

HeartWare Limited (ASX:HTW)



- » **Corporate Update**
November 2008
- » **Doug Godshall**
CEO

Disclosures

Not an Offer for Securities

This Presentation does not constitute nor does it contain an offer or invitation to buy or subscribe for securities in HeartWare Limited (the Company) or an inducement to make an offer or invitation with respect to those securities.

Relevant Law

The Company's shares are listed for quotation on the Australian Securities Exchange (**ASX**), but offerings of its shares are subject to Australian, US and applicable European securities laws. The Company's securities have not been registered under the United States Securities Act of 1933 (as amended) (**US Securities Act**), and may not be sold by the Company in the United States or to any US person without such registration or an exemption therefrom. The information in this presentation is not for publication or distribution within the United States of America, its territories or possessions or to any US person (within the meaning of Regulation S of the US Securities Act) unless such US person is either a "qualified institutional buyer" within the meaning of Rule 144A under the US Securities Act or an "accredited investor" within the meaning of Regulation D under the US Securities Act.

Forward looking Statements

This Presentation contains '*forward looking statements*' which involve subjective judgment and analysis and are subject to significant uncertainties, risks, and contingencies, many of which are outside the control of, and are unknown to the Company and its subsidiary. In particular, these forward looking statements are made only as of the date of this Presentation, they assume the success of the Company's business strategies, and are subject to significant regulatory, business, competitive and economic uncertainties and risks. No representation, warranty or assurance (express or implied) is given or made in relation to any forward looking statement by any person (including the Company). In particular, no representation, warranty or assurance (express or implied) is given in relation to any underlying assumption or that any forward looking statement will be achieved. Actual future events may vary materially from the forward looking statements and the assumptions on which the forward looking statements are based. Given these uncertainties, recipients are cautioned to not place undue reliance on such forward looking statements. Subject to any continuing obligations under applicable law or any relevant listing rules of the ASX, the Company disclaims any obligation or undertaking to disseminate any updates or revisions to any *forward looking statements* in this Presentation to reflect any change in expectations in relation to any *forward looking statements* or any change in events, conditions or circumstances on which any such statement is based. Nothing in this Presentation shall under any circumstances create an implication that there has been no change in the affairs of the Company since the date of this Presentation.

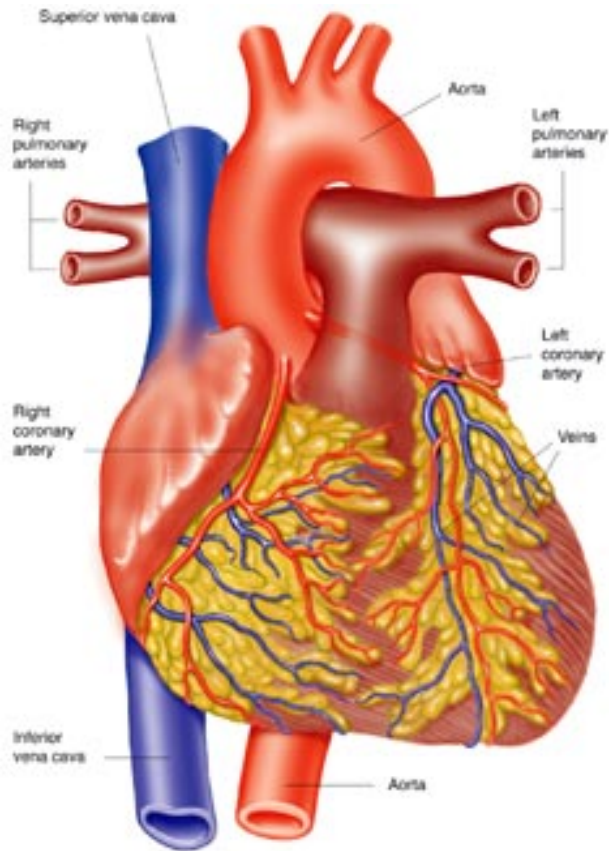
Disclaimer

To the maximum extent permitted by applicable laws, none of the Company or any of its "related bodies corporate" (as that term is defined in the Corporations Act 2001 (Cth)), or any of their directors, employees or agents makes any representation and can give any assurance as to the validity, accuracy, suitability or completeness of any information, statement or opinion contained in this Presentation or shall be liable for any errors in, or omissions from, any information, statement or opinion contained in this Presentation. No one should act or refrain from acting in reliance on this Presentation material. This overview of the Company does not purport to be all-inclusive or to contain all information which its recipients may require in order to make an informed assessment of the Company or its prospects. The provision of this Presentation is not, and should not be considered as, the provision of investment or financial product advice. This notice and the Presentation contain general information only and do not take into account the recipient's individual objectives, taxation position, financial situation or needs.

