



# Annual Shareholder Meeting

May 2015

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

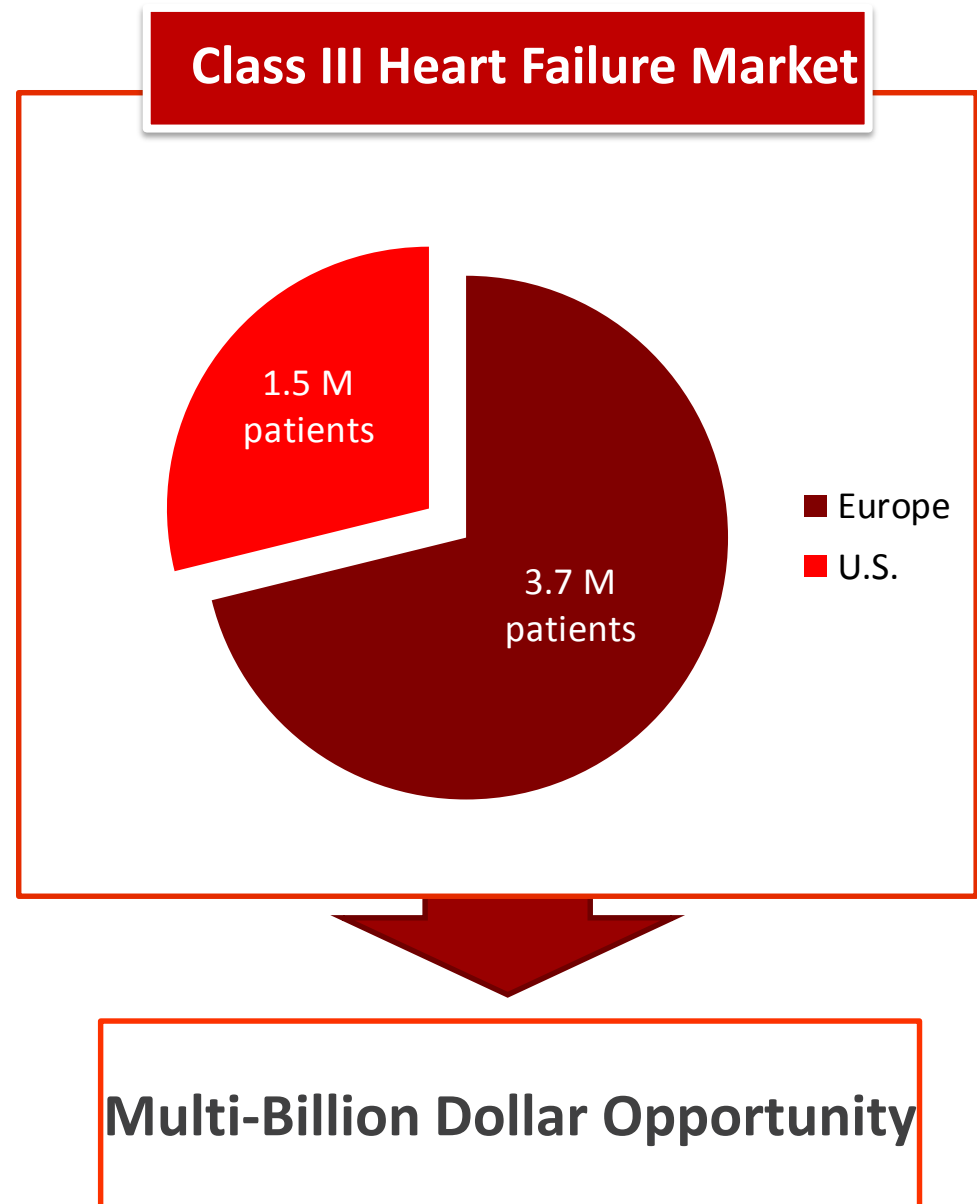


Offer a minimally invasive therapy  
for **moderate to severe heart failure**  
that provides symptomatic relief and  
halts the disease progression

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



- C-Pulse 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



# Class III NYHA HF Unmet Need

NYHA III

NYHA III/IV

NYHA III/IV ( $\pm$  CRT)

NYHA IV

Optimal Medical Therapy



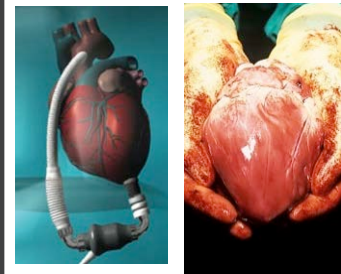
CRT



Unmet Need:

C-Pulse

LVAD / HTX

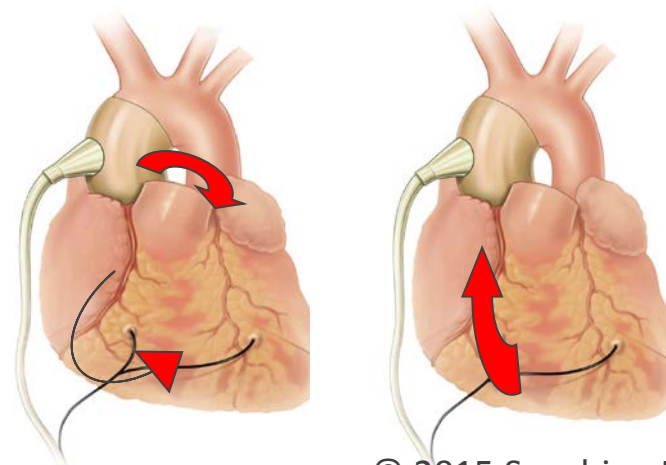
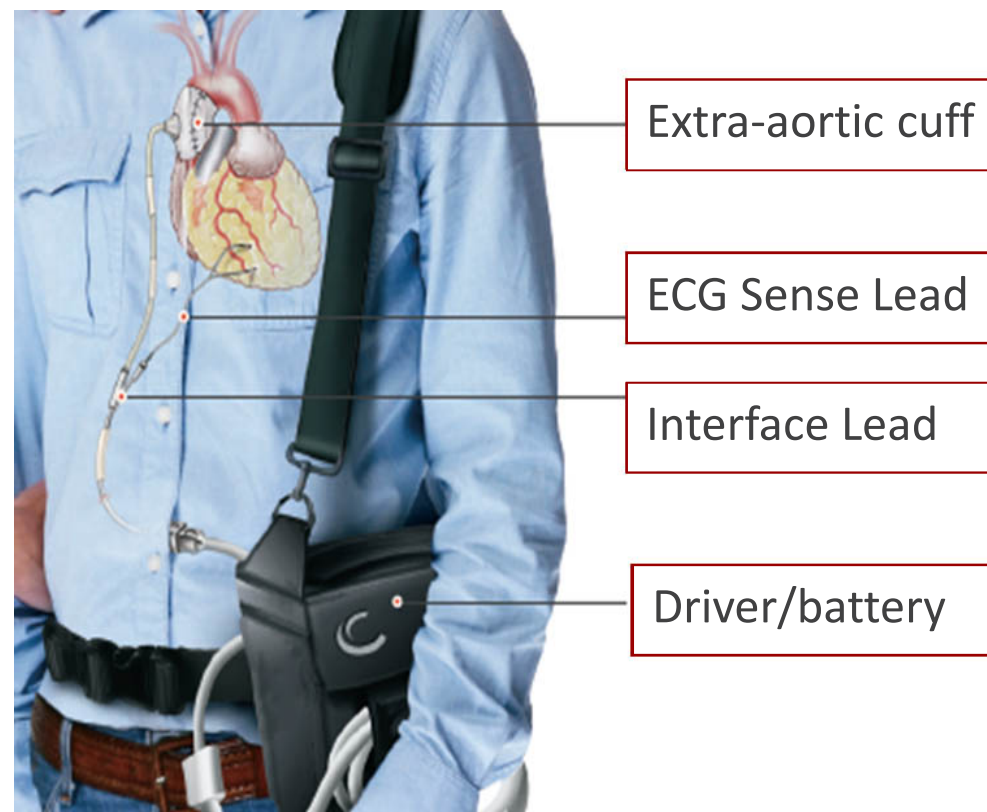


## Patients with progressive class III/ambulatory IV HF:

- 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 oxygen to heart muscle
  - Balloon deflates – reduces left ventricle work
- 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

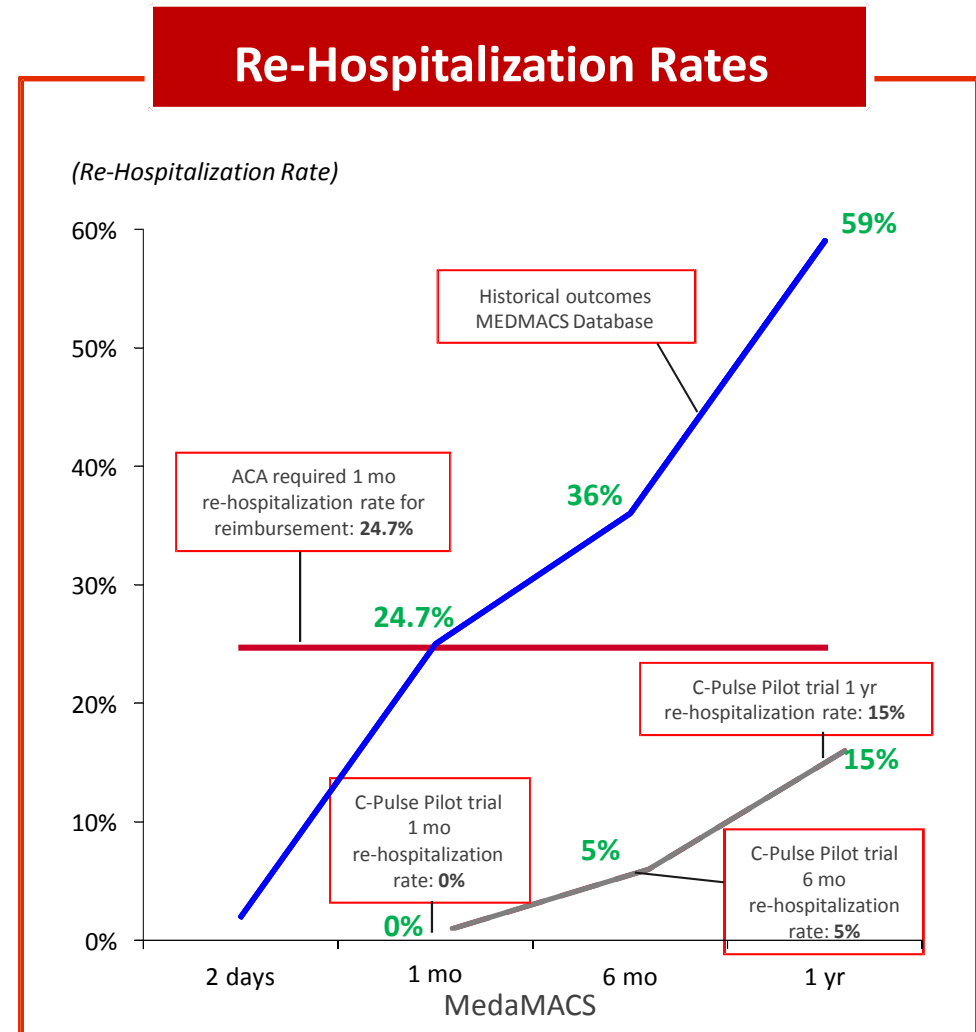


- CircuLite – mini pump technology placed in bloodstream acquired by HeartWare
- LVADs –primarily for Class IV heart failure; expansion to Class III will be limited by clot, stroke and bleeding risks; Thoratec stopped Class III REVIVE-IT study
- Gene therapy – Celladon – Failed Phase III trial
- Sleep apnea related HF - RESMED Inc. - Failed pivotal trial
- No known competitive technology that has C-Pulse features

# 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%
- Significant financial impact on health care institutions





# Affordable Care Act(ACA)



- Signed into law 3/10/10
- 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- Delivering Evidence



- Dr. Bill Abraham and Dr. Margarita Camacho trial PI's
- 35 - 40 centers
  - 24 sites activated
  - All activated centers have identified patients
  - 15/21 sites have enrolled patients
  - 48 enrollments through Q1 2015
- N=388 patients, randomized 1:1 (265 events)
  - FDA approved interim analysis Q1 2015(194 randomized by end of 2016)
  - Study enrollment halted March 2015 due to 4 all-cause deaths in treatment arm
  - All deaths adjudicated by CEC(DSMB agreed) as non device/non therapy related
  - Expect resumption this week
  - Minor protocol changes: Subject Eligibility Committee, exclusion criteria changes
  - Investigator meeting last week – 25 centers attended
  - Centers expected to restart beginning in July – August

# COUNTER HF Progress



(Q)	# Pts. Presented for study Review	# Pts. Enrolled in study	Consent Rate
1/2014	13	3	23%
2/2014	15	7	47%
3/2014	84	14	17%
4/2014	74	13	17%
1/2015	100 projected	8	NA

# Current Challenges with Clinical Trials



## FINDING PATIENTS FOR CLINICAL TRIALS HAS GROWN DIFFICULT

UCSD ambitiously trying to double the 16,000 people currently enrolled in programs within next few years

By Gary Robbins 5:05 a.m. May 4, 2015

LA JOLLA — UC San Diego will try to double the number of patients it enrolls in clinical trials in the next few years, a push that could prove to be one of the toughest undertakings in campus history. Research schools and pharmaceutical companies nationwide are struggling to recruit people for such tests because of long-standing problems, from finding patients who meet each trials' exacting criteria to the public's confusion over the nature of drug and therapeutic studies.

**Medical experts said about 15 percent of trials don't enroll any participants.** Other trials end up being canceled because they can't keep the patients they do recruit.

It's a vexing issue at UC San Diego, where 16,000 people are enrolled in clinical trials.

The university's medical school receives strong financial support from drug companies such as Merck and Pfizer. And the school is building a \$269 million translational research center that's meant, in part, to speed drug development. But efforts to recruit new patients often turn out to be fruitless.

