BioCardia®

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

Corporate Presentation
BioCardia, Inc. (NASDAQ: BCDA)

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Executive Summary

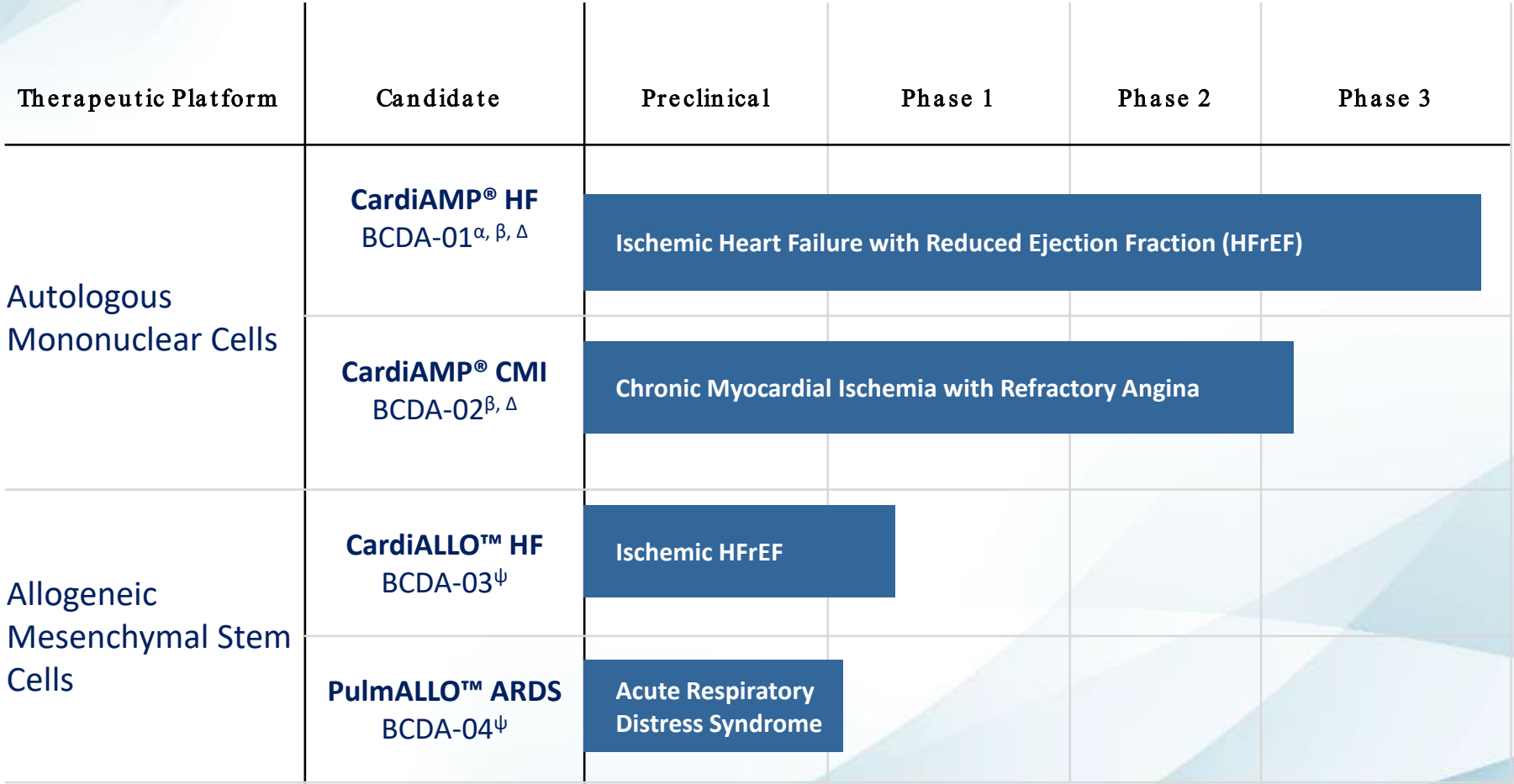
Late Stage Cell and Cell Derived Biotherapeutics for Cardiac and Pulmonary Diseases

- **Phase III CardiAMP® cell therapy for ischemic heart failure with TAM of > $17 Billion in USA[1].**
  - Program with FDA breakthrough designation enhancing regulatory process, and CMS reimbursement reducing costs of studies. >200 patient procedures in three clinical trials.
  - CardiAMP HF I interim results with 90% of data available, showed 37% relative risk reduction (RRR) in all cause death and 9% RRR in major adverse cardiac events. Patients with elevated markers of heart failure (NTproBNP>500pg/ml) had 86% RRR in all cause death, and 20% RRR in major adverse cardiac events. Final results to be presented at the American College of Cardiology late breaking clinical trials session on March 30, 2025, in Chicago. FDA and Japan PMDA consultations to follow.
  - CardiAMP HF II trial underway in USA focused on the greatest responders with a modified endpoint that was met in CardiAMP HF 1 interim analysis (p=0.026).
- **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)
- **Leading 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.
- **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

Therapeutic Product Pipeline

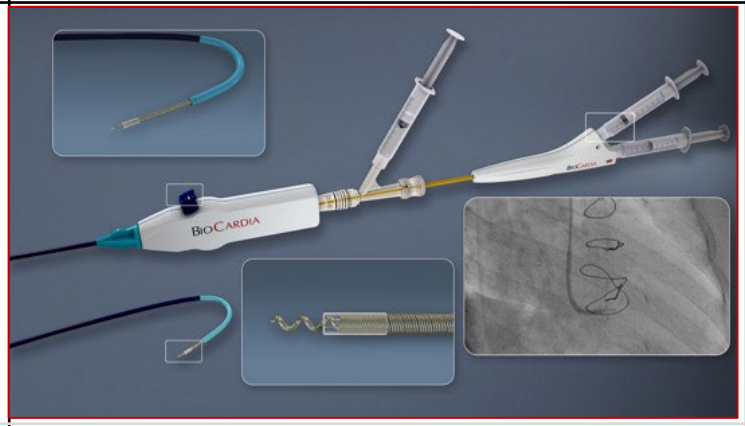
Autologous and Allogeneic Cardiac Cell Therapy for Cardiac and Pulmonary Disease.



