

# HEARTWARE LIMITED

ABN 34 111 970 257



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Manager of Company Announcements  
Australian Stock Exchange Limited  
Level 6  
20 Bridge Street  
SYDNEY NSW 2000

23 May 2006  
**BY E-LODGE MENT**

Dear Sir / Madam

## **Annual General Meeting Presentation**

In accordance with ASX Listing Rule 3.13.3 the Company provides a copy of the presentations which are to be delivered today at the Company's Annual General Meeting.

The AGM is being held at the Company's auditors, Grant Thornton, at Level 17, 383 Kent Street, Sydney, commencing at 10am.

The AGM may also be viewed by webcast at the following address:

<http://www.streamx.com.au/heartware/agm06/start.htm>

Yours faithfully

**David McIntyre**  
**Chief Financial Officer &**  
**Company Secretary**



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## **HeartWare Limited (ASX : HTW)**

ABN 34 111 970 257

A Medical Device Company

**Stuart McConchie, Chief Executive Officer**

**Annual General Meeting, 23 May 2006**

# Overview



- Heart failure is a leading cause of death in the developed world and represents a significant emerging medical device market
- HeartWare is developing a family of implantable heart pumps for the treatment of advanced heart failure
- HeartWare's HVAD, the smallest 3<sup>rd</sup> generation heart pump, is demonstrating outstanding early clinical results
- By the end of 2006, HeartWare aims to complete enrolment in its EU / Australian clinical trial and to commence its US clinical trials, subject to approvals
- HeartWare's next generation device, the MVAD, is in pre-clinical studies
- HeartWare has a strong IP portfolio and proven management capability

# Magnitude of the Problem



Heart Failure is one of the largest unmet medical needs in the developed world

- A degenerative and terminal disease
- Affects approximately 10 million people globally (5 million in US), with 1 million new cases diagnosed every year
- 1 million patients in NYHA Class IV, the end-stage of the disease
- In the US, heart failure remains Medicare's greatest area of healthcare-related spending

# Current Treatment Options



Available therapies are inadequate compared with the scale of the disease

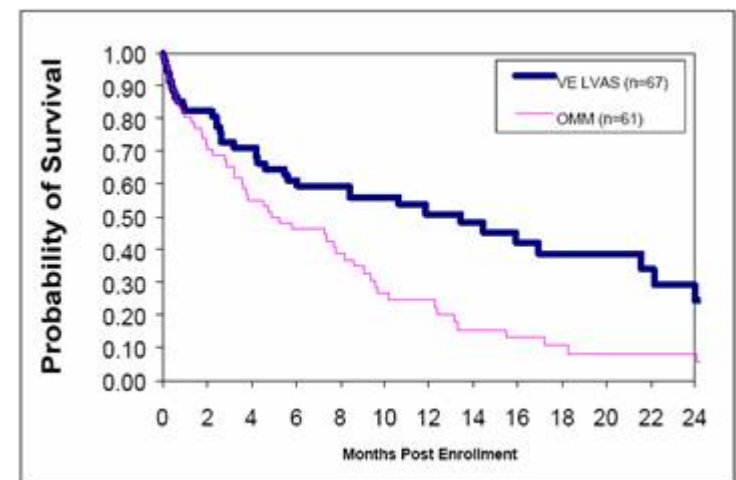
- Heart transplantation is a proven therapy, but only 3,000 donor hearts are available worldwide each year
- Drug therapies have proven ineffective at halting the progression of the disease
- Heart pumps are recognised as the only viable option, but technical limitations of earlier devices have limited their widespread use

# The Opportunity



The introduction of clinically acceptable devices is expected to unlock a major market

- REMATCH study demonstrated a statistically significant survival benefit of long term device treatment compared with medical therapy
  - of this, typically USD75,000 is for the device
- The procedure is reimbursed in the US at a minimum USD136,000
- Of the 1 million NYHA Class IV CHF patients, an estimated 100,000 per year would benefit from the implant of a heart pump



REMATCH Study Results

# HeartWare's Competitive Position



HeartWare is well placed to establish a leading position in the market over the long term