# EU Post-Market Study: OPTIONS HF

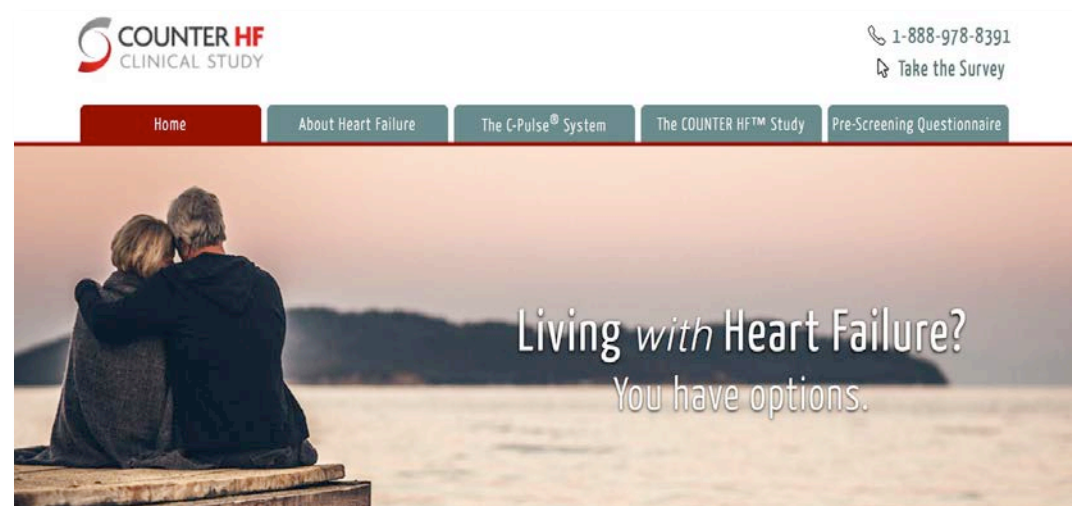
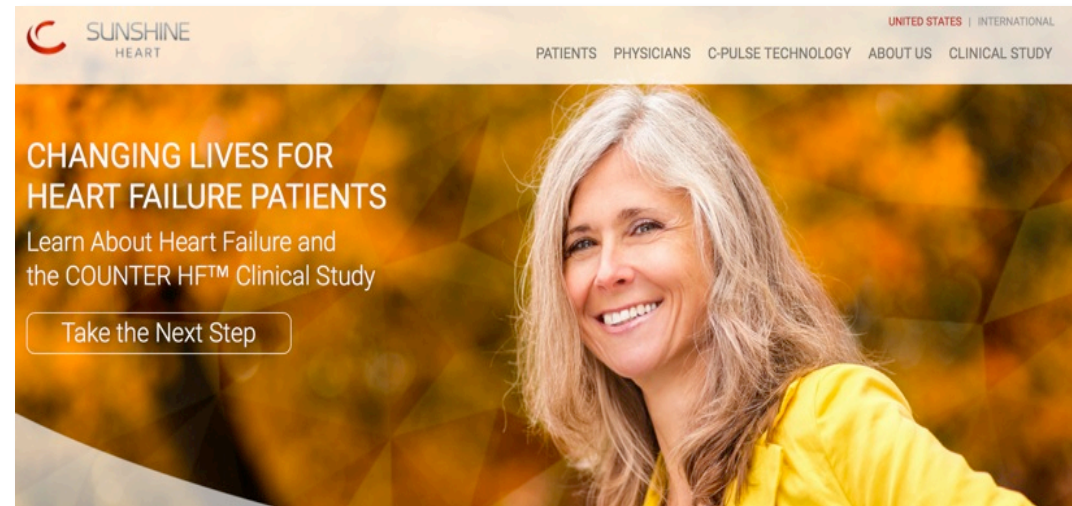


- 15 patient implants in Europe
- Trial will enroll 50 patients across 8 - 10 centers in Germany, Austria and U.K.
- Provide additional clinical data for publications, reimbursement and communicate results to the market
- Trial design/endpoints mirror U.S. pivotal trial
- One patient weaned at 6.5 months with EF of 55%
- Improvements in 6 minute walk, reduction of HF class and increased quality of life
- To date, lower rate of exit site infections(2/15 potential ESI's) as compared to US pilot study(8/20)
- German reimbursement update

# SHI Websites: Awareness and Enrollment




- **Sunshineheart.com**
  - Clinically focused to physician, patients, and technology/therapy
  - Go live Date: Following FDA clearance
- **HFclinicalstudy.com**
  - Search Engine Optimization plan in effect (Already jumped to 1st page on Google for keyword: 'Heart Failure Clinical Study' previously on page 6)
  - Targeted Web marketing campaigns (PPC) targeting set and awaiting approval for launch






# For Patients






PATIENTS | PHYSICIANS | C-PULSE TECHNOLOGY | ABOUT US | CLINICAL STUDY

UNITED STATES | INTERNATIONAL



 Watch The C-Pulse® Heart Failure Video  
Learn about the condition and treatment.

