HeartWare Limited (ASX:HTW)

» **Doug Godshall**
CEO

» *November 2007*

HeartWare

Overview

- HeartWare is commercialising the world's smallest heart pumps for the treatment of advanced heart failure
- Heart failure is a leading cause of death in the developed world and represents a significant emerging medical device market
- The HeartWare® LVAD System is demonstrating promising clinical results
  - » *Completion of patient enrolment in international (OUS) clinical trial*
  - » *22 implants; >4,000 implant days*
- CE mark and first sales anticipated early 2008
- US clinical trials to commence late 2007 / early 2008
- Promising results of next generation products
  - » *MVAD™ in acute animal studies, IV VAD at design stage, TETS prototype*

HeartWare

The HeartWare® LVAD System - Product Animation

HeartWare

Transforming quality of life – HeartWare's first patient

Before receiving his HVAD™ implant:

- » *Couldn't sleep lying down*
- » *Couldn't digest food*
- » *Constantly cold*
- » *Could barely walk up stairs*
- » *Took several minutes to tie his shoes*
- » *Was "**waiting to die…**"*

6 Months Later:

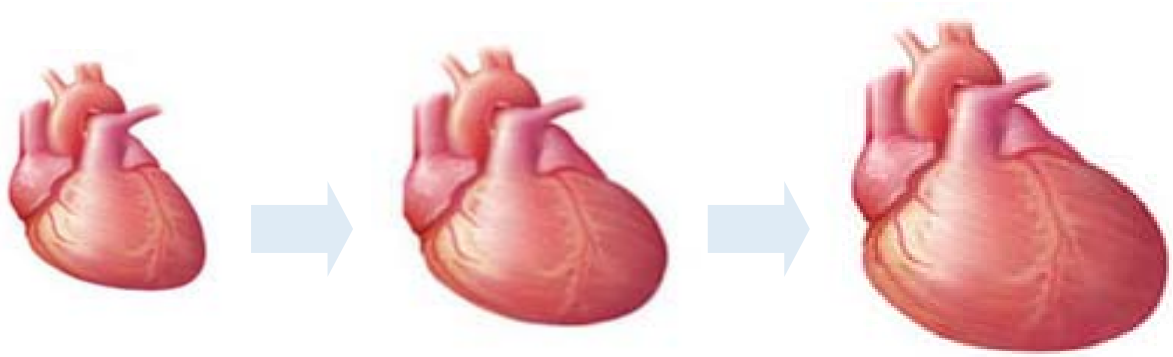
9 Months Later:

12 Months Later:

HeartWare's first patient, 6, 9 and 12 months following surgery at Vienna General Hospital in March 2006

Heart Failure is a dramatic issue for society

- A degenerative and terminal disease
- Affects over 10 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 cost of $30B in 2006*

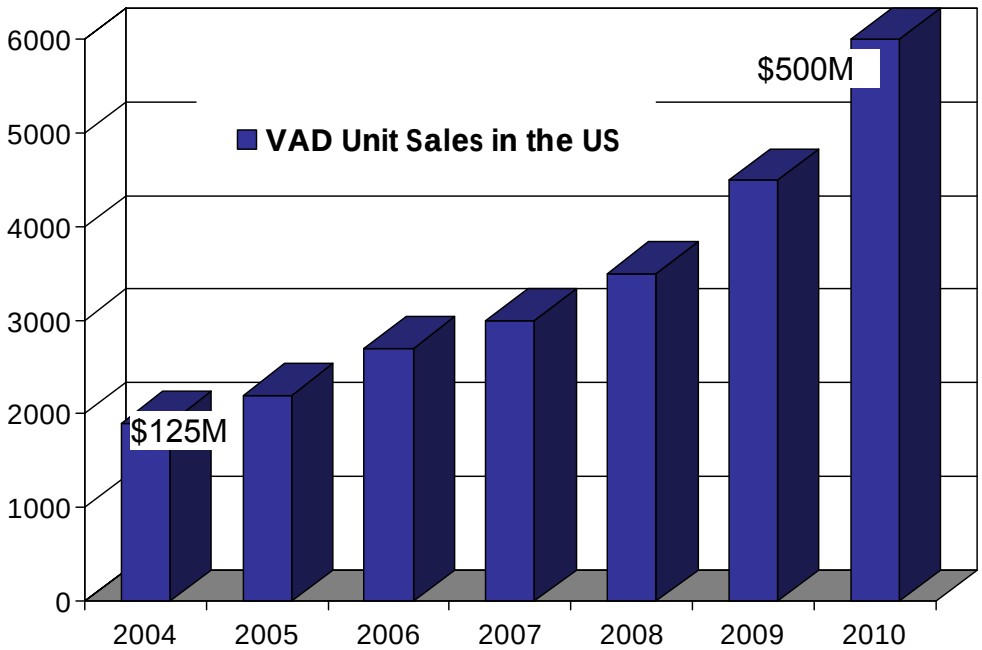


Source: Circulation, AHA update, February 14, 2006
Heart Failure Society of America / NHLBI

