



HeartWare Limited (ASX: HTW)

Heart Failure Device Company

Corporate Update

August 2005

Stuart McConchie, Chief Executive Officer

Overview

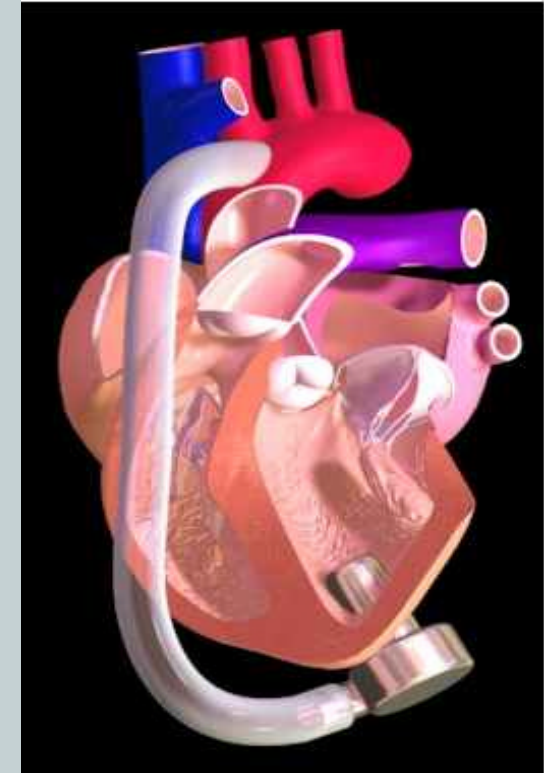


- **HeartWare's Product Family**
 - The HVAD – the smallest full output pump in development
 - The MVAD – the next generation in ventricular support
- **HeartWare's Market Opportunity**
 - 10 million people have heart failure, with 1 million new cases per year
 - Growing clinical acceptance of device-based treatments
 - US\$136,000 approved re-imburement per patient in the US
- **HeartWare's Positioning**
 - “Best in Class” technology and outstanding Intellectual Property
 - Experienced management and unmatched clinician support
 - Aggressive commercialisation path – first implant Q1/2006, first revenue 2007

HeartWare's HVAD Device



At only 45cc, the HVAD is the smallest full output pump in development



The HVAD is implanted directly in the pericardial space

How the HVAD Works

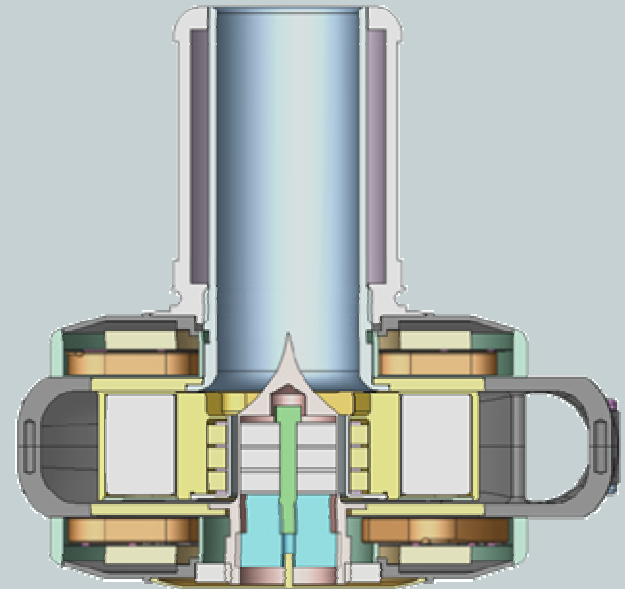


Please see video
animation of the HVAD
operation, which can be
downloaded from
HeartWare's website:

www.heartware.com.au

The HVAD's Advantages

- **The smallest full output pump in development**
 - 45cc / 145g
 - Pericardial placement
 - Shorter and less complex operating procedure
- **Fully suspended impeller**
 - Only one moving part
 - No mechanical bearings
 - Will never wear out
- **“Best in Class” Design**
 - Proprietary integrated inflow cannula
 - Proprietary wide bladed impeller
 - Superb blood flow characteristics



