Bringing personalized medicine to cell therapy for heart disease
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Building a leading cardiovascular RM product portfolio

- **Company:** Founded 2002, OTCQB: BCDA, HQ in San Carlos, CA, 25 employees.

- **Mission:** To develop regenerative medicine (RM) therapies to treat cardiovascular disease.

- **Treatments:** Cell therapies derived from bone marrow using a personalized and minimally-invasive approach in the treatment of ischemic heart disease.

- **Opportunity:** To build the leading cardiovascular RM company with a first potential therapy for heart failure patients in the market targeted for 2021. With success in the ongoing trials, the Company anticipates launch into a $5B achievable market with anticipated margins of 90%.

- **Status:** Enrolling in Phase III /pivotal trial of its lead cell therapy for the treatment of heart failure at 18 US Centers. Clinical costs substantially offset by National CMS reimbursement.
Investment Proposition Overview
Building a leading cardiovascular RM product portfolio

- Mechanisms of cardiac repair 5
- Personalized approach to cell therapy 6-7
- Advanced pipeline of cell based therapies 8
- Targeting life threatening conditions with unmet needs 9-21
- Enabling product portfolio 22
- Intellectual property 23
- Commercially viable comprehensive approach 24
- Financial 25
- Investment highlights and catalysts 26
Cardiac cell therapy: mechanistic basis for regeneration

Transplanted cells are hypothesized to benefit the heart through direct and indirect pathways.

- **Direct Regeneration:** Transplanted cells actively home to injury sites and differentiate into new functional tissue to augment organ function.

- **Indirect Regeneration:** Transplanted cells secrete stimulatory cytokines to instigate an innate regenerative response from resident stem cells.

- **Accelerating a natural process:** Cells from bone marrow home to injury in the heart. Animal work supports reduced fibrotic scar and enhanced micro vessel density. Clinical work supports that there is benefit in this approach.

Afzal MR et al Adult Bone Marrow Cell Therapy for Ischemic Heart Disease, Circulation Research. 2015.
Investigational CardiAMP Cell Therapy System
Novel, rapid, and personalized approach to cell therapy

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

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

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

CardiAMP™ Therapy

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

Post-procedure
Patient leaves hospital the next day

FDA CBER regulated as device system.
CMS reimbursement established for two pivotal trials.
Potential Solution: Investigational CardiAMP Cell Therapy System
Pre-procedure Screening Selects Patients Likely to Respond to CardiAMP

- CardiAMP Potency Assay bone marrow biomarker panel analysis at core lab:
  
  Anticipated to select 70% most likely to respond based on therapeutic potential of their bone marrow

- One marker is CD34+ cell count, which has shown therapeutic benefit in clinical trials for CMI (Povzic EHJ, 2018). Other markers confidential.

- Personalized approach to autologous cell therapy:
  - Reduces problematic patient to patient variation in bone marrow cells
  - Significantly lowers cost of therapy by enabling point of care treatment and excluding patients from therapy not likely to respond
  - Attractive to patients, physicians, and payers alike
## Advanced Clinical Pipeline

<table>
<thead>
<tr>
<th>Product / Indication</th>
<th>Pre Clinical</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Approved</th>
</tr>
</thead>
</table>
| **BCDA-01: CardiAMP Cell Therapy**  
Indication: Ischemic Heart Failure | •Pivotal /Phase III has CMS reimbursement  
–Actively enrolling 18 US Sites |         |         |         |          |
| **BCDA-02: CardiAMP Cell Therapy**  
Indication: Chronic Myocardial Ischemia with Refractory Angina | •Pivotal/ Phase III has CMS reimbursement |         |         |         |          |
| **BCDA-03: CardiALLO Cell Therapy**  
Indication: Ischemic Heart Failure | •IND submission 2018 anticipated |         |         |         |          |
| **Helix Partner 01: Cell Pro Thera**  
Indication: Acute Infarction | • Funded by partner |         |         |         |          |
| **Helix Partner-02: Univ of Milan**  
Indication: Heart Failure | •Funded by partner |         |         |         |          |
BCDA-01 CardiAMP Cell Therapy System
Targeting Ischemic Heart Failure

Burden of Illness and Unmet Need

- Chronic disease with 50% mortality at five years, impacts 1 in 5 adults over age of 40.
- Annual cost estimated to be $39 billion annually, projected to increase to $70 billion in 2030, half related to hospitalization

Minimal Treatment Options

- Despite advances in pharmaceutical chemistry and device development, options are limited.