Overview

- **HeartWare is developing the world's smallest implantable pumps for the treatment of advanced heart failure**
- **Heart failure is nearing epidemic with few good treatment options**
- **The HeartWare® HVAD is demonstrating promising clinical results**
- **CE mark and first sales anticipated by end of 2008**
- **US clinical trials have commenced**
- **Encouraging progress of next generation products**
- **Company has transitioned to US**

Heart Failure



- A degenerative and terminal disease
- Affects over 20 million people globally (5+ million in the US)
 - » 1 million new cases diagnosed every year
 - » 300,000 deaths per year in the US
- At least 1 million patients in NYHA Class IV, the end-stage of the disease
- In the US, heart failure represents Medicare's greatest area of spending
 - » Estimated annual cost of \$35B
 - » 1.1M hospital discharges; up 171% since 1979
- VADS emerging as only viable option for many with late stage disease

Source: Circulation, AHA update, January 2008
Heart Failure Society of America / NHLBI

All signs Point to Market Expansion



Aging Population



Decreasing Transplant availability



Outcomes for VADS improving markedly



VAD sizes decreasing (generally) and reliability improving



Reimbursement Stable to Increasing



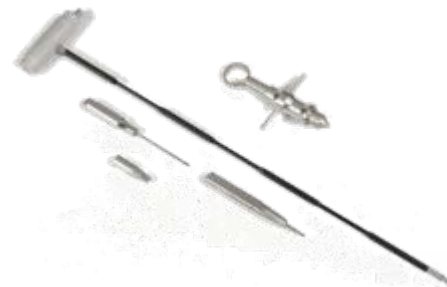
MI survival improving; primary contributor to HF pool



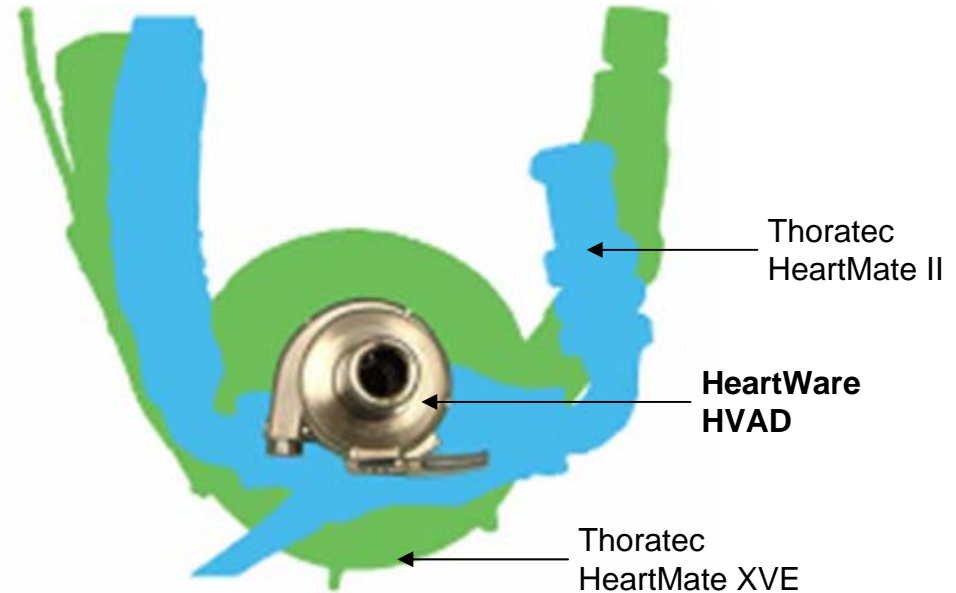
Market undergoing substantial growth with Heartmate II

