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Manager of Company Announcements
ASX Limited
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20 November 2008

Dear Sir / Madam

MVAD & HVAD Update

Please see the attached corporate presentation provided by the Chief Executive Officer earlier today in New York regarding the Company's current and future technology.

Yours sincerely

David McIntyre
HeartWare International, Inc.

HeartWare Limited (ASX:HTW)



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

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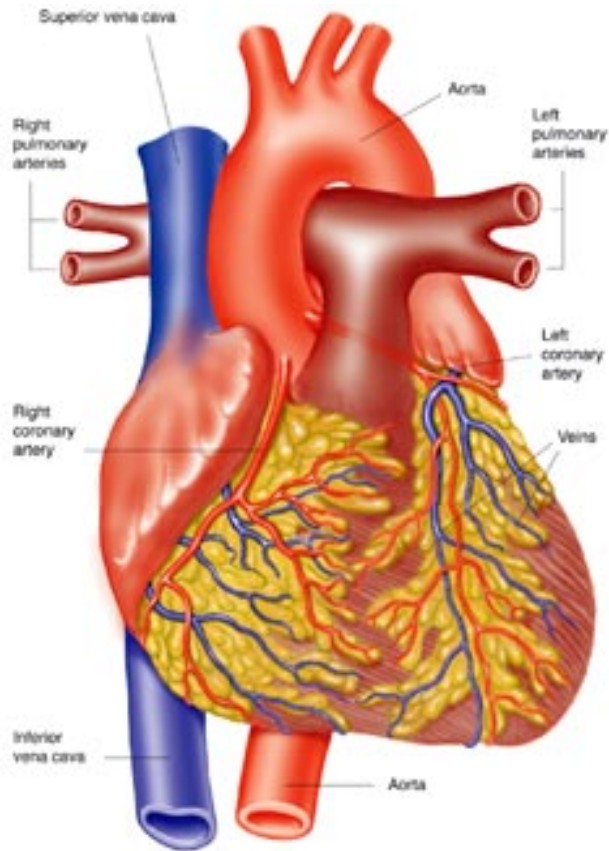
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Overview

- **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



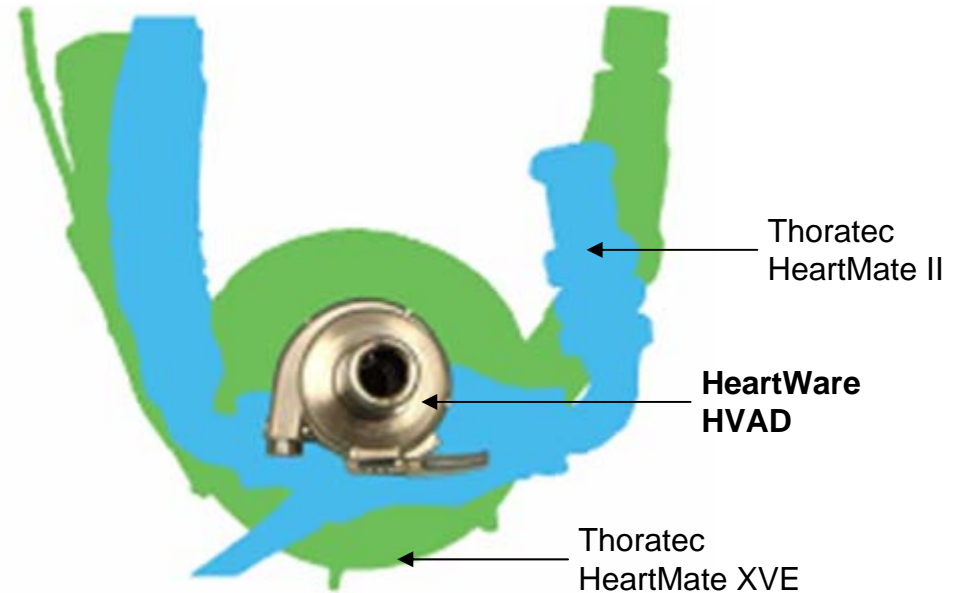
Market undergoing substantial growth with Heartmate II

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 entitled to 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