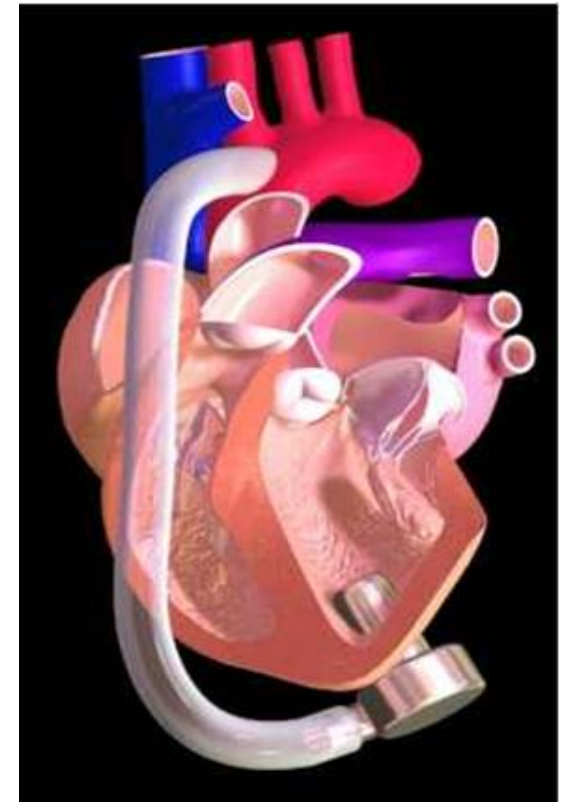
- **The leading “3rd generation” heart pump today**
- **Miniaturisation platform underpinning future product leadership**
- **Significant and growing clinical support**
- **Operational advantages underpinning efficient, cost effective production capability**

# HeartWare's HVAD

## - The Leading "3rd Generation" Heart Pump



- **The smallest full output pump available today**
  - Thoracic placement – no abdominal surgery
  - Shorter and less complex procedure
  - Improved patient outcome
- **Improved blood flow characteristics**
  - Eliminate haemolysis (damage to blood cells)
    - Plasma Hb in physiological range
  - Reduce requirement for anti-coagulants
- **Long term reliability**
  - No mechanical bearings – wearless design
  - Destination or "Lifelong" Therapy



# The HeartWare HVAD - Product Animation



[Click here for animation](#)

# HeartWare's HVAD Clinical Study



## ■ Successful human implants at Vienna General Hospital

- Cumulative implant days >96
- Rapid implant procedure and post-operative recovery
- No significant operative or post operative events
- No evidence of haemolysis
- Use of lower levels of anti-coagulants
- Both patients discharged from hospital
- Excellent patient outcomes



# HeartWare's HVAD Clinical Study



## ■ Trial Parameters

- 20 patients, Class IV Heart Failure
- Endpoint: survival to 180 days or transplantation
- Aim to complete enrolment during 2006
- Submission for CE Mark Q1 2007

