

# Corporate Presentation January 2014

www.sunshineheart.com

## **Forward Looking Statement**



- This presentation contains forward-looking statements. All forward-looking statements are management's present expectations of future events and are subject to a number of risks and uncertainties. Various factors could cause actual results to differ materially from these statements including timing, clinical enrollment, clinical results, financing availability, product sales and marketing or efficacy of products, and the other risks set forth under the caption "Risk Factors" and elsewhere in our periodic and other reports filed with the U.S. Securities and Exchange Commission, including our Annual Report or Form 10-K for the fiscal year ended December 31, 2012.
- Although the Company believes that the forward-looking statements are reasonable and based on information currently available, it can give no assurances that the Company's expectations are correct. All forward looking statements are expressly qualified in their entirety by this cautionary statement.
- Caution: C-Pulse ® is an investigational device. The device is limited by federal (United States) law to investigational use only.
- C-Pulse is a registered trademark of Sunshine Heart Inc.

### **Company Vision**

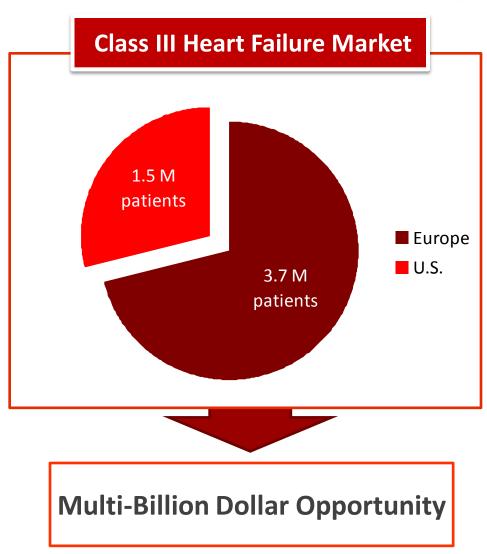


Offer a minimally invasive therapy for moderate to severe heart failure that provides symptomatic relief and halts the disease progression

## C-Pulse U.S. Market Opportunity



- C-Pulse population: Class III/ambulatory Class IV
- Patients that have failed drug therapy and CRT (if indicated)
- Average age 50's
- Symptoms: shortness of breath, dizziness when performing normal or strenuous daily activities; inability to sleep
- Patients usually unable to drive, work or perform normal daily activities; poor quality of life
- Highest re-hospitalization rates in U.S. due to worsening HF



# C-Pulse -Targeting the treatment gap for moderate to severe HF



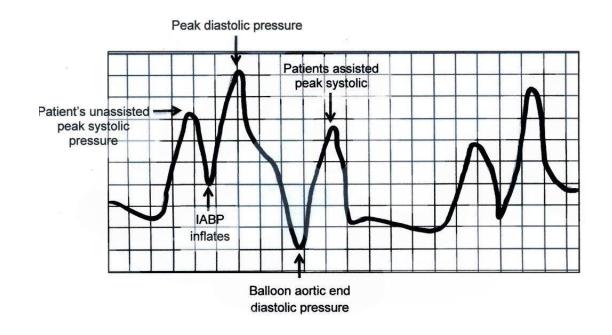
	Progressing HF Severity			
	NYHA Class I	NYHA Class II	NYHA Class III	NYHA Class IV
EF > 35		Medical Manag	ement	VAD
EF ≤ 35		CRT/ICD	C-Pu	lse / HT

- Despite Current Therapies, Heart Failure Morbidity and Mortality Remain High
  - Re-hospitalization rates are high
  - 5-year mortality ranges from 15% to more than 50% depending on disease severity

# Balloon Counterpulsation Mechanism of Action



- Increase myocardial oxygen supply(coronary blood flow)
- Decrease myocardial demand
- Acute therapy
- Support AMI patients
- Stabilize ventricular arrhythmia
- Manage unstable angina
- Support patients post cardiac surgery
- Support patients in cardiogenic shock

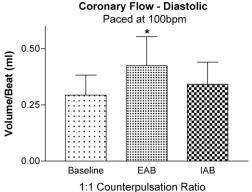


**Normal Inflation** 

### **C-Pulse Impact on Coronary Flow**

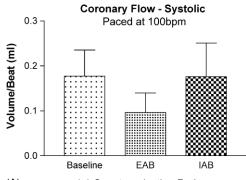


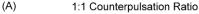
- Diastolic flow in the aorta increased from .84 (+/- .36)ml/beat to 3.92 (+/- .55) ml/beat Davies study<sup>1</sup>
- ☐ 67% increase in coronary blood flow Legget<sup>2</sup>
- 31% reduction in left ventricular wall stress Leggett<sup>2</sup>
- ☐ Data on initial Canadian patients showed improved coronary flow Cecere<sup>3</sup>