LVAD's are the only viable option for most

- Heart transplantation is a proven therapy, but is limited
  - » *Fewer than 4,000 donor hearts available worldwide each year*
  - » *Many patients not suitable for transplantation*
- Alternative therapies don't work
  - » *Drugs & pacing do not halt disease progression*
  - » *Surgical techniques and other devices have not addressed the need*
  - » *Cell therapy is in its infancy and has mixed results*
- LVAD's provide the only therapy that can rehabilitate patients from NYHA Class IV to Class I
  - » *Data continues to improve and demonstrate long term benefits*

The market is growing and poised to accelerate

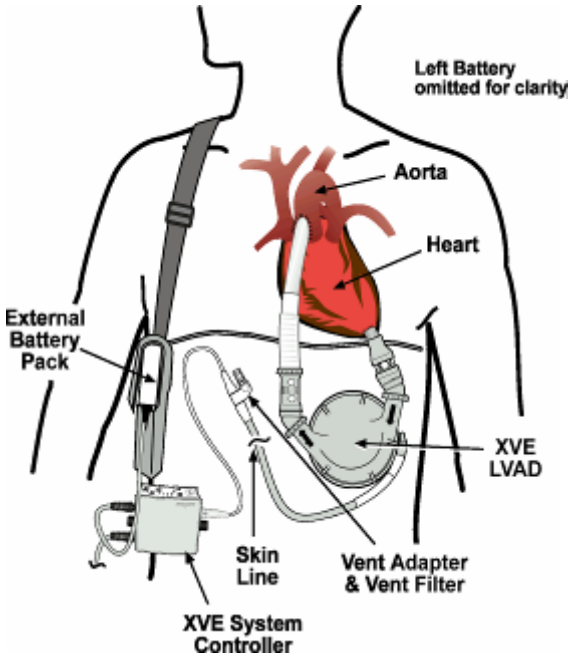


- >12% pa compound growth in past 3 years with no new technology since 1998
- NIH estimates 100,000 patients per year in the US could benefit from an LVAD
- Medicare & Medicaid reimbursement – US$136,000 for the procedure (incl. ~US$75,000 for the device)
- Implied market potential US$7B

Source: 2006 Frost and Sullivan, US Congestive Heart Failure Device Markets; and HeartWare internal projections

The market has grown despite sub-optimal technology

- Large device size
- Invasive surgery
- Risk of infection
- Adverse G.I. effects
- Limited durability
- Risk of stroke due to blood clots



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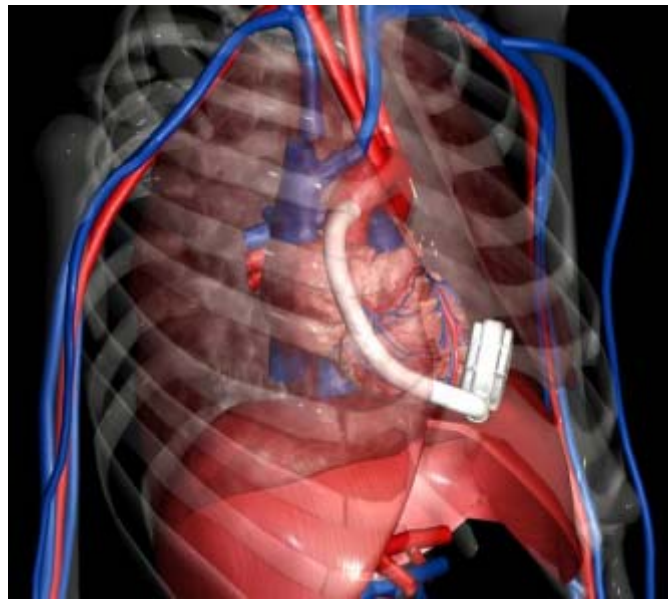
Source: NHLBI Working Group, April 2005:
Limitations of Currently Available VADs

The Thoratec HeartMate XVE - the only VAD with FDA approval for Destination Therapy

