



# Corporate Update

August 2015

[www.sunshineheart.com](http://www.sunshineheart.com)

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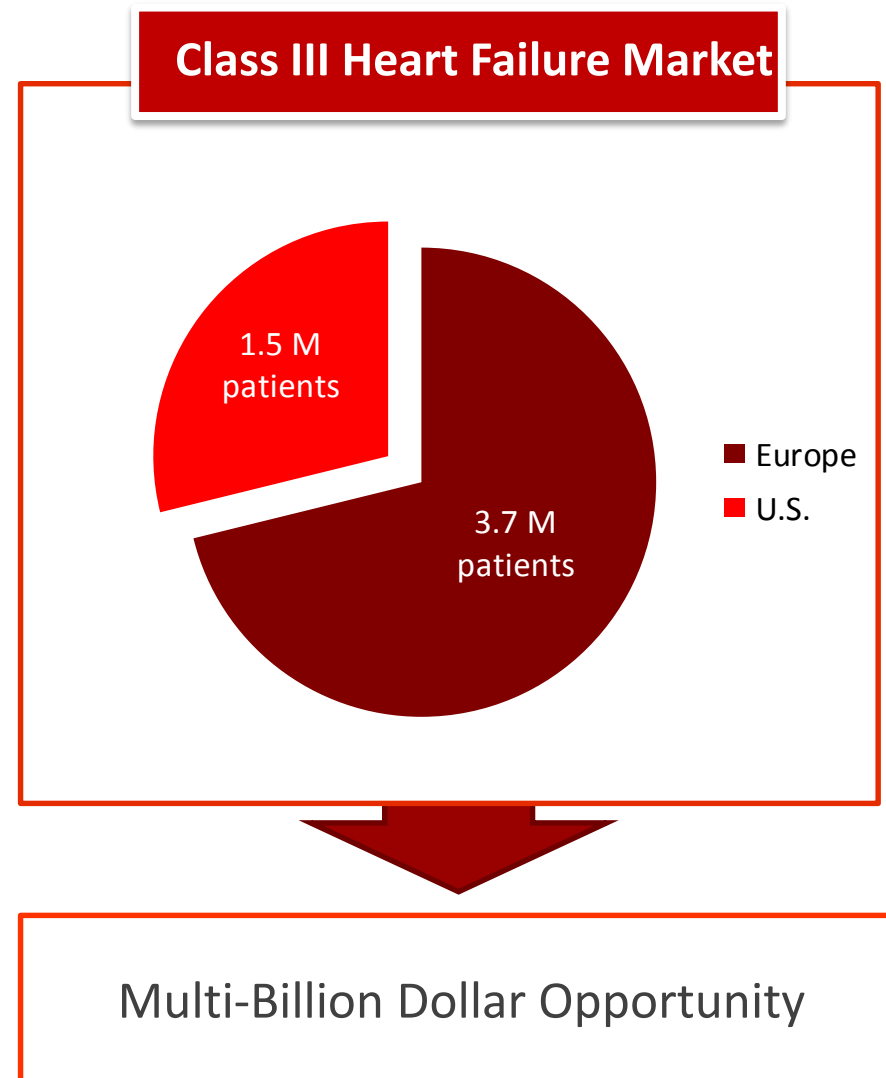
# Forward Looking Statement

- 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.

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

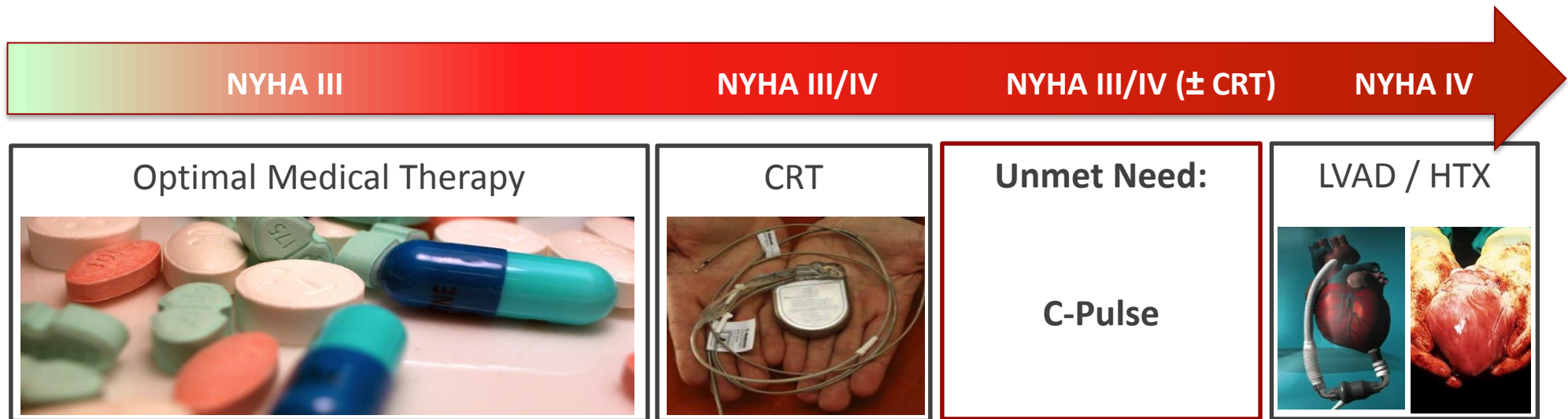
# C-Pulse U.S. Market Opportunity\*

- C-Pulse segment: Class III
- Failed CRT and OMT
- Average age – 50's
- Symptoms: shortness of breath, dizziness when performing normal or strenuous daily activities; inability to sleep, poor QOL
- 88%(23/26) of COUNTER HF sites will have Medicare payment reductions related to unplanned heart failure readmissions



*\*Source: Framingham Study, Windover 2007 Report, AHA 2010 Stroke Update, HRI 2010.*

# There is a large unmet need



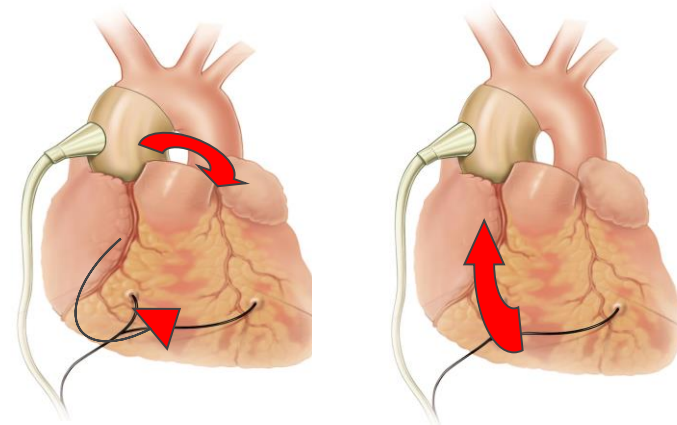
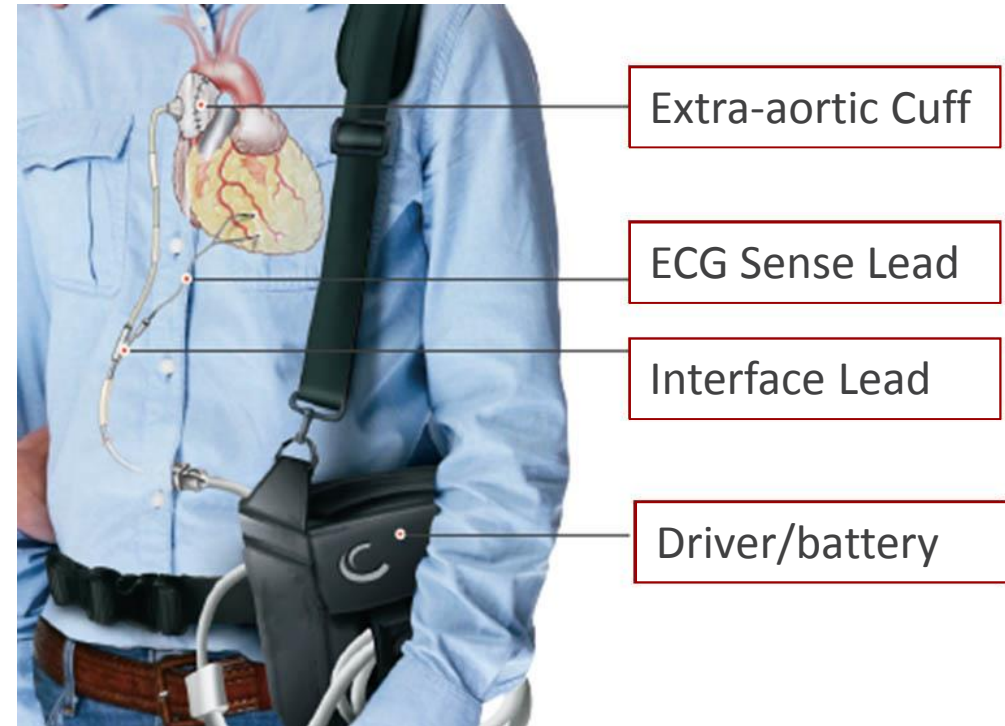
## C-Pulse target population:

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

# Current C-Pulse System

- Reduce work of Left Ventricle, increase flow:
  - Balloon inflates – increases coronary perfusion (addresses hemodynamics - primary pathophysiology of heart failure)
  - Balloon deflates – reduces LV afterload
- **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



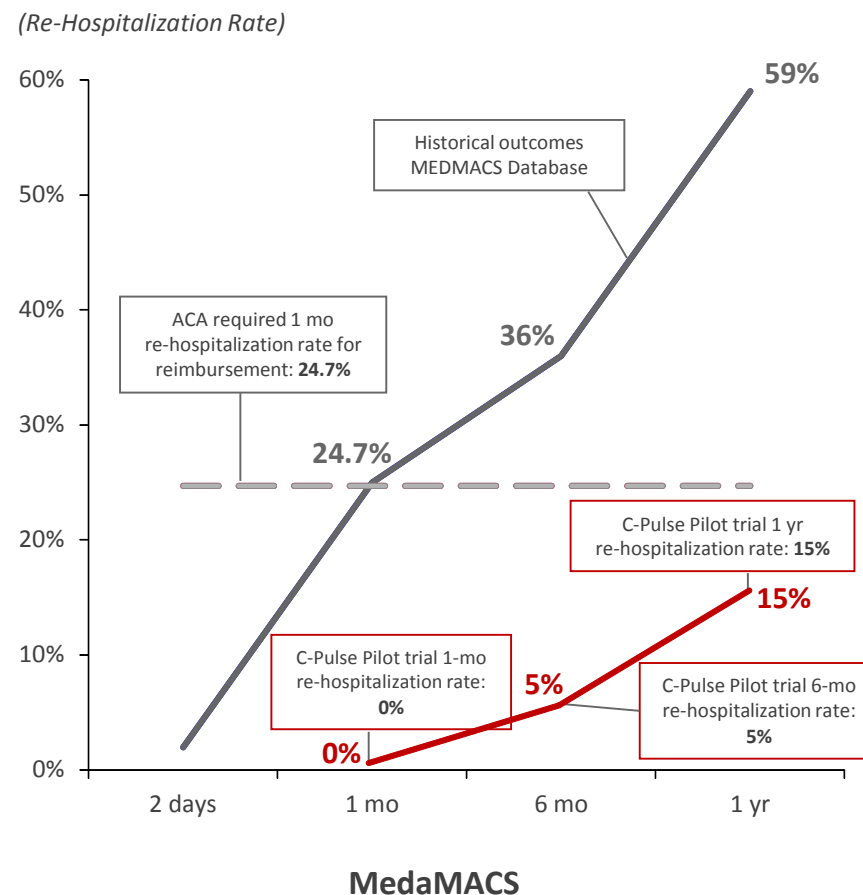
# Affordable Care Act (ACA) focuses on the economics of Heart Failure

- 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

# Our Pilot trial showed significantly improved Class III Heart Failure re hospitalization rates

- Patients may progress to Class IV or die
- Historical medical therapy 30-day re-hospitalization rate – 24.7%; 0% for C-Pulse
- C-Pulse pilot trial 6 month re-hospitalization rates for worsening HF - 5%
- Current European based OPTIONS HF data: No reported re-hospitalization for worsening HF at 6 months; overall rate 16.7%

## Re-Hospitalization Rates





# Class III Competitive Landscape

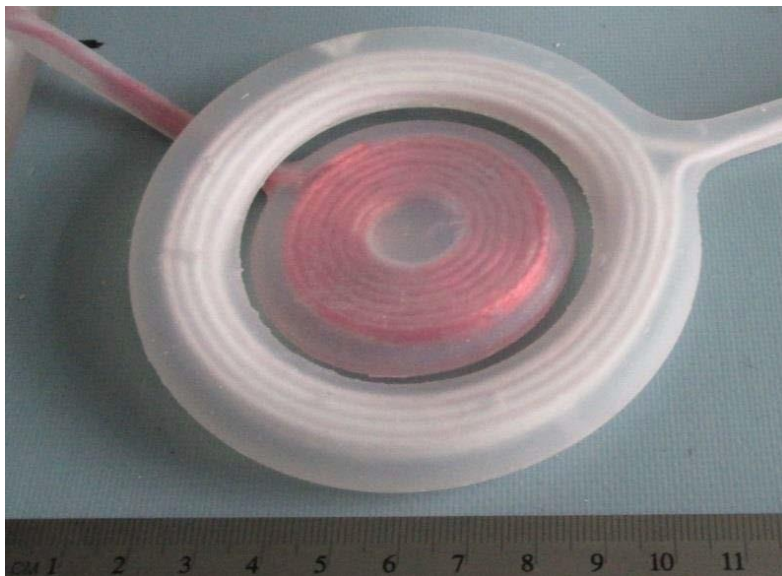
- **CircuLite:** mini pump technology acquired by HeartWare – off EU market
- **LVADs:** Class IV heart failure; Thoratec and HW Class III studies halted
- **Gene therapy:** Celladon and Bellerophon– Failed Phase III trials in 2015
- **Resmed:** Failed pivotal trial in 2015



- No known competitive technology that has C-Pulse features
- Sunshine Heart is one of a few remaining HF assets available

# Pipeline: Fully Implantable C-Pulse System

- 90 day chronic animal study expected in late 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 Q3 2016**
- FDA meeting regarding regulatory strategy January 15, 2015



# 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

# U.S. Pivotal: COUNTER HF



- Dr . Bill Abraham and Dr . Margarita Camacho trial National PI's
- 35 - 40 centers
  - 15/27 sites re-activated
  - Patient pipeline increasing rapidly
  - 3 enrollments in past 7 days
  - 51 current enrollments through 8/3/2015
  - Site team approach being utilized to increase patient consent rate
  - New efficacy data generating enthusiasm at sites
- N=388 patients, randomized 1:1 (265 events)
  - FDA approved interim analysis request Q1 2015(194 enrolled by end of 2016)
  - 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
  - Minor protocol changes: Patient selection committee, exclusion criteria changes
  - Investigator meeting held in May – 25 centers attended
  - All centers expected to be re-activated by end of August