α = FDA Breakthrough Designation
β = Reimbursed by Center for Medicare and Medicaid Services
Δ = Regulated by CBER through IDE/PMS Pathway in USA
Ψ = Regulated by CBER through IND/BLA Pathway in USA

BIOCARDIA®

Enabling Biotherapeutic Delivery Systems and Commercial Devices

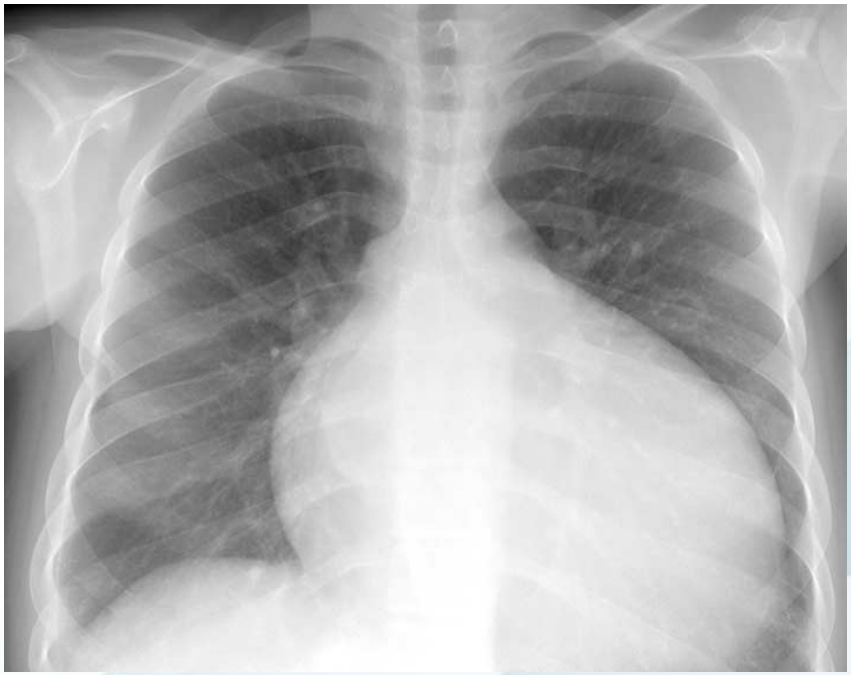
Therapeutic Platform	Image	Status
Helix™ Transendocardial Biotherapeutic Delivery Device (uses Morph DNA)		Investigational use with CardiAMP HF, CardiAMP CMI, and CardiALLO HF clinical trials. Partnered with CellProThera and StemCardia.
Morph® DNA Steerable Introducers		Approved in a wide variety of configurations and commercially available in a few.

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 = $17B based current reimbursement. [1,4,5,6]



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

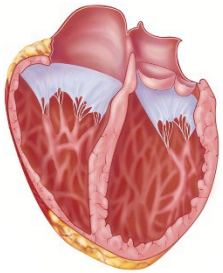
Sources of data:

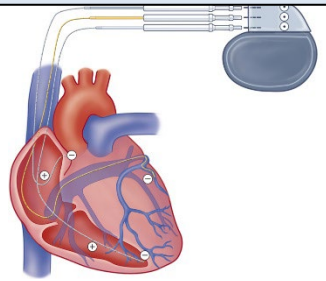
1. Martin et al 2024 Heart disease and statistics from the American Heart Association
2. EMPOROR -Reduced Trial, NEJM, 2020.
3. PARADIGM-HF, NEJM, 2014.
4. Vedin 2017 Significance of Ischemic Heart Disease in Patients With Heart Failure and Preserved, Midrange, and Reduced Ejection Fraction
5. Results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

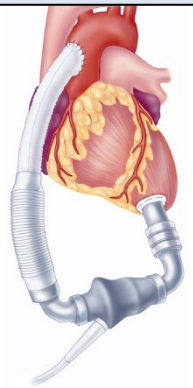
Current Options for Patients - Expensive, Unable to Heal Failing Hearts

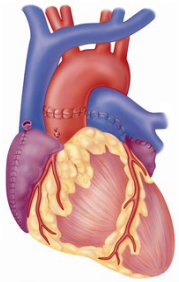
Demonstrating a reduction in mortality without replacing the heart remains a challenge in heart failure.

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

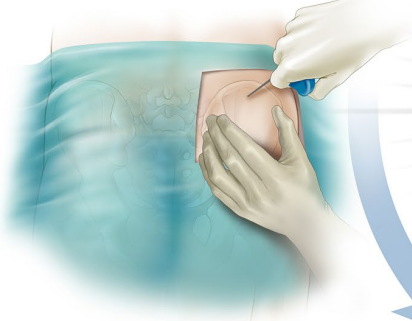
BIOCARDIA®

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

Pre-procedure Screening
Small amount of bone marrow collected from hipbone and sent to lab for testing

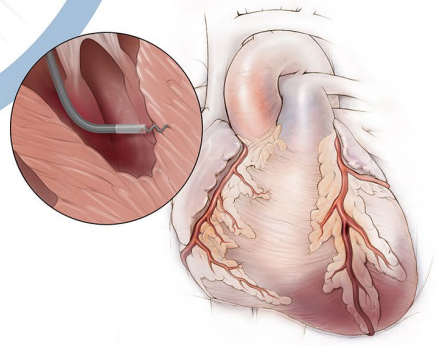
Post-procedure
Patient leaves hospital the next day

1 Cell Collection
Small amount of bone marrow obtained from hipbone
~ 20 minutes



CardiAMP™ Therapy

3 Cell Delivery
Bone marrow cells injected into damaged heart tissue through a catheter-based procedure
~30 to 45 minutes