Market Opportunity

- Targeting HFrEF NYHA Class II & III secondary to heart attack (ischemic etiology), excluding ~30% based on cell potency. Approximately 1.4M patients in USA

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

Sources of data:
American Heart Association and American Association of HF Nurses Certification Board 2013.
Go, A.S. et al., Heart Disease and Stroke Statistics 2013 Update:, A Report From the American Heart Association
Povsic T. et al EHJ 2018
BCDA-01 CardiAMP Cell Therapy in Heart Failure : Phase I Trial Design

Transendocardial Autologous Bone Marrow in Myocardial Infarction (TABMMI) NCT00507468

20 Ischemic Heart Failure Patients
LVEF<40%
NYHA Class I, II, and III

Open Label Safety Study
100 Million BMC
10 peri-infarct injection sites - Helix System

Left ventricular EF measurements - 2D echocardiography
24-hour Holter Monitor
Exercise Tolerance Testing (ETT)

BCDA-01 CardiAMP: Phase I Trial Results from TABMMI
Safety: No Treatment Emergent-MACE; Improved Cardiac Function

Improved LV Ejection Fraction
Improvement at 12 & 24M:
~ +7 %, p=0.000006, p=0.00005

Exercise Tolerance Time
Improvement at 12 & 24M:
~ +125 sec, p=0.006

Improved survival at 3 and 5 year follow-up
1st 10 patients – No death
All 20 patients – 2 deaths:
D177 Elective heart transplant
D695 Unknown causes


BCDA-01 CardiAMP Cell Therapy in Heart Failure: Phase 2 Trial Design

Transendocardial Autologous Cells in Heart Failure Trial (TAC-HFT), NCT00768066

34 Ischemic Heart Failure Patients
LVEF<50%
NYHA Class I, II, and III

Open Label Dose Escalation
100 M to 200M Cells (N=4)
Randomized Placebo Controlled Therapy at 200M cells
to Treatment (N=30) 2:1
10 peri-infarct injection sites
Helix System

Primary endpoint was safety based on TE MACE. Secondary efficacy endpoints six minute walk distance, quality of life, NYHA CLASS, echocardiography (LVESV, LV EDV, LVEF).

Wong Po Foo et al, World Congress of Regenerative Medicine, 2015.
**BCDA-01 Phase 2 Placebo Controlled Randomized Trial Results**

- TACHFT-BMC were results superior to TACHFT-MSC
- Primary safety endpoint met: no treatment emergent MACE at 30 days
- No death or MACE in BMC treatment group at one year follow-up
- All secondary efficacy endpoints at one year follow-up favor therapy (below)
- Multiple endpoints that are statistically significant and clinically meaningful

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

Wong Po Foo et al, World Congress of Regenerative Medicine, 2015.

*NS: not significant
BCDA-01: Phase 2 Efficacy Results in Six Minute Walk Relative to other heart failure therapies

- CRT = Cardiac Resynchronization Therapy or Biventricular Pacing, a $3Bn US Market
- 50% of patients in CardiAMP placebo controlled Phase II already had AICD or CRT devices
- 6MW has been used for approval in PAH, and CRT
- This data is from trials used for CRT product registration
BCDA-01 Phase 2 Efficacy Results in Quality of Life Relative to other heart failure therapies

- 50% of patients in CardiAMP placebo controlled Phase II already had AICD or CRT devices
- QOL has been used as pivotal endpoint in CRT trials
- This data is from trials used for CRT and Entresto product registration
BCDA-01 CardiAMP Cell Therapy in Heart Failure: Phase 3 Trial Design

CardiAMP Heart Failure Trial, NCT02438306, IDE Trial for Premarket Approval

- **New in Phase 3:**
  - Focus on NYHA Class II & III Patients with cell potency assay inclusion criteria
  - Point of Care Cell Processing

- **Trial has > 95% power based on Phase 2 Results**
- **Trial is reimbursed by CMS**