# COUNTER HF Enrollment Progress



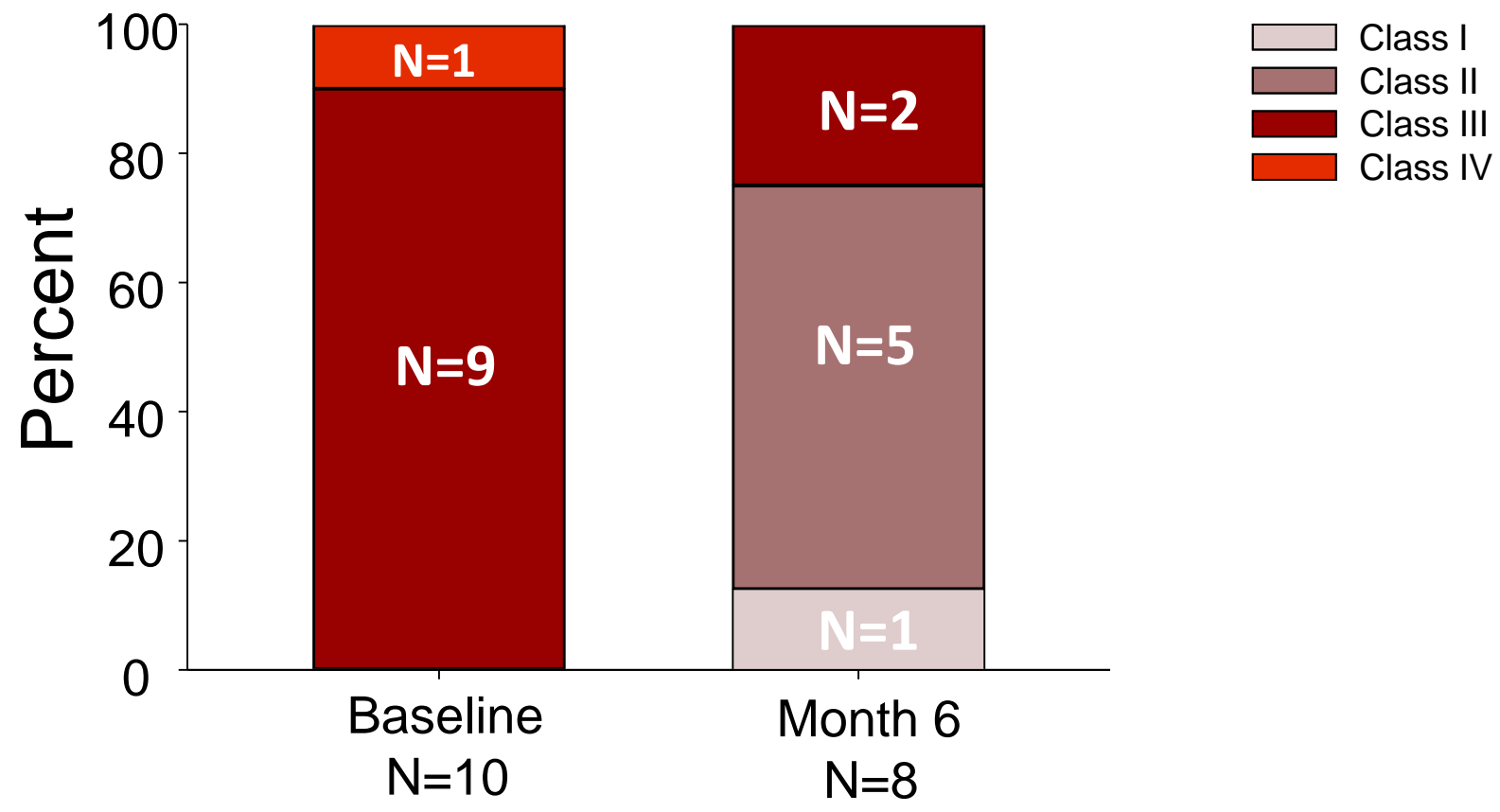
Quarter	# Pts. Presented for study Review	# Pts. Enrolled in study	Consent Rate
Q1/2014	13	3	23%
Q2/2014	15	7	47%
Q3/2014	84	14	17%
Q4/2014	74	13	17%
Q1/ 2015	100 projected	8	NA
Q2/2015	Paused	N/A	N/A
Q3/2015	60 and growing	3	TBD