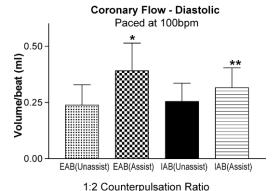


(A) \* p<0.05 compared to Baseline

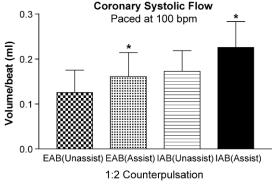
(B) \* p<0.05; \*\* p<0.01 - Unassisted vs Assisted







(B) \* p<0.05 - Unassisted vs Assisted.



1)Extra-Ascending Aortic Versus Intra-Descending Aortic Balloon Counterpulsation – Effect on Coronary
Blood Flow – Heart Lung and Circulation 2005,14:178-186, Andrew Davies

2)Extra-Aortic Balloon Counterpulsation:An Intraoperative Feasibility Study- Circulation 2005:112;26-31

3) Improvements in Myocardial Perfusion Observed in Patients Supported With the C-Pulse
Counterpulsation Device. TCT 2011

### **Unmet Need**



NYHA III	NYHA III/IV	NYHA III/IV (± CRT)	NYHA IV
Optimal Medical Therapy	CRT	Unmet Need:	LVAD / HTX
		C-Pulse	

# C-Pulse population: Patients in NYHA Class III/ambulatory Class IV with progressive HF symptoms despite:

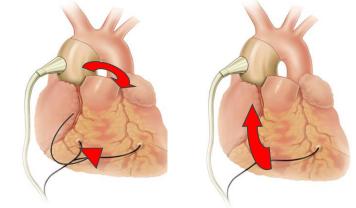
- Optimized medical treatment
- CRT (if indicated)
- Prior to the need for traditional circulatory assist devices

## **Current C-Pulse System**



- Reduce LV work, increase flow
  - Balloon inflates increases
     coronary perfusion (addresses
     hemodynamics primary
     pathophysiology of heart failure)
  - Balloon deflates creates vacuum pulling blood from LV
- Minimally invasive procedure can be done in 90 minutes
- No blood contact lower likelihood of clot or stroke
- Ability to disconnect patient comfort and convenience





### Class III Competitive Landscape



- CRT persistent problems with high % of non-responders and patients who deteriorate after initial improvement
- CircuLite mini pump technology placed in bloodstream acquired by HeartWare undergoing design changes
- LVADs –primarily for Class IV heart failure; expansion to Class III will be limited by stroke and bleeding risks
- No known competitive technology that has C-Pulse features

## CircuLite Acquisition Analysis

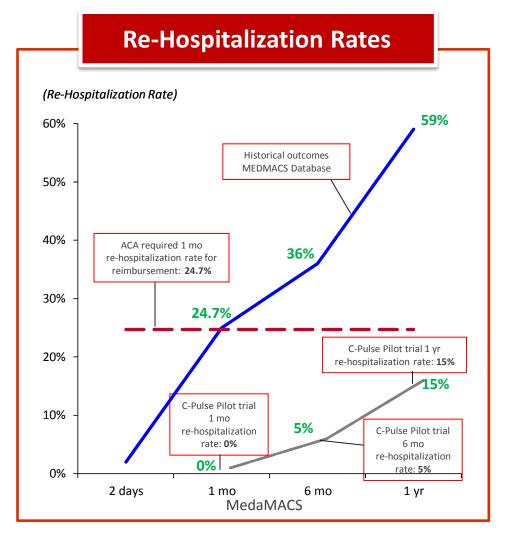


- Validates that there is a viable Class III heart failure market
- Raises questions of the confidence level regarding current/future
   LVAD technology for Class III population
- Valuation reported to be impacted by device issues
- Overall good for the Class III space that there is a larger player increasing the exposure
- LVAD technologies under pressure the past year regarding thrombus and stroke concerns; C-Pulse has not had any of these outcomes to date

### Class III Heart Failure Outcomes Today



- No current effective solution for patients
- Patients may progress to Class IV or die
- Current 30-day re-hospitalization rate – 24.7%
- C-Pulse pilot trial 6 month
   re-hospitalization rates for worsening HF 5%
- No reported re-hospitalization for worsening HF for C-Pulse patients in OPTIONS HF trial



### C-Pulse Feasibility North American Sites



National PI: Dr. William Abraham - Ohio State University

Site	Investigators	Subjects
Saint Luke's Hospital-Mid America Heart Institute	Sanjeev Aggarwal, MD and Andrew Kao, MD	5
University of Louisville-Jewish Hospital	Mark Slaughter, MD and Sumanth Prabhu, MD	4
McGill University Health Centre	Renzo Cecere, MD and Nadia Giannetti, MD	3
University of Alabama at Birmingham	Salpy Pamboukian, MD and William Holman, MD	3
Ohio State University Medical Center	Garrie Haas, MD and Benjamin Sun, MD	2
United Heart and Vascular Clinic	Alan Bank, MD and John Grehan, MD	2
Penn State-Milton S. Hershey Medical Center	Walter Pae, MD and John Boehmer, MD	1

## **Feasibility Trial Population**



	N = 20
Age, mean ± SD years (range)	56 ± 9 (34-71)
Gender Female Male	8 12
Failed pacemaker patients Patients with ICDs Patients on optimal medical therapy Patients on Inotropes	9 20 20 4
NYHA class Class III Ambulatory Class IV	18 2
Non-Ischemic Ischemic	12 8

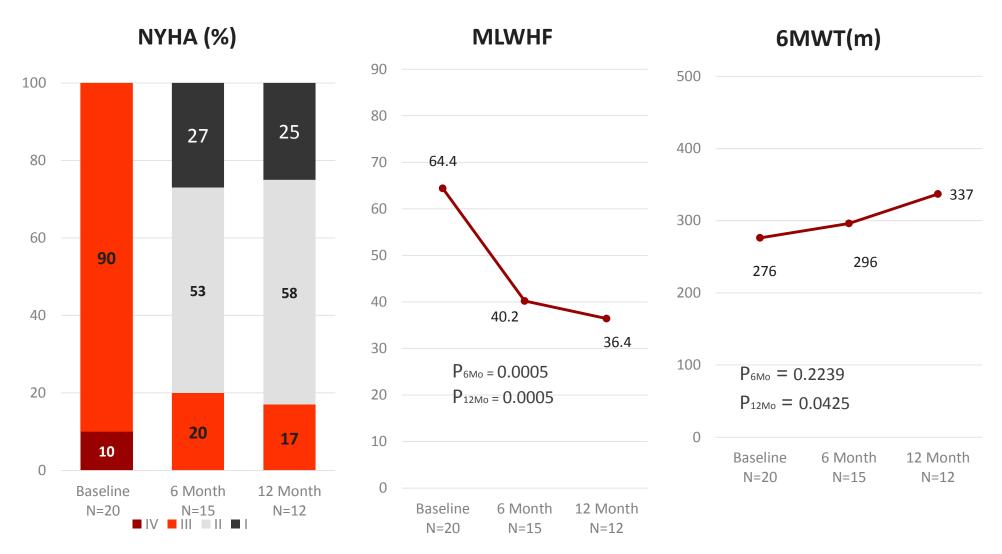
### Implant Success



- 100% of patients successfully implanted
- No procedural device related complications
- 6/20 with minimally invasive procedure
- Total hospital median LOS 8.5 days
- High rate of infections and complications related to PIL required device and patient management modifications

### **Feasibility Trial Study Results**

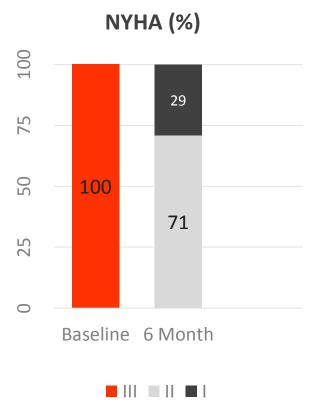


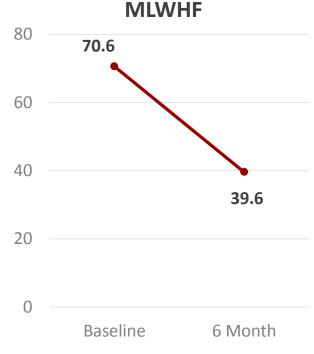


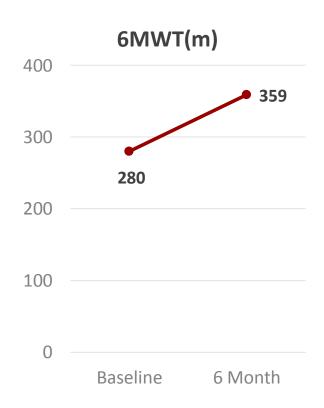
## **Feasibility Trial Study Subset**



### <u>N=7</u>







# **Primary Safety Device Events**



French	# of Patients		
Event	0 - 6 mths	6 - 12 mths	
Composite Device-related AE <sup>1</sup>	10	0	
Major Infection Localized Non-Device Infection – PICC Line (1/9) Exit Site (8/9) Internal Pump Component (PIL) (1/9)	9	0	
Acute Renal Dysfunction <sup>3</sup>	1	0	
Death <sup>2</sup> Within 30 Days (0/1) 30-Days to 6-Months (1/1)	1	0	
Neurological Dysfunction	0	0	
<sup>1</sup> All event types and relationship to device have been adjudicated by the CEC. <sup>2</sup> Patient required re-do surgery for mediastinitis with an outcome of death <sup>3</sup> CT with contrast for the assessment of possible device infection resulted in Acute Renal Dysfunction			

### **Feasibility Trial Observations**



- Extensive follow up longest implanted patient over 2 years
- Short hospital stays/procedural time, minimal perioperative complications
- C-Pulse demonstrates acute effects versus other remodeling therapies that take 3 months or longer to demonstrate an impact
- Medication reductions (diuretics and 4/4 weaned from inotropes)
- 6/12 month improvements in NYHA Class, 6MWT and QOL (significant) at 12 months suggest a durable effect
- No strokes, clots, bleeding or heart attacks
- Five patients weaned from therapy
- One re-hospitalization for worsening heart failure in first 6 months

### **U.S. Pivotal: COUNTER HF**



- Dr. Bill Abraham and Dr. Margarita Camacho trial Pl's
- 40 centers
  - 8 sites activated, total of 30 committed to date
- N=388 patients, randomized 1:1
- CMS confirmed reimbursement of C-Pulse procedures to qualifying sites
- All U.S. pilot trial sites are participating in the pivotal trial except United Hospital which is a core lab for the study

### U.S. Pivotal: Activated sites



- Saint Luke's Hospital Mid America Heart Institute
- Jewish Hospital Louisville
- University of Alabama Birmingham
- Ohio State University
- Minneapolis VA
- Barnes-Jewish Hospital St. Louis
- Newark Beth Israel
- Virginia Commonwealth University

### **COUNTER HF: US Pivotal Trial Design**



#### **Overview**

- Primary efficacy endpoint freedom from worsening heart failure resulting in hospitalization, LVAD implant, heart transplant and heart failure related death
- Primary safety endpoint all serious procedure and device-related adverse events as determined by CEC adjudication
- 1-year follow-up expected for safety
- Estimated time to complete enrollment ~ 2.5 years

#### **Key Inclusion Criteria**

- Left ventricular ejection fraction (LVEF) ≤ 35%
- Patient has NYHA Class III ambulatory Class IV heart failure despite optimal medical therapy
- Six minute walk test of >175<375 meters
- At least one hospitalization for decompensated heart failure while on heart failure medications, within 12 months prior to randomization or BNP level > 300 or NTproBNP > 1500

### **Key Exclusion Criteria**

- Any evidence, as assessed within 90 days prior to enrollment, of ascending aortic calcification
- Mid ascending aortic outside diameter less than 28mm or greater than 42mm
- Patient has ascending aorto-coronary artery bypass grafts

## **EU Post-Market Study: OPTIONS HF**



- First patient implanted May, 2013 at Berlin German Heart Institute
- 8 patient implants at end of 2013
- Target countries Germany, Italy and the U.K.
- Trial will enroll 50 patients across 8 10 centers in Germany, Italy and the U.K; additional expansion expected in Austria and Switzerland
- Study rationale: provide additional clinical data for publications, reimbursement and communicate results to the market
- German reimbursement decision expected in February 2014
- Trial design/endpoints mirror U.S. pivotal trial