Find out if you qualify for the clinical study [Take the survey now!](#)

## Patients

Classifications of Heart Failure

Treatment of Heart Failure

Study Centers

Resources

## Understanding Heart Failure

### What is Heart Failure?

Heart failure is a serious condition for which there is currently no cure. The heart delivers oxygen and nutrients to various organs of the body to provide adequate blood flow. When the heart's pumping action is weakened, the amount of blood flow is reduced and organs or cells of the body do not receive enough oxygen and nutrients. As a result, the heart cannot pump enough blood to meet the body's needs.

In heart failure, the body tries to compensate for reduced pumping ability. Sometimes this response helps in the short term, but can cause even more problems in the long term. As a result, heart failure is progressive, meaning that it gets worse over



## Patients

Classifications of Heart Failure

Treatment of Heart Failure

Study Centers

Resources

## Clinical Study Participating Centers

For a complete list of study centers, please visit [clinicaltrials.gov](http://clinicaltrials.gov)

### United States, Alabama



**The University of Alabama at Birmingham Hospital**  
Birmingham, Alabama, United States, 35249

**Contact:**  
Deborah Lowe  
205-975-9964 | [dlowe@uab.edu](mailto:dlowe@uab.edu)

**Principal Investigator:**  
Salpy Pamboukian, MD

Study Centers

Resources

condition. The major types of heart failure treatments include:

- Lifestyle changes
- Heart Medications
- Surgery for correctable problems
- Implantable devices
- Heart transplant

The following interactive graphic illustrates the condition and the overall progression of heart failure. All existing and approved treatment goals are to slow the progression of heart failure. The C-Pulse Heart Assist System may offer physicians an effective new option for treating heart failure, enabling them to relieve symptoms and halt the progression.

## The C-Pulse Heart Assist System

Currently, there is a treatment gap for patients with moderate to severe heart failure:

- There are situations where OMT, CRT, and ICD therapies are not enough to stop the progression of heart failure for some patients. Today, the next treatment option would be a more invasive implant that would replace the function of the heart (LVAD).
- C-Pulse provides a treatment option that assists the heart to improve its pumping ability. It is designed to halt or reverse the progression of heart failure, and allows patients to disconnect for short periods of time. [Learn more](#)



## Left Ventricle Assist Device

Treatment of end-stage heart failure:

- Your doctor may recommend a Left Ventricle Assist Device (LVAD) as an alternative to heart transplantation, or as a bridge to heart transplantation.

What is an LVAD?

- LVAD is a mechanical pump that is implanted in the chest to assist the heart in pumping blood to the rest of the body.
- LVADs are commonly a bridge to heart transplantation, or as a bridge to heart transplantation.



# For Physicians



## C-Pulse® Heart Assist System

The C-Pulse System is an innovative treatment option for Class III and ambulatory Class IV heart failure (HF) patients. The extra-vascular design is intended to augment the failing heart by adding a secondary pulse to every heartbeat. The C-Pulse System truly assists the heart with the intent to improve cardiac function and patient's quality of life.



### Physicians

C-Pulse Technology

Clinical Evidence

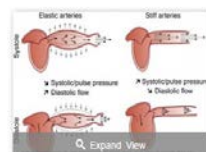
## The C-Pulse System

Every Pulse. Every Day.

The C-Pulse Heart Assist System leverages the concept of counterpulsation in a novel way. Through its extra-vascular design, patients do not require device related anti-coagulation. The position of the cuff, on the ascending aorta, provides a unique

### Mechanism of Action

The C-Pulse mechanism of action is based off the concept of counterpulsation. C-Pulse evolves this concept with the development of a chronic ambulatory circulatory support therapy that works by reducing left ventricular afterload during systole and augmenting blood pressure and systemic and coronary perfusion during diastole.

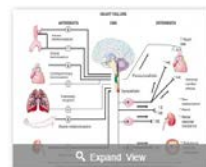


### Improved Myocardial Perfusion

The C-Pulse is positioned on the ascending aorta, the most elastic part of the arterial system. The ascending aorta acts as a reservoir for the heart to eject blood into. The inflation of the C-Pulse balloon during diastole creates a second pulse, increasing coronary flow and perfusion throughout the body.

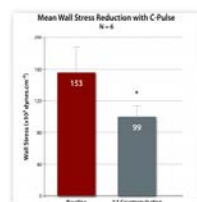
### Stimulation of Aortic Baroreceptors

Previous studies using the intra-aortic balloon pump have shown hemodynamic effects which have been attributed to stimulation of baroreceptors in the aortic arch.<sup>13</sup> The C-Pulse balloon placement on the aortic arch aligns anatomically with the aortic baroreceptors. In addition to direct mechanical compression, the rapid inflation and deflation during diastole and systole may provide optimal physiologic activation of these receptors. Activation of aortic baroreceptors has neuromodulatory effects resulting in reduction in sympathetic activity and increase in parasympathetic activity, reduced peripheral resistance and improvement in the kidney's ability to excrete salt and water. Current studies are underway to assess this potential mechanism of C-Pulse therapy.