The MVAD – Next Generation LVAD Technology



- **HeartWare’s proprietary technology enables the miniaturisation of its devices – one of the company’s foremost competitive advantages**
- **HeartWare’s Miniaturised VAD (MVAD) has the potential to revolutionise the LVAD industry:**
 - Approximately one tenth the size of the HVAD
 - Implantable by minimally invasive techniques
 - Intra-vascular placement
- **The MVAD is approximately 24 months behind the HVAD:**
 - Currently in prototype
 - Very promising “bench” performance
 - Animal studies planned to commence this quarter

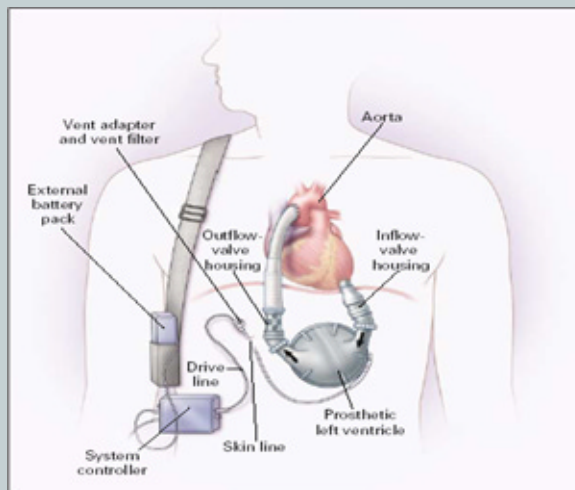


The LVAD Market Opportunity

- **Congestive Heart Failure (CHF) will be “the number one cause of death in the world by 2010” (World Health Organisation)**
 - 10M people suffer CHF, 5M in the US
 - 1M new diagnoses annually, 0.5M in the US
- **The HVAD will address patients in NYHA Class IV (end stage) heart failure**
 - 1M patients in NYHA Class IV heart failure
 - Estimated 100,000 patients eligible for an LVAD implant
 - US reimbursement US\$136,000 per procedure (~US\$75,000 for the device)
- **The MVAD has potential to target NYHA Class III patients**
 - 2.5M patients in NYHA Class III (~1.25M in the US)
 - Generally treated at cardiology centres rather than cardiac surgery centres
 - 250,000 potential additional eligible patients per year

Limitations of Current Devices

- **Thoratec's HeartMate XVE is the only LVAD with FDA approval for destination therapy**
 - Abdominal placement
 - Long and complex surgical procedure
 - Mechanical Wear - 1 to 2 years working life
 - Large size – Impacts patient quality of life