# Europe Experience – OPTIONS HF Study

- Short hospital stays/procedural time, minimal perioperative complications
- One patient(6 WW) unintentionally weaned - asymptomatic
- Clinically significant improvement in ejection fraction – avg. improvement 33%
- Reduction in HF medications among majority of patients
- All patients have experienced a reduction in HF class
- UK severely ill patient was able 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
- 13.3% exit site infection rate
- 15 total implants
- Results expected in mid 2016
- Reimbursement submission for Germany in October

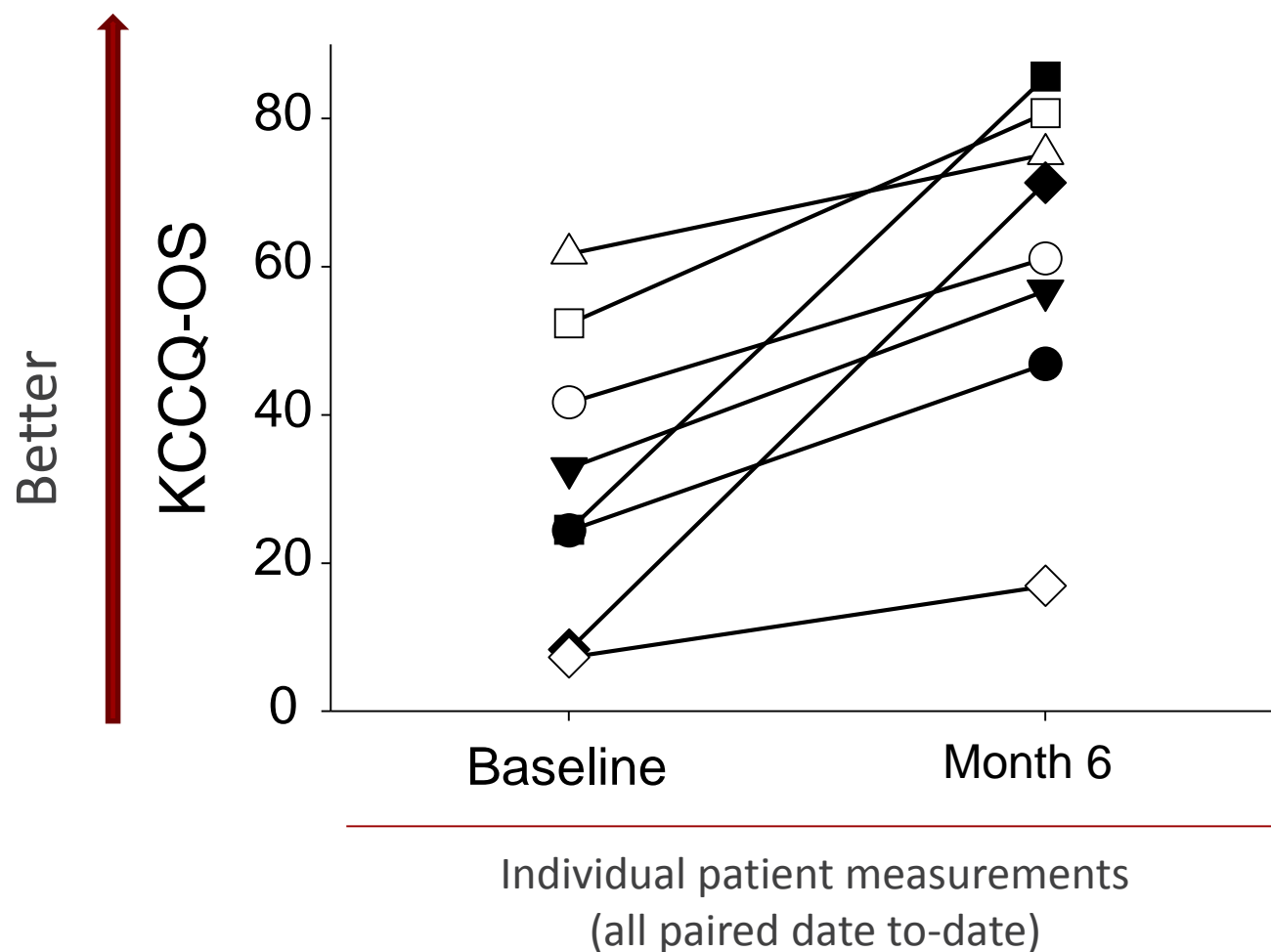
# OPTIONS-HF Efficacy:

## NYHA Class



# OPTIONS-HF Efficacy:

## Kansas City Quality of Life-Overall Score

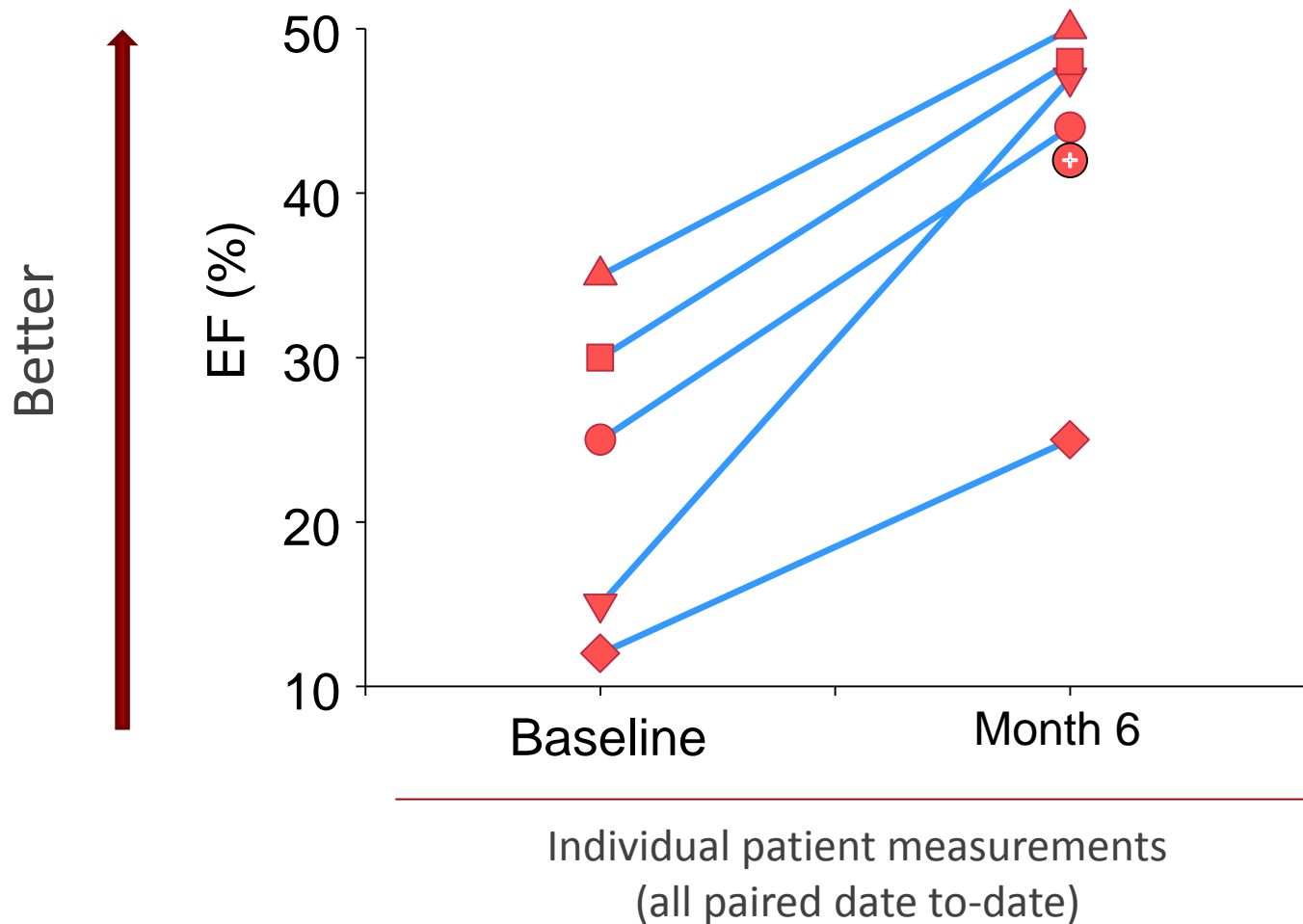


All patients experienced improved quality of life



# OPTIONS-HF Efficacy:

## Ejection Fraction



• Missing baseline data

All patients experienced improved cardiac structure and remodeling

# Current Research Studies

HEART

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	Begin Aug 2015
Dr. Mark Slaughter, University of Louisville	Preclinical ovine, Pulmonary HTN	Sept. 9, 11 2015
Dr. Wiegman, 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

# Key Financial Data



	NASDAQ
Symbol:	SSH
Market Cap:	\$57M
Shares o/s:	18.3M
Price per Share (as of 8/3/2015):	\$3.11
52-week high:	\$6.90
52-week low:	\$2.41
Avg. Daily Trading Volume (shares)	77,000
% Institutional / Mut. Fund / VC Ownership	31%

Largest Shareholders: (5/15/2015)	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



<b>Operations Summary</b> <i>(\$ in millions)</i>	<b>Year ended Dec 31, 2014</b>	<b>Year ended Dec 31, 2013</b>	<b>1H 2015</b>	<b>1H 2014</b>
Net Loss	\$25.6M	\$21.8M	\$13.4M	\$12.7M
Non GAAP Net Loss (*)	\$22.5M	\$17.9M	\$11.8M	\$11.6M
Loss per share	\$1.51	\$1.71	\$ 0.75	\$0.75
Net change in cash – Incr (Decr)	\$(22.8M)	\$39.9M	\$2.1M	\$(12.0M)

<b>Summary Balance Sheet</b>	<b>6/30/2015</b>	<b>12/31/2014</b>
Cash & Cash Equivalents:	\$33.4.0M	\$31.3M
Long-term Debt	\$ 8.0M	\$ --
Total Stockholders' Equity:	\$24.5M	\$29.2M

(\*) 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, \$1.6M in 1H 2015, and \$1.5M in 1H 2014.