- **40 center, 260 Ischemic Heart Failure Patients LVEF<40% NYHA Class II and III**

- **Open Label Roll In**
  - 200M Cells (N=10)
  - Randomized Sham Controlled Therapy at 200M cells to Treatment (N=250) 3:2
  - 10 peri-infarct injection sites Helix System

- **Primary endpoint six minute walk distance composite that incorporates MACE. Hierarchical secondary endpoints of MACE, survival, quality of life.**

Raval A et al. The CardiAMP Heart Failure trial: A randomized controlled pivotal trial of high-dose autologous bone marrow mononuclear cells using the CardiAMP cell therapy system in patients with post–myocardial infarction heart failure: Trial rationale and study design, AM Heart Journal, April 2018.
BCDA-01 Phase 3 Roll In Cohort Safety and Efficacy Results

Data Safety Monitoring Board (DSMB) has completed the 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. The DSMB indicated there were no significant safety concerns with the CardiAMP study results and recommended that the trial continue, as planned.

First efficacy data from this cohort published in Circulation Research shows improvements in primary endpoint of 6 minute walk, New York Heart Association Class, and quality of life as measured my the Minnesota Living with Heart Failure Questionaire.

Trial has been activated at 18 centers in the USA

Johnston P et al, Not All Stem Cells Are Created Equal: The Case for Prospective Assessment of Stem Cell Potency in the CardiAMP Heart Failure Trial, Circulation Research, August 2018.
Burden of Illness and Unmet Need

- 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 RA, 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

- Reachable market estimated as 200,000 patients in the United States per year, 500,000 world wide. Of note, Ranexa from Gilead Sciences sales estimated as $800M/Year.

Characterized by significant debilitating chest pain that greatly reduces quality of life.

Sources of data:
Povsic T. et al EHJ 2018
BCDA-02 CardiAMP Chronic Myocardial Ischemia: Phase 3 Trial Design

CardiAMP Chronic Myocardial Ischemia Trial, NCT03455725, IDE Trial for Premarket Approval

**40 center, 343 Ischemic Heart Failure Patients**
LVEF<40%
NYHA Class II and III

**Open Label Roll In**
200M Cells (N=10)
Randomized Sham Controlled Therapy at 200M cells to Treatment (N=333) 2:1
10 peri-infarct injection sites
Helix System

**Primary endpoint change from baseline in total exercise time.**
Hierarchical secondary endpoints of MACE, survival.

**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

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

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

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

- Adaptive statistical analysis plan with anticipated read out at 100 patients.
- Trial is reimbursed by CMS.
- Capital efficient.

BioCardia®
## Burden of Illness and Unmet Need

1. Chronic disease with 50% mortality at five years, impacts 1 in 5 adults over age of 40.
2. Annual cost estimated to be $39 billion annually, projected to increase to $70 billion in 2030, half related to hospitalization.

## Minimal Treatment Options

1. Despite advances in pharmaceutical chemistry and device development, options are limited.
2. BCDA-1 may not be appropriate for 30% of patients who do not meet cell potency assay.

## Market Opportunity

1. Targeting ~30% excluded from BCDA-01 based on cell potency, approximately 600K patients in USA.
2. Potential to be advanced for other indications.

Sources of data:
- American Heart Association and American Association of HF Nurses Certification Board 2013.
- Go, A.S. et al., Heart Disease and Stroke Statistics 2013 Update; A Report From the American Heart Association
- Povsic T. et al EHJ 2018
Three BCDA co-sponsored Phase 1/2 culture expanded mesenchymal cell trials in heart failure have been completed:

Transendocardial Autologous Cells in Heart Failure Trial (TAC-HFT), NCT00768066
- Comparing culture expanded autologous to minimally processed autologous cells at same dosage delivered with Helix
- Conclusion the latter were superior

Percutaneous Stem Cell Injection Delivery Effects on Neomyogenesis Pilot Study (The POSEIDON-Pilot Study) NCT01087996
- Comparing allogenic to autologous MSC delivered with Helix
- Conclusion both showed similar benefits and risks.

The Transendocardial Stem Cell Injection Delivery Effects on Neomyogenesis Study (The TRIDENT Study) (Trident) NCT02013674
- Comparing low dose to high dose allogenic MSC delivered with Helix
- Conclusion: high dose was superior.

