

# HEARTWARE LIMITED

ABN 34 111 970 257



**HeartWare**  
Level 57

**MLC Centre**  
**19-29 Martin Place**  
**Sydney NSW 2000**

Ph: (+61 2) 9238 2064

Fax: (+61 2) 9238 2063

[www.heartware.com.au](http://www.heartware.com.au)

Manager of Company Announcements  
Australian Securities Exchange Limited  
Level 6  
20 Bridge Street  
SYDNEY NSW 2000

9 May 2008

**BY E-LODGEMENT**

Dear Sir / Madam

## **Annual General Meeting Presentation**

In accordance with ASX Listing Rule 3.13.3 the Company provides a copy of the presentations that are to be delivered today at the Company's Annual General Meeting, together with Chairman's address.

The AGM is being held at the Company's auditors, Grant Thornton, at Level 17, 383 Kent Street, Sydney, commencing at 10.30am.

The AGM may also be viewed by webcast by following the link at the Company's website.

Yours faithfully

**David McIntyre**  
**Chief Financial Officer &**  
**Company Secretary**

# HeartWare Limited (ASX:HTW)



» **Doug Godshall**  
*CEO Presentation*  
*2008 AGM*

# Topics

- Year in Review
- Opportunity Update
- Clinical/Regulatory Status
- Pipeline Review
- Financials

## Since last AGM

### **Achieved:**

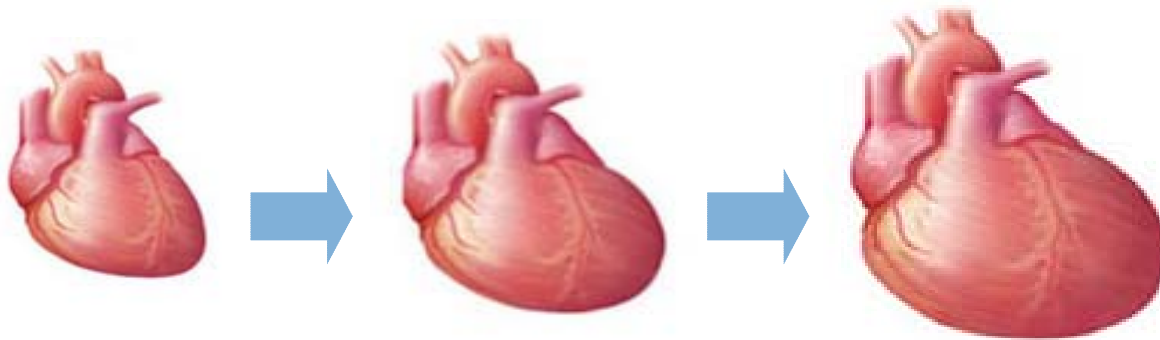
- Completed 20 patient enrollment
  - » *Extended to 30 and again to 50*
- Received conditional IDE approval
- Presented data at ISHLT meeting
- Conducted multiple MVAD preclinical studies and refined design concepts
- Advanced TETS to working prototype
- Secured upgraded new facility and commenced move
- Significantly improved manufacturing yield and output
- Raised AU\$36M
- Maintained US and Australian dual compliance
- Re-organized operations group
- Added Chief Medical Officer, Operations Engineering leader, new Marketing leadership, new Regulatory leadership
- Bolstered board with new Director

### **Pending:**

- CE mark

# Heart Failure is a significant problem for society

- 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 in 2004*
  - » *1.1M hospital discharges; up 171% since 1979*



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



HeartWare Limited © 2006

# Heart Failure is Fatal

- 75% of HF patients under age 65 will die within 8 years
- HF kill 7 times more people than breast cancer annually
- 1 in 8 death certificates in US mentions HF
- Sudden cardiac death 9x more likely in patients with HF

Cause	# Deaths in '04
Heart Failure	284,000
Heart Attack	158,000
Stroke	150,000
Diabetes	73,000
Aids	13,000

AHA update, January 2008

# LVAD's are the only viable option for most

- Heart transplantation is a proven therapy, but availability is severely limited
  - » *Fewer than 4,000 donor hearts annually*
  - » *Many patients ineligible for transplantation*
- Alternative therapies not delivering on initial promise
  - » *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 has been proven to rehabilitate patients from NYHA Class IV to Class I...and resume a normal life
  - » *Data continues to improve and demonstrate long term benefits*

# Acceleration in 2008

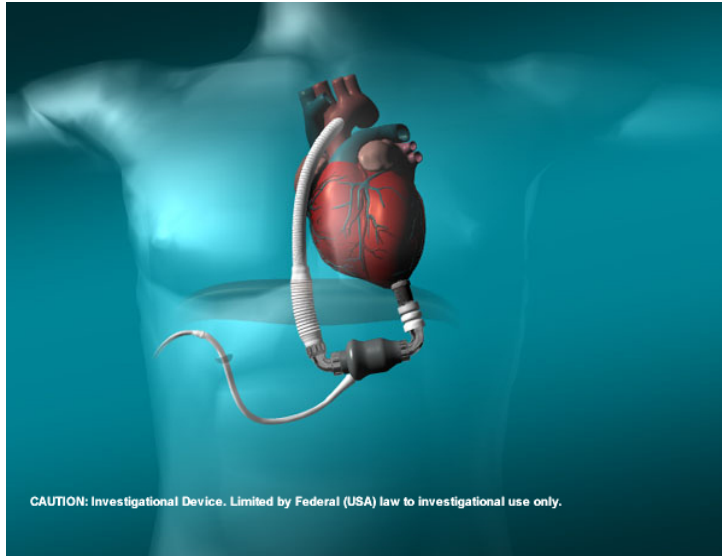
*Market growth now in double digits*

- Technology: **significant improvements**
  - » *Thoratec HMII approved in US April '08 - first new pump since 1998*
  - » