

# **Corporate Presentation**

December 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, 2013.
- 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 <sup>®</sup> 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**

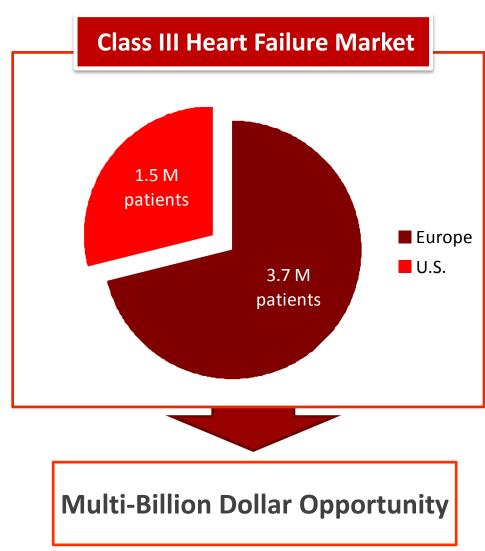


Offer a minimally invasive therapy for moderate to severe heart failure that provides symptomatic relief and halts the disease progression

# C-Pulse U.S. Market Opportunity

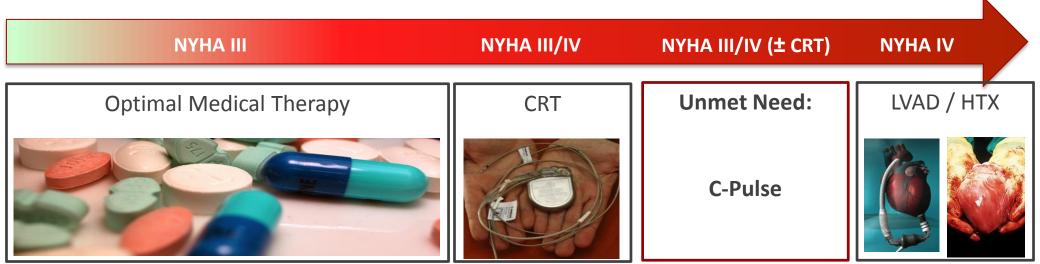


- C-Pulse population: Class III/ambulatory Class IV
- Patients that have failed drug therapy and CRT (if indicated)
- Average age 50's
- Symptoms: shortness of breath, dizziness when performing normal or strenuous daily activities; inability to sleep
- Patients usually unable to drive, work or perform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



#### **Unmet Need**





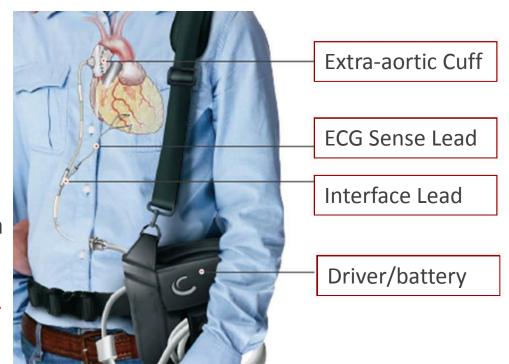
# C-Pulse population: Patients in NYHA Class III/ambulatory Class IV with progressive HF symptoms despite:

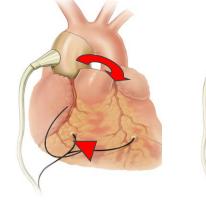
- Optimized medical treatment
- CRT (if indicated)
- Prior to the need for traditional circulatory assist devices

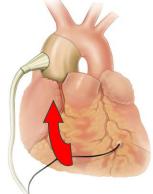
## **Current C-Pulse System**



- 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

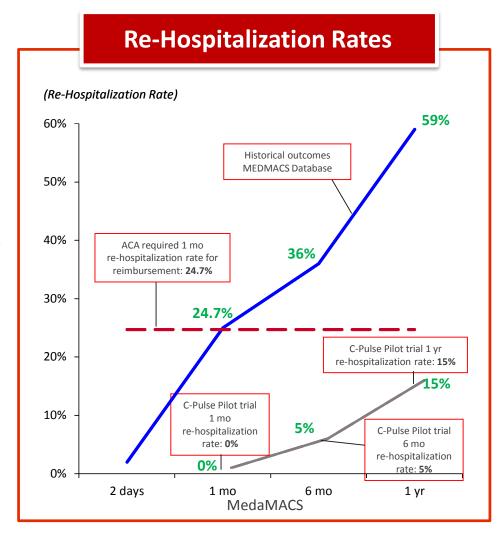


- CRT persistent problems with high % of non-responders and patients who deteriorate after initial improvement; failed CRT patients target for C-Pulse
- CircuLite mini pump technology placed in bloodstream acquired by HeartWare undergoing design changes; validated Class III market
- LVADs –primarily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

#### Class III Heart Failure Outcomes Today



- Patients may progress to Class IV or die
- Historical medical therapy 30-day rehospitalization 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 at 6 months; overall rate 16.7%
- 71%(15/21) of current COUNTER HF sites will have Medicare payment reductions related to unplanned heart failure readmissions



# C-Pulse Feasibility Study 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
- Data published October 2014 in JACC HF journal

### Feasibility Trial Observations



- Extensive follow up longest implanted patient over 4 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
- 35 40 centers
  - 21 sites able to enroll at Oct 31st 2014, 25 targeted for EOY
  - All activated centers have identified patients
- N=388 patients, randomized 1:1 (265 events)
  - 27 patients enrolled at Sep 30th 2014, including 14 enrolled in Q3
  - Interim analysis to potentially reduce timelines proposed to FDA
- CMS confirmed reimbursement of C-Pulse procedures to all qualifying sites;
  Cardiomems has received reimbursement add-on code
- All U.S. pilot trial sites are participating in the pivotal trial except United Hospital which is a core lab for the study
- A number of sites have proposed additional substudies evaluating angina and depression