Planned Phase 2 IND in heart failure to follow these three trials, with enhanced approach, initially in patients excluded from BCDA-01 by potency assay.

An additional diagnostic approach will also be deployed.

Hare J et al, POSEIDON, JAMA 2012.
CardiAMP cell processing platform processes bone marrow aspirate at the point of care to concentrate mononuclear cells and prepare the dosage form.

Helix™ transendocardial biotherapeutic delivery system delivers therapeutics to heart with a penetrating helical needle

Morph® vascular access provides enhanced control for Helix biotherapeutic delivery and other common interventions

Helix / Morph System also used in partner programs.

Intellectual property

Intellectual Property

- Company has exclusive rights to 75 issued US patents and pending applications, as well as international counterparts, covering CardiAMP cell therapy system, CardiALLO cell therapy system, Helix biotherapeutic delivery system and Morph products and product candidates. Most recently issued patents are below.

<table>
<thead>
<tr>
<th>US Patent No.</th>
<th>Patent Title</th>
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<tbody>
<tr>
<td>10,035,982</td>
<td>Method of preparing autologous cells and methods of use for therapy</td>
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<tr>
<td>9,945,854</td>
<td>Methods of measuring therapeutic potency potential and defining dosages for autologous cell therapy</td>
</tr>
<tr>
<td>9,752,123</td>
<td>Method of Preparing Autologous Cells and Methods of Use for Therapy</td>
</tr>
<tr>
<td>9,517,199</td>
<td>Treatment for chronic myocardial infarct</td>
</tr>
<tr>
<td>9,504,642</td>
<td>Treatment for chronic myocardial infarct</td>
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<tr>
<td>9,301,975</td>
<td>Method of preparing autologous cells and method of use for therapy</td>
</tr>
<tr>
<td>8,496,926</td>
<td>Treatment for chronic myocardial infarction</td>
</tr>
<tr>
<td>8,027,740</td>
<td>Drug delivery catheters that attach to tissue and methods for their use</td>
</tr>
<tr>
<td>7,500,970</td>
<td>Catheter drug delivery system and method for use</td>
</tr>
</tbody>
</table>

- Company has exclusive licenses to a number of additional patent portfolios and broad nonexclusive rights generated from technology access programs.
Commercially viable comprehensive approach

- **CardiAMP cell therapy system** is regulated and manufactured as a device based procedure kit with anticipated low cost of goods and long shelf life. For both leading indications, it fits into standard interventional cardiology device channels.

- **CardiALLO cell therapy system** commercial launch will leverage the CardiAMP experience, training, and delivery systems. As an “off the shelf” cell therapy multiple doses per donor will be available. BioCardia has a unique approach to 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 assay
CardiAMP heart failure and chronic myocardial ischemia programs have extensive non-dilutive financial support from the U.S. Center for Medicare and Medicaid Services (CMS)

Because of CMS support of both trials, additional cash to fund CardiAMP heart failure to top line data AND CardiAMP in Chronic myocardial ischemia to a meaningful interim readout is modest.

**Second Quarter 2018 Financial Results:**

- Net loss of $3.2 million
- Cash and cash equivalents $6.8 Million
- Liabilities $1.9 million

- Shares outstanding: 38 million

**Clean balance sheet**
Highlights

- Statistically significant and clinically meaningful data that supports two parallel pivotal programs
- Large and growing addressable market opportunity
- Robust intellectual property portfolio
- Significant non-dilutive funding support from CMS trial reimbursement

Near Term Catalysts

✓ CardiAMP Chronic Myocardial Ischemia pivotal FDA approved Q1 ‘18
✓ CardiAMP Chronic Myocardial Ischemia CMS reimbursement Q2 ‘18
✓ CardiAMP Ischemic Heart Failure roll in data Q3 ‘18
✓ CardiALLO Cell Therapy System FDA IND submission Q4 ‘18
✓ Advanced steerable sheath FDA submission Q4 ‘18
✓ CardiAMP Chronic Myocardial Ischemia First Patient In Q1 ‘19

More information:
www.BioCardia.com
OTCQB: BCDA