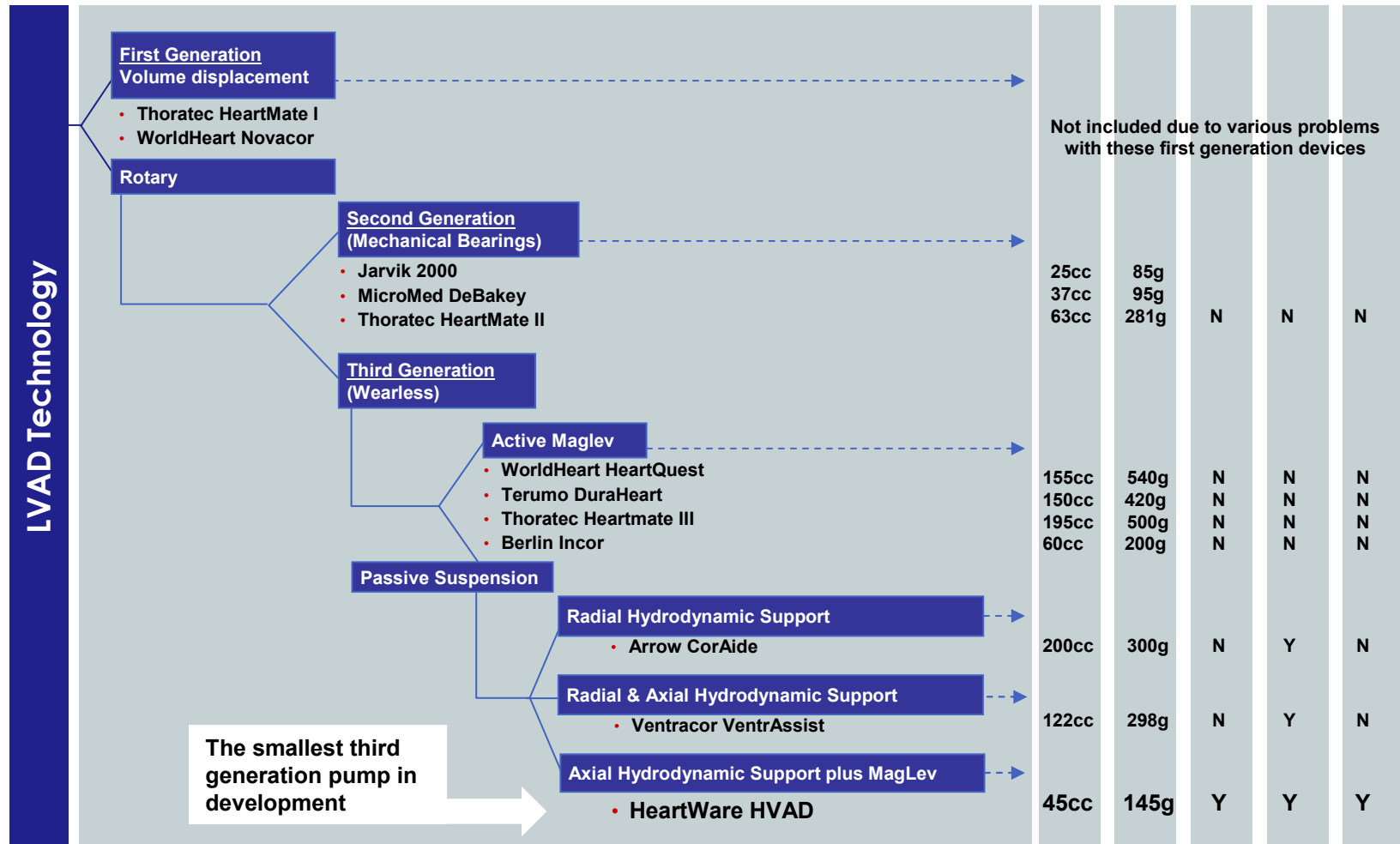


The HeartMate (and all competing full-output pumps) are implanted below the diaphragm



The HVAD is approximately one tenth the size of the HeartMate device

The Competitive Landscape





The Competitive Landscape (Cont'd)

- There are 10 second and third generation devices under development, none FDA approved
- Market shares will be determined over the next 5 years by competing devices' relative technical and clinical performances
- The HVAD is expected to demonstrate significant clinical advantages over competing LVAD's

Company	LVAD		Ownership	EU Trial	CE Mark	US BTT Trial	US DT Trial	FDA Approval	Notes
Jarvik Heart	Jarvik 2000	2G	Private	Stage Complete	Stage Complete	Stage Underway			May-05 CE mark for BTT and DT. US BTT trial underway.
MicroMed	DeBaKey	2G	Private	Stage Complete	Stage Complete	Stage Underway	Stage Underway		May-01 CE mark for BTT and DT. US BTT and DT trial underway.
Thoratec	HeartMate II	2G	NASDAQ			Stage Underway	Stage Underway		US trial commenced Nov 03. First to include both BTT and DT.
Berlin Heart	Incor	3G	Private	Stage Complete	Stage Complete				April-03 CE mark based on 26 patients. No US trials.
Terumo	DuraHeart	3G	Tokyo EX	Stage Underway					EU trial commenced Jan-04.
Arrow	Coraide	3G	NASDAQ	Stage Underway					EU trial suspended, resumed in Feb-05.
Ventracor	VentrAssist	3G	ASX	Stage Underway		Stage Underway			May-05 First EU implant. Jul-05 First US implant
Thoratec	HeartMate III	3G	NASDAQ						Early preclinical development.
WorldHeart	HeartQuest	3G	NASDAQ						Aims to start trials in 2006.
HeartWare	HVAD	3G	ASX						Trials to commence early 2006.

