

# **Corporate Update**

December 2015

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, 2014.
- 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**

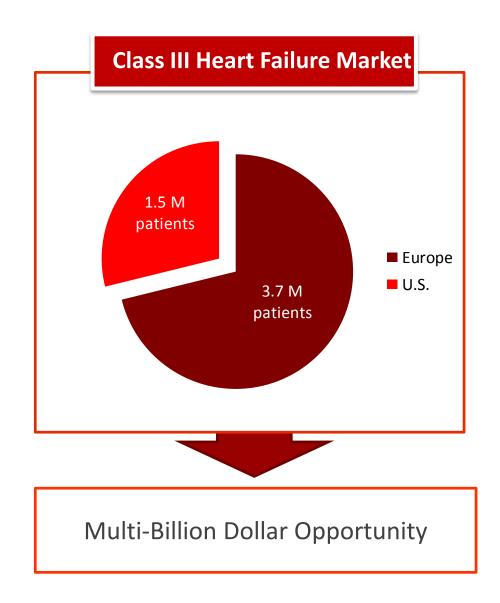


Offer a minimally invasive therapy for moderate to severe heart failure that provides symptomatic relief and halts the disease progression

### C-Pulse U.S. Market Opportunity\*



- C-Pulse population
  - Class III/ambulatory Class IV
  - INTERMACS 4-7
  - ACC Stage C
  - Failed CRT and OMT
- Average age 50's
- Symptoms: shortness of breath, dizziness when performing normal or strenuous daily activities; inability to sleep, poor quality of life



# There is a large unmet need





#### **C-Pulse target 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

#### Class III Competitive Landscape



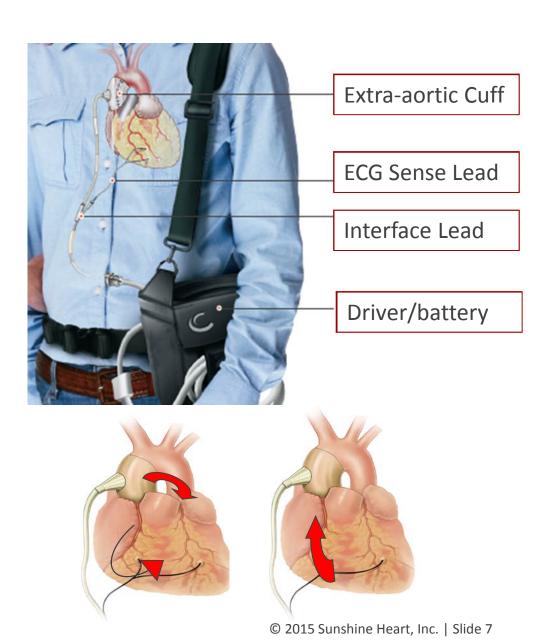
- Acorn & Paracor: failed passive technologies
- CircuLite: mini pump technology acquired by HeartWare off EU market
- LVADs: Class IV heart failure; REVIVE-IT trial stopped after unsuccessful enrollment of LVAD's in Class III population
- **Drugs:** Entresto, Ivabradine
- Gene therapy: Celladon and Bellerophon

  Failed Phase III trials in 2015
- **Resmed:** Failed pivotal trial in 2015
- Biocontrol Failed pivotal trial in 2015 due to futility
- Cardiokinetix: Targeting only ischemic heart failure patients post MI in the Left Anterior Descending(LAD) region
- Sunshine Heart is one of a few remaining HF assets available

### What makes C-Pulse Unique?



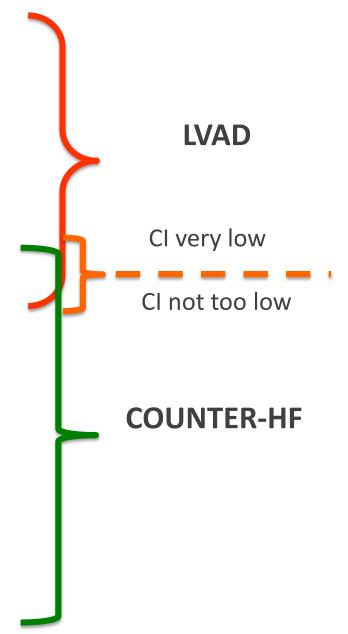
- Mechanical unloading
- Minimally invasive procedure can be done in 90 minutes
- No blood contact lower likelihood of clot or stroke
- Ability to disconnect enhanced patient comfort and convenience
- Potential to wean 6 patients weaned
- Baroreceptor/Neuromodulation impact



