

"Innovative devices for treating heart failure"

**JUNE 2006** 



### **Forward looking statements**

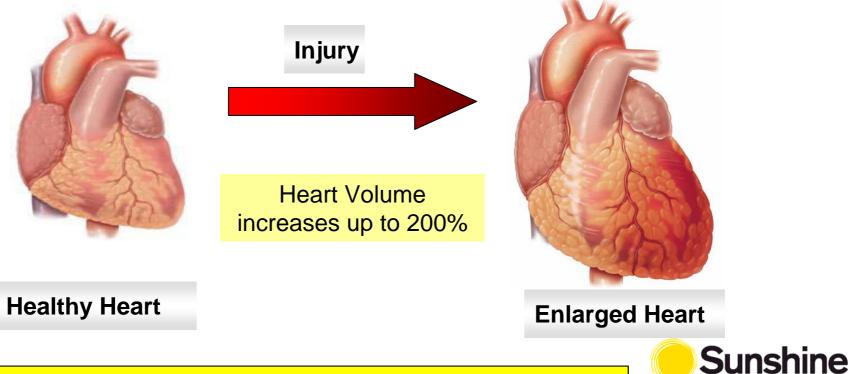
This presentation may contain forward looking statements. Various factors could cause actual results to differ materially from these projections including timing, clinical results, financing availability, product sales & marketing or efficacy of products. Although the Company believes that the forward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



### What is Heart Failure ?

#### The heart losses its ability to pump blood efficiently

- Injury (such as viral and heart attack)
- Characterized by enlargement of the heart
- Progressive disease
- NYHA classification; Class I to Class IV



### **Target Market: Heart Failure NYHA III**

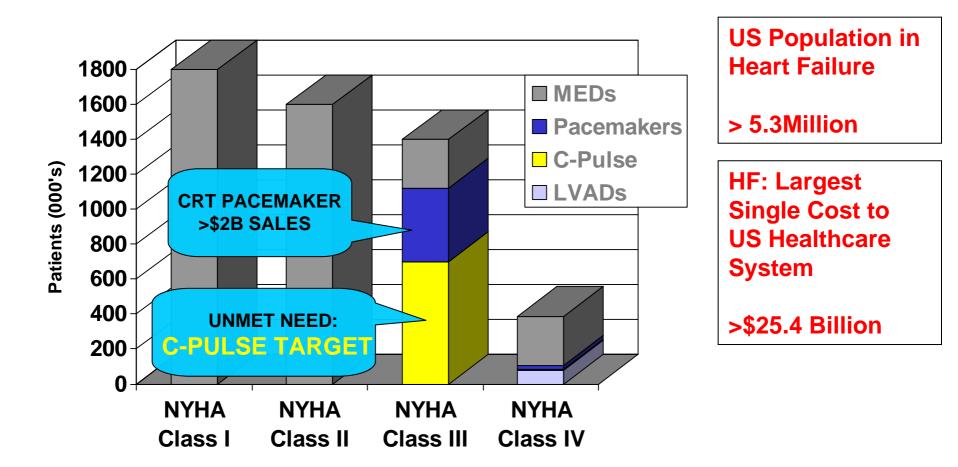
### Signs & Symptoms:

- Feeling tired, fatigued
- •Short of breath (SOB) at rest or with minimal exertion
- •Dizziness or collapse
- Swollen legs or ankles
- Difficulty sleeping (sudden SOB)
- Repeat hospitalisations
- Poor Quality of Life





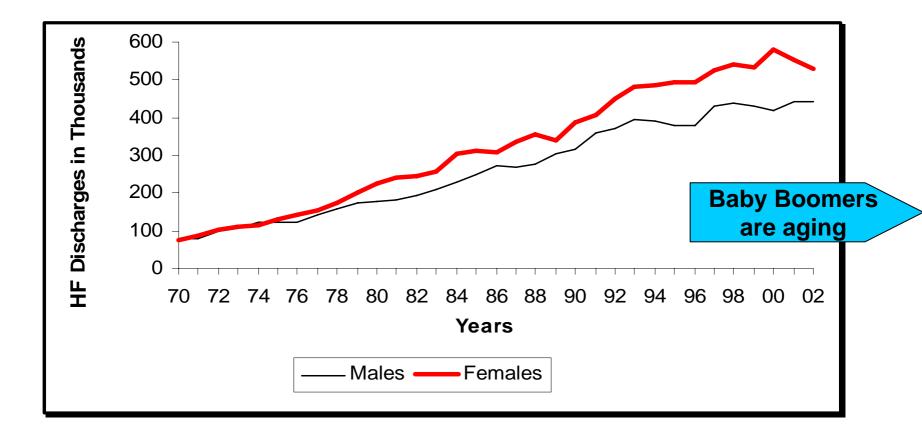
## Heart Assist Therapy (Potential Market)



Source: American Heart Association



### Heart Failure Market (US): GROWING!!



### Heart Failure is an epidemic

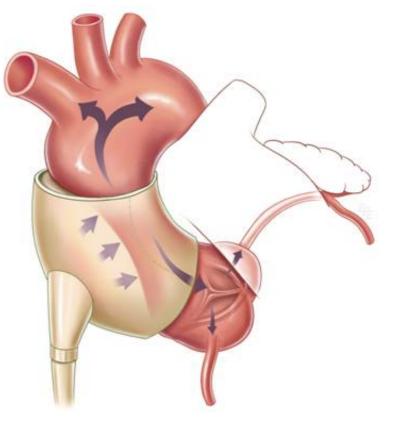
Source: US Center of Disease Control



# **C-Pulse Implanted Counterpulsation Pump (ICP)**

# **Counterpulsation action:**

- 64% increase in coronary blood flow\*
- 18% reduction in size\*
- No Blood contact
- Benefit with lower risks
- Turn on and off
- Wean slowly for recovery



Low cost, simple C-Pulse™



\*Legget et al. Circulation Suppl. 2005

# **C-Pulse – to improve Quality of Life**

- **C-Pulse patient lifestyle:**
- Optimise drug therapy
- Manage lead exit-site
- Manage battery-powered Driver

(rechargeable via mains or separate battery charger)

• Relief of symptoms for an improved, more active lifestyle





### **C-Pulse – the lifestyle heart assist pump**

• Disconnect from Driver for convenience or personal hygiene







# **C-Pulse- Designed for Class III Patients**

- Simple, safe surgery
- Can turn on and off
- Assists and unloads the heart
- Can wean for recovery
- Reduced complication profile
- Low total cost of therapy
- Implant into less sick patients
- Implant at more hospitals
- Good gross margin





# **C-Pulse Pilot Clinical Study**

# **ANZ Clinical Sites**

- Auckland City Hospital
- St Vincents, Sydney
- The Alfred, Melb.
- Southern Health, Melb.

ANZ DSMB CVS (chair) +2 HF cardiologists



World first C-Pulse implant - ACH



### **C-Pulse Clinical Experiences**

#### **Uncomplicated surgery**

- 2.5 hour minimum invasive implant
- no heart-lung machine; no blood transfusions

### **Quickly Discharged home**

- Symptomatic relief; high device compliance
- Turn device on/off for convenience

### Performance

- Improved heart function and improved symptoms
- Safety study patients: in process



# **C-Pulse Pathway to Market - IN PROCESS**

# **Product Partnerships – outsourced to experts**

- Plexus, Inc, WI Driver Systems
- PTG, Inc, CA Sterile Cuffs



# **C-Pulse FDA IDE Application in process**

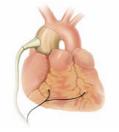
- Medical Advisory Board guidance
- SHC and consulting Regulatory expertise
- Pre- IDE FDA interactions



# **Sunshine Heart: Medical Advisory Board**

#### Surgeons

Cliff Hughes, FRACS, AO (Royal Prince Alfred, AUS) Don Esmore, FRAC, AO (the Alfred, AUS) Robert C. Robbins, MD (Stanford) Michael Acker, MD (U of Penn) Patrick McCarthy, MD (Northwestern University) Thomas Fogarty, MD (Stanford University)



#### Cardiologists

James B. Young, MD (Cleveland Clinic) Marc Silver, MD, PhD (Christ Advocate) David Kaye, MD PhD (Baker Heart Institute, AUS) Spencer Kubo, MD (Acorn Cardiovascular)

#### **Scientists**

Hani Sabbah, PhD (Henry Ford Heart)



# **SHC Management Team**

Name	Position	Experience
Don Rohrbaugh	Chief Executive Officer	<ul> <li>• 25+ yr medical device executive experience</li> <li>• Acorn Cardiovascular (Founding CEO, President)</li> <li>• Ex- Baxter Novacor LVAD Exec (6 years)</li> </ul>
William Peters MD	Medical Director Chief Technical Officer	<ul> <li>Surgeon/inventor</li> <li>Pioneer of minimally invasive cardiac surgery (Heartport)</li> </ul>
Victor Windeyer	Chief Operating Officer	•Experienced Medical Device Executive •HF/ LVAD Executive @ Ventracor •Invetech & Cochlear experience

### **Medical Device Experienced Team**

(Heart Failure, Heart Assist, Cardio-Vascular, Start-up & Global Businesses)



### **Sunshine Heart Board of Directors**

	Name	Position	Experience
	Malcolm McComas	Chairman	<ul> <li>20 years investment banking and 5 years legal experience</li> <li>Experience in equity, debt, acquisitions, divestments and implementation of major equity issues</li> </ul>
	Don Rohrbaugh	Chief Executive Officer	<ul> <li>• 25+ years medical device executive experience</li> <li>• Acorn Cardiovascular (Founding CEO, President)</li> <li>• Ex- Baxter Novacor LVAD Executive (6 years)</li> </ul>
<b>E</b>	William Peters MD	Executive Director	<ul> <li>Surgeon/inventor</li> <li>Pioneer of minimally invasive cardiac surgery (Heartport)</li> <li>Sunshine Heart Co- founder</li> </ul>
	Crispin Marsh	Non Executive Director	<ul> <li>Patent Attorney (30 years)</li> <li>Technology licensing and commercialisation experience</li> <li>Sunshine Heart Co- founder</li> </ul>
	Geoffrey Brooke MB BS (GBS Ventures)	Non Executive Director	<ul> <li>Managing Director of GBS Venture Partners with 15 years of venture capital experience</li> <li>Co-founded MedVest together with Johnson &amp; Johnson</li> <li>5 years of clinical experience</li> </ul>
	Donal O'Dwyer	Non Executive Director	<ul> <li>Recently retired as worldwide president Cordis Cardiology (cardiology division of Johnson and Johnson subsidiary)</li> <li>Ex- Baxter Healthcare - medical device experience (12 years)</li> </ul>
	Richard Lin MD (Three Arch Partners)	Non Executive Director	<ul> <li>Partner in Three Arch Partners</li> <li>Co - founder and co- inventor of Spiration</li> </ul>



# Sunshine Heart, Inc (SHC): Corporate Structure

### **SHC History**

- Australian Pty Ltd: 2000
- Private (AU\$1.5M) and Australian Grant (AU\$2.55M) funding
- US incorporation: 2002; VC investment US\$2M
- ASX IPO: Sep 2004; AU\$0.50/share; AU\$15M (AU\$13M net)
- Aus Comm Ready Grant: Oct 2005; AU\$2.23M (payments)
- Placement: Dec 2005; \$3.3M (with strong insider support)

#### **Facilities**

- St Leonards, NSW: ..... Corp Admin; R&D, ANZ Clin
- Irvine, CA: .....

### Financials (31 Mar 06)

- Cash.....
- Share Price .....
- Shares Outstanding: .....
- Market Cap:....

AU\$5.6M AU\$0.16 81,917,328 AU\$13M

**RA/QA, US OPS** 



# **C-Pulse Summary**

- Large unmet Target Market
- Simple, Elegant, Patented Concept
- Cost effective therapy, high margin
- Designed for Destination Therapy
- Initial Validation Compelling
- AUS/NZ Trial ongoing
- US Trial 07
- Proven Cuff & driver durability
- Experienced Management and Board







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