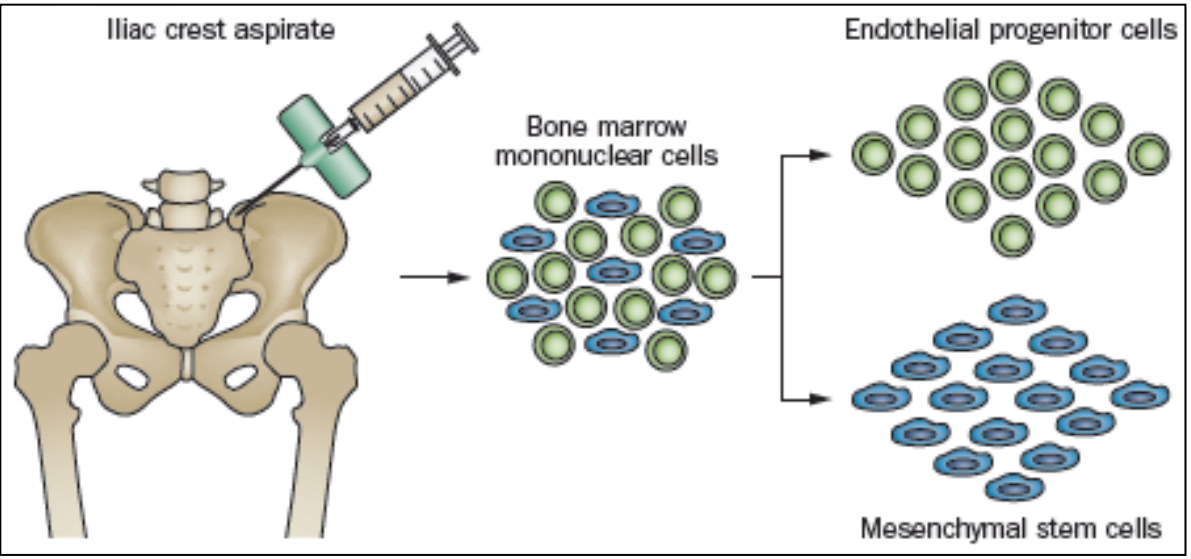
2 Cell Processing
Bone marrow cells prepared for transfer at point of care
~ 25 minutes

04142-C (MKT)

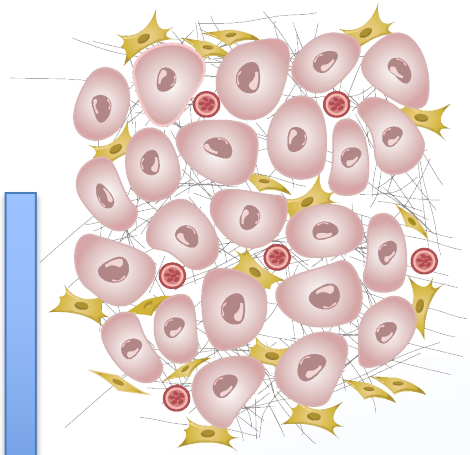
FDA CBER regulated as device system.

Medicare reimbursement established for two pivotal trials.

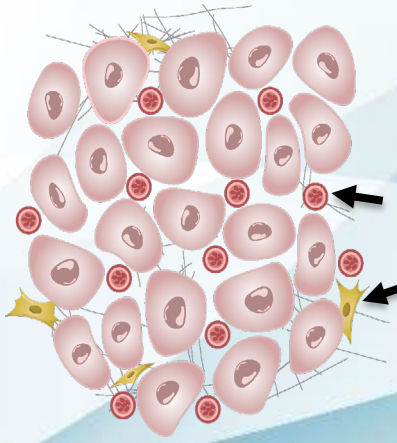
Mechanism of Action of Cells



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

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

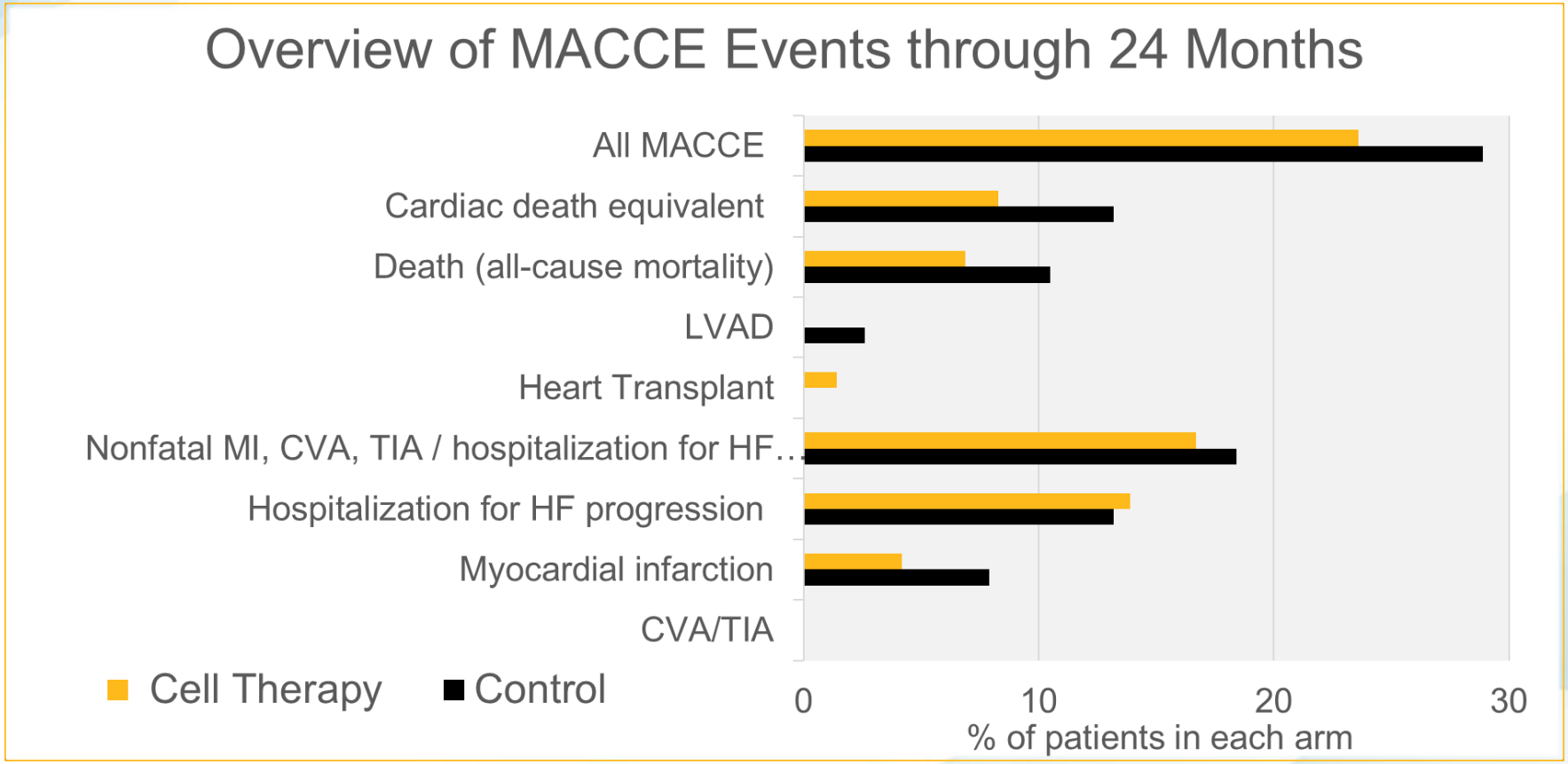
Reimbursement Code C9782 for CardiAMP Cell Therapy for both treated and control patients (reduced clinical study costs by $25,000 per patient).