HeartWare

The HeartWare® LVAD System addresses the clinical need

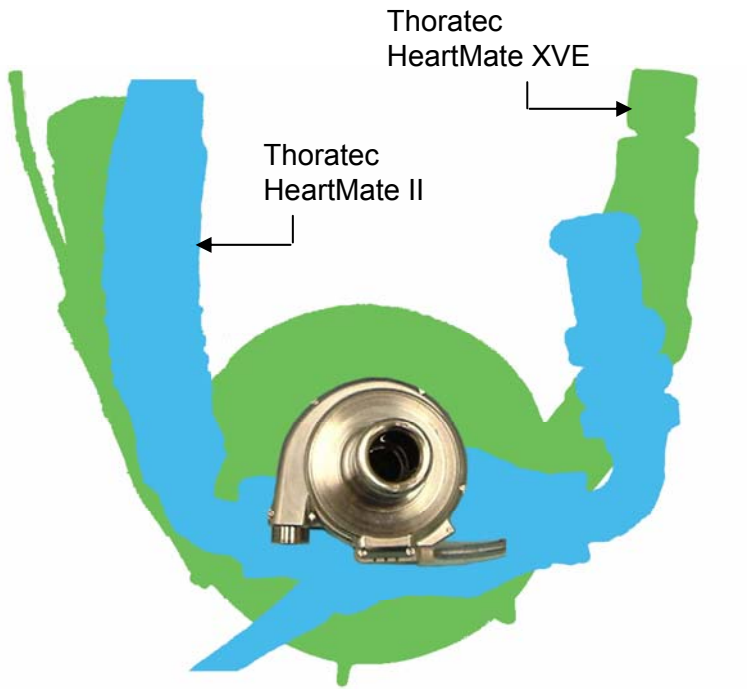
- The smallest full output pump available
  - » *Thoracic placement – no abdominal surgery*
  - » *Shorter and less complex procedure (~ 1.5 hours) relative to competing devices*
- Improved blood flow characteristics
  - » *Minimal haemolysis*
- Long term reliability
  - » *One moving part, no mechanical bearings, wearless suspension*
  - » *Dual motor stators*
  - » *Designed for 10+ years of pump performance*



The HeartWare pump is implanted directly into the apex of the left ventricle

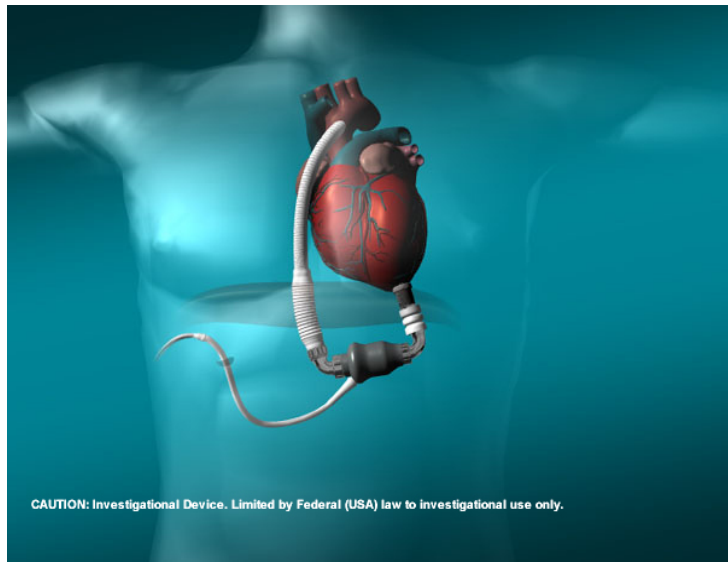
Size REALLY matters

- The HeartWare® LVAD System pump is the only full output LVAD implantable within the pericardial space in all patients
  - » *No abdominal surgery*
  - » *No postoperative drains*
  - » *No pump pocket infections*
  - » *No GI distress related to abdominal wall pressure*
  - » *Reduced procedural invasiveness and complexity*
  - » *Very short pump implant time*
  - » *Low procedural morbidity*
  - » *Reduced recovery time*



The Thoratec HeartMate II

- The market leader's most advanced device
- CE Mark in November 2005
- BTT trial enrolment (133 pts) completed May 2006
- DT trial enrolment (200 pts) completed May 2007
- BTT data presented March 2007:
  - » 133 patients implanted
  - » 100 patients (75%) reached the principal endpoint*
    - *56 transplanted*
    - *43 supported by the pump and eligible for transplant*
    - *1 cardiac recovery*
- FDA Panel review November 2007. BTT Approval anticipated early 2008.



