BIOCARDIA®

Developing cellular and cell-derived therapeutics for the treatment of cardiovascular and pulmonary diseases

Corporate Presentation
BioCardia, Inc. (NASDAQ: BCDA)

Peter Altman, PhD
President and CEO
paltman@biocardia.com

www.biocardia.com

Presentation Content and Disclaimer

Presentation Content

No part of this presentation or the information herein may be reproduced, photocopied, redistributed or passed on, directly or indirectly, to any other person, or published, in whole or in part, for any purpose without the consent of BioCardia, Inc.

Disclaimer

This presentation contains forward-looking statements that are subject to many risks and uncertainties. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from current expectations and beliefs. These factors include, but are not limited to, those found in our documents filed with the Securities and Exchange Commission, including our recent filings on Form 8-K, Form 10-K and Form 10-Q, particularly any statements under the caption entitled “Risk Factors” therein. Any forward-looking statements contained in this presentation speak only as of the date hereof, and the Company specifically disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

We own or have rights to various trademarks, service marks and trade names that it uses in connection with the operation of its business. This presentation also contains trademarks, service marks, trade names and copyrights of third parties, which are the property of their respective owners. The use or display of third parties’ trademarks, service marks, trade names or products in this presentation is not intended to, and does not imply, a relationship with us, or an endorsement or sponsorship by or of us. Solely for convenience, the trademarks, service marks, trade names and copyrights referred to in this presentation may appear without the TM, SM, ® or © symbols, but such references are not intended to indicate, in any way, that we, or the any third-party will not assert, to the fullest extent under applicable law, their rights or the right of the applicable licensor to these trademarks, service marks, trade names and copyrights.

The market data contained herein is derived from various internal and external sources. All of the market data in the presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Further, no representation is made as to the reasonableness of the assumptions made within or the accuracy or completeness of any projections or modeling or any other information contained herein. Any data on past performance or modeling contained herein is not an indication as to future performance. We assume no obligation to update the information in this presentation.

Executive Summary

Late-Stage Cell and Cell Derived Biotherapeutics for Cardiac and Pulmonary Diseases

- **CardiAMP® cell therapy for ischemic heart failure with TAM of > $17.5 Billion in USA[1].**
  - Granted FDA breakthrough designation and CMS reimbursement at $17,500 per procedure in place.
  - CardiAMP-HF Phase 3 trial showed increased survival and reduced major adverse cardiac and cerebrovascular events observed study-wide.
  - Statistically significant and clinically meaningful improvement in patients with elevated NTproBNP, p=0.026.
  - Seeking regulatory approval based on current data in USA and Japan for these patients and advancing confirmatory study in USA.

- **Three additional clinical stage cell therapy programs addressing large markets.**
  - CardiAMP in chronic myocardial ischemic, CardiALLO™ in ischemic heart failure and PulmAllo™ in Acute Respiratory Distress (for partnering)

- **Helix™ biotherapeutic delivery platform and enabling Morph DNA steerable introducers.**
  - Provides for minimally invasive targeted delivery of biologic agents to the heart. Potential for revenues and meaningful royalties under existing partnership agreements.
  - Expect to file for FDA approval in Q3 2025.

- **Heart3D™ Fusion Imaging to Enhance Biotherapeutic Delivery and Biopsy Procedures**

- **Operations**
  - Device manufacturing in house with FDA 2023 audit having no observations.
  - Cell manufacturing in house licensed for clinical drug manufacturing.

[1] Martin et al 2024 Heart Disease and Statistics; CMS Code C9782

BIOCARDIA®

Problem: Heart failure, a disease with enormous unmet need

- Affects more than **56.2 million people** worldwide [1], with **50% mortality at five years** [2].
- No existing therapies are curative, they currently only slow disease progression.
- Recent data shows newer meds only reduce mortality by 0.6%/year (sodium-glucose cotransporter-2 inhibitors)[2] and 0.6%/year (sacubitril/valsartan)[3].

Heart Failure in the United States [1]

- The CDC reported that heart failure was a contributing cause of 1 in 8 deaths
- Projected to increase to $70 billion in 2030, half related to hospitalization. LVADs and heart transplant end-stage treatment options cost in excess of $250,000 per procedure.
- ~ **1 million patients** with ischemic NYHA II & III are believed to have potent cells for therapy. [1, 4, 5]
- Total Addressable Market = $17.5B based on current reimbursement. [1,4,5,6]

Characterized by a large spherical heart that has lost pumping capacity.

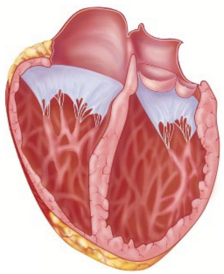
Sources of data:
1. Martin et al 2024 Heart disease and statistics from the American Heart Association
2. EMPOROR -Reduced Trial, NEJM, 2020.
3. PARADIGM-HF, NEJM, 2014.
4. Vedin 2017 Significance of Ischemic Heart Disease in Patients With Heart Failure and Preserved, Midrange, and Reduced Ejection Fraction
5. Results from CardiAMP HF I Trial
6. CMS Code C9782

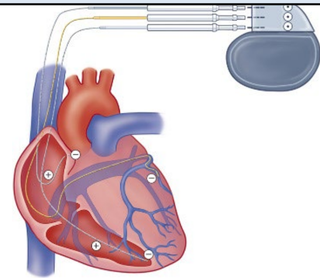
BIOCARDIA®

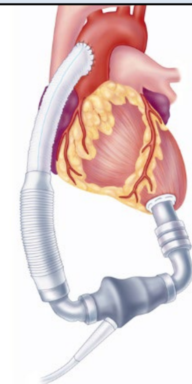
Current Options for Patients - Expensive, Unable to Heal Failing Hearts

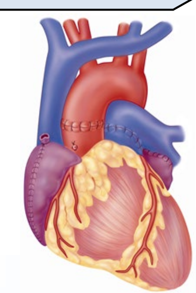
Demonstrating a reduction in mortality without replacing the heart remains a challenge in heart failure.

Class I, II. & III → Class III → Class IV









Medications
- Beta-Blockers
- Mineralocorticoid receptor antagonists
- Angiotensin receptor–neprilysin inhibitors
- Sodium–glucose cotransporter-2 inhibitors

Devices
- CRT & CRT-D
- Mitral valve repair/replacement
- Pressure monitoring

Hemodynamic Support
- IV Inotropes
- Left Ventricular Assist Devices (LVAD)

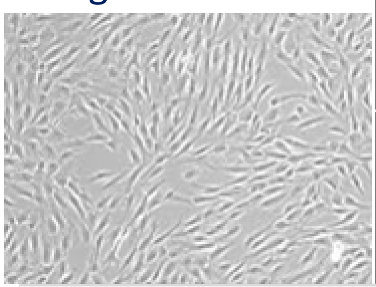
Transplantation (Tx)
- Immuno-suppression

Images from Cleveland Clinic

BIOCARDIA®

Developing solutions: Therapeutic Product Pipeline

Autologous and allogeneic cells for cardiac and pulmonary disease
Supported by best-in-class interventional biotherapeutic delivery.

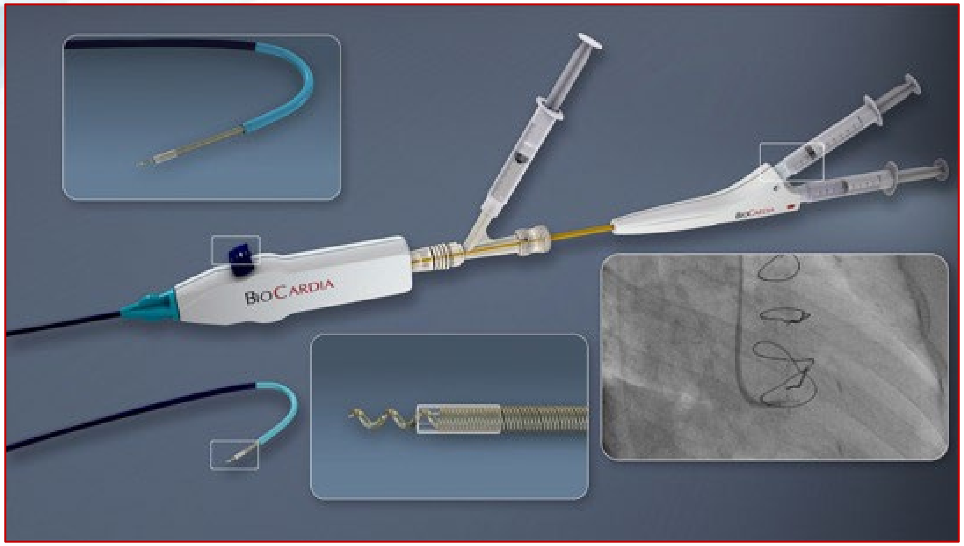
Therapeutic Platform	Candidate	Preclinical	Phase 1	Phase 2	Phase 3
Autologous Mononuclear Cells 	**CardiAMP® HF** BCDA-01 Δ	**Ischemic Heart Failure TAM = $17B FDA Breakthrough Designation; CMS Reimbursement**			
	CardiAMP® CMI BCDA-02 Δ	**Chronic Myocardial Ischemia TAM = $8B CMS Reimbursement**			
Allogeneic MSC 	**CardiALLO™ HF** BCDA-03Ψ	**Ischemic Heart Failure TAM = $17B**			
	PulmALLO™ ARDS BCDA-04Ψ	**Acute Respiratory Distress Syndrome**	IND approved but not active.		

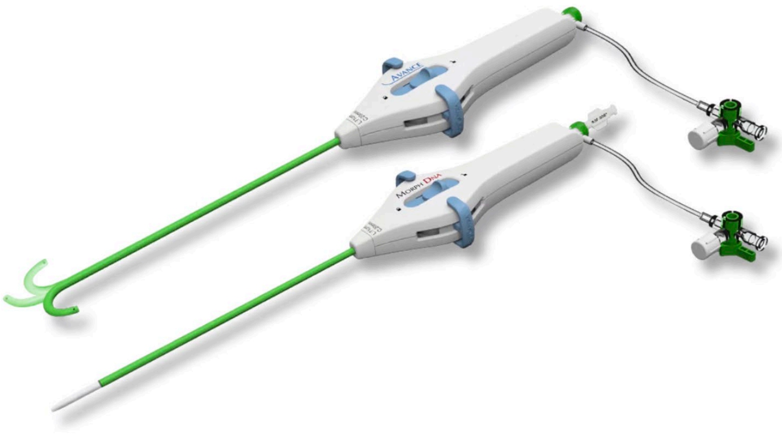
Δ = Regulated by CBER through IDE/PMS Pathway in USA
Ψ = Regulated by CBER through IND/BLA Pathway in USA

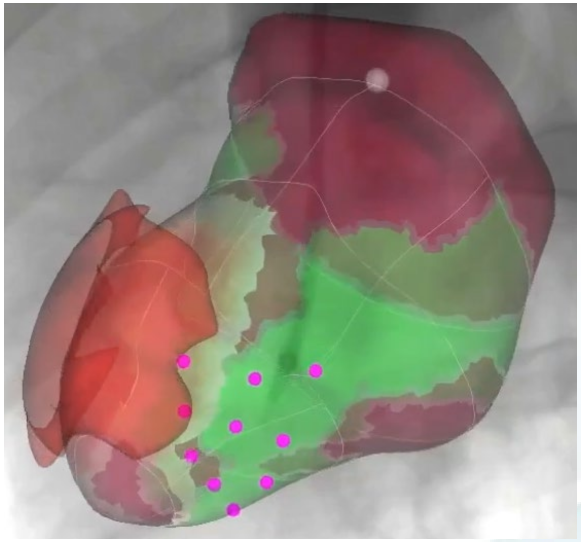
BIOCARDIA®

Biotherapeutic Delivery: Helix™, Morph®, and Heart3D™

Empowering a seamless transition from bench to commercialization for partners.







Partners:

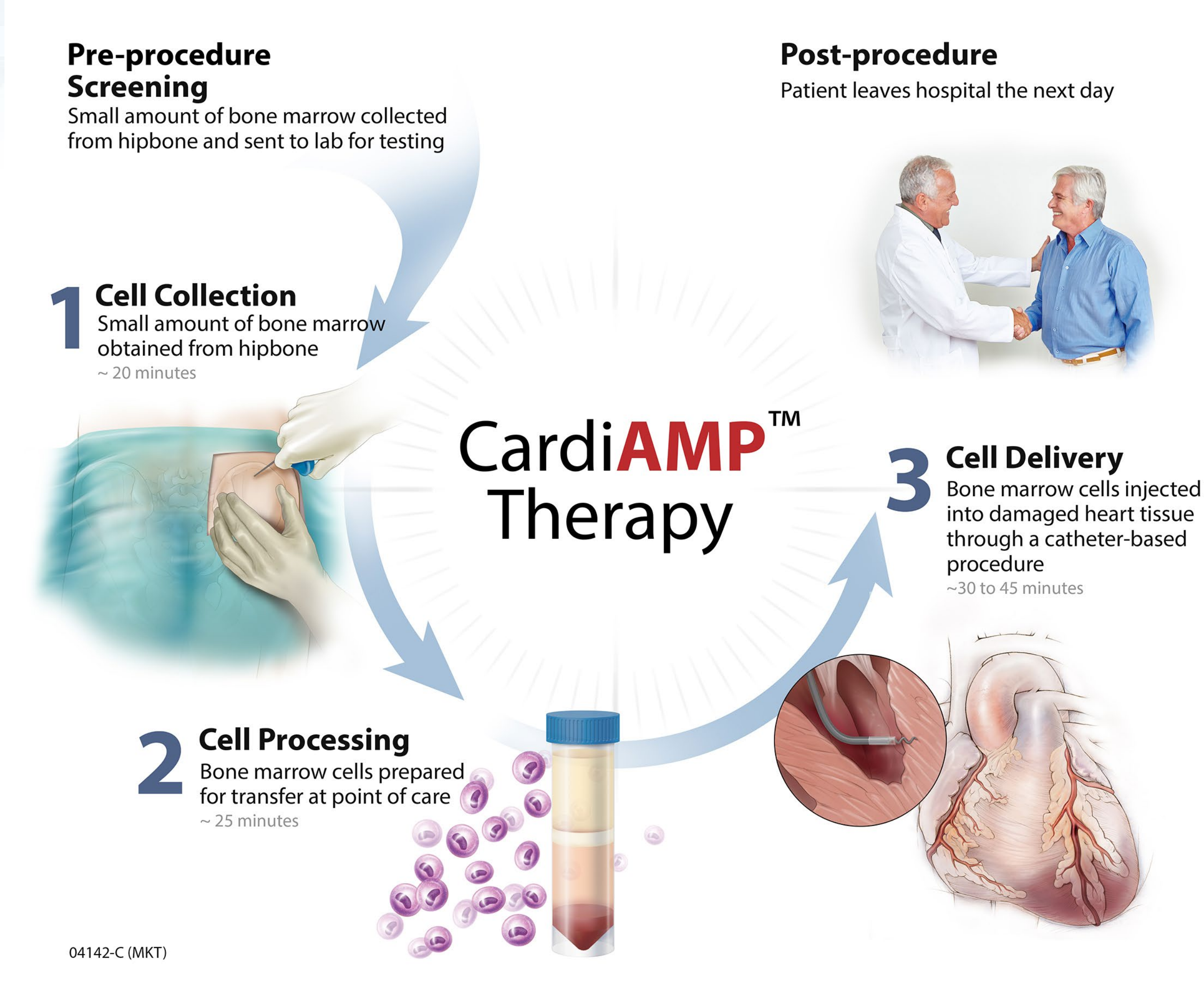
CELLPROTHERA DISCOVERY CELL CULTURE TRANSPLANT

STEMCARDIA

CART-TECH

BIOCARDIA®

Potential Solution: CardiAMP Cell Therapy For ischemic HFrEF (BCDA-01)

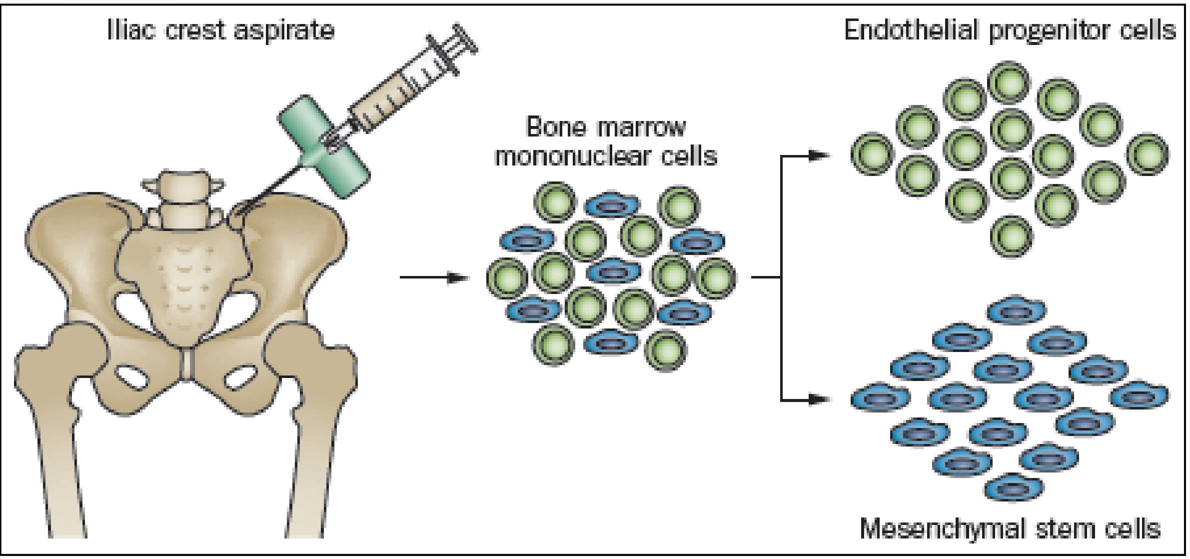


FDA CBER regulated as device system.

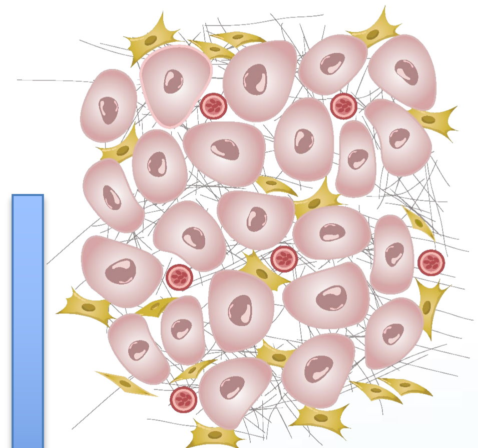
Medicare reimbursement established for two pivotal trials.

BIOCARDIA®

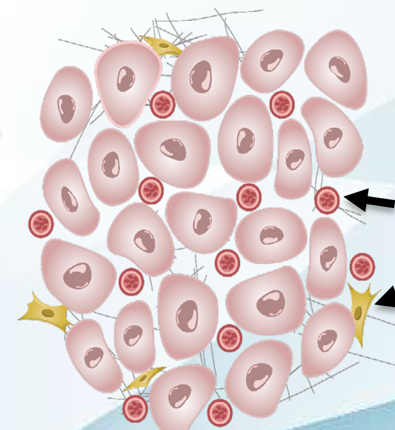
CardiAMP Cell Therapy Mechanism of Action



Pre therapy



Post therapy



2X Increased Capillary Density

80% Decreased Fibrosis

Silva et al. Tex Heart Inst J (2011);38(3):219-24.

Takahashi, M. et al. (2006) Am J Physiol Heart Circ 291:H886-H893.

CardiAMP Cell Therapy is a Significant Advance

The 1st cardiac cell therapy that combines a pre-procedural assay, point of care cell processing system and transendocardial delivery system.

How is it unique from other cardiac cell therapies?

- **Precision Medicine Dx**
- **High Dose**
- **Efficient Delivery**
- **Autologous AND cost effective**

1 Raval et al, Cardiovascular Revascularization Medicine (2020).
2 Mitsutake et al, Int. Heart J. (2017).

CardiAMP HF Current Status

FDA Breakthrough Device Designation granted based on results from trials to date.

CMS Reimbursement Code C9782 for CardiAMP Cell Therapy for both treated and control patients for Calendar Year (CY) 2025, is assigned to APC 1590 (New Technology – Level 39: $15,001–$20,000) with a payment rate of $17,500.50.

TABMMI Ph I Cell Therapy Trial

Open label : Results in 20 patients at two years: no safety concerns, improvement in exercise tolerance and heart function. [1]

TAC-HFT Ph II Cell Therapy Trial

Randomized placebo-controlled trial (RPCT): Results in 33 patients at one year: no safety concerns, improvement in exercise tolerance and quality of life. All outcomes favor therapy relative to dedicated placebo. [2, 3]

CardiAMP HF Ph III Cell Therapy Trial

RPCT: Results 125 patients at two years: no safety concerns. Reduced MACCE for duration of trial. Missed primary endpoint. **Subgroup with NTproBNP>500pg/ml all outcomes favor therapy relative to control with composite endpoints p=0.07 and p=0.02.**[4] See backup slides.

CardiAMP HF II Ph III Cell Therapy Trial

RPCT: confirmatory 250 patient trial, reimbursed by CMS, actively enrolling in USA, five centers active.

1. De la Fuente, Eurointervention 2011, 2. Wong Po Foo WCRM 2015, 3. Heldman JAMA 2014, 4. Raval ACC 2025.

CardiAMP HF approval is being sought based on this data

2025	2026
CardiAMP HF Top Manuscript FDA/ Japan PMDA Meetings CardiAMP HF II Enrolling	Potential CardiAMP HF submission in Japan and USA CardiAMP HF II enrolling

- Japan approval pathway may have greater potential for near-term approval as we believe we have far more data supporting safety and efficacy than other cell therapies for heart failure approved conditionally or expected to seek conditional approval[1]. There are an estimated 1 million patients in Japan suffering from heart failure today[2], and it is expected that 150,000 may benefit from CardiAMP cell therapy.
  - Advantages over what is available today in Japan:
    - Autologous therapy requires no immunosuppression.
    - Cells do not become heart cells, requiring no antiarrhythmic drug dosing.
    - Minimally invasive delivery, patient could be discharged same day from hospital.
- FDA has previously approved 10 new high-risk cardiovascular therapeutic medical devices which did not meet at least 1 pivotal study primary end point[3]. An application for allogenic surgically delivered cell therapy is expected to be submitted to FDA in 2025.

1 Terumo Heartsheet was previously conditionally time limited approved based on 7 patients. Cuorips to seek approval based on 8 patients press 5/24/24. Heartseed to seek approval after LAPIS 10 patient study (per April 2023) of which 5 have been enrolled (July 2024). Both have interest in minimally invasive delivery. Both potential partners.

2 ESC Heart Failure - 2016 - Konishi - Heart failure epidemiology and novel treatments in Japan facts and numbers.

3 Assessment of FDA Approval for New High-risk Therapeutic Devices Not Meeting Pivotal Study Primary End Points, 2016-2020, JAMA Intern Med, 2021;181;(10):1409-1412.

BIOCARDIA®

Design of CardiAMP HF II Confirmatory Trial

- FDA Approved protocol for up to 250 patients at up to 40 centers
  - Focused on NYHA II and III ischemic HFrEF with NTproBNP >500 pg/ml
  - Primary endpoint is Finkelstein Schoenfeld composite of heart death, major adverse cardiac and cerebrovascular events, and quality of life at minimum of 12 months and maximum of 24 months.
  - Trial has > 90% power based on CardiAMP HF Results
  - Approved by FDA in Q4 2023, approved by CMS for reimbursement in Q1 2024
  - Changes:
    - NTproBNP patient selection
    - Dosing based on tissue screening to include more screened patients and accelerate trial completion
    - Use of FDA Approved Morph DNA to enhance procedural ease
    - Expect to roll out Heart3D™ Fusion Imaging

BIOCARDIA®

CardiAMP Cell Therapy 2nd Indication

Chronic Myocardial Ischemia with Refractory Angina

CardiAMP Cells in Chronic Myocardial Ischemia Trial (BCDA-02)

NCT03455725, IDE Trial for Premarket Approval

Burden of Illness and Unmet Need

- Characterized by severe chest pain.
- Patients suffer from poor perceived health status and psychological distress, have significant impairment in quality of life, and represent a burden to the healthcare system due to significant use of resources.
- Estimated that between 600,000 and 1.8 million patients suffer from refractory angina, with approximately 75,000 new cases diagnosed each year.

Minimal Treatment Options

- Current therapies have limitations or are associated with minimal reduction in angina.

Market Opportunity

- Prior to the release of generics in 2019, Ranexa from Gilead Sciences for patients with chronic myocardial ischemia had sales estimated at $938M/Year.

Trial Design:

Open Label Roll-in: 200M Cells

Randomized Controlled Trial (N=333)

40 centers

Primary endpoint is total exercise time at 6 months.

Sources of data:
Cheng Refractory Angina 2016.

CardiAMP Cells in Chronic Myocardial Ischemia Trial (BCDA-02)
Roll-in Cohort Clinical Results

Early results are compelling for both improved angina episode reduction and increase in exercise tolerance time (ETT) which has only been shown with cell therapy.

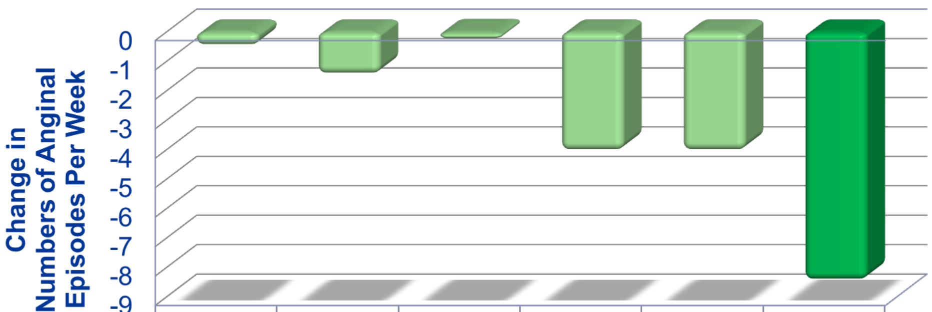
Last open label roll-in cohort patient reached primary 6-month endpoint in February 2025.

CMS reimbursement can support patient research costs.

Adaptive statistical analysis plan in development for early readout at or before 100 patients.

Positive results coupled with existing safety data in ischemic heart failure indication could support FDA submission.

Change in Angina Episodes per Week
100% of patients responded in CardiAMP CMI



	ERICA	CARISA	EECP	CD34-6 Month	CD34-12 Month	CardiAMP - 6 Month
Angina/week	-0.43	-1.4	-0.22	-4	-4	-8.4

Change in Exercise Tolerance Testing at 6 Months
75% of patients responded in CardiAMP CMI

	EECP Treated	EECP Control		RENEW CD34-Treatment 3M	RENEW Control 3M	RENEW CD34-Treatment 6M	RENEW Control 6M		CardiAMP CMI 3M	CardiAMP CMI 6M
Seconds	44	32		77	31	99	49		102	107

NS = Not significant

[1] ERICA Trial, JACC 2006
[2] CARISA TRIAL, EJPP 2012
[3] MUST Trial JACC 1999,
[4] Henry CD34+ Meta Analysis, ESCHF 2018

CardiALLO Cell Therapy

2nd Therapeutic Platform

Ischemic Heart Failure

Allogeneic Mesenchymal Stem Cells in Heart Failure (BCDA-03) CardiALLO MSC

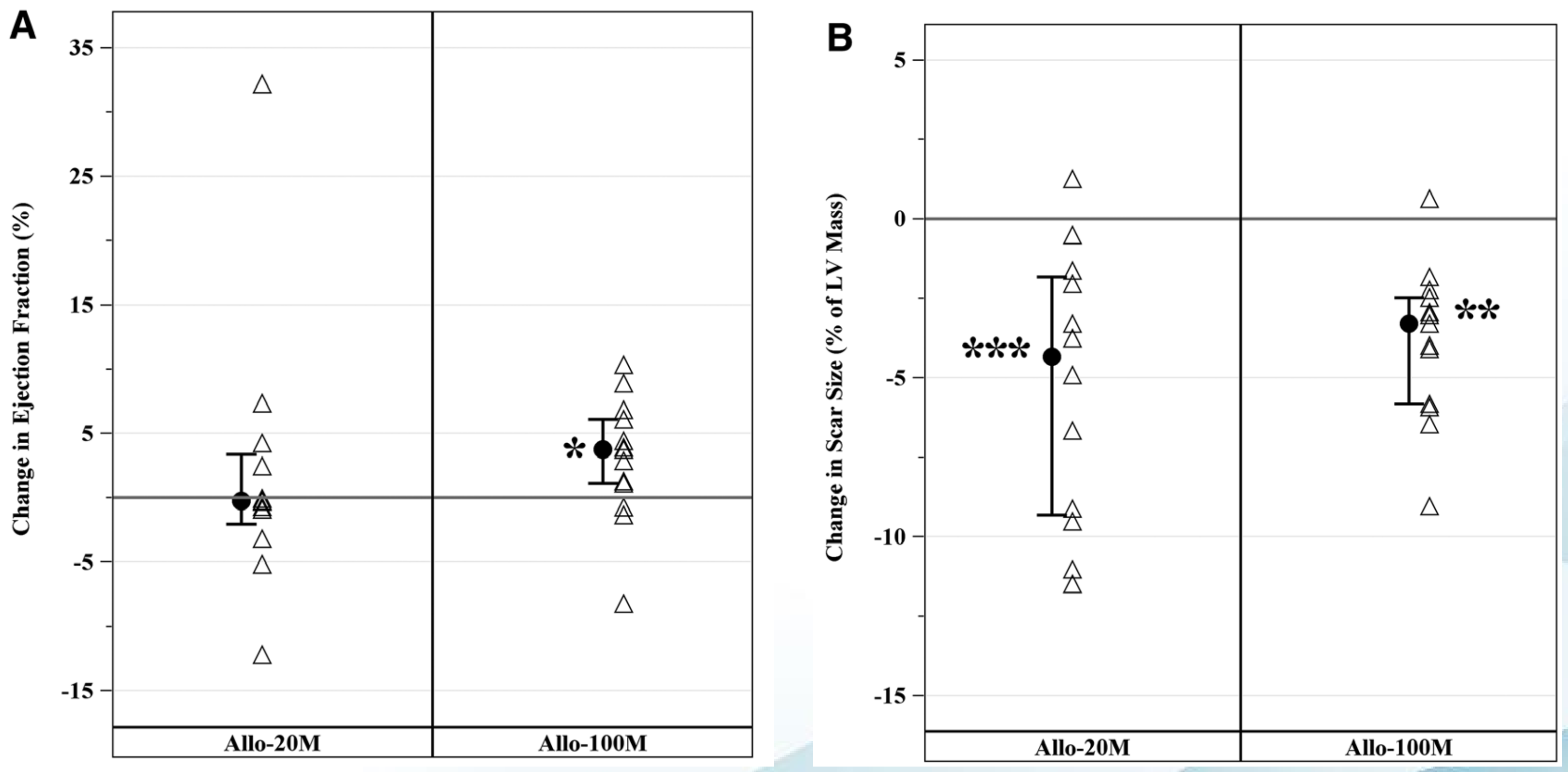
- “Off the shelf” cell therapy based on cells from a single donor to treat many patients, using the same delivery system as CardiAMP programs.
- Has advantages for patients who do not qualify for CardiAMP because of their cells.
- Has advantages as cells have immunomodulatory character.
- Previous trials (POSEIDON AND TRIDENT) have shown cells to be safe with no overt immunological response in 45 patients.
- Patients do not require any immunosuppression therapy.

Allogeneic cells manufactured at BioCardia from donor cells to create a cell bank for multiple patients.

Allogeneic Mesenchymal Stem Cells in Heart Failure (BCDA-03) Phase I/II TRIDENT Clinical Study, NCT02013674

Allogeneic MSC at 20M and 100M cells (N= 30) delivered at ten sites with Helix. Primary outcome measures: thirty-day post catheterization incidence of predefined treatment-emergent serious adverse events (SAEs) showed no safety issues.

Efficacy assessments demonstrated Improvement in heart function as measured by left ventricular ejection fraction at higher dose and reduced scar size in both the high dose and low dose groups.



Florea V, et al. Dose Comparison Study of Allogeneic Mesenchymal Stem Cells in Patients With Ischemic Cardiomyopathy (The TRIDENT Study). Circ Res. 2017 Nov 10;121(11):1279-1290.

Allogeneic Mesenchymal Stem Cells in Heart Failure (BCDA-03)

CardiALLO MSC, NCT05925608, IND Phase I/II

Trial Design:

Open Label Roll-in: 3X3 Dose Escalations (N=9)

Randomized Controlled Trial

(up to N=30)

Primary endpoint is composite of heart death, MACCE, and functional capacity.

The clinical trial will be testing prospectively an optimized dosage and delivery of allogeneic MSC in patients with ischemic inflammatory heart failure of reduced ejection fraction. Recent data[1] has shown enhanced benefits of MSCs in patients having ischemic inflammatory heart failure.

CardiALLO MSC has a lower cell passage with 2x to 4x higher effective cell dosage than previous trials, with procedural safety and physician control enhanced by the incorporation of Morph DNA.

Dose escalation followed by Data Safety Monitoring Board Reviews to confirm safety before proceeding.

Dose 1
N=3

Dose 2
(N=3)

Dose 3
N=3

Status at arrow: Dose 1 DSMB review completed. No adverse events observed. Study to continue per plan.

[1] Perin, E.C., et al. (2024), Mesenchymal precursor cells reduce mortality and major morbidity in ischaemic heart failure with inflammation: DREAM-HF. Eur J Heart Fail.

Intellectual Property

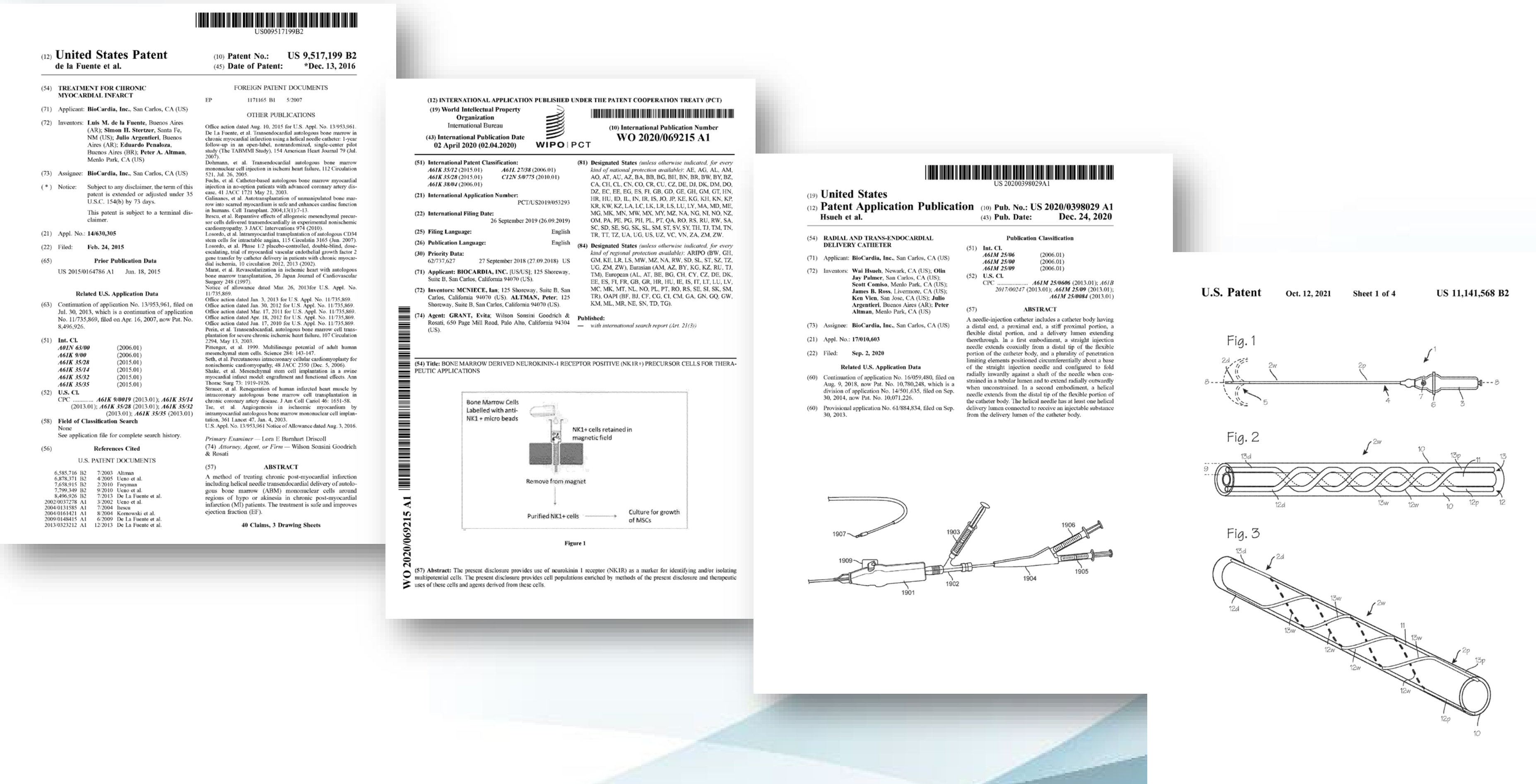
Team

Finance

Catalysts

Intellectual Property Overview

- Exclusive rights to over 60 patents and patent applications in USA, Europe, China, India, and Japan with goal to protect the company's platform and therapeutic initiatives.



BIOCARDIA®

Executive Management Team

Peter Altman, PhD	David McClung	Debby Holmes-Higgin	Edward Gillis
CEO	CFO	VP Clinical	SVP Devices

Board of Directors:

- Andrew Blank, Chairman of the Board, CEO Archive America, Board Member Neumentum
- Jay Moyes, Chairman Audit Committee, Board Member Puma Biotechnology, Inc.
- Simon Stertzer, M.D., Professor of Medicine Cardiology Emeritus, Stanford
- Richard Krasno, PhD, Board Member OPKO, Ladenberg Thalman
- Bill Facteau, CEO Earlens, Board member Aerin Medical
- Jim Allen, CEO United Toll Systems, LLC.

Selected Financial Data

	Year Ended 31-Dec-24 ($mm)	Year Ended 31-Dec-23 ($ mm)	Year Ended 31-Dec-22 ($ mm)	Year Ended 31-Dec-21 ($ mm)
Revenues	$0.06	$0.5	$1.4	$1.0
Net Loss	$7.9	$11.6	$11.9	$12.6
Cash used in operations	$8.0	$10.0	$10.6	$10.4
Cash & Equivalents	$2.4	$1.1	$7.4	$12.9
Debt	N/A	N/A	N/A	N/A

5.6 M shares of common stock issued and outstanding as of July 31, 2025.

BIOCARDIA®

Anticipated Catalysts

BCDA-01 CardiAMP Autologous Cell Therapy in Heart Failure (HF)

- Japan PMDA meetings on approvability based on subgroup analysis and safety~Q4 2025. This could enable submission for approval in 2026.
- USA FDA meetings on approvability based on subgroup analysis and safety~Q4 2025
- Manuscript with additional echo and NTproBNP data ~Q4 2025

BCDA-02 CardiAMP Autologous Cell Therapy in Chronic Myocardial Ischemia

- Top line Data Roll in Cohort ~Q4 2025

BCDA-03 CardiALLO Allogeneic MSC Cell Therapy in Heart Failure

- Nondilutive Funding – NIH SBIR Grant with enthusiasm and recommended budget of $3M from the review panel has been resubmitted addressing minor deficiencies. Revised evaluation expected January 2026.