Stage Complete

Stage Underway

BTT - Bridge to Transplant
DT - Destination Therapy

Advancing Towards the Clinic



- **HVAD GLP Studies Nearing Completion**
 - Six sheep successfully implanted under the GLP program
 - Four studies complete, with the devices removed after 90 days
 - Fifth study due for completion in August 2005
 - Over 12 months cumulative GLP experience
 - Pathology tests confirm that the devices are performing well
 - Data to support applications to commence clinical trials
- **Life Cycle Testing Underway**
 - Test platform to simulate long term real world operating conditions
 - Platform operational and pumps performing well
 - Data accumulating in support of regulatory submissions



Advancing Towards the Clinic (Cont'd)

- **Participation of Clinical Trial Centres Confirmed**
 - Parallel participation of up to 7 hospitals
 - Five European Centres - UK, Germany, Austria and Italy
 - Two Australian Centres
- **Trial Protocol Established**
 - Refined in collaboration with investigators and Advisory Board
 - Submission to ethics committees in Q4 2005
- **Clinical Timeline Remains on Track**
 - Q1 2006 : First implant in Europe / Australia
 - Q2 2006 : First implant in the US



Update on Patent Dispute

- **Developments**

- Dec 04: Ventracor initiates legal action against HeartWare subsidiary HeartWare, Inc., alleging infringement of two patents in the US
- Feb 05: HeartWare files “Motion to Dismiss” on grounds of “Safe Harbour” exemption
- June 05: Court orders Discovery
- August 05: HeartWare lodges its defence and counterclaims

- **HeartWare’s Position**

- HeartWare denies any infringement of Ventracor patents
- HeartWare claims that the Ventracor patents are invalid and unenforceable
- HeartWare has filed six counterclaims and is seeking costs and damages
- HeartWare has an exceptionally strong IP portfolio including 25 issued patents in the US, Europe and Australia, with 1996 earliest priority dates

Board of Directors



Name	Role	Relevant Experience
Rob Thomas	Non Executive Chairman	<ul style="list-style-type: none"> • 30 years experience in securities industry • Previously Chairman, Citigroup Australia, CEO of Salomon Smith Barney, CEO of County NatWest Securities • Directorships include Deputy Chairman of Benitec Limited
Seth Harrison, MD	Deputy Chairman, Non-Executive Director	<ul style="list-style-type: none"> • Qualified surgeon, Presbyterian Hospital, New York • 14 years in life science venture capital • 8 years with HeartWare as an investor • Number of successful biomedical and biotech start ups
Stuart McConchie	CEO, Managing Director	<ul style="list-style-type: none"> • 25 years in medical device industry internationally • Over a decade in heart failure devices – Jarvik Heart Inc • Based in Sydney
Dr Christine Bennett	Non Executive Director	<ul style="list-style-type: none"> • Qualified paediatrician and previous advisor to Health Dept • Currently CEO of Research Council of Australia Limited • Previously CEO Westmead Hospital, Head of KPMG Health • Number of directorships including Resonance Health Limited
Dr Denis Wade AM	Non Executive Director	<ul style="list-style-type: none"> • Formerly Managing Director J&J Research • Former Foundation Professor of Clinical Pharmacology, UNSW