### **OPTIONS HF Initial Observations**



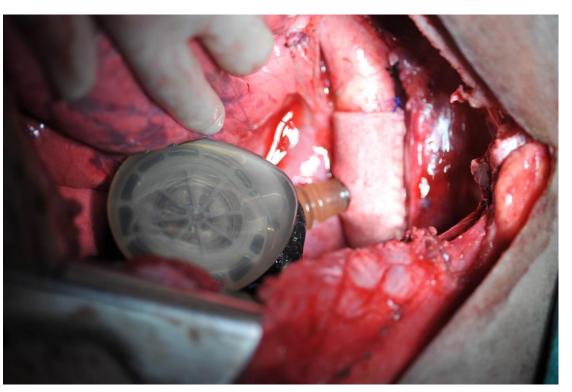
- First clinical presentation at TCT on October 28, 2013 by Prof.
   Krabatsch of German Heart Center Berlin
  - Clinical response to date is greater than the U.S. pilot trial results
  - Avg. 6 minute walk improvement of 66M at 6 weeks
  - Reduction in HF medications among majority of patients
  - 75% of patients have measured weight loss at 6 weeks, 4% 9% of body weight
  - Clinically significant improvement in ejection fraction
  - No instances of:
    - Re-hospitalization due to worsening HF
    - Exit site (or other) infections
    - Neurologic dysfunction
    - Major bleeding
    - Renal dysfunction

## Pipeline: Fully Implantable C-Pulse System



- Fliminates exit site infections.
- Opens up new market for stable angina patients ~ 1M/yr in U.S.
- Contract with pump and TETS development partners complete
- Acute animal study successfully completed in November 2013
- Chronic pump study initiated on December 11, 2013





### Financial Update



#### (\$ in thousands)

Summary Income Statement*			LTM	LTM
	3Q 2013	3Q 2012	9/30/2013	9/30/2012
Operating Loss:	\$(6,174)	\$(3,297)	\$(19,986)	\$(16,132)
Net Loss:	\$(6,035)	\$(3,296)	\$(18,720)	\$(15,234)
Cash Used in Operations:	\$(4,184)	\$(2,851)	\$(15,172)	\$(13,095)

#### (\$ in thousands)

Summary Balance Sheet*	As of 9/30/2013
Cash & Cash Equivalents:	\$59,807
Long-term Debt	\$
Total Stockholders' Equity:	\$57,856

- Cash and cash equivalents at 12/31/13 was >\$54 million (unaudited).
- Company now funded through US Pivotal Trial, European commercial launch and continued development of fully implantable system.
- Purchase Agreement commits Aspire Capital to purchase up to additional \$24 million of common stock at Sunshine Heart's sole discretion.

<sup>\*</sup>Per SSH Form 10-K as filed 3/12/13 and Form 10-Q as filed 11/12/13.

### **Share Information**



- Listed on NASDAQ Feb 2012
- IPO Aug 2012 \$21M
- Corporate Investor \$3M
- Follow-on April 2013 \$15M
- Follow-on September 2013 \$46M

Largest Shareholders: (9/30/2013)	Shares (000's)
Talu Ventures	1,626
GBS Ventures	1,195
<b>Great Point Partners, LLC</b>	1,088
Wall Street Associates	700
DWS Funds (4)	624
Redmile Group	470
Corporate Investor	428
The Vanguard Group, Inc.	283
Millennium Partners LP	244

	NASDAQ
Symbol:	SSH
Market Cap:	\$181M
Shares o/s:	16.8M
Price per Share (as of 1/9/2014):	\$10.76
52-week high:	\$13.80
52-week low:	\$4.85
Avg. Daily Trading Volume (shares)	263,000
% Institutional / Mut. Fund / VC Ownership	50%

### 2013 Results



- Initiated COUNTER HF U.S. Pivotal Trial 1Q
  - 8 sites activated, 22 additional sites in progress
  - CMS reimbursement approval granted
  - Three patient enrollments
- Initiated OPTIONS HF post-market EU study 1Q
  - 8 implants completed
  - 8 sites implant-ready
  - Patients currently responding very well with C-Pulse
- 25 patient years, 25 implants milestone 3Q
- 5 patients weaned by physicians from Pilot trial
- Fully implantable system acute study successfully completed
- Contracts signed with pump designer and TETS provider for fully implantable system
- Appointment of CMO (Dr. Patrick Verta)
- Closed two public offerings for combined \$61.1M
- Established \$25M equity line of credit

### **2014** Milestones



Event	Timing
Results of fully implantable pump chronic trial	Q1 2014
COUNTER HF National Investigator meeting	Q1 2014
Initiation of pilot program PR/Awareness Campaign for COUNTER HF Trial	Q1 2014
Presentation / publication of paper on aortic impact after 2 years, OPTIONS HF trial clinical update(presentation), Paper/presentation on experience at center with greatest C-Pulse experience, C-Pulse Mode of operation paper/presentation	Q1/Q2 2014
Reimbursement Update	February 2014
Publication of Pilot trial manuscript	Q2 2014
European targeted commercialization initiated	Q3 2014
OPTIONS HF Trial data released	Mid 2015
US trial fully-enrolled	Q4 2015/Q1 2016
US trial data	2016