



# 2011 AGM

**November 29, 2011**

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

# Forward looking statement



- This presentation may contain forward looking statements. Various factors could cause actual results to differ materially from these projections including timing, clinical results, financing availability, product sales and marketing or efficacy of products.
- Although the Company believes that the forward looking statements are reasonable, 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.

# 2011 – A Year of Transition



- Development company to clinical to commercial(in 2012)
- Full time staff grew from 16 to 24 employees
- Move to larger facility to address internal growth
- Board structure
- Broadening investor/public outreach
- Commercial ready technology approach



# 2011 Management Team



- Dave Rosa - CEO
- William Peters M.D. – Founder & CMO
- **Jeff Mathiesen** – CFO
- **Jim Yearick** – VP of Sales and Marketing
- Kevin Bassett – VP of R&D/Quality
- Deb Kridner – VP of Clin. & Reg. Affairs
- **Elaine Stead** – VP of Corporate Development, Australia

Red denotes new hires in 2011

# 2011 Corporate Board



- Nick Callinan - Chairman
- William Peters
- **Mark Harvey**
- **Paul Buckman**
- Geoff Brooke
- Donal O'Dwyer
- **Greg Waller**
- Dave Rosa

# 2011 Clinical and Regulatory Achievements



- Completed North American 20 patient feasibility trial
- Received FDA approval to implant 20 new patients and add 2 sites
- Negotiated CE Mark path to include 20 patient feasibility data
- Submitted feasibility trial data to FDA
- CE Mark submission on schedule for December
- Established FDA meeting in January 2012 to discuss protocol

# 2012 Clinical and Regulatory Plans



- Gain FDA approval to initiate pivotal trial protocol
- Continue to build internal infrastructure to conduct trial
- Secure CE Mark
- Collaborate with European key investigators to initiate trial

# Feasibility Study Population



|                                  | N = 20             |
|----------------------------------|--------------------|
| Age, mean $\pm$ SD years (range) | 56 $\pm$ 9 (34-71) |
| Gender                           |                    |
| Female                           | 8                  |
| Male                             | 12                 |
| Race                             |                    |
| African American                 | 3                  |
| Caucasian                        | 17                 |
| NYHA Class Ranking               |                    |
| Class III                        | 18                 |
| Class IV                         | 2                  |
| Etiology                         |                    |
| Ischemic                         | 8                  |
| Non-ischemic                     | 12                 |

- All on optimal medical therapy
- 100% with and ICD
- 45% with pacemakers



# Feasibility Procedural Data

- 6/20 cases performed via MIS
- ICU length of stay 2 days, Hospital stay 9 days
- Average procedure time - 2.5 hours(decreased with experience)
- 15/20 patients met 6 month endpoint
  - 1 patient transplant at 3 months(elective)
  - 3 total deaths due to: drug allergic reaction, respiratory event and during surgery to treat sternal infection
  - 1 received LVAD @ 3 months



# Feasibility Primary Efficacy Endpoints

Based on as treated cohort\*



| <b>N = 15</b>               | <b>Responder</b>  | <b>Indeterminate</b> | <b>Non-Responder</b> |
|-----------------------------|---|----------------------|----------------------|
| <b>NYHA Class Reduction</b> | 12<br>4 Class III to Class I<br>7 Class III to Class II<br>1 Class IV to Class II | 3                    | 0                    |
| <b>VO2</b>                  | 3   | 6                    | 6                    |
| <b>QOL</b>                  | 13  | 1                    | 1                    |
| <b>6 Minute Walk</b>        | 5   | 9                    | 1                    |

11/28/2011

Green denotes statistical significance; Blue denotes trend

NC denotes device used < 80%

# Feasibility Primary Safety Endpoints



| <b>N = 15</b>           | <b>Number of Patients</b> |
|-------------------------|---------------------------|
| Death/Aortic Disruption | 1                         |
| Neurological Events     | 0                         |
| Myocardial Infarction   | 0                         |
| Major Infection         | 9(8 related to exit site) |

# Additional Trial Observations



- **>5,500** total patient days follow up; 1 patient supported 22 months
- **Ejection Fraction** – 10 improved
- **LVEDD** – 7 improved
- **Diuretics and Inotropes** reduced or discontinued
- **Device Related Bleeding** – 0
- Results typically better when C-Pulse used at least 80% of time
- Improvements may continue after 6 months
- **2 “super responders” – permanently disconnected**

# How does C-Pulse compare?



| Endpoint                | SHI             | VAD |
|-------------------------|-----------------|-----|
| Stroke                  | 0               | 18% |
| Other neurologic events | 0               | 20% |
| Days in hospital        | 9               | 19  |
| Exit site infection     | 40%             | 29% |
| Sepsis                  | 0%              | 36% |
| Death                   | 5%              | 24% |
| Bleeding                | 10%(non device) | 77% |
| NYHA Class I or II      | 80%             | 68% |
| 6 MW(>350m)             | 47%             | 70% |
| Improved QOL            | 87%             | 90% |