Advisory Board



Name	Relevant Experience
Bud Frazier, MD <i>(Texas Heart Institute)</i>	<ul style="list-style-type: none"> • Chairman of Advisory Board • Chief of Transplant Services, Texas Heart Institute • Implanted almost 300 LVADs
Steven Boyce, MD <i>(Washington Hospital Centre)</i>	<ul style="list-style-type: none"> • Director of Heart Transplantation, Washington Hospital Centre • Involved with the development of HeartWare devices since 1996
Leslie Miller, MD <i>(Lillehei Heart Institute University of Minnesota)</i>	<ul style="list-style-type: none"> • Director of Heart Failure/Heart Transplant Program at the University of Minnesota • Past President of the International Society for Heart and Lung Transplantation
Laman A. Gray, Jr., MD <i>(University of Louisville School of Medicine)</i>	<ul style="list-style-type: none"> • Professor of Surgery and Director of Thoracic and Cardiovascular Surgery at the University of Louisville School of Medicine • Was the original investigator for the Novacor VAD System, and implanted the first AbioCor Implantable Replacement Heart
Stephen Westaby MD, PhD <i>(John Radcliffe Hospital, Oxford)</i>	<ul style="list-style-type: none"> • Cardiothoracic surgeon, John Radcliffe Hospital • Over 500 cardiac operations annually • Implanted the longest surviving LVAD patient, Peter Houghton
Georg Wieselthaler, MD <i>(Vienna General Hospital)</i>	<ul style="list-style-type: none"> • Clinical Director of Mechanical Circulatory Support, Vienna General Hospital • Secretary General of the International Society of Rotary Blood Pumps



Other Senior Management

Name	Role	Relevant Experience
David McIntyre	Chief Financial Officer, Company Secretary (Sydney)	<ul style="list-style-type: none"> • Previously CFO & General Counsel for a listed medical device company • Served as a corporate and commercial law specialist at an international law firm, plus senior financial roles at multinationals • Qualified Solicitor and CPA, Australia
Jeff LaRose	Chief Technical Officer	<ul style="list-style-type: none"> • Inventor of HeartWare's platform technology • 18 years in hydraulic design and blood pump development • Leader in Computational Fluid Dynamics modelling
Janice Piasecki	VP Regulatory Affairs (Consultant)	<ul style="list-style-type: none"> • 30 years of regulatory experience • FDA compliance officer for heart devices • Responsible, as VP Regulatory, for bringing Abiomed's TAH to market
Jane Reedy	VP Clinical Affairs	<ul style="list-style-type: none"> • 20 years experience in directing clinical affairs, sales and marketing in the circulatory assist device industry • Former Director of Clinical Services and market development for Thoratec – integrally involved in bringing HeartMate I to market
Bill Rissmann	VP Manufacturing and Product Development	<ul style="list-style-type: none"> • 25 years experience in medical device engineering and manufacturing • Involved in the development of over 20 FDA approved medical devices • Previous roles with Guidant, Medtronic and St Jude
Howard Leibman	Director, Corporate Development (Sydney)	<ul style="list-style-type: none"> • Previously corporate finance executive for a life-sciences investment bank • 10 years experience in engineering, venture capital and corporate finance

HTW Market Statistics



- **IPO, 31 January 2005:** Raised AU\$32.4M / US\$24.95M at AU\$0.50 per share
- **Shares on Issue:** 155.70 million
- **Market Capitalisation:** AU\$70 million (at 45c Share Price)
- **Cash:** AU\$23.5 million (at 30 June 2005)
- **Cash Burn:** ~AU\$1.5M per month
- **10 largest holders:** 73.9% of total stock
- **Cornerstone shareholder:** Apple Tree Partners (59.1%, escrowed to Feb 2007)

Important Notice



Not an Offer for Securities

This Presentation does not constitute nor does it contain an offer to buy or subscribe for securities in HeartWare Limited (the “**Company**”).

Restrictions on US Persons

The Company’s shares are listed for quotation on the Australian Stock Exchange (“**ASX**”) with a ‘FORUS’ restriction. The Company’s securities have not been registered under the United States Securities Act of 1933 (as amended) and they may not be offered, sold or delivered in the United States, or to, or for the account or benefit of, any US Person, as such term is defined in Regulation S of the US Securities Act. In addition, hedging transactions with regard to the shares may not be conducted unless in accordance with the US Securities Act.

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