

# Bringing personalized medicine to cell therapy for heart disease

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BioCardia, Inc. is developing regenerative biologic therapies to treat cardiovascular disease. Autologous CardiAMP and NK1+ Allogenic cell therapies are the Company’s biotherapeutic product candidates in clinical development. The Company’s approved products include the Helix™ transendocardial delivery system and its steerable guide and sheath catheter portfolio.

## INVESTMENT HIGHLIGHTS

- Over \$10B in total addressable market
- Truly unmet clinical need with great clinical promise seen in early results
- Unique patented technology
- Large revenue potential in global markets
- Expanding body of clinical research
- FDA cleared devices
- Clean capital structure
- Stable financials
- Medicare reimbursed trials
- Large corporate partners
- History of meeting milestones

Recently announced positive preclinical results for its “off the shelf” CardiALLO™ program. The company intends to submit an IND to treat Acute Respiratory Distress Syndrome (ARDS) caused by COVID-19.

## Advancing the Best of Both Worlds: Autologous and Allogenic Cell Based Therapies

### *A patient’s own (autologous) CardiAMP cell therapy in Heart Failure and Chronic Ischemia (BCDA-01, BCDA-02):*

- 1.6 million patients in the USA alone with no curative therapies
- Regulated and manufactured as a procedure kit with anticipated low cost of goods and long shelf life
- For both leading indications, CardiAMP fits into standard interventional cardiology device channels
- Most components approved in EU and/or USA, but not for cardiovascular therapeutic usage



### *A young donor’s (allogenic) CardiALLO cell therapy for patients whose own cells don’t pass potency assay (BCDA-03):*

- “The stem cells that respond to pain and inflammation”
- Treats patients not possible to be treated with CardiAMP
- Potential orphan indication
- “Off the shelf” cell therapy
- Leverages delivery system



**Pre-procedure Screening**

Small amount of bone marrow collected from hipbone and sent to lab for testing

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



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

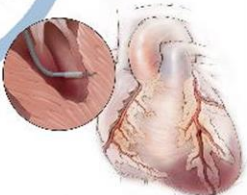


**Post-procedure**

Patient leaves hospital the next day



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



**CardiAMP™ Therapy**

04142-C-0MKT

- The 1<sup>st</sup> cardiac cell therapy that combines a pre-procedural assay, point of care cell processing system and transendocardial delivery system.
- The 1<sup>st</sup> U.S. pivotal trial for any cardiac cell therapy.
- The 1<sup>st</sup> U.S. cardiac cell therapy program supported with Medicare reimbursement.
- 74 patients enrolled and the independent data safety monitoring board recommends no changes to trial design Q1 2020.

**1.8 Million+ Patients Per Year with Heart Failure and Chronic Myocardial Ischemia and a High Value Therapy**

Program	Indication	Reachable market USA	Potential Market Size
Autologous CardiAMP BCDA-01	Ischemic Heart Failure	1,400,000	\$28 Billion
Autologous CardiAMP BCDA-02	Chronic Myocardial Ischemia	200,000	\$4 Billion
NK1+ Allogenic CardiALLO BCDA-03	Ischemic Heart Failure	200,000	\$6 Billion
	<b>TOTAL</b>	<b>1.8 M</b>	<b>\$38 Billion</b>

**MEDICARE IS REIMBURSING BOTH CARDIAMP HF AND CARDIAMP CMI PROGRAMS SUBSTANTIALLY REDUCING COST OF CLINICAL DEVELOPMENT**

**Creating Value: Anticipated Milestones 2020**

- Q2 Phase III pivotal trial commencement/first sites activated in CardiAMP Chronic Myocardial Ischemia (CMI) Trial, a second Phase III pivotal program for CardiAMP (BCDA-02)
- Q2 FDA acceptance of Investigational New Drug Application for CardiALLO Neurokinin-1 Receptor Positive Mesenchymal Stem Cell Therapy (BCDA-03), the Company's second therapeutic platform
- Q4 FDA acceptance of Investigational New Drug application for BCDA-03 for the potential treatment of ARDS as a result of COVID-19 infection
- Q4 Pre-specified Data Safety Monitoring Board Review of all patients enrolled, including futility analysis, based on sixty (60) patients that will have reached the primary one-year follow-up endpoint at the time of analysis (BCDA-01)
- Q4 Pre-specified Data Safety Monitoring Board Review of safety data from roll-in cohort in CardiAMP CMI Trial (BCDA-02)

**Hospital Partners Include**



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