The HeartWare[®] Left Ventricular Assist System

- Miniaturized implantable blood pump (50cc / 145g)
- The only centrifugal pump designed to be implanted ***in the chest***, directly adjacent to the heart
- Designed to produce up to 10 liters of flow
- Only one moving part
 - » *Hybrid magnetic / hydrodynamic suspension mechanism*
 - » *Wearless system designed for long-term reliability*
- Advanced battery and peripherals
- Custom surgical tools facilitating a rapid implant procedure



Pericardial placement – a key differentiator



Potential Benefits:

- » *No abdominal surgery*
- » *Reduced procedural invasiveness and complexity*
- » *No pump pocket*
- » *Shorter pump implant time*
- » *Reduced Recovery time*

International clinical trial nearing completion

- 46 patients enrolled (out of 50)
- Cumulative support - approx 33 yrs
- Average support - 262 days per patient
- 90% survival (of first 32 patients, 29 have successfully passed trial endpoint)
- Total transplants to date - 12
- Longest supported patient - 650 days
- Patients supported >12 months – 14
- Complications in line with historical data
- System showing high reliability



Dr George Wieselthaler, Principal Investigator at Vienna General Hospital, with three of his HeartWare patients

US clinical trial underway

- Granted full IDE approval from FDA in September 2008
- 150 patients at a maximum 28 centers
- Implants at Washington Hospital Center and Jewish Hospital (Louisville) with Mark Slaughter M.D.
- 7 centers now have IRB approval
 - » *Up from 1 IRB approval 4 weeks ago*
- Strong interest from leading transplant centres throughout the US
- FDA Classification as a Category “B2” device (eligible for reimbursement)



Dr Steven Boyce, cardiothoracic surgeon at Washington Hospital Center, conducted the first implant in the US

First revenues - US

- HeartWare eligible for reimbursement from CMS during US clinical trial
 - » FDA Classification as a Category “B2” device
 - » Procedure reimbursed at ~US\$140,000
 - » HeartWare revenue per implant ~US\$70,000
- Reimbursement revenue from BTT Clinical Trial
 - » 150 patients
 - » Enrolment underway, estimated time 18 months from start
- Reimbursement revenue from DT Clinical Trial
 - » 200 Patients
 - » Enrolment start mid-2009, estimated time 24 months



First revenues - EU

- Technical Dossier submitted September 2008
- CE Mark anticipated end of CY2008
 - » *Triggers the start of commercial sales throughout European Union*
 - » *Existing trial sites will switch to paying customers and serve as cornerstone hospitals in key markets*
- Commercial rollout through 2009
 - » *Direct sales strategy. Distribution & Logistics partner in place.*
 - » *HeartWare personnel and infrastructure already established in Europe*
 - » *Strong interest throughout the continent*
 - » *TGA Approval in Australia to follow*

Operational Update

Capacity expansion and capability requirements identified in 2007

- » *General facility upgrade*
- » *Expanded clean room capability*
- » *Validation / verification of all equipment and processes*
- » *Yield and throughput improvement*
- » *Improved inventory and supplier management*
- » *Increasing number of highly skilled operators*

All complete and now in Continuous Improvement mode

Miami Lakes Significant Upgrade

Clean Room Then: 180 sq ft



Clean Room Now: 4,700 sq ft



“Telephone Box” Clean Room —————> ISO Class 100,000 Clean Rom

Caution – Investigational Device, Limited by United States Law to Investigational Use

Pipeline: Exceeding Expectations



- **Three MVAD designs all proving effective in pre clinical studies**
- **Will pick a winner within the next 6 months and move towards clinic**