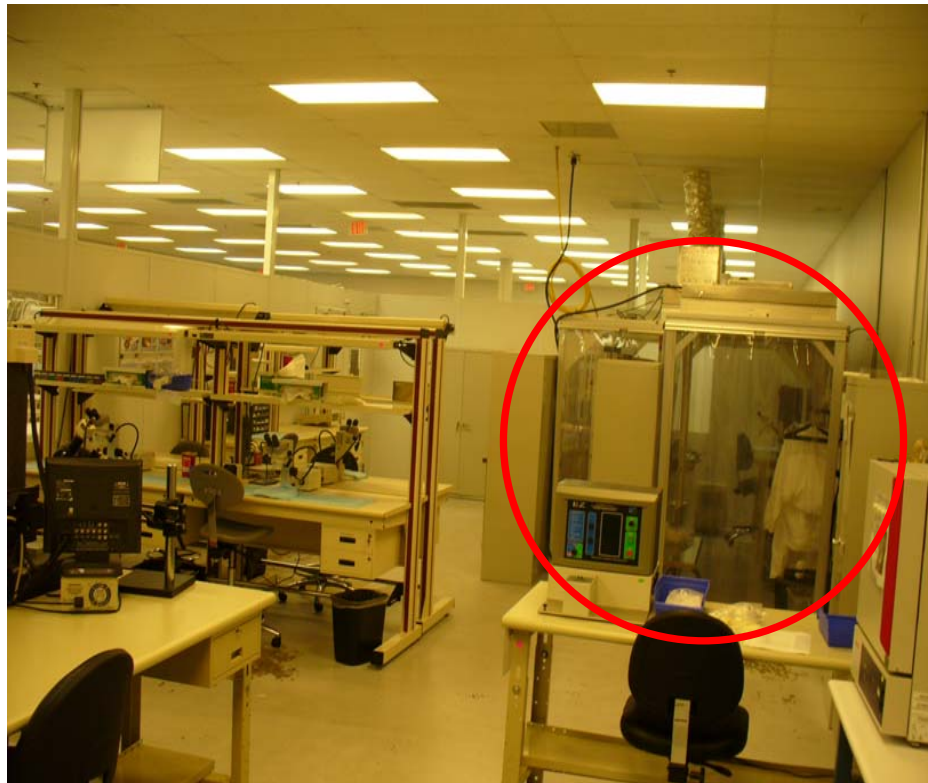
Capacity expansion and capability requirements identified in 2007

- » *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 Room

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**

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

Version 1: MVAD Trans-Apical

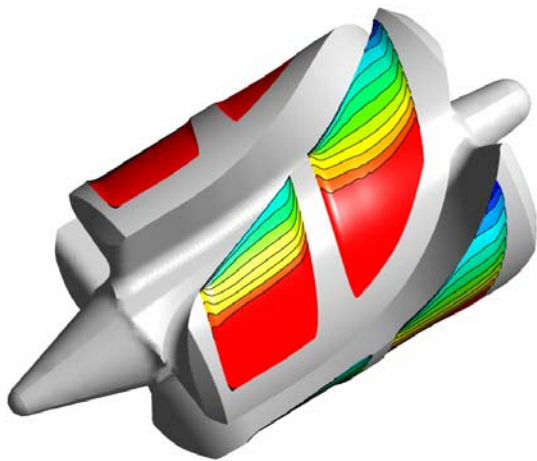
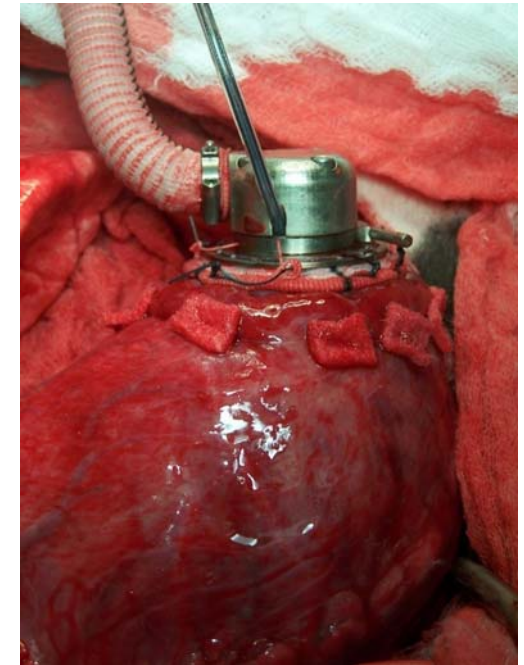
Left Thoracotomy or Sternotomy