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* Principal endpoint: heart transplantation, cardiac recovery, or survival at 180 days with ongoing mechanical support

The HeartWare® LVAD System patient and hospital equipment

Battery Packs and Charger

Clinical Monitor

Wearable Controller

International CE Mark clinical trial

- Trial enrolment completed August 2007 (20 patients)
- Extension approved to allow up to 30 patients (currently 22)
- Primary endpoint is survival to 180 days or transplant
- Submission of Technical Dossier expected Q4 2007, CE mark anticipated Q1 2008

Centre	Country	Principal Investigator	Implants
Vienna General Hospital	Austria	Dr Georg Wieselthaler	7
Royal Perth Hospital	Australia	Dr Gerry O'Driscoll	4
Hannover Medical Center	Germany	Dr Martin Strűber	6
Harefield Hospital	UK	Dr Asghar Khaghani	2
St Vincents Hospital, Sydney	Australia	Dr Paul Jansz	3

Promising clinical results

- 22 implants
- Cumulative support >4,000 days
- Average duration of support >180 days per patient
- Successful completion of primary endpoint for 12 patients
- 3 transplants, at 425, 348 and 157 days respectively
- 1 successful “recovery” patient - pump explanted after 268 days.
- Rapid implant procedure and post-operative recovery
- Excellent clinical outcomes

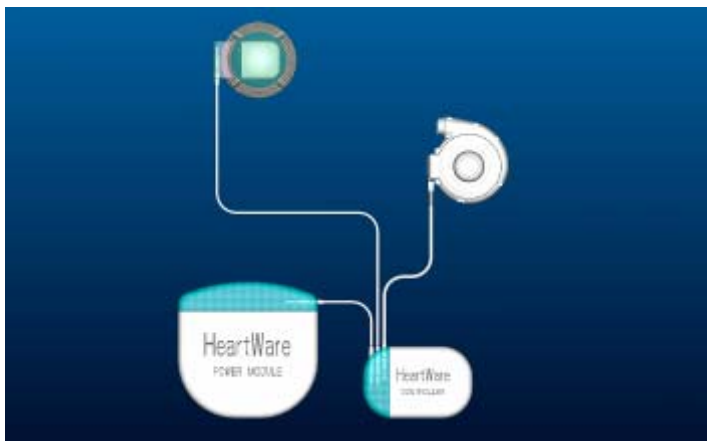
Dr George Wieselthaler, Principal Investigator at Vienna General Hospital, with three of his HeartWare patients

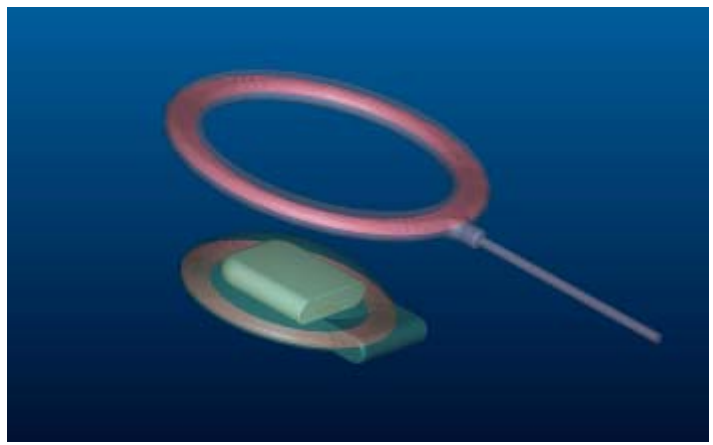
Pipeline: getting bigger by getting smaller

	HVAD™	MVAD™	IV-VAD™
			
Procedure	Surgical	Minimally Invasive	Catheter Delivery System
Flow	10 L/min	10 L/min	3 L/min
Patient Class	Late Class IV	Class IV	Class III / Early Class IV
Treatable Pop.	100,000	350,000	1,000,000

The next major advance: TETS

- Transcutaneous Energy Transfer
  - » *Enables transfer of energy and information across the skin*
  - » *Replaces driveline cable and eliminates risk of driveline complications*
  - » *Enables patient to be un-tethered from the charging system for extended periods*
  - » *TETS system compatible with The HeartWare® LVAD System, MVAD™ and IV-VAD platforms*





Key Upcoming Milestones

Milestone	Indicative Timing	Completed
Submission of IDE to US FDA	Q4 2007	✓
Extension of International Trial to allow additional implants	Q4 2007	✓
Submission of Technical Dossier to Competent Authority	Q4 2007	
Receipt of CE Mark (European Regulatory Approval)	Q1 2008	
Commencement of US Clinical Trial	Q1 2008	
First revenue	Q1 / Q2 2008	

Financial snapshot

• Cash on hand	~ $38M (at 30 Sep 07)
• Burn rate	~ $2M per month
• First revenue	Anticipated early 2008
• Shares on issue	~ 248M
• Market Cap	~ $190M
• Number of employees	75
• Apple Tree Partners	~39% of shares
• Top 20 shareholders	~75% of shares

Summary

- Heart Failure is a disease of epidemic proportions
- LVAD's are emerging as the only viable treatment option
- HeartWare has the most compelling LVAD in the clinic today AND the most advanced pipeline of future products