## ■ Participating Centres

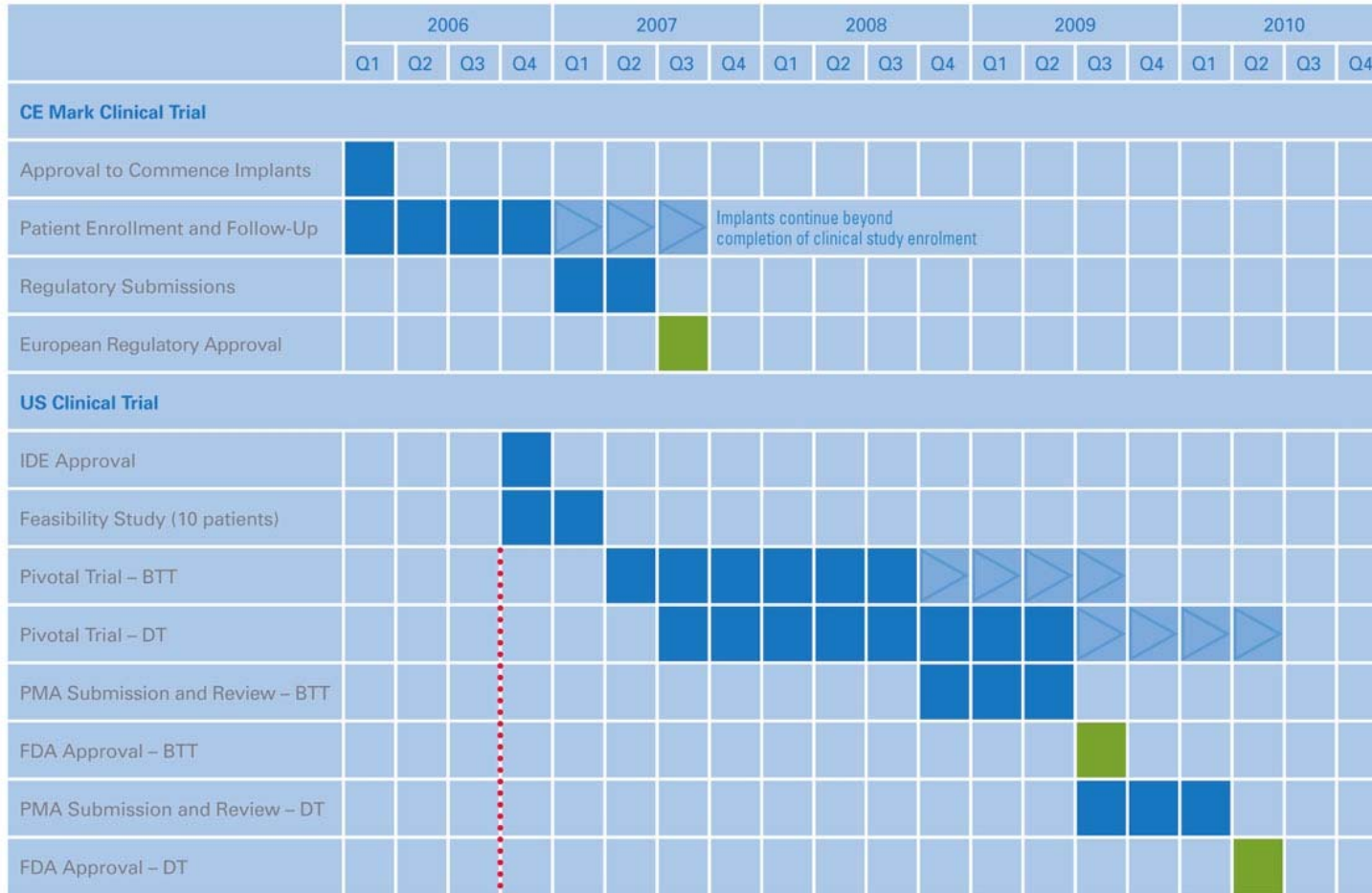
- Vienna General Hospital, Austria
- Royal Perth Hospital, Australia
- Harefield Hospital, UK
- Hanover Medical Centre, Germany



# First Patient on Austrian Television



# The HVAD Development Timeline



Note: Timeline estimates based on current FDA protocols

Revenues earned through reimbursement of HVADs used in U.S. trials

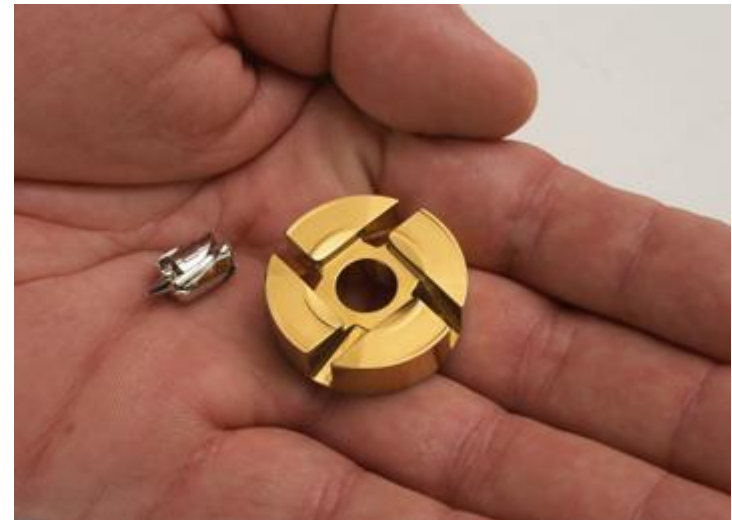
# HeartWare's Next Generation Device

## - The Miniaturised VAD (MVAD)



A quantum advance in technology, with potential to revolutionise the management of heart failure