Interim Results: Phase III Clinical Trial Interim Results Presented 2024, Randomized Controlled Trial, N=125, 18 centers.

Primary endpoint is composite of heart death, major adverse cardiac and cerebrovascular events (MACCE), and six-minute walk distance.

Final Results: Accepted as late breaking clinical trial by the American College of Cardiology Scientific Sessions for presentation March 30, 2025.

CardiAMP HF I Phase III Study
Interim Safety Outcomes (N=110)



MACCE = Major Adverse Cardiovascular and Cerebrovascular events
LVAD = Left Ventricular Assist Device; MI = myocardial infarction
CVA/TIA = Cerebrovascular Accident / Transient Ischemic Attack

Raval et al THT 2024

CardiAMP HF I Phase III Study Treatment Effectiveness Outcomes
Composite endpoint with three tiers

Primary Outcome All Patients Through Month 24 (p>0.05; n=110)			
Raval et al THT 2024	Cardiac Death Equivalents	Non-fatal MACCE	Six Minute Walk Distance Meters (median, ± st dev)
Cell Therapy	8.3%	16.7%	2 ± 76
Control	13.2%	18.4%	17 ± 96
Relative Risk reduction	37%	9%	
Notes			More is better
Subgroup: Patients with NTproBNP >500 pg/ml Through Month 24 (p=0.07, n=54)			
Cell Therapy	2.9%	20.0%	19± 63
Control	21.1%	26.3%	3 ± 113
Relative Risk Reduction	86%	24%	
Notes			More is better

Lessons learned:

- 6MWD should not have been used as an inclusion/exclusion and component of the primary endpoint. Baseline values believed skewed due to trial design.
- NTproBNP patients were great responders with 86% relative risk reduction (RRR) Cardiac Death Equivalent and 24% RRR Major Adverse Cardiac Events

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Design of CardiAMP HF II Trial

- CardiAMP HF II Trial is focused on these patients with Quality of Life as 3rd tier of composite outcome instead of Six Minute Walk Distance which resulted in p=0.026.

Raval et al THT 2024	Cardiac Death Equivalents	Non-fatal MACCE	Quality of Life Points (median ± st dev)
Cell Therapy	2.9%	20.0%	-10 ± 23
Control	21.1%	26.3%	6.5 ± 21
Relative Risk Reduction	86%	24%	Improvement = -16.5
Notes			Less is better

- 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. Substantially same design as V-Wave Relieve-HF Trial.
  - Trial has > 90% power based on CardiAMP HF I Interim Results
  - Approved by FDA in Q4 2023, approved by CMS for reimbursement in Q1 2024
  - Targeting completion of enrollment in two years from first patient treated
  - World class executive steering committee

CardiAMP Heart Failure 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.

CardiAMP HF Anticipated Timeline is Driven by Data

2025

- CardiAMP HF I Top Line Data
- FDA/ Japan PMDA Meetings
- Late Breaking Data presentation 3/30/25 at American College of Cardiology
- CardiAMP HF II Enrolling

2026

- Potential CardiAMP HF approval in Japan assuming 2025 submission
- 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 and in development 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

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

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.

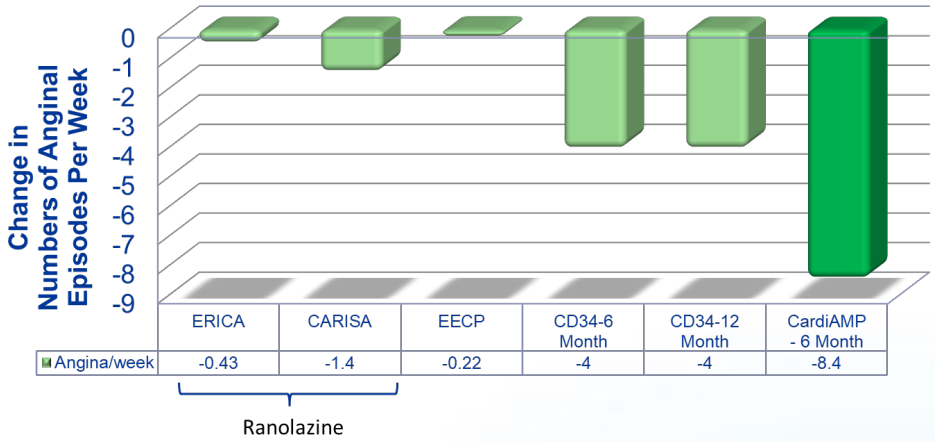
Last open label roll in cohort patient reached primary 6-month endpoint in February 2025.

CMS reimbursement can support patient research costs.

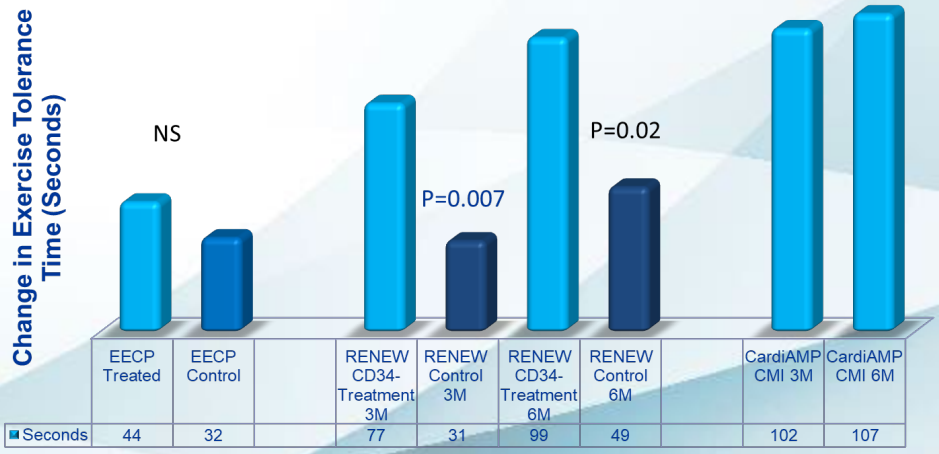
Adaptive statistical analysis plan in development for early readout at or before 100 patients.