# Who is the patient?



PROFILE-LEVEL	Official Shorthand	NYHA Class
INTERMACS LEVEL 1	"Crash and burn"	Beyond Class IV (Stage D)
INTERMACS LEVEL 2	"Sliding fast"	Beyond Class IV (Stage D)
INTERMACS LEVEL 3	Stable but Inotrope Dependent	Beyond Class IV (Stage D)
INTERMACS LEVEL 4	"Frequent Flyer" Resting symptoms on oral therapy at home	Class IV-B
INTERMACS LEVEL 5	"Housebound", Comfortable at rest, symptoms with minimum activity	Class IV-A
INTERMACS LEVEL 6	"Walking wounded" ADLs possible but meaningful activity limited	Class III-B
INTERMACS LEVEL 7	Advanced Class III-B	Class III-B
-	-	Class III-A



#### **Feasibility Trial**

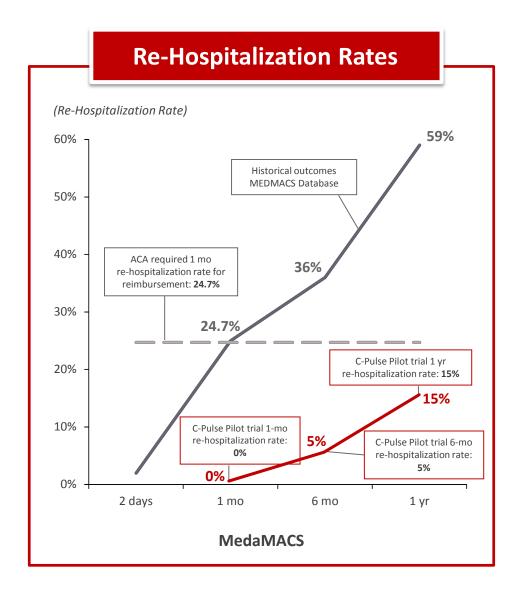


- Data published October 2014 in JACC HF journal:
  - Extensive follow up longest implanted patient over 5 years
  - Short hospital stays/procedural time, minimal perioperative complications
  - C-Pulse demonstrates immediate effects versus other remodeling therapies that take 3 months or longer to demonstrate 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 device related strokes, clots, bleeding or heart attacks
  - Five patients weaned from therapy
  - One re-hospitalization for worsening heart failure in first 6 months

# Our Feasibility trial showed significantly reduced hospital readmission rates compared to MedaMACS



- 30-day re-hospitalization rate:
  - 24.7% MedaMACS; 0% C-Pulse
- 6 month re- hospitalization rates for worsening HF:
  - 36% MedaMACS; 5% C-Pulse
- Current European based OPTIONS HF data:
  - No reported re-hospitalization for worsening HF at 6 months
  - overall rate 16.7%



# Affordable Care Act (ACA) focuses on the economics of Heart Failure



- Signed into law March 2010
- 2015 changes focused on health care value versus volume
- ACA requires CMS to establish value-based plans
- Reduced DRG payments for 25% of lowest performing centers
- Reduced HF hospitalizations are critical for patients, centers and health care providers

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



- Dr. Bill Abraham and Dr. Margarita Camacho trial National Pl's
- 40 US centers
  - 27 sites activated, 13 in process
- N=388 patients, randomized 1:1 (265 events)
  - FDA approved interim analysis Q1 2015
  - 60 enrollments through 11/3/2015
  - Study enrollment halted March 2015 due to a total of 4 all-cause deaths in treatment arm
  - All deaths adjudicated by CEC(DSMB agreed) as non device/non therapy related
  - Stopping rule amendment approved by FDA in August 2015 to mortality associated with device, procedure or therapy
  - New European clinically meaningful data generating enthusiasm at sites; Patient pipeline increasing rapidly