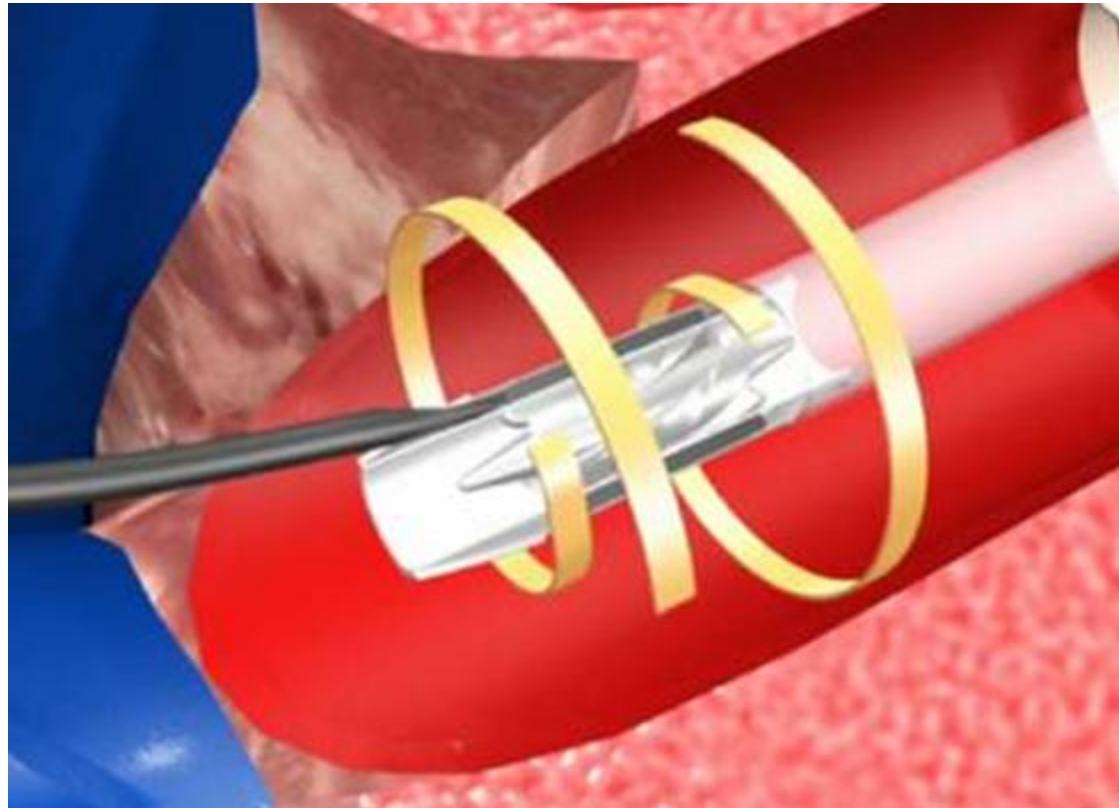
- **Miniaturisation program based on HeartWare proprietary technology**
  - Existing HVAD patents
  - Additional MVAD patents
- **Current MVAD prototype:**
  - Approximately 1/10th the size of the HVAD
  - Animal studies progressing – chronic use
  - Approximately 2 years from clinical introduction
- **Further miniaturisation underway**
  - Targeting an intravascular heart pump
  - Implantable by catheter
  - Moving from Surgeon to Cardiologist



HeartWare's current MVAD rotor (left) alongside the HVAD impeller

# HeartWare 's Intravascular Pump

## – Product Animation



**HeartWare's intravascular heart pump currently in development**

# The Competitive Landscape



		Volume	Mass	Pericardial Placement	Wearless
LVAD Technology	<b>FIRST GENERATION</b> Volume Displacement	These are large, heavy, mechanically complex devices. They are implanted in the abdomen and have limited long term reliability.			
	• Thoratec Heartmate I • Worldheart Novacor				
	<b>Rotary</b>				
	<b>SECOND GENERATION</b> Mechanical Bearings				
	• Jarvik 2000 • Micromed DeBakey • Thoratec HeartMate II	25cc 37cc 63cc	85g 95g 281g	Y N N	N N N
	<b>THIRD GENERATION</b> (Wearless)				
	<b>Active Maglev</b>				
	• WorldHeart HeartQuest • Terumo DuraHeart • Thoratec HeartMate III • Berlin Incor	155cc 150cc 195cc 60cc	540g 420g 500g 200g	N N N N	Y Y Y Y
	<b>Passive Suspension</b>				
	<b>Radial Hydrodynamic Support</b>				
Arrow CorAide	200cc	300g	N	Y	
<b>Radial &amp; Axial Hydrodynamic Support</b>					
Ventractor VentrAssist	122cc	298g	N	Y	
<b>Axial Hydrodynamic Support Plus MagLev</b>					
<b>The smallest third generation pump in development</b>					
HeartWare HVAD	45cc	145g	Y	Y	
<b>FOURTH GENERATION</b>					
HeartWare MVAD (in development)	5cc	15g	Y	Y	