Helix Biotherapeutic Delivery System

- FDA Submission for Approval ~Q3 2025
- Partnering Revenue

Morph Steerable Introducers

- Partnering in electrophysiology
- Revenues

BIOCARDIA®

Back up slides:
CardiAMP HF data slides

CardiAMP Heart Failure and CardiAMP HF II Trial Executive Steering Committee

- Dr. Carl Pepine, University of Florida

Professor of Medicine, Division of Cardiovascular Medicine, co-director of CTSI Multi-site Study Support Team at the National Center for Research, has been on the editorial boards of all major cardiovascular journals, is founding editor of Cardiology Today and Editor-in-Chief for American Heart Journal Plus: Cardiology Research and Practice, formerly served as President of the American College of Cardiology.

- Dr. Amish Raval, University of Wisconsin

Professor of Medicine, Division of Cardiovascular Medicine and Affiliate Professor, Biomedical Engineering, Director of the Clinical Cardiovascular Research and Director of the UW Heart Attack Program; UW Director of Clinical Cardiovascular Research; and Chair, Cardiovascular Regeneration Focus Group.

- Dr. Peter Johnston, Johns Hopkins School of Medicine, Maryland

Associate Professor of Clinical Medicine, primary research interest is in novel therapies for heart failure.

- Dr. Jay Traverse, University of Minnesota School of Medicine

Associate professor of medicine, senior consulting cardiologist and director of research at Minneapolis Heart Institute®. His special interests include interventional cardiology, stem cell therapy, biomaterials, and ischemia/reperfusion injury.

- Dr. Duncan Stewart, Ottawa Heart Research Institute

CEO & Scientific Director of the OHRI and Executive Vice-President, Research at The Ottawa Hospital, Senior Scientist in OHRI's Regenerative Medicine Program and a Professor in the Department of Medicine at the University.

- Dr. Leslie Miller, Baycare Health System, Florida

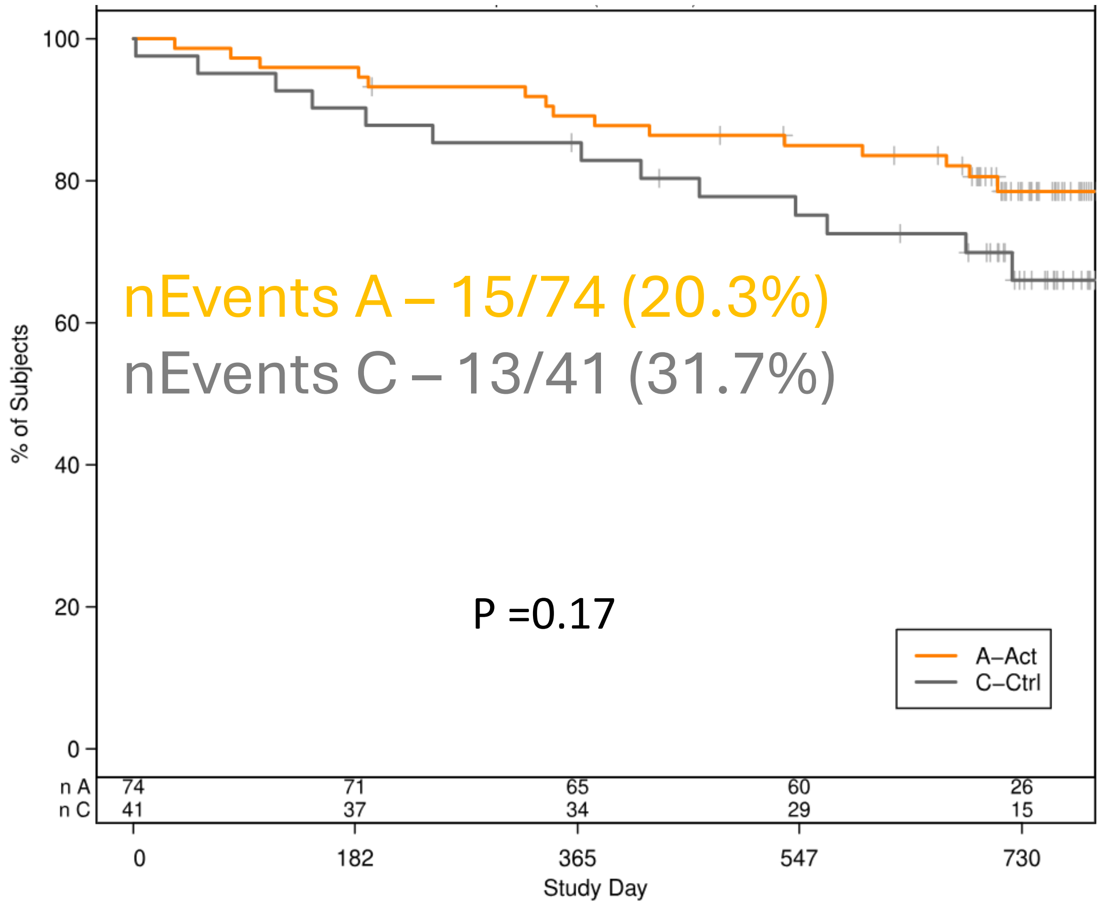
Director of the Heart Failure Clinic, formerly served as President of the International Society for Heart and Lung Transplantation and the American Society of Transplantation, research focuses on innovative heart failure treatments, including the use of adult stem cell therapy in the treatment of patients with cardiovascular disease and heart failure.

- Dr. Wai Hong Wilson Tang, Cleveland Clinic Foundation

Professor of Medicine at the Cleveland Clinic Lerner College of Medicine of Case Western Reserve University , Research Director, and staff cardiologist in the Section of Heart Failure and Cardiac Transplantation Medicine in the Sydell and Arnold Miller Family Heart, Vascular & Thoracic Institute at the Cleveland Clinic.