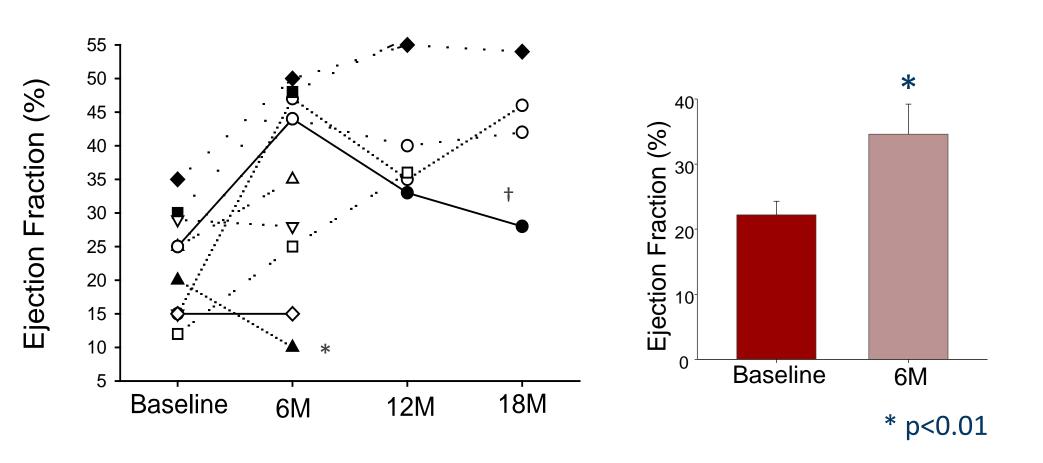
#### Europe Experience – OPTIONS HF Study



- 15 total implants
- Results expected in mid 2016
- Data so far:
  - Short hospital stays/procedural time, minimal perioperative complications
  - One patient(6 WW) weaned asymptomatic
  - Clinically significant improvement in ejection fraction
  - Reduction in HF medications among majority of patients
  - All patients have experienced a reduction in HF class
  - No strokes, clots, bleeding or heart attacks
  - No re-hospitalization for worsening heart failure in first 6 months 16.7% overall
  - 13.3% exit site infection rate
- Reimbursement submission for Germany in October

# OPTIONS HF™ Efficacy: 18 Ejection Fraction Units Improvement





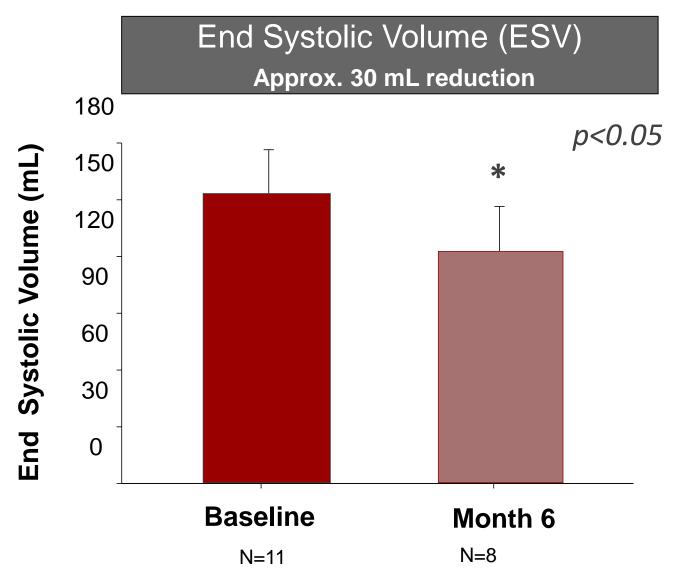
<sup>\*</sup> Patient experienced cancer recurrence and therapy discontinued

<sup>†</sup> Patient developed exit site infection due to swimming in lake, device explanted

# OPTIONS-HF™ Efficacy:

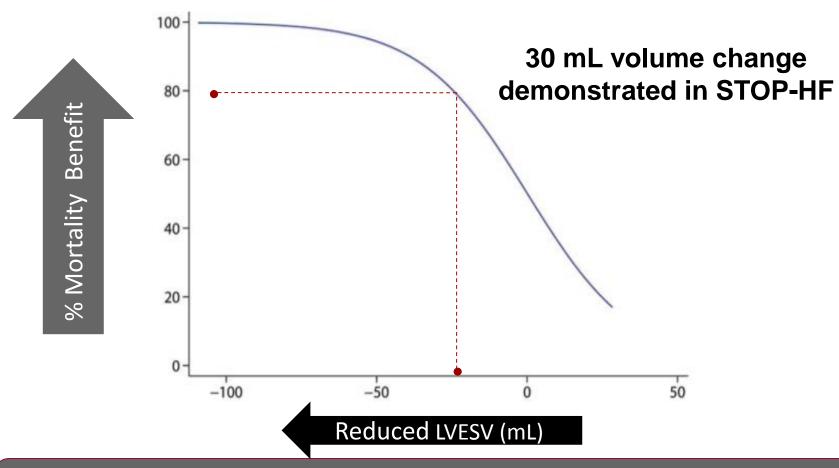
# SUNSHINE HEART

#### Cardiac Function and Structural Remodeling



# LVESV is Correlated with Mortality Meta Analysis of 30 trials\*



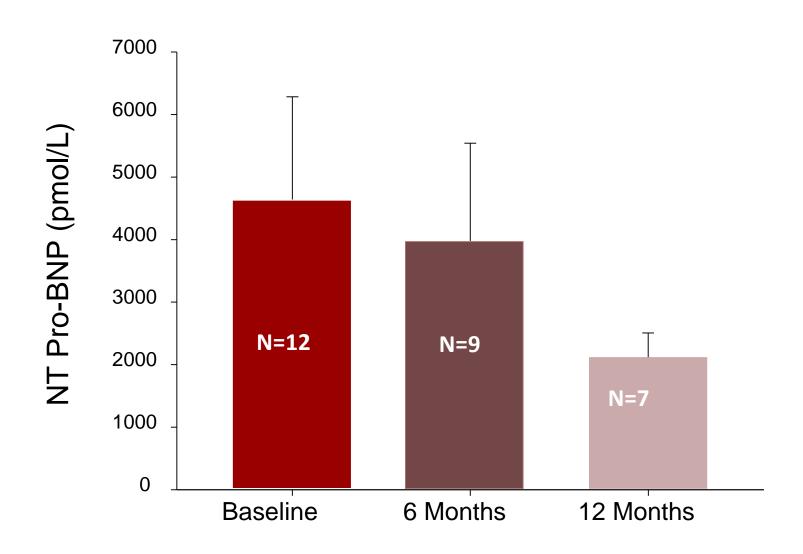


Studies indicate that a 30 mL LVESV change correlates with~80% improvement in mortality.

# OPTIONS-HF™ Efficacy:



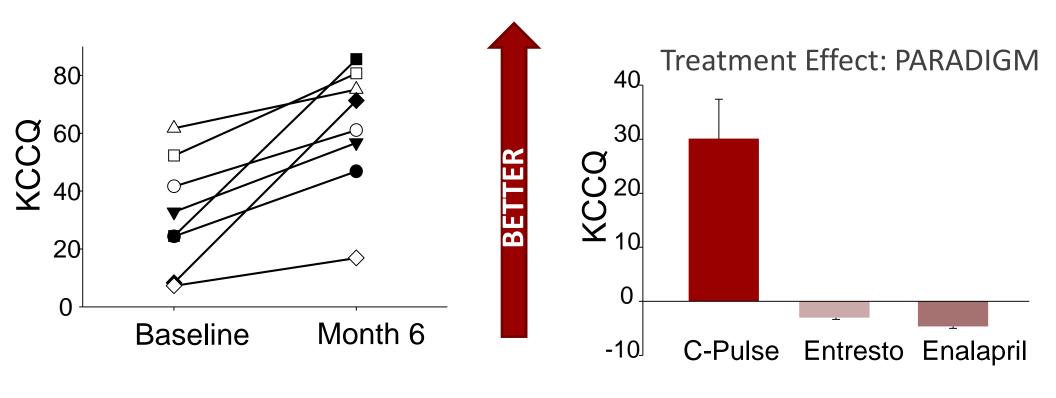
# Reduction in Neuro-hormones NTproBNP correlates with overall cardiac improvement



#### OPTIONS-HF™ Efficacy:



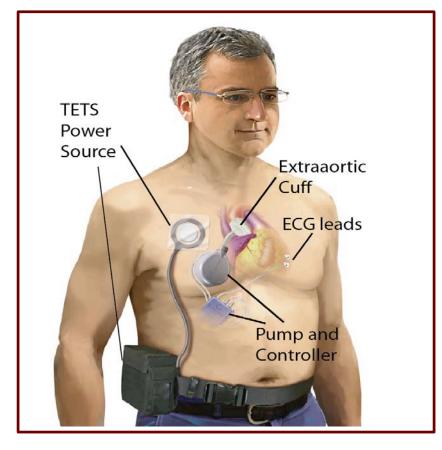
Improved Overall Score In Kansas City Cardiomyopathy Questionnaire (KCCQ)