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



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



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

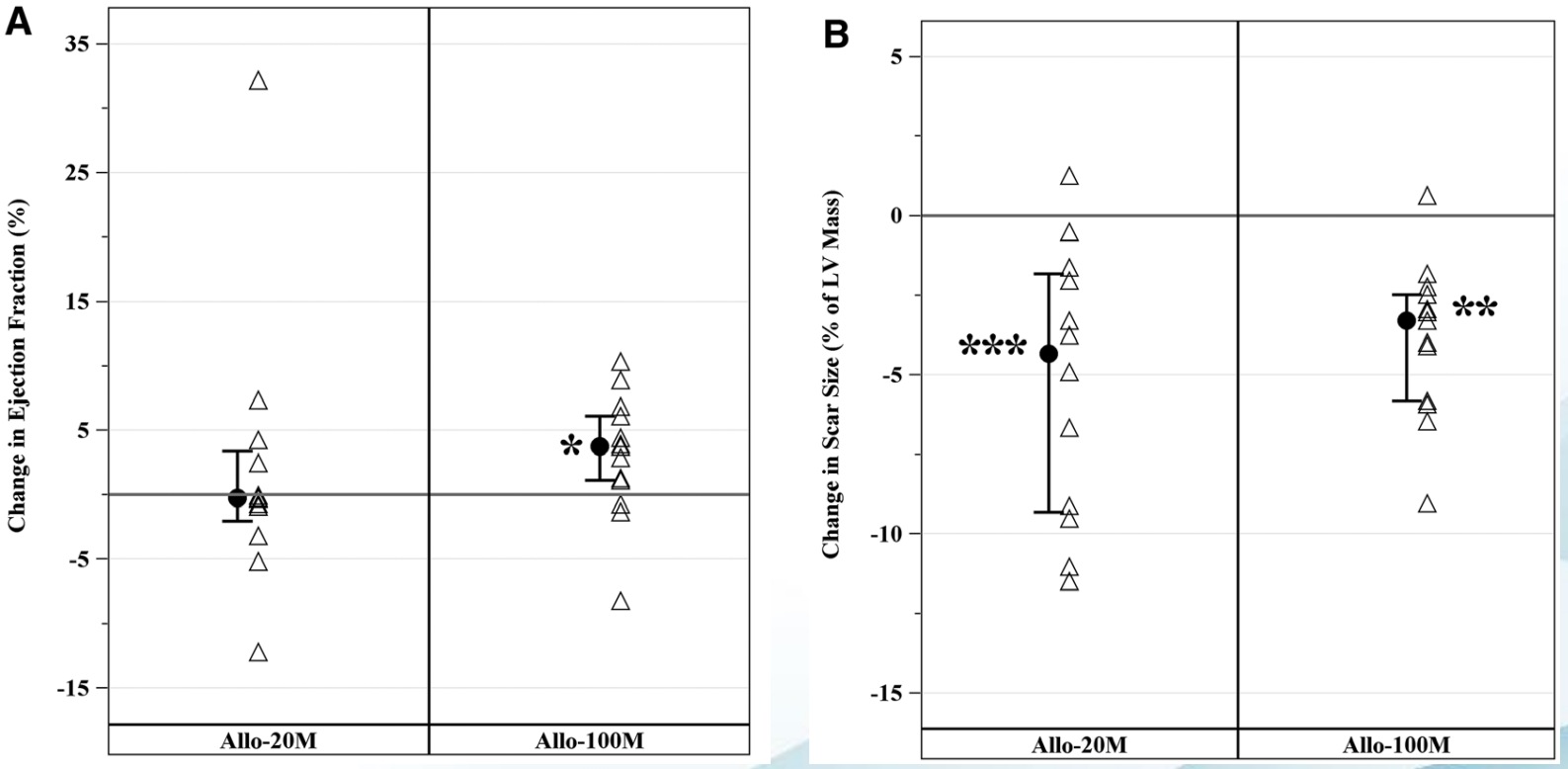
- "Off the shelf" cell therapy based on cells from a single donor to treat many patients, using the same delivery system as CardiAMP programs.
- Has advantages for patients who do not qualify for CardiAMP because of their cells.
- Has advantages as cells have immunomodulatory character.
- Previous trials (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

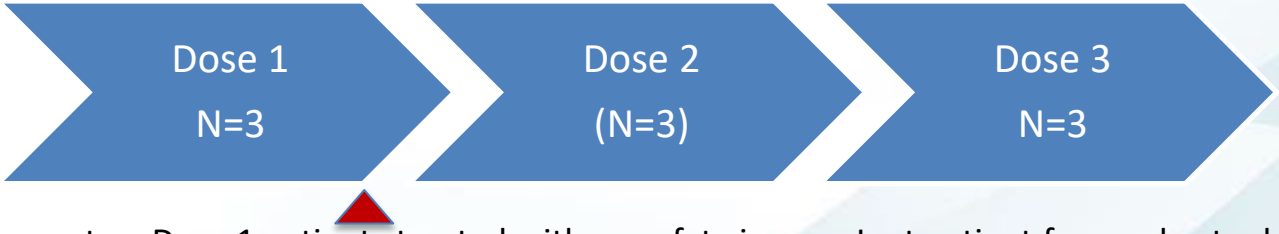
(up to N=30)

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.



Status at arrow: two Dose 1 patients treated with no safety issues. Last patient from cohort scheduled for February 2025.

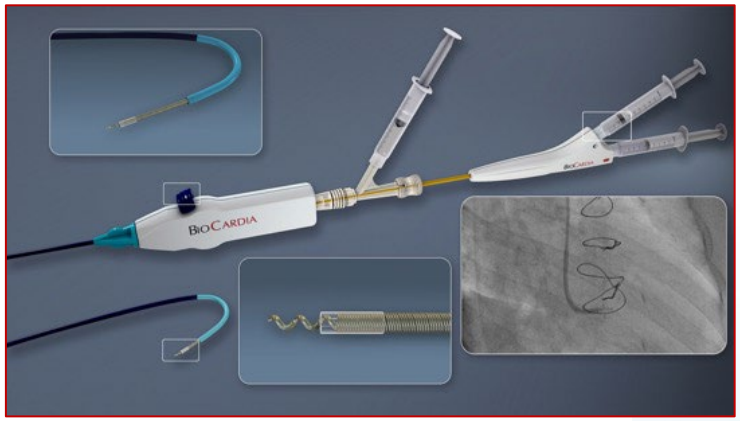
[1] Perin, E.C., et al. (2024), Mesenchymal precursor cells reduce mortality and major morbidity in ischaemic heart failure with inflammation: DREAM-HF. Eur J Heart Fail.