# Market leader paving the way...



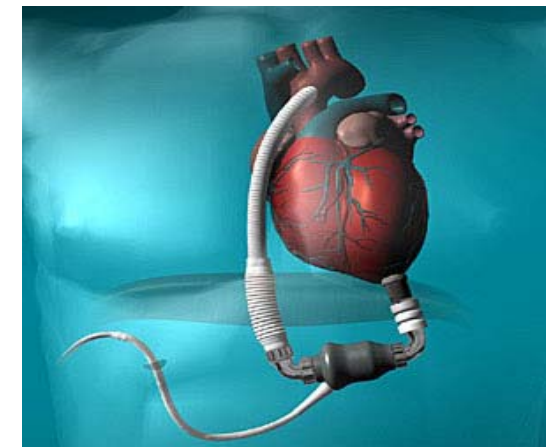
## ■ The Thoratec HeartMate VE LVAS™

- Originally approved as Bridge-to-Transplant
- Only device with FDA approval for Destination Therapy
- Limited uptake due to size (1.15kg) and lack of long term reliability (1.5 years mean time to failure)



## ■ The Thoratec HeartMate II™

- Second generation pump with mechanical bearings
- CE mark approval in Q4, 2005
  - Over 20 pumps sold in EU in Q1 2006
- Currently in pivotal US trial. Over 200 US implants and enrolling ~20 patients per month
- Generating significant support and driving clinical acceptance of Destination Therapy



Reprinted with permission from Thoratec Corporation

# Manufacturing Approach



- **Efficient manufacturing philosophy**
  - Sub-assemblies outsourced to specialist US component manufacturers
  - Supplier economies of scale and experience
  - Reduced capital costs
  - Effective risk management
- **Robust Process**
  - Stable, consistent, predictable, high quality and high yield
- **Cost advantages inherent in pump design**
  - Reduced component numbers
  - Reduced reliance on human assembly
  - HVAD standardised variable cost (materials and direct labour): <USD7,500 per pump
- **Scalable Production Capacity**
  - Production targets in line with clinical trial demands
  - Controlled scale-up of manufacturing output in line with corporate objectives

# Cash Position and Cash Burn



## ■ Cash position

- 30 April 2005 - approx. \$8 million
- Capital raising - \$30.7 million (after issue costs)
- Shareholder Share Purchase Plan - closing early June 2006

## ■ Cash burn

- \$1.5 million per month – trending upwards
- Expected to increase to approx. \$2-2.5 million per month by mid 2007

# Headline Expenditure Items – 2006



- **Head count growth as manufacturing output increases**
  - At ASX Listing (31 Jan 2005) – 27 employees
  - 31 December 2005 – 41 employees
  - 30 April 2006 – 51 employees
  - 31 December 2006 – 85 employees (projected)
- **Capital expenditure**
  - During 2005 – A\$1.9 million
  - 2006 projection – A\$2.6 million
- **Research & development**
  - Changing focus from “externals” to MVAD
- **Focus on manufacturing processes and scale up**

# Senior Management



Name	Role	Relevant Experience
<b>Dozier Rowe</b>	Chief Operating Officer	<ul style="list-style-type: none"> <li>• 25 years medical devices experience</li> <li>• Previous roles with Boston Scientific, St Jude Medical, Baxter Healthcare</li> <li>• Formerly General Manager, Operations at Boston Scientific's Florida operations centre – responsible for &gt;1000 staff and budget &gt;USD100M</li> </ul>
<b>David McIntyre</b>	Chief Financial Officer, Company Secretary	<ul style="list-style-type: none"> <li>• Previously CFO &amp; General Counsel for ASX listed medical device company</li> <li>• Served as a corporate and commercial law specialist at an international law firm, plus senior financial roles at multinationals</li> </ul>
<b>Jeff LaRose</b>	Chief Technical Officer	<ul style="list-style-type: none"> <li>• Inventor of HeartWare's platform technology</li> <li>• 18 years in hydraulic design and blood pump development</li> <li>• Leader in Computational Fluid Dynamics modelling</li> </ul>
<b>Janice Piasecki</b>	VP Regulatory Affairs (Consultant)	<ul style="list-style-type: none"> <li>• 30 years of regulatory experience</li> <li>• FDA compliance officer for heart devices</li> <li>• Responsible, as VP Regulatory, for bringing Abiomed's TAH to market</li> </ul>
<b>Jane Reedy</b>	VP Clinical Affairs	<ul style="list-style-type: none"> <li>• 20 years experience in clinical affairs in circulatory assist device industry</li> <li>• Former Director of Clinical Services for Thoratec</li> </ul>
<b>Bill Rissmann</b>	VP Manufacturing and Product Development	<ul style="list-style-type: none"> <li>• 25 years experience in medical device engineering and manufacturing</li> <li>• Previous roles with Guidant, Medtronic and St Jude</li> </ul>
<b>Howard Leibman</b>	VP, Corporate Development	<ul style="list-style-type: none"> <li>• Previously corporate finance executive at eG Capital, Sydney</li> <li>• 10 years experience in engineering, venture capital and corporate finance</li> </ul>