Version 1: MVAD Trans-Apical

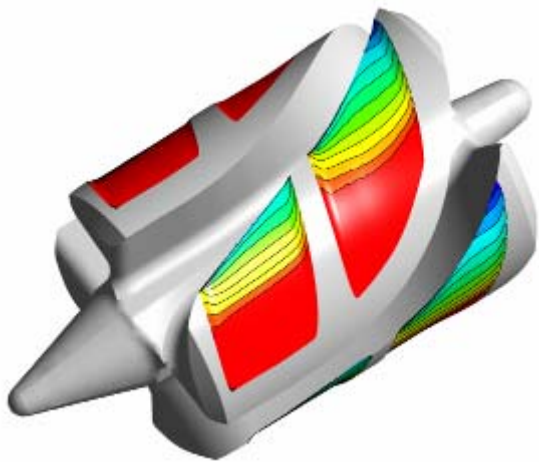
Left Thoracotomy or Sternotomy

Up to 10 liters per minute of flow

Exceptional fluid dynamics

1/3 the size of HVAD

11 In-Vivo Studies: platform “works”



Version 2: “VCAN” Right Thoracotomy

Right Thoracotomy

One incision for implant and anastomosis

Up to 7 liters per minute

No pump pocket

13 In-Vivo studies



Version 3: Longhorn

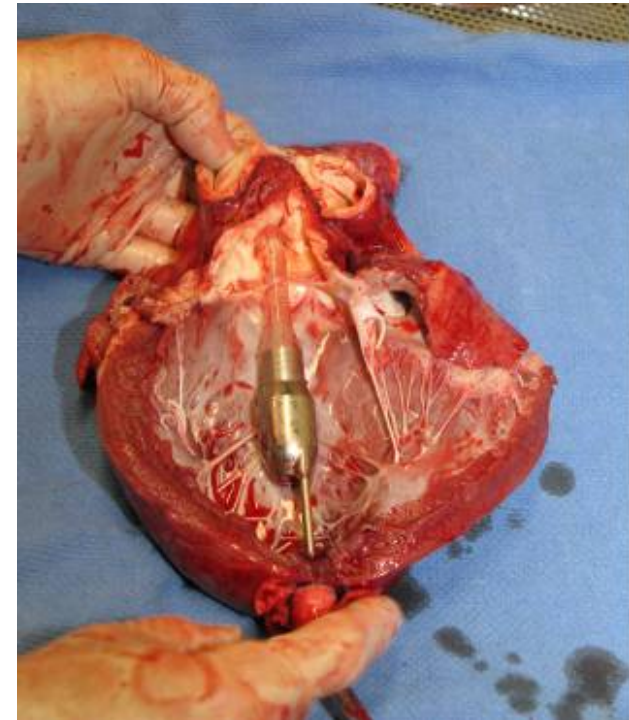
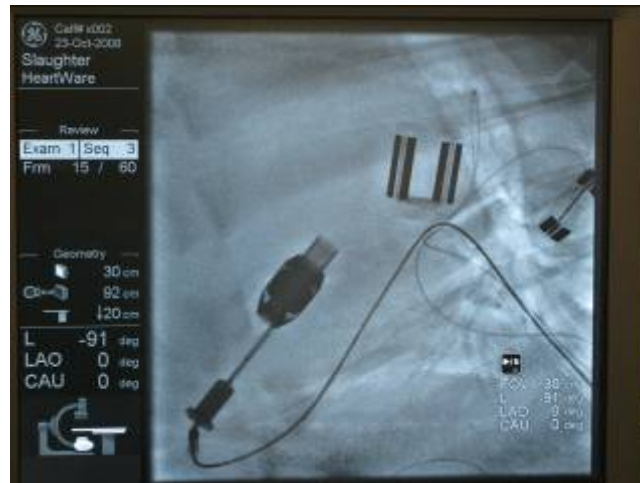
Subcostal Incision: NO anastomosis

Up to 7 liters per minute

“30 Minutes Skin to Skin”

Acute In-Vivo studies very successful

Average M.D. reaction: WOW



Milestone Review

<u>Milestone</u>	<u>Timing</u>	<u>Status</u>
Receipt of full IDE from FDA	Q3 2008	✓
Commencement of US Clinical Trial	Q3 2008	✓
Raise Capital	Q3 2008	✓
First Revenue	Q3 2008	✓
Submission of Technical Dossier	Q3 2008	✓
Upgrade Operations Facility	Q3 2008	✓
ISO Certification	Q4 2008	✓
Receipt of CE Mark	Q4 2008	On Target
Redomiciliation to United States	Q4 2008	✓
Submit TGA	Q1 2009	On Target
Commence Destination Therapy Trial	Mid 2009	On Target

Financial snapshot (\$USD)

- Cash on hand \$31M (30 Sept)
- Burn rate \$2.5M per month
- First revenue Sept 2008
- Shares on issue 310M
- Market Cap \$100M
- Number of employees 112
- Top 20 shareholders > 75% of shares
- US Ownership > 80%

Thank You