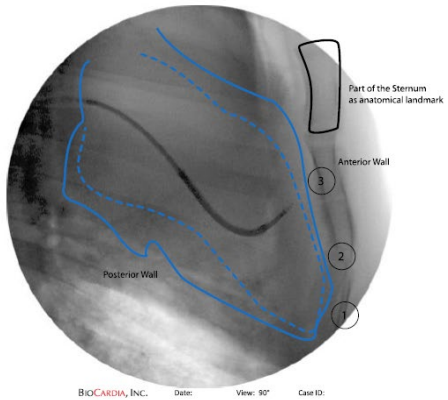
Helix Biotherapeutic Delivery Platform

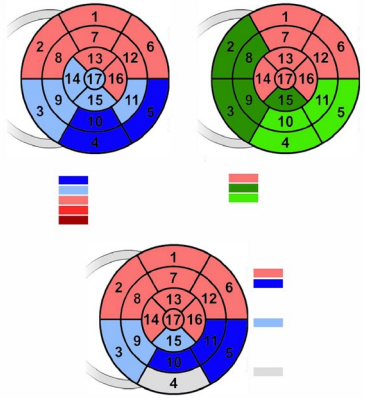
Helix Transendocardial Biotherapeutic Delivery System

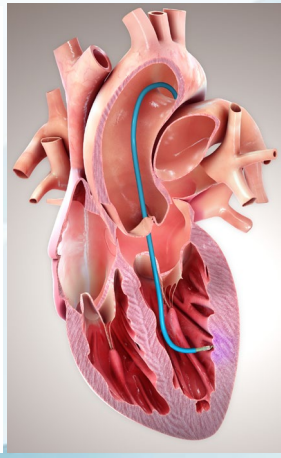
Therapeutic-enabling platform for minimally invasive targeted delivery of biologic agents to the heart. Helix empowers a seamless transition from bench to commercialization for partners.

- Helix provides better Rx retention than surgical delivery and ability to target anywhere in the heart with minimally invasive procedure that is repeatable in all hands. Stability of helical needle engaged in the heart provides ability to confirm location and control the time course of delivery.
- Enhanced safety of the minimally invasive approach may accelerate clinical development as patients are more likely to participate in minimally invasive therapy. Time is money during development . No surgical incision wound healing releasing cytokine cascades to confound outcomes data.
- Experience – ~500 clinical procedures have been performed in heart failure, chronic myocardial ischemia, & acute infarction to deliver cell and gene therapies.
- Images below show Helix™ system, navigation in vivo, and present & past partners.









CELLPROTHERA DISCOVERY CELL CULTURE TRANSPLANT
mesoblast the regenerative medicine company
BlueRock Therapeutics
Heartseed
AstraZeneca
ORIZURU THERAPEUTICS
STEMCARDIA
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Morph DNA Steerable Introducers

Approved Q3 2024 in a wide variety of configurations and commercially available.

Commercializing FDA Approved Enabling Products

See brochure at www.biocardia.com

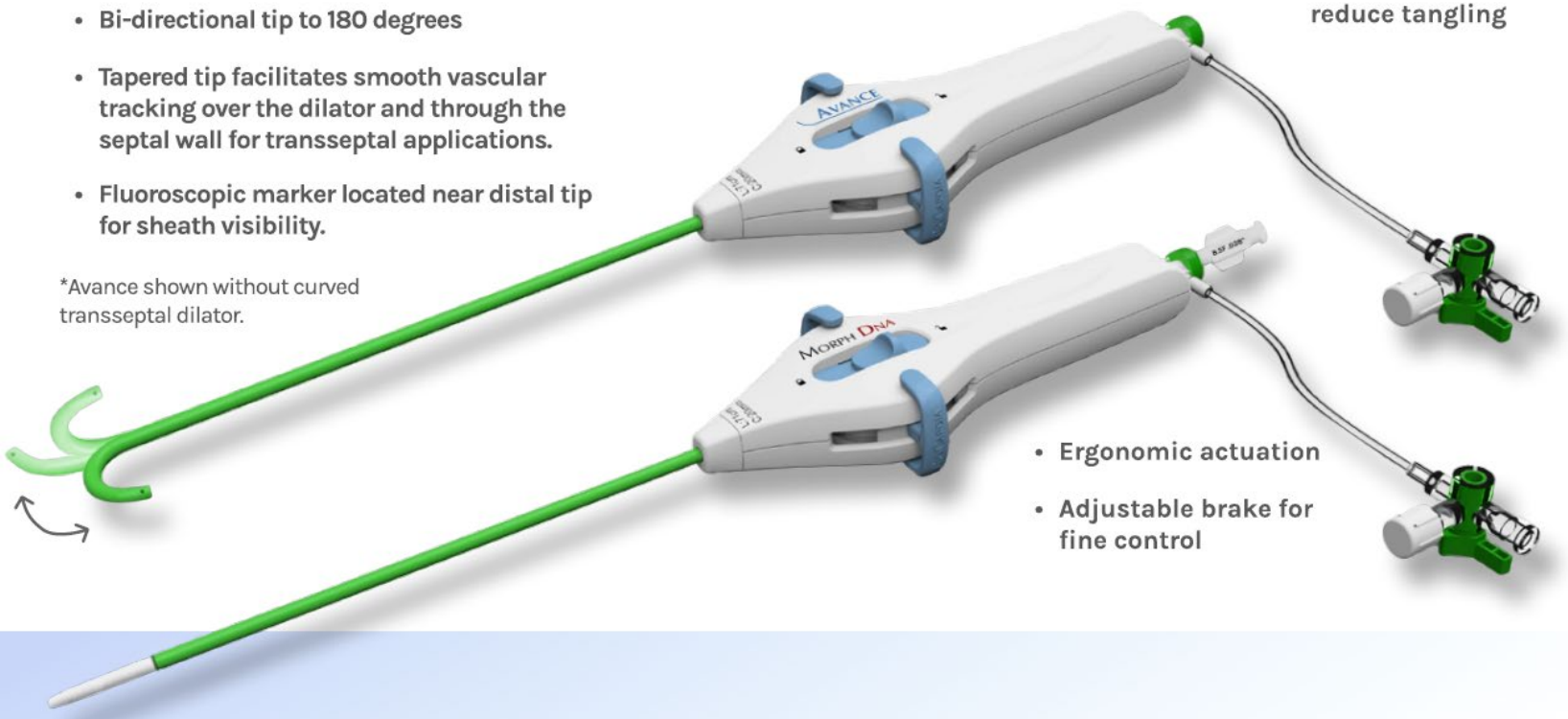
Morph®DNA and Avance™ Steerable Introducers