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



- 12 patient implants after Q3 2014
- Trial will enroll 50 patients across 15 centers(13 centers activated) starting in Germany, U.K.
  and Canada; additional expansion in Austria and Switzerland
- Study rationale: provide additional clinical data for publications, reimbursement and communicate results to the market
- Study design/endpoints mirror U.S. pivotal trial
- German reimbursement application submitted 10/2014
  - NUB assigned Status 4
  - OPS (Procedure code) established unique to C-Pulse
  - 5-376.9 permanent implantable extra aortic cardiac assist device
  - .90 Implantation.91 change of the full system
  - .92 isolated change of the connecting line
  - .93 isolated change of epicardial ECG-electrode and connecting line
  - .94 removal

#### **Europe Experience**



- Short hospital stays/procedural time, minimal perioperative complications – 90 minutes required for 1<sup>st</sup> case at Harefield
- One patient unintentionally weaned asymptomatic (6 WW)
- UK severely ill patient demonstrated excellent results which allowed him to attend daughter's wedding
- No strokes, clots, bleeding or heart attacks
- No re-hospitalization for worsening heart failure in first 6 months –
  16.7% overall
- 8.3% exit site infection rate
- 13 total implants
- Reimbursement for Germany to be filed in October

#### **OPTIONS HF – Recent Presentation**



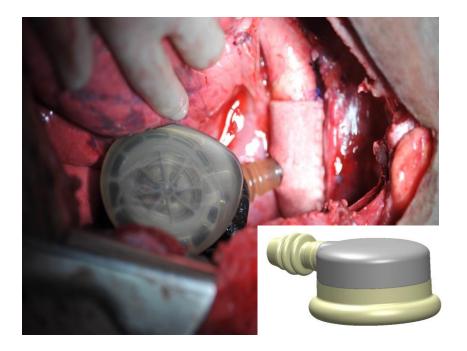
- ISHLT presentation by Dr. Holger Hotz on 6 patients
  - Clinical response to date is greater than the U.S. pilot trial results
  - Reduction in HF medications among majority of patients
  - All patients have experienced a reduction in HF class
  - Clinically significant improvement in ejection fraction avg. improvement 33%
  - One patient weaned at 6.5 months with EF of 55%
  - 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



- 90 day chronic animal study completed in Q2 2014
- Opens up new market for stable angina patients ~ 1M/yr in U.S.
- All histology results positive for chronic trial
- TETS project underway
- Efforts focused on miniaturizing pump design
- Full system testing expected in Q1 2015





#### **Financial Transformation**



- \$61.1 M equity raised in 2013
- \$54.1 M cash at year end 2013
- Increased institutional ownership
- Increased and enhanced research coverage
- Completed delisting from ASX in May 2013
- Expanded alternatives for capital availability and flexibility
  - Equity line of credit Jan 2013 up to \$24M available
  - \$100M shelf registration March 2014
  - \$40M at-the-market (ATM) facility March 2014
- Registered underlying shares for warrants issued from previous private placements

## Financial Update



#### (\$ in thousands)

Summary Income Statement*	3Q 2014	3Q 2013	LTM 9/30/2014	LTM 9/30/2013
Operating Loss:	\$(6,110)	\$(6,174)	\$(26,126)	\$(19,986)
Net Loss:	\$(6,132)	\$(6,035)	\$(25,948)	\$(18,720)
Non-GAAP Net Loss:	\$(5,432)	\$(4,957)	\$(22,022)	\$(16,154)
Cash Used in Operations:	\$(5,436)	\$(4,184)	\$(22,965)	\$(15,172)

#### (\$ in thousands)

Summary Balance Sheet*	9/30/2014	12/31/2013
Cash & Cash Equivalents:	\$36,575	\$54,136
Long-term Debt	\$	\$
Total Stockholders' Equity:	\$35,062	\$51,727

- Cash on hand to be used for US Counter HF study, European Options HF study, European commercial launch and continued development of fully implantable system.
- Additional financing instruments available, at Company's discretion, include shelf registration, ATM facility and equity line of credit.

#### **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: (6/30/2014)	Shares (000's)
Talu Ventures	1,626
GBS Ventures	1,195
DWS Funds (3)	788
Wall Street Associates	722
Corporate Investor	428
<b>Great Point Partners, LLC</b>	424
The Vanguard Group, Inc.	327

	NASDAQ
Symbol:	SSH
Market Cap:	\$80M
Shares o/s:	16.9M
Price per Share (as of 11/6/2014):	\$4.75
52-week high:	\$11.49
52-week low:	\$4.15
Avg. Daily Trading Volume (shares)	115,000
% Institutional / Mut. Fund / VC Ownership	46%

#### Milestones



Event	Timing
Results of initial 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
German Reimbursement – NUB assigned Status 4	Q1 2014
Presentation of data on aortic impact after 21 months - ISHLT	Q2 2014
OPTIONS HF trial clinical update(presentation) - ISHLT	Q2 2014
Paper/presentation on experience at center with greatest C-Pulse experience, C-Pulse Mode of operation paper/presentation, publication of data on aortic impact after 2 years	Q3 / Q4 2014
Results of additional fully implantable pump chronic trial	Q3 2014
Publication of feasibility study manuscript in peer-reviewed JACC	Q4 2014
OPTIONS HF Trial data released	Ongoing
European targeted commercialization initiated	Q1 2016