# Core Observations



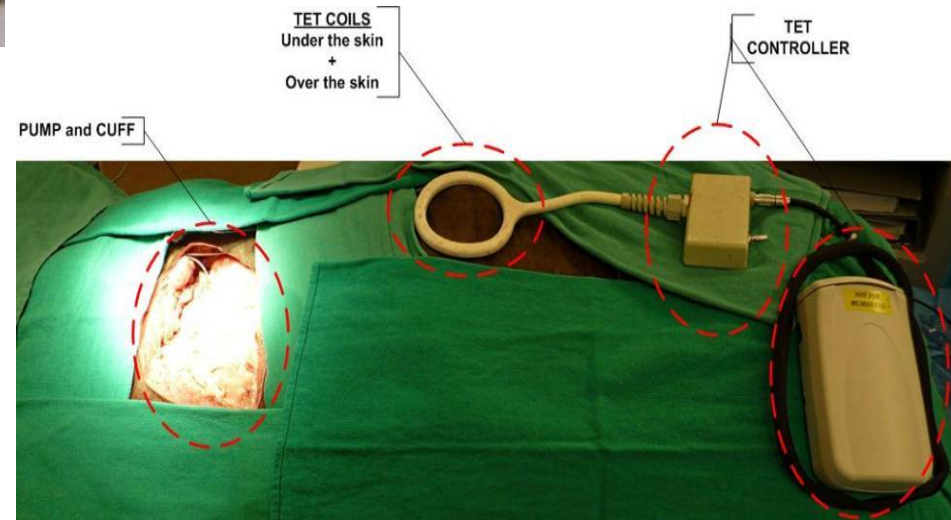
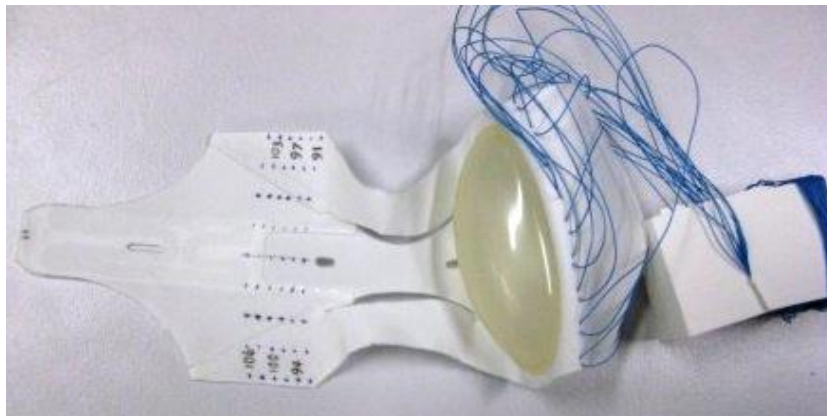
## Key advantages

- Minimally invasive
- Evidence of efficacy signals
- Improvements at 1 month through 12 months
- QOL is greatly improved
- Device safety
- Non VAD centers are appropriate

## Areas to address

- Exit site infection management
- Improve equipment: C-Patch, PIL, Driver, Cuff, Tunneler
- Perform 6MW first; use standard instructions
- Compliance
- Protocol inclusion/exclusion criteria

# 2011 R & D Accomplishments



# 2012 R&D Plans



- Incorporate new Driver software enhancements
- Communicate/accelerate development of fully implantable system
- Develop “through the skin” placement for tubing
- Continue progress regarding pacemaker/C-Pulse interface



# 2011 Operational Accomplishments



- Added key staff from major cardiovascular companies
- Upgraded key suppliers
- Identified new facility to address company growth
- Began construction of clean-room to allow for in house cuff assembly

# 2012 Operational Plan

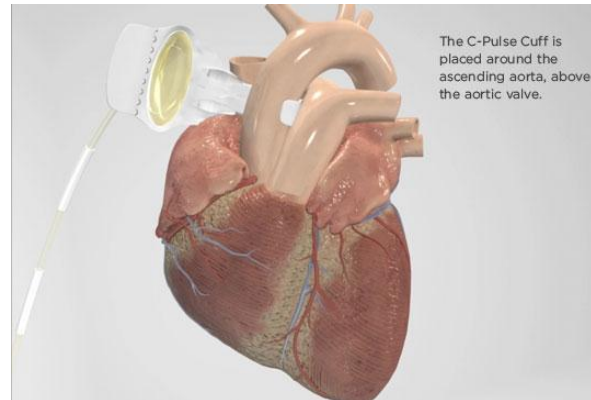


- Reduce system cost of goods
- Complete move to new facility
- Implement in house assembly of cuff
- Work with vendors to ensure adequate worldwide product supply

# 2011 Sales and Marketing Accomplishments



- Department formalized in October
- Hired industry veteran from Medtronic to lead efforts
- Acquired booth for trade show exhibitions
- Exhibited at TCT, largest worldwide interventional cardiology show
- Two C-Pulse physician presentations held at TCT
- Completed re-launch of company brand and website



# 2012 Sales and Marketing Plan



- Initiate European activity
- Hire representatives to support international commercialization
- Publish clinical trial data and other pertinent device experience
- Increase worldwide exposure

# 2011 Financial Accomplishments



- Hired US based CFO
- Closed financing of \$7.7M in Q3 2011
- Attracted new North American investors
- 3/6 largest investors from North America
- NASDAQ listing application filed: expect to be effective in Q4

# 2012 Financial Plan



- Raise capital via US and Australian markets to support plan
- Formalize relationships with key investment banks
- Evaluate key strategic partnerships
- Expand company investor worldwide exposure

# 2011 Sunshine Heart Inc. Summary



- Sunshine Heart has accomplished its 2011 objectives
- Company successfully transitioned from development stage to one approaching commercialization
- Numerous device enhancements are in place
- 2012 plans include European initiation, US pivotal trial commencement, further development of fully implantable technology, and in house assembly of product