Product families with whipless double helix pull wire designs and integrated valves

- Proprietary layup to provide excellent torque response
- Bi-directional tip to 180 degrees
- Tapered tip facilitates smooth vascular tracking over the dilator and through the septal wall for transseptal applications.
- Fluoroscopic marker located near distal tip for sheath visibility.

*Avance shown without curved transseptal dilator.

- Swiveling port in hemostasis valve to reduce tangling

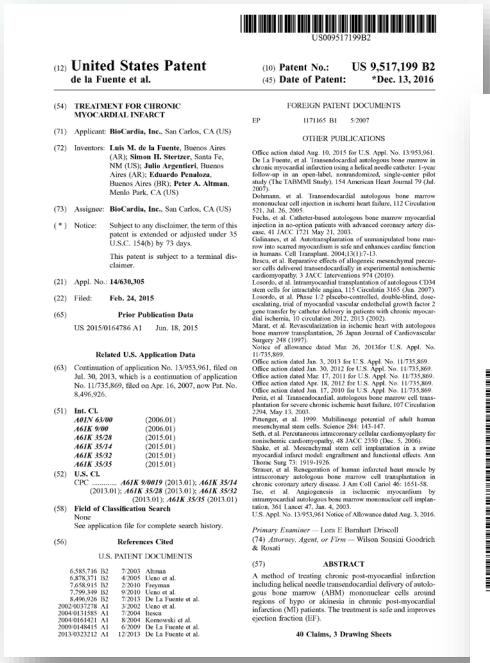


- Ergonomic actuation
- Adjustable brake for fine control

BIOCARDIA®

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



US009517199B2

(12) **United States Patent**
de la Fuente et al.

(10) **Patent No.: US 9,517,199 B2**
(45) **Date of Patent: *Dec. 13, 2016**

(54) **TREATMENT FOR CHRONIC MYOCARDIAL INFARCT**

(71) Applicant: **BioCardia, Inc.**, San Carlos, CA (US)

(72) Inventors: **Luis M. de la Fuente**, Buenos Aires (AR); **Simon H. Stertzer**, Santa Fe, NM (US); **Julio Argentieri**, Buenos Aires (AR); **Eduardo Pendoza**, Buenos Aires (BR); **Peter A. Altman**, Menlo Park, CA (US)

(73) Assignee: **BioCardia, Inc.**, San Carlos, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 73 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/630,305**

(22) Filed: **Feb. 24, 2015**

(65) **Prior Publication Data**

US 2015/0164786 A1 Jun. 18, 2015

Related U.S. Application Data

(63) Continuation of application No. 13/953,961, filed on Jul. 30, 2013, which is a continuation of application No. 11/735,869, filed on Apr. 16, 2007, now Pat. No. 8,496,926.

(51) **Int. Cl.**

A01N 63/00	(2006.01)
A61K 9/00	(2006.01)
A61K 35/28	(2015.01)
A61K 35/14	(2015.01)
A61K 35/32	(2015.01)
A61K 35/35	(2015.01)

(52) **U.S. Cl.**
CPC ***A61K 9/0019*** (2013.01); ***A61K 35/14*** (2013.01); ***A61K 35/28*** (2013.01); ***A61K 35/32*** (2013.01); ***A61K 35/35*** (2013.01)

(58) **Field of Classification Search**
None
See application file for complete search history.

(56) **References Cited**

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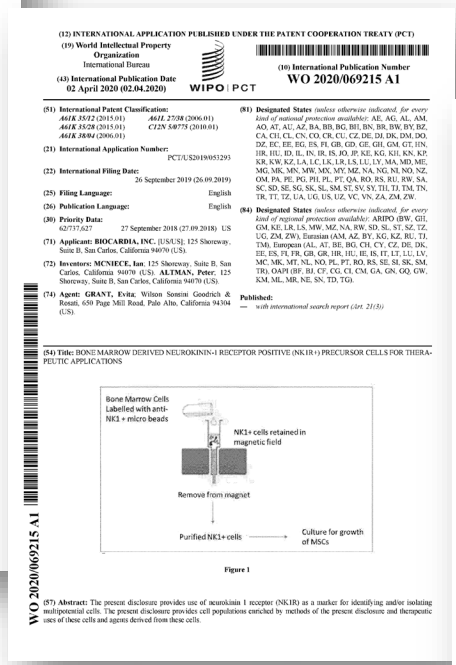
U.S. Appl. No. 13/953,961 Notice of Allowance dated Aug. 3, 2016.

Primary Examiner — Lorn E Barnhart Driscoll
(74) *Attorney, Agent, or Firm* — Wilson Sonsini Goodrich & Rosati

(57) **ABSTRACT**

A method of treating chronic post-myocardial infarction including helical needle transendocardial delivery of autologous bone marrow (MBM) mononuclear cells around regions of hypo or akinesia in chronic post-myocardial infarction (MI) patients. The treatment is safe and improves ejection fraction (EF).

40 Claims, 3 Drawing Sheets



WO 2020/069215 A1

(12) **INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)**

(19) **World Intellectual Property Organization**
International Bureau

(10) **International Publication Number**
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(43) **International Publication Date**
02 April 2020 (02.04.2020)

WIPO | PCT

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A61K 35/12 (2015.01) ***A61L 27/38*** (2006.01)
A61K 35/28 (2015.01) ***C12N 5/0775*** (2010.01)
A61K 38/04 (2006.01)

(21) **International Application Number:**
PCT/US2019/053293

(22) **International Filing Date:**
26 September 2019 (26.09.2019)

(25) **Filing Language:** English

(26) **Publication Language:** English

(30) **Priority Data:**
62/737,627 27 September 2018 (27.09.2018) US

(71) **Applicant: BIOCARDIA, INC.** [US/US]; 125 Shoreway, Suite B, San Carlos, California 94070 (US).