# Board of Directors



Name	Role	Relevant Experience
<b>Rob Thomas</b>	Non-Executive Chairman	<ul style="list-style-type: none"> <li>• 30 years experience in securities industry</li> <li>• Previously Chairman, Citigroup Corporate and Investment Bank Australia, CEO of Salomon Smith Barney, CEO of County NatWest Securities</li> </ul>
<b>Stuart McConchie</b>	Managing Director CEO & President,	<ul style="list-style-type: none"> <li>• 25 years in medical device industry internationally</li> <li>• Over a decade in heart failure devices</li> <li>• Previous roles with Telectronics and Jarvik Heart, Inc.</li> </ul>
<b>Seth Harrison, MD</b>	Non-Executive Director	<ul style="list-style-type: none"> <li>• Surgeon, Presbyterian Hospital, New York</li> <li>• 14 years in life science venture capital</li> <li>• 8 years with HeartWare as an investor</li> <li>• Number of successful biomedical and biotech start ups</li> </ul>
<b>Dr Christine Bennett</b>	Non-Executive Director	<ul style="list-style-type: none"> <li>• Qualified paediatrician and previous advisor to Health Dept</li> <li>• Currently Chief Medical Officer at MBF</li> <li>• Previously CEO of Research Australia, CEO Westmead Hospital, Head of KPMG Health</li> </ul>
<b>Dr Denis Wade AM</b>	Non-Executive Director	<ul style="list-style-type: none"> <li>• Formerly Managing Director J&amp;J Research</li> <li>• Former Foundation Professor of Clinical Pharmacology, UNSW</li> </ul>

# Medical Advisory Board



Name	Relevant Experience
<b>Bud Frazier, MD</b> <i>(Texas Heart Institute)</i>	<ul style="list-style-type: none"> <li>• Chairman of Advisory Board</li> <li>• Chief of Transplant Services, Texas Heart Institute</li> <li>• Implanted over 565 LVADs</li> </ul>
<b>Steven Boyce, MD</b> <i>(Washington Hospital Centre)</i>	<ul style="list-style-type: none"> <li>• Director of Heart Transplantation, Washington Hospital Centre</li> <li>• Involved with the development of HeartWare devices since 1996</li> </ul>
<b>Leslie Miller, MD</b> <i>(Lillehei Heart Institute University of Minnesota)</i>	<ul style="list-style-type: none"> <li>• Director of Heart Failure/Heart Transplant Program at the University of Minnesota</li> <li>• Past President of the International Society for Heart and Lung Transplantation</li> </ul>
<b>Laman A. Gray, Jr., MD</b> <i>(University of Louisville School of Medicine)</i>	<ul style="list-style-type: none"> <li>• Professor of Surgery and Director of Thoracic and Cardiovascular Surgery at the University of Louisville School of Medicine</li> <li>• Was the original investigator for the Novacor VAD System, and implanted the first AbioCor Implantable Replacement Heart</li> </ul>
<b>Stephen Westaby MD, PhD</b> <i>(John Radcliffe Hospital, Oxford)</i>	<ul style="list-style-type: none"> <li>• Cardiothoracic surgeon, John Radcliffe Hospital</li> <li>• Over 500 cardiac operations annually</li> <li>• Implanted the longest surviving LVAD patient, Peter Houghton</li> </ul>
<b>Georg Wieselthaler, MD</b> <i>(Vienna General Hospital)</i>	<ul style="list-style-type: none"> <li>• Clinical Director of Mechanical Circulatory Support, Vienna General Hospital</li> <li>• Secretary General of the International Society of Rotary Blood Pumps</li> </ul>
<b>Gerry O'Driscoll, MD</b> <i>(Royal Perth Hospital)</i>	<ul style="list-style-type: none"> <li>• Consultant Cardiologist, Royal Perth Hospital</li> <li>• Medical Head, West Australian Advanced Heart Failure and Cardiac Transplant Service</li> <li>• Extensive experience with a range of LVAD devices</li> </ul>
<b>Asghar Khaghani, MD</b> <i>(Royal Brompton and Harefield Hospital Trust)</i>	<ul style="list-style-type: none"> <li>• Consultant Cardiac Surgeon at Harefield Hospital, UK</li> <li>• Head of cardiac transplantation and mechanical circulatory assist programs</li> <li>• Extensive experience with a range of LVAD devices</li> </ul>

