8,700	13,709	17,721	25,004	46,388	49,082	49,278	49,476	49,674	49,873	50,073	50,273	50,475	50,677

Source: Dawson James estimates.

Companies mentioned in this report:

Athersys (ATHX): Buy Rated

Cytori (CYTX): Not Covered

Caladrius (CLBS): Buy rated

Mesoblast (MESO): Not Covered

## **Important Disclosures:**

### **Price Chart:**



### **Price target and ratings changes over the past three years:**

Initiated – Buy – September 17, 2019 – Price Target \$24.00

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The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

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<b>Ratings Distribution</b>	<b># of Companies</b>	<b>% of Total</b>	<b># of Companies</b>	<b>% of Totals</b>
Market Outperform (Buy)	26	84%	5	19%
Market Perform (Neutral)	5	16%	0	0%
Market Underperform (Sell)	0	0%	0	0%
<b>Total</b>	<b>31</b>	<b>100%</b>	<b>5</b>	<b>16%</b>

*Accurate as of 9.17.19*

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