(72) **Inventors: MCNIECE, Ian**, 125 Shoreway, Suite B, San Carlos, California 94070 (US). **ALTMAN, Peter**, 125 Shoreway, Suite B, San Carlos, California 94070 (US).

(74) **Agent: GRANT, Evita**; Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, California 94304 (US).

(81) **Designated States** *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

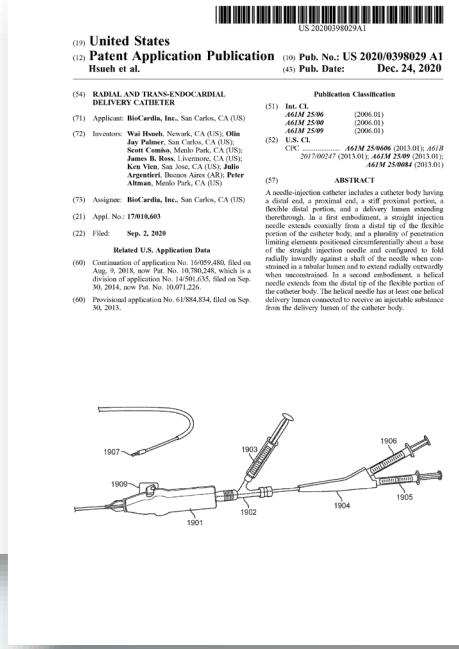
(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report (Art. 21(3))*

(54) **Title:** BONE MARROW DERIVED NEUROKININ-1 RECEPTOR POSITIVE (NK1R+) PRECURSOR CELLS FOR THERAPEUTIC APPLICATIONS

Figure 1

(57) **Abstract:** The present disclosure provides use of neurokinin 1 receptor (NK1R) as a marker for identifying and/or isolating multipotential cells. The present disclosure provides cell populations enriched by methods of the present disclosure and therapeutic uses of these cells and agents derived from these cells.



US 20200398029A1

(19) **United States**
(12) **Patent Application Publication**
Hsueh et al.

(10) **Pub. No.: US 2020/0398029 A1**
(43) **Pub. Date: Dec. 24, 2020**

(54) **RADIAL AND TRANS-ENDOCARDIAL DELIVERY CATHETER**

(71) Applicant: **BioCardia, Inc.**, San Carlos, CA (US)

(72) Inventors: **Wai Hsueh**, Newark, CA (US); **Olin Jay Palmer**, San Carlos, CA (US); **Scott Combs**, Menlo Park, CA (US); **James B. Ross**, Livermore, CA (US); **Ken Vien**, San Jose, CA (US); **Julio Argentieri**, Buenos Aires (AR); **Peter Altman**, Menlo Park, CA (US)

(73) Assignee: **BioCardia, Inc.**, San Carlos, CA (US)

(21) Appl. No.: **17/010,603**

(22) Filed: **Sep. 2, 2020**

Related U.S. Application Data

(60) Continuation of application No. 16/059,480, filed on Aug. 9, 2018, now Pat. No. 10,780,248, which is a division of application No. 14/501,035, filed on Sep. 30, 2014, now Pat. No. 10,071,226.

(60) Provisional application No. 61/884,834, filed on Sep. 30, 2013.

Publication Classification

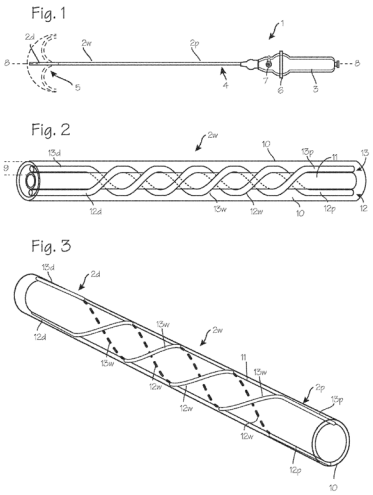
(51) **Int. Cl.**

A61M 25/06	(2006.01)
A61M 25/00	(2006.01)
A61M 25/09	(2006.01)

(52) **U.S. Cl.**
CPC ***A61M 25/0606*** (2013.01); *A61B 2017/00247* (2013.01); ***A61M 25/09*** (2013.01); ***A61M 25/0084*** (2013.01)

(57) **ABSTRACT**

A needle-injection catheter includes a catheter body having a distal end, a proximal end, a stiff proximal portion, a flexible distal portion, and a delivery lumen extending therethrough. In a first embodiment, a straight injection needle extends coaxially from a distal tip of the flexible portion of the catheter body, and a plurality of penetration limiting elements positioned circumferentially about a base of the straight injection needle and configured to fold radially inwardly against a shaft of the needle when constrained in a tubular lumen and to extend radially outwardly when unconstrained. In a second embodiment, a helical needle extends from the distal tip of the flexible portion of the catheter body. The helical needle has at least one helical delivery lumen connected to receive an injectable substance from the delivery lumen of the catheter body.



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- Jim Allen, CEO United Toll Systems, LLC.

Selected Financial Data

	Nine Months Ended 30-Sep-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	$5.7	$11.6	$11.9	$12.6
Cash used in operations	$5.5	$10.0	$10.6	$10.4
Cash & Equivalents	$4.9	$1.1	$7.4	$12.9
Debt	N/A	N/A	N/A	N/A

4.6 M shares of common stock issued and outstanding

Anticipated Near Term Catalysts Q1 and Q2 2025

- BCDA -01 CardiAMP HF with two randomized placebo-controlled trials
  - HF 1: Late Breaking Presentation at American College of Cardiology March 30, 2025
  - Japan PMDA Clinical Consultation request/submission
  - FDA Meeting request/submission
  - HF 2: Joining Baycare will be Emory, University of Wisconsin, Cleveland Clinic, Henry Ford, and others.
- BCDA-02 CardiAMP CMI
  - Completed roll in cohort data submitted for presentation/publication
- BCDA-03 CardiALLO HF
  - Data Safety Monitoring Board review of completed low dose cohort
- Helix
  - FDA Meeting request/submission
  - Partnering
- Morph
  - Sales and case support