# Financial Highlights



- \$33.4M cash at June 30, 2015
- Loan Agreement with Silicon Valley Bank (February 2015)
  - \$6M funded at closing
  - \$2M funded June 2015 – available upon approval for interim analysis
  - \$2M available additional milestone based on enrollment
  - Currently negotiating with SVB and other lenders for a \$15M facility with longer interest-only and repayment terms
- Opportunistic use of our \$40M at-the-market (ATM) facility:
  - \$7.0M raised in 2015 – Average price per share \$5.80

# 2015 – 2017 Clinical Milestones



Event	Timing
<b>2015</b>	
Results of initial fully implantable pump chronic trial with TETS system	Q1 2015
COUNTER HF Investigator meeting	Q2 2015
Resumption of COUNTER HF study	Q2 2015
C-Pulse® System Extra-Aortic Counterpulsation for Heart Failure: Driveline Infections and Management presented at ISHLT by Dr. Mark Slaughter	Q2 2015
Clinical experience with the C-Pulse Extra Aortic Counterpulsation system in patients previously treated with Optimal Medical Therapy and CRT presented at HRS by Dr. William Abraham	Q2 2015
Pulmonary hypertension pre-clinical trial initial data	Q3 2015
Initiation of chronic animal trial for fully implantable system	Q4 2015
<b>2016</b>	
Feedback from FDA on fully implantable C-Pulse regulatory path	Q1 2016
OPTION HF data released	Q2 2016
First in man fully implantable system	Q3 2016
Enrollment expected complete for interim analysis cohort	Q4 2016
<b>2017</b>	
DSMB recommendation on interim analysis results	Q4 2017
COUNTER HF study fully enrolled	Q4 2017