Thank You





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## HeartWare Limited

ABN 34 111 970 257

Annual General Meeting

23<sup>rd</sup> May 2006

# Resolution No. 1



## Adoption of the Remuneration Report

**“That the Remuneration Report (which forms part of the Directors' Report) for the reporting period ended 31 December 2005 be adopted.”**

## Resolution No. 2



### Re-Election of Mr Robert Thomas as a Non-Executive Director

“That Mr Robert Thomas, who retires by rotation in accordance with the Company’s Constitution, and being eligible offers himself for re-election as a Director, be re-elected as a Non-Executive Director.”

## Resolution No. 3



### Re-Appointment of Auditors

**“That the Remuneration Report (which forms part of the Directors' Report) for the reporting period ended 31 December 2005 be adopted.”**

## Resolution No. 4



### Approval of Employee Share Option Plan

“For the purposes of ASX Listing Rule 7.2, Exception 9, and for all other purposes, shareholders of the Company approve the Company's consolidated Employee Share Option Plan constituted and administered in accordance with the Rules of the Employee Share Option Plan which are summarised in the Explanatory Memorandum.”

### Voting Exclusion Statement

The Company will disregard any votes cast on Resolution 4 by a Director and any associate of a Director. However, the Company need not disregard a vote if it is cast by a person as a proxy for a person who is entitled to vote, in accordance with the direction on the proxy form, or it is cast by the person chairing the Meeting as a proxy for a person who is entitled to vote, in accordance with a direction on the proxy form to vote as the proxy decides.

## Resolution No. 5



### Increase in Directors' Fees

“For the purposes of ASX Listing Rule 10.17 and for all other purposes, the maximum aggregate remuneration out of the funds of the Company to which the Directors are entitled in each year for their services as Directors be increased from \$340,000 to \$550,000 being distributed in such proportions and manner as the Directors may decide. Such increase to take effect from the date of the Annual General Meeting.”

### Voting Exclusion Statement

The Company will disregard any votes cast on Resolution 5 by any Director and any associate of a Director. However, the Company need not disregard a vote if it is cast by a person as a proxy for a person who is entitled to vote, in accordance with the direction on the proxy form, or it is cast by the person chairing the Meeting as a proxy for a person who is entitled to vote, in accordance with a direction on the proxy form to vote as the proxy decides.

## Resolution No. 6



### Approval of Share Issue

“For the purposes of ASX Listing Rule 7.1 and for all other purposes, shareholders of the Company approve and authorise the Directors to issue and allot Shares up to a total value of \$30,000,000, at a price per Share no less than 80% of the average market price (as defined in the ASX Listing Rules) for Shares calculated over the 5 trading days prior to the date of issue of the Shares on the terms and conditions contained in the Explanatory Memorandum.”

### Voting Exclusion Statement

The Company will disregard any votes cast on Resolution 6 by a person who may participate in the proposed issue and a person who might obtain a benefit if the Resolution is passed (except a benefit solely in the capacity of a holder of ordinary securities) and any associate of those persons. However, the Company need not disregard a vote if it is cast by a person as a proxy for a person who is entitled to vote, in accordance with the direction on the proxy form, or it is cast by the person chairing the Meeting as a proxy for a person who is entitled to vote, in accordance with a direction on the proxy form to vote as the proxy decides.



# HeartWare Limited

ABN 34 111 970 257

## Annual General Meeting

23<sup>rd</sup> May 2006