### Reducing Left Ventricular Wall Stress

The C-Pulse therapy has shown to reduce arterial afterload in the ascending aorta leading to improved cardiac performance through increased velocity of shortening of the left ventricle.<sup>7</sup> A reduction in left ventricular wall stress is also achieved while maintaining adequate coronary perfusion. This is expected to result in improved cardiac efficiency.



### References

<sup>7</sup>Feola et al. Direct and reflex vascular effects of intra-aortic balloon counterpulsation in

## Physicians

C-Pulse Technology

Clinical Evidence

Resources

## Clinical Evidence

Sunshine Heart is committed to studying the C-Pulse Heart Assist System through clinical studies that answer important safety, patient outcome, and healthcare economic questions.

## Scientific Meeting Abstracts

C-Pulse® System Extra-Aortic Counterpulsation for Heart Failure: Driveline Infections and Management

Slaughter, et. al. ISHLT 2015

[Download File](#)

Preliminary Results from the C-Pulse OPTIONS HF European Multicenter Post-Market Study

Hotz, et. al. EUMS 2014

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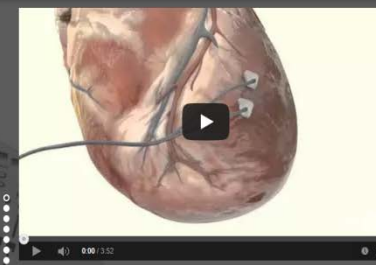
Preliminary Results from the C-Pulse OPTIONS HF European Multicenter Post-Market Study

Hotz, et. al. AHA 2014 presentation

[Download File](#)

## C-Pulse® Heart Assist System

The C-Pulse System is an innovative treatment option for people suffering from moderate to severe heart failure (HF). C-Pulse therapy is intended to augment (strengthen) the failing heart by adding a secondary pulse to every heartbeat. The C-Pulse System truly assists the heart with the intent to improve cardiac function, reduce HF symptoms, and improve patient's quality of life.<sup>1</sup>



## C-Pulse Technology

Clinical Study

Clinical Evidence

Resources

## The C-Pulse System

Every Pulse. Every Day.

The C-Pulse Heart Assist System leverages the known concept of counterpulsation. The C-Pulse system applies this concept in a novel way. Through the application of a balloon wrapped around the outside of the aorta, the C-Pulse System inflates and deflates the balloon in rhythm with the natural heartbeat, applying a "secondary pulse" with the intent to augment (strengthen) the heart's function.

The C-Pulse is designed to improve the heart function in three ways:

- Increase coronary blood flow with more oxygenated blood flowing to the blood vessels and heart muscle
- Decrease cardiac afterload reducing how hard the heart has to work to pump blood through the body





# For Investors



## About Us

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## Corporate Office

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Phone +1 952 345 4200

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[cknoll@bplifescience.com](mailto:cknoll@bplifescience.com)  
+1 415 375 3340 (ext. 105)

## Media

Russo Partners LLC  
12 West 27th Street, 4th floor  
New York, NY 10001

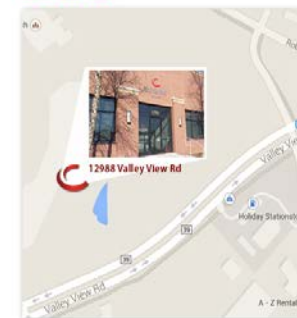
David Schull  
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Andreas Marathovouniotis  
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## Career Opportunities

For a complete listing of current job openings [click here](#)

Connect:



## Send us a Message

Please send us your questions and we will respond as quickly as we can.

Name	<input type="text"/>
Email	<input type="text"/>
Subject	<input type="text"/>
Message	<input type="text"/>

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## Investor Relations

Sunshine Heart is a global medical technology company, committed to the commercialization of C-Pulse®, an implantable, non-blood contacting, heart assist therapy for the treatment of people with class III and ambulatory class IV heart failure. Sunshine Heart is listed on the NASDAQ Capital Market.



Intra  
3 mo.  
6 mo.  
1 yr.

## Press Releases

### Sunshine Heart Announces First Quarter 2015 Results and Provides Corporate Update

Posted on May 5, 2015

EDEN PRAIRIE, Minn., May 5, 2015 (GLOBE NEWSWIRE) – Sunshine Heart, Inc. (Nasdaq:SSH) announced today its financial results and provided a corporate update for the first quarter of 2015. The Company will host a conference call and webcast at 9:00 AM ET today to discuss its financial results and pro...

