

#### Presentation at the Australian Biotechnology Expo

On 14 June 2006 HeartWare CEO, Mr Stuart McConchie delivered a presentation at the Australian Biotechnology Expo in Melbourne, Australia. Please find attached a copy of the presentation.

With reference to the clinical trial currently underway for HeartWare's HVAD left ventricular assist device, Mr McConchie commented:

"The first two patients to have been implanted with the HVAD continue to recover extremely well. Both are now at home, having been released from the Vienna General Hospital where the procedures were conducted. We now have some 140 days of cumulative clinical implant experience with the device. We have seen no evidence whatsoever of pump related haemolysis or thrombosis and are extremely encouraged by the performance of the device in these first two cases. We look forward to commencing our Australian implant program at the Royal Perth Hospital in coming weeks."

Mr McConchie's presentation included news footage recently screened on Austrian National Television. The video includes brief interviews with the first patient to be implanted with the HVAD and with Dr Georg Wieselthaler, who conducted the procedure. The news broadcast can be accessed via the HeartWare website at http://www.heartware.com.au/IRM/content/investor\_media.html#

#### About HeartWare

HeartWare is developing a family of proprietary circulatory assist devices to treat patients with congestive heart failure. HeartWare's lead device, the HVAD, commenced human clinical trials in March 2006. First sales are anticipated in late 2007. With a volume of 45cc, the HVAD is the smallest "3rd generation" pump and the only full output device implantable within the pericardial space.

In parallel with the HVAD clinical development, HeartWare is pursuing its MVAD program, aimed at developing a family of miniaturized cardiac assist devices, implantable by minimally invasive surgical techniques. The current MVAD prototype, approximately one tenth the volume of the HVAD, commenced animal studies in August 2005.

For further information:

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### HeartWare Limited (ASX : HTW)

ABN 34 111 970 257

## A Medical Device Company

Stuart McConchie, Chief Executive Officer Australian Biotechnology Expo, June 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
- HeartWare's next generation device, the MVAD, is in pre-clinical studies
- HeartWare has a strong IP portfolio and proven management capability



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



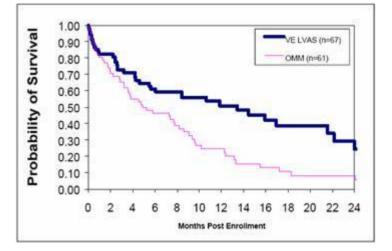
Available therapies are inadequate compared with the scale of the disease

- 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
- The procedure is reimbursed in the US at a minimum USD136,000
  - of this, typically USD75,000 is for the device
- 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 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

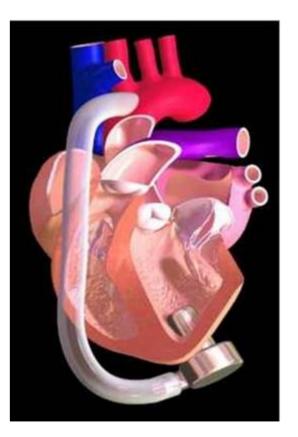
- Thoracic placement no abdominal surgery
- Shorter and less complex procedure
- Improved patient outcome

#### 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 >135
- Rapid implant procedure and postoperative 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**

	2006			2007				2008				2009				2010				
	01	Q2	03	Q4	01	02	03	Q4	Q1	02	03	Q4	Q1	02	Q3	Q4	01	02	03	0
CE Mark Clinical Trial																				
Approval to Commence Implants																				
Patient Enrollment and Follow-Up					$\geq$		$\geq$	Implan	ts cont ation of	inue be clinical	yond I study e	nrolmer	n							
Regulatory Submissions																				
European Regulatory Approval																				
US Clinical Trial																				
IDE Approval																				
Feasibility Study (10 patients)																				
Pivotal Trial – BTT													$\geq$	$\geq$						
Pivotal Trial – DT	1																$\geq$	>		
PMA Submission and Review – BTT																				
FDA Approval – BTT																				
PMA Submission and Review – DT																				
FDA Approval – DT																				
Timeline estimates based on current FD.	A prote	ocols		l						reimt	nues e bursen sed in	nent o	of HVA							•

## 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

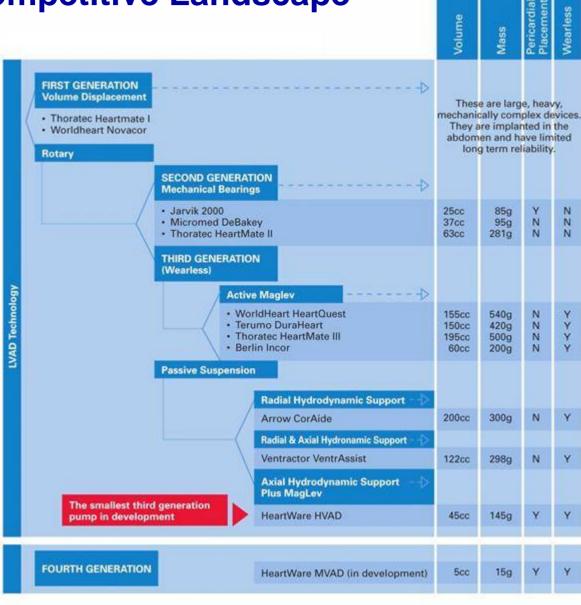
- Targeting an intravascular heart pump
- Implantable by catheter
- Moving from Surgeon to Cardiologist



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



# **The Competitive Landscape**

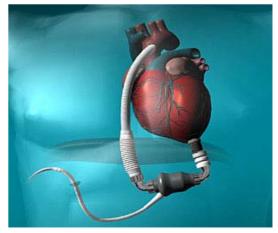


## Market leader paving the way...



- 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<sup>™</sup>
  - 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





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# **Financial Position**

#### Cash position

- 30 April 2006 Balance approx. \$8 million
- 24 May 2006 Capital Raising \$30.7 million (after issue costs)

#### Cash burn

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



# **Senior Management**

Name	Role	Relevant Experience						
Dozier Rowe Chief Operating Officer		<ul> <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>						
David McIntyre	Chief Financial Officer, Company Secretary	<ul> <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>						
Jeff LaRose	Chief Technical Officer	<ul> <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>						
Janice Piasecki	VP Regulatory Affairs (Consultant)	<ul> <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>						
Jane Reedy	VP Clinical Affairs	<ul> <li>20 years experience in clinical affairs in circulatory assist device industry</li> <li>Former Director of Clinical Services for Thoratec</li> </ul>						
Howard Leibman	VP, Corporate Development	<ul> <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
Rob Thomas	Non-Executive Chairman	<ul> <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>
Stuart McConchie	Managing Director CEO & President,	<ul> <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>
Seth Harrison, MD	Non-Executive Director	<ul> <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>
Dr Christine Bennett	Non-Executive Director	<ul> <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>
Dr Denis Wade AM	Non-Executive Director	<ul> <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
Bud Frazier, MD (Texas Heart Institute)	<ul> <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> (Washington Hospital Centre)	<ul> <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> (Lillehei Heart Institute University of Minnesota)	<ul> <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>
Laman A. Gray, Jr., MD (University of Louisville School of Medicine)	<ul> <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> (John Radcliffe Hospital, Oxford)	<ul> <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> (Vienna General Hospital)	<ul> <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> (Royal Perth Hospital)	<ul> <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>
Asghar Khaghani, MD (Royal Brompton and Harefield Hospital Trust)	<ul> <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