MACE-Free Survival

CardiAMP HF
Cell Therapy TRIAL

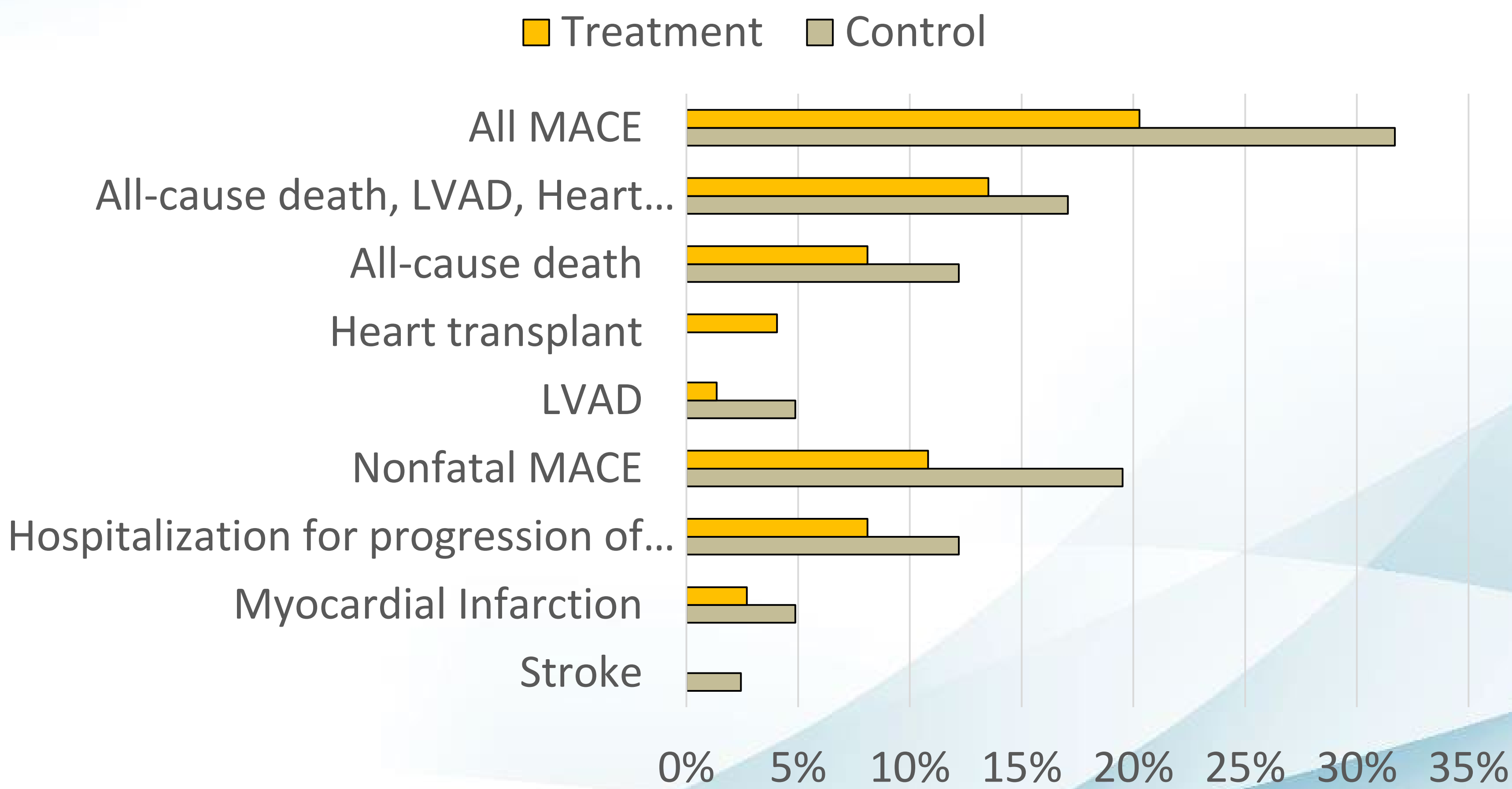


05993-C (CLIN) CardiAMP HF Trial CSR 2025 07 20

BIOCARDIA®

CardiAMP HF
Cell Therapy TRIAL

Major Adverse Cardiovascular Events (MACE)



BIOCARDIA®

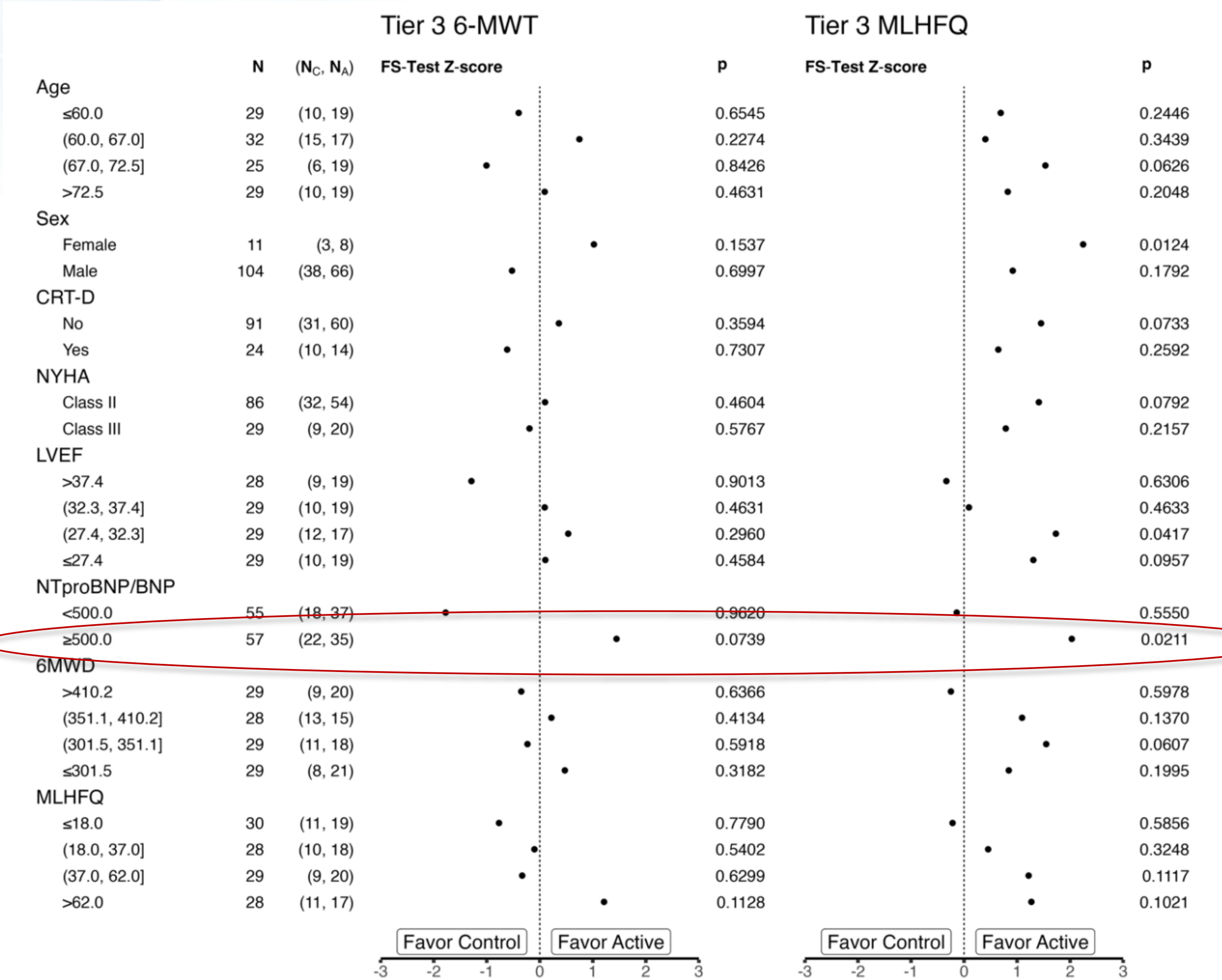
Primary and secondary efficacy measures

	Active Treatment (N=74)	Control (N=41)	P-value
Primary effectiveness outcome: hierarchical composite of all-cause death, LVAD or cardiac transplantation, non-fatal HFHs, MI, stroke and change in 6MWD from baseline through 24 months	WR = 1.01		0.939
Secondary effectiveness outcome: hierarchical composite of all-cause death, LVAD or cardiac transplantation, non-fatal HFHs, MI, stroke and change in QOL‡ from baseline through 24 months	WR = 1.39		0.140
All MACCE	15 (20.3%)	13 (31.7%)	0.171
All-cause death, LVAD or cardiac transplantation	10 (13.5%)	7 (17.1%)	0.606
All-cause death	6 (8.1%)	5 (12.2%)	0.475
LVAD	1 (1.4%)	2 (4.9%)	0.256
Cardiac transplantation	3 (4.1%)	0	0.191
Non-fatal MACCE (HFHs, MI, and stroke)	8 (10.8%)	8 (19.5%)	0.197
Heart failure hospitalizations	6 (8.1%)	5 (12.2%)	0.475
Myocardial infarction	2 (2.7%)	2 (4.9%)	0.542
Stroke	0	1 (2%)	0.177
Freedom from Serious Adverse Events∞	40 (54.1%)	21 (51.2%)	0.770
Sustained VT	5 (6.8%)	5 (12.2%)	0.320
6MWD change, meters	6.8 ± 74.1	24.1 ± 87.4	0.172
MLHFQ change, score	-8.6 ± 22.5	-3.1 ± 16.3	0.352

HF indicates heart failure; HFH, heart failure hospitalization; LVAD, left ventricular assist device; MI, myocardial infarction; MACE, major adverse cardiovascular and cerebrovascular events; 6MWD, 6-minute walk distance and QOL, quality of life. ‡Measured by the Minnesota Living with Heart Failure Questionnaire. ∞Investigator reported; All MACCE were adjudicated by the study's independent CEC. P-values should be viewed as screening tools only because no adjustment was made for multiple comparisons.