[Read More](#)

### Sunshine Heart to Release First Quarter 2015 Results on May 5, 2015

Posted on Apr 28, 2015

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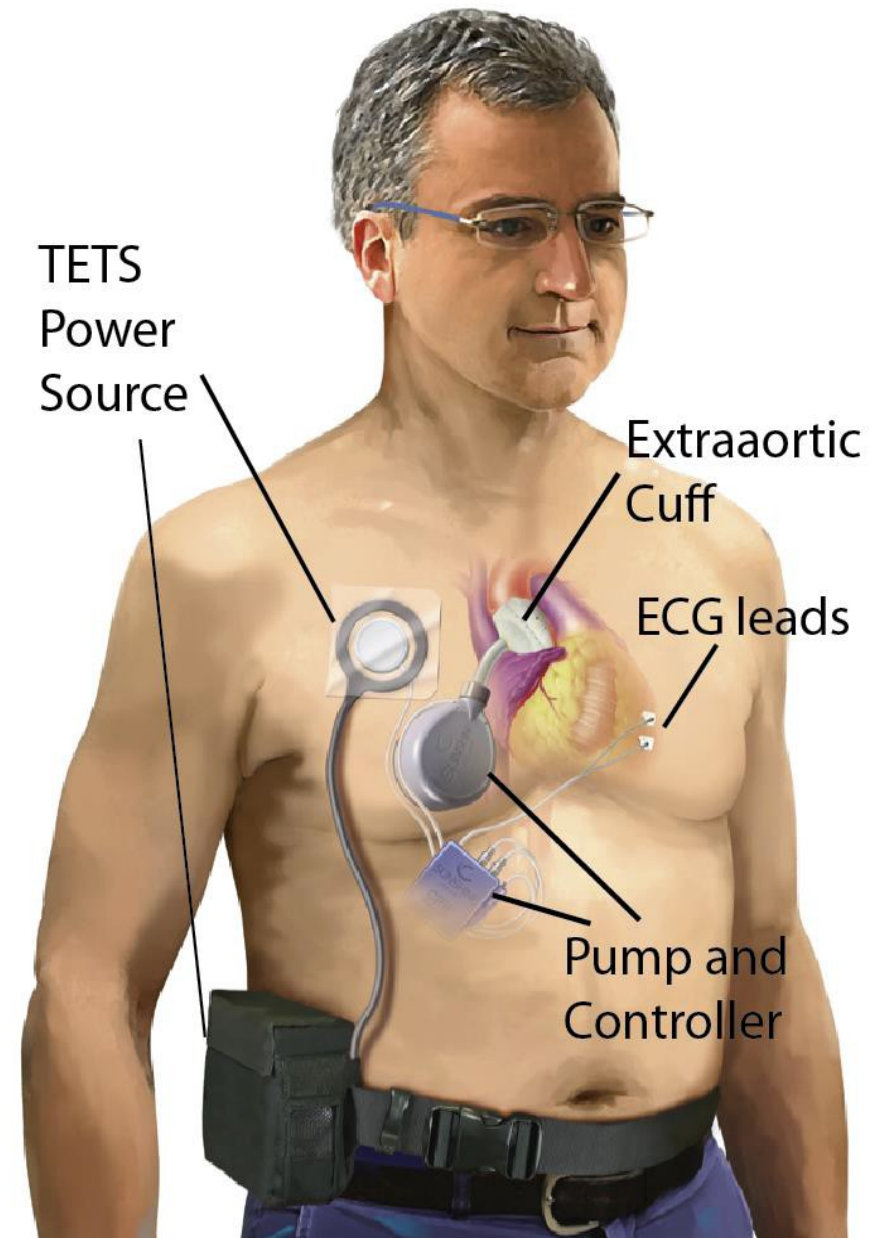
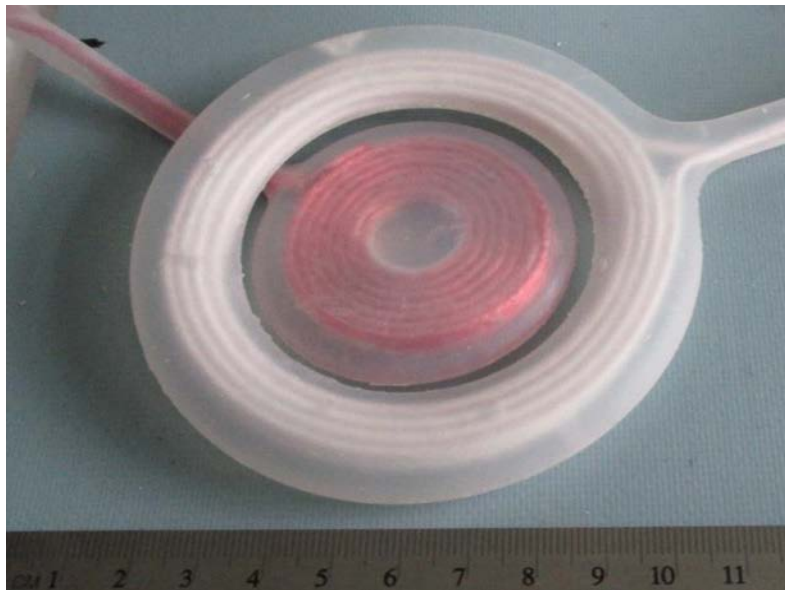
## Sunshine Heart Story

Sunshine Heart is a global medical device company founded by a cardiac surgeon that saw an incredible opportunity for how to treat heart failure. Heart failure (HF) affects millions and is a progressive condition that prevents patients from living normal lives. Sunshine Heart® is in a clinical study to determine if the C-Pulse® System is safe and effective for treating moderate to severe heart failure. C-Pulse therapy is designed to reduce overall heart failure symptoms, improve quality of life, and reduce re-hospitalizations.