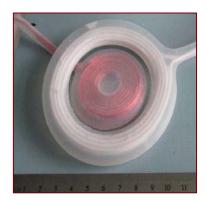
#### Pipeline: Fully Implantable C-Pulse System



- 90 day chronic animal study initiated in Q3 2015
- Opens up new market for stable angina patients ~ 1M/yr in U.S.
- Initiated pulmonary hypertension pre-clinical work with U. Of Louisville
- All histology results positive for chronic trial
- FIM scheduled for EOY 2016
- Initiated discussions with FDA regarding Expedited Access Pathway to market







# Current Research Studies – New data promising



Investigator	Study Description	Status
Prof. Segers, Ghent University	Hemodynamics, Tonometry, Echo ON/OFF OPTIONS-HF pts	Completed
Prof Segers, Ghent University	Benchtop comparison of C-Pulse and IABP	Began Aug 2015
Dr. Mark Slaughter, University of Louisville	Preclinical ovine Pulmonary HTN	Sept. 9, 11 2015
Dr. Wiegn, Cornwell, Levine; Dallas VA and UT Southwestern	Sympathetic Nerve Activity, Tilt Table; COUNTER-HF pts	Sept. 2015
Prof Frits Prinzen, Maastricht University	Preclinical HF Porcine model, wall stress, energetics, renal hemodynamics	Fall 2015

### C-Pulse: Unique Therapy for Heart Failure



- Placement on ascending aorta optimal location for hemodynamic and neural effects
  - strong IP protection.
- Compatible with any device and pharmacologic therapy.
- Mechanical compression and rapid pressure changes optimal for stimulation of baroreceptors.
- Automatic 'dose' mode: increased demand met by increased frequency of counterpulsation.
- Automatic adjustment to CRT timing changes.
- Ideal system to implement weaning protocol due to modular nature, non-obligatory therapy, extra-vascular implant.

# **Key Financial Data**



	NASDAQ
Symbol:	SSH
Market Cap:	\$41M
Shares o/s:	18.3M
Price per Share (as of 11/3/2015):	\$2.42
52-week high:	\$6.90
52-week low:	\$1.99
Avg. Daily Trading Volume (shares)	66,000
% Institutional / Mut. Fund / VC Ownership	31%

Largest Shareholders: (11/15/2015)	Shares (000's)
CM Capital Investments	1,625
GBS Ventures	1,195
Wall Street Associates	695
DWS Global Small Cap Growth	488
The Vanguard Group, Inc.	380
Deutsche Asset Mgmt	313

- Listed on NASDAQ Feb 2012
- Equity Offerings:

- IPO Aug 2012: \$21M

- CMPO April 2013: \$15M

CMPO Sept 2013 \$46M

- ATM 2015: \$7M

# **Key Financial Metrics**



Operations Summary	Year ended	Year ended	YTD Se	ept 30
(\$ in millions)	Dec 31, 2014	Dec 31, 2013	2015	2014
Net Loss	\$25.6M	\$21.8M	\$20.0M	\$18.8M
Non GAAP Net Loss (*)	\$22.5M	\$17.9M	\$17.9M	\$16.7M
Loss per share	\$1.51	\$1.71	\$ 1.11	\$1.12
Net change in cash — Incr (Decr)	\$(22.8M)	\$39.9M	\$(3.4M)	\$(17.6M)

Summary Balance Sheet	9/30/2015	12/31/2014
Cash & Cash Equivalents:	\$27.9M	\$31.3M
Long-term Debt	\$ 8.0M	\$
Total Stockholders' Equity:	\$18.4M	\$29.2M

<sup>(\*)</sup> Excludes impact of equity compensation costs, which are non cash items. Equity compensation costs were \$3.1M in the year 2014, \$3.8M in the year 2013, and \$2.1M and \$2.2M YTD through Sept 30, 2015, and 2014.

#### Financial Highlights



- \$27.9M cash at September 30, 2015
- Loan Agreement with Silicon Valley Bank (February 2015)
  - \$6M funded at closing
  - \$2M funded June 2015 available upon approval for interim analysis
  - \$20M equity raise by March 2016: in current discussions with SVB
- Opportunistic use of our \$40M at-the-market (ATM) facility:
  - \$7.0M raised in 2015 Average price per share \$5.80