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

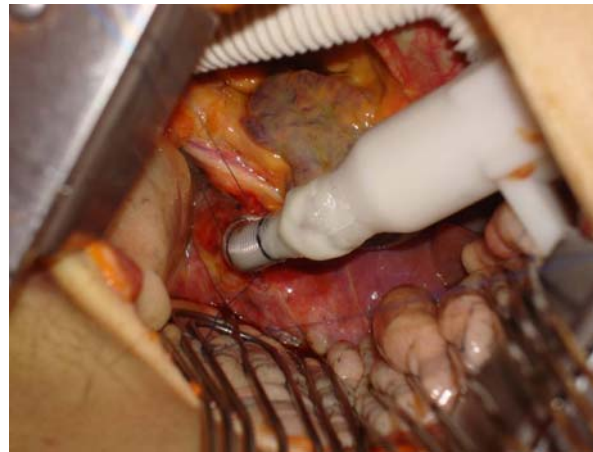
Right Thoracotomy

One incision for implant and anastomosis

Up to 7 liters per minute

No pump pocket

13 In-Vivo studies



Version 3: Longhorn

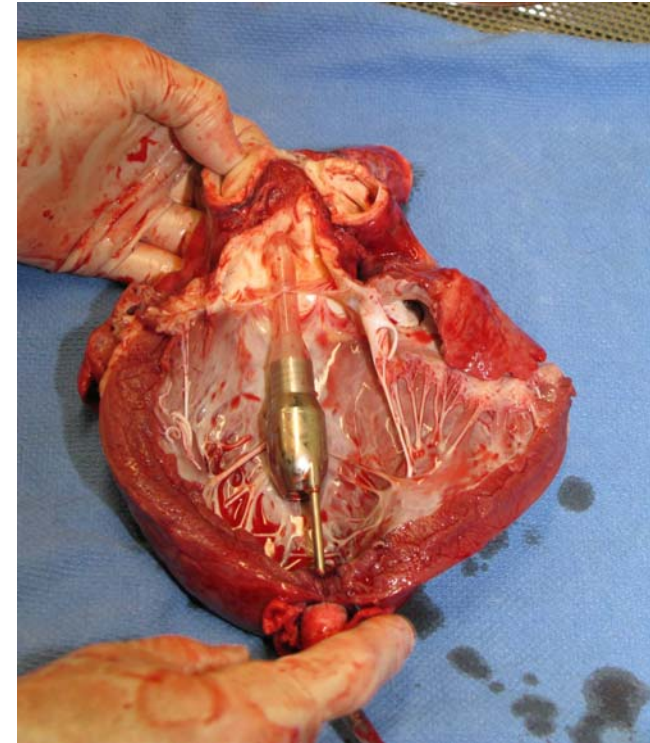
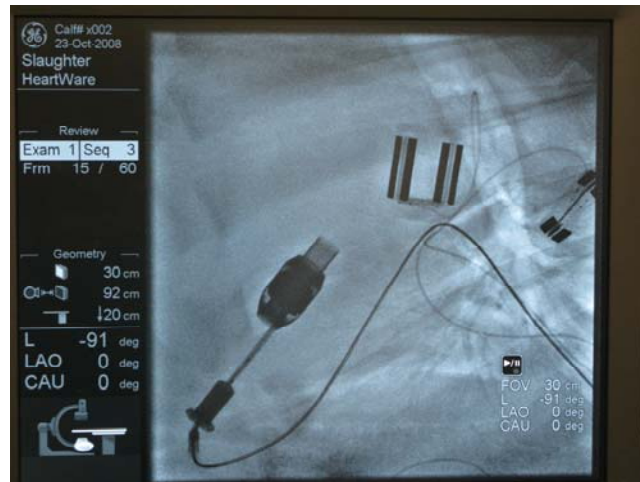
Subcostal Incision: NO anastomosis

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