## Innovative Technology

Sunshine Heart's C-Pulse® Heart Assist System is designed to support the heart's function, not replace it and may be implanted using a minimally invasive surgical approach. The C-Pulse Heart Assist System is designed to treat clinical

# Fully Implantable C-Pulse II



# Abstracts: Accepted/Presented



## Q2 2015

### ISHLT (Nice)

- C-Pulse® System Extra-Aortic Counterpulsation for Heart Failure: Driveline Infections and Management
  - Presented April 2015; Dr. Slaughter

### HRS (Boston)

- Clinical experience with the C-Pulse Extra Aortic Counterpulsation system in patients previously treated with Optimal Medical Therapy and CRT
  - Presented May 2015: Dr. Abraham

# Abstracts: Submitted Q2 2015



## HFSA (Maryland)

- Monitored hemodynamics in a patient supported with the C-PULSE device using the CardioMEMS sensor (Dr. Emani)

## AHA (Orlando)

- Reduced Heart Failure Readmission Rates: Clinical Experience with the C-Pulse® Extra-Aortic Counterpulsation System (Dr. Aggarwal)
- Arterial and Cardiac Hemodynamics In Advanced HF Patients Implanted with A Para-Aortic Counterpulsation Device Assessed by Pulse Wave Analysis (Dr. Rame, Abraham)

# Future / Potential manuscripts



## **OPTIONS HF:**

1. Cardiac and Arterial Hemodynamics
2. All patients with 6-m follow up completed (QoL, Functional Capacity, Echo)

## **From COUNTER HF:**

1. Neuromodulation and MSNA (Dr. Ben Levine)
2. Pressure-Volume Loop (Dr. Sumanth Prabhu)
3. Sub-study cognitive function

## **From RESEARCH:**

1. CP II: theory, design, chronic HF (Maastricht, Louisville)
2. Energetics, wall stress chronic, rapid pacing HF (Maastricht; Prof Fritz Prinzen)
3. Pulmonary mechanics in acute HF and chronic pulmonary HTN mode (Louisville; Dr. Mark Slaughter)

# Financial Highlights



- \$31.3M cash at year end 2014
- Loan Agreement with Silicon Valley Bank (February 2015)
  - \$6M funded at closing
  - \$2M available upon approval for interim analysis
  - \$2M available upon enrollment of 100th patient on COUNTER HF on or before Sept 30, 2015
- Opportunistic use of our \$40M at-the-market (ATM) facility:
  - \$7.0M raised in 2015 so far
- Extended current lease for Eden Prairie facility for another 3 years, to 2019.
  - Lease renewal includes expansion option into adjacent space



# Key Financial Metrics



Operations Summary (\$ in millions)	Year ended Dec 31, 2014	Year ended Dec 31, 2013		Q1 2015	Q1 2014
Net Loss	\$(25.6M)	\$(21.8M)		\$7.1M	\$6.3M
Non GAAP Net Loss (*)	\$(22.5M)	\$(17.9M)		\$6.2M	\$5.6M
Loss per share	\$(1.51)	\$(1.71)		\$(0.40)	\$(0.38)
Net change in cash	\$(22.8M)	\$39.9M		\$5.7M	\$(6.7M)

Summary Balance Sheet	3/31/2015	12/31/2014
Cash & Cash Equivalents:	\$37.0M	\$31.3M
Long-term Debt	\$ 6.0M	\$ --
Total Stockholders' Equity:	\$30.1M	\$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, \$0.9M in Q1 2015, and \$0.7M in Q1 2014.

# Key Financial Metrics



	NASDAQ
Symbol:	SSH
Market Cap:	\$80M
Shares o/s:	18.2M
Price per Share (as of 5/19/2015):	\$4.32
52-week high:	\$6.90
52-week low:	\$3.49
Avg. Daily Trading Volume (shares)	286,000
% 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
  - Corporate Investor \$3M
  - Follow-on April 2013 - \$15M
  - Follow-on September 2013 - \$46M
  - ATM 2015: \$7.0M



# 2015 – 2017 Milestones



Event	Timing
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
Enrollment expected complete for interim analysis cohort	Q4 2016
Feedback from FDA on fully implantable C-Pulse regulatory path	Q1 2016
First in man fully implantable system	Q4 2016 – 1H 2017
DSMB recommendation on interim analysis results	Q4 2017
COUNTER HF study fully enrolled	Q4 2017