Subgroup Analysis

CardiAMP HF
Cell Therapy TRIAL



	N	(N_C, N_A)	Tier 3 6-MWT p	Tier 3 MLHFQ p
Age				
≤60.0	29	(10, 19)	0.6545	0.2446
(60.0, 67.0]	32	(15, 17)	0.2274	0.3439
(67.0, 72.5]	25	(6, 19)	0.8426	0.0626
>72.5	29	(10, 19)	0.4631	0.2048
Sex				
Female	11	(3, 8)	0.1537	0.0124
Male	104	(38, 66)	0.6997	0.1792
CRT-D				
No	91	(31, 60)	0.3594	0.0733
Yes	24	(10, 14)	0.7307	0.2592
NYHA				
Class II	86	(32, 54)	0.4604	0.0792
Class III	29	(9, 20)	0.5767	0.2157
LVEF				
>37.4	28	(9, 19)	0.9013	0.6306
(32.3, 37.4]	29	(10, 19)	0.4631	0.4633
(27.4, 32.3]	29	(12, 17)	0.2960	0.0417
≤27.4	29	(10, 19)	0.4584	0.0957
NTproBNP/BNP				
<500.0	55	(18, 37)	0.9620	0.5550
≥500.0	57	(22, 35)	0.0739	0.0211
6MWD				
>410.2	29	(9, 20)	0.6366	0.5978
(351.1, 410.2]	28	(13, 15)	0.4134	0.1370
(301.5, 351.1]	29	(11, 18)	0.5918	0.0607
≤301.5	29	(8, 21)	0.3182	0.1995
MLHFQ				
≤18.0	30	(11, 19)	0.7790	0.5856
(18.0, 37.0]	28	(10, 18)	0.5402	0.3248
(37.0, 62.0]	29	(9, 20)	0.6299	0.1117
>62.0	28	(11, 17)	0.1128	0.1021

05993-C (CLIN) CardiAMP HF Trial CSR 2025 07 20

BIOCARDIA®

CardiAMP HF
Cell Therapy TRIAL

Primary and secondary efficacy measures NTproBNP>500pg/ml

	Active Treatment (N=35)	Control (N=22)	P-value
Primary effectiveness outcome: hierarchical composite of all-cause death, LVAD or cardiac transplantation, non-fatal HFHs, MI, stroke and change in 6MWD from baseline through 24 months	WR = 1.61		0.07
Secondary effectiveness outcome: hierarchical composite of all-cause death, LVAD or cardiac transplantation, non-fatal HFHs, MI, stroke and change in QOL‡ from baseline through 24 months	WR = 2.02		0.02
All MACCE			
All-cause death, LVAD or cardiac transplantation	14.3%	27.3%	--
All-cause death	5.7%	18.2%	--
LVAD, cardiac transplantation	11.4%	9.1%	--
HF related deaths	2.9%	9.1%	--
Non-fatal MACCE (HFHs, MI, and stroke)	17.1%	31.8%	--
HF hospitalizations	11.4%	22.7%	--
6MWD change, meters	13.7±69.9	-0.2±101.2	--
QOL change, score	-8.1±22.5	2.4±20.5	--

HF indicates heart failure; HFH, heart failure hospitalization; LVAD, left ventricular assist device; MI, myocardial infarction; MACE, major adverse cardiovascular and cerebrovascular events; 6MWD, 6-minute walk distance and QOL, quality of life. ‡Measured by the Minnesota Living with Heart Failure Questionnaire. LVESV, left ventricular end systolic volume; LVEDV, left ventricular diastolic volume; LVEF, left ventricular ejection fraction. ∞Investigator reported; all MACE were adjudicated by the study's independent CEC.

BIOCARDIA®

Primary and secondary efficacy measures NTproBNP>500pg/ml

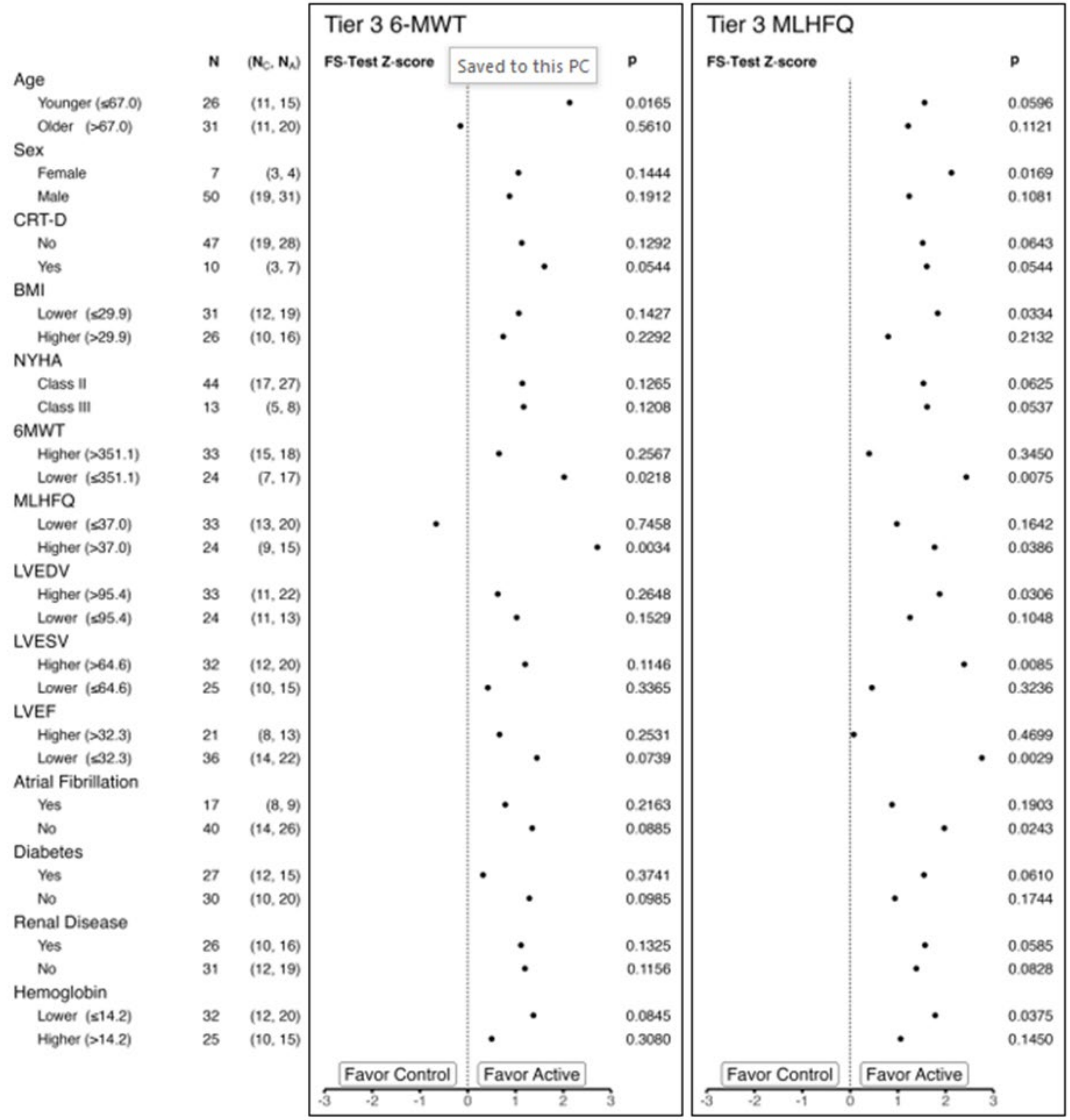
Active Treatment (n=35) → 770 Patient Pairs ← **Control (n=22)**

	Active Treatment Wins	770 Patient Pairs	Control Wins
Tier 1	193 (25%)	492 Ties (64%)	85 (11%)
Tier 2	103 (13%)	333 Ties (43%)	56 (7%)
Tier 3: MLHFQ	168 (22%)	78 Ties (10%)	87 (11%)
Tier 3: 6MWT	147 (19%)	51 Ties (7%)	135 (40%)
MLHFQ Totals	464 Wins (60%)	78 Ties (10%)	228 Wins (30%)
6MWT Totals	443 Wins (57%)	51 Ties (7%)	276 Wins (36%)

Win-Ratio with Tier 3 MLHFQ = 464/228 = 2.04; Finkelstein-Schoenfeld Statistic, p=0.020
Win-Ratio with Tier 3 6MWT = 443/276 = 1.61; Finkelstein-Schoenfeld Statistic, p=0.074

Covariate Analysis for NTproBNP > 500pg/ml

CardiAMP HF
Cell Therapy TRIAL



BIOCARDIA®

CardiAMP HF Trial Results

CONCLUSIONS: Intramyocardial delivery of autologous mononuclear cells for patients with ischemic HFrEF is safe but the primary efficacy 3-tier composite outcome was not met using six-minute walk distance test at tier 3, due to improved 6MWD in both groups. **Significant clinical benefit was observed for patients with NTproBNP >500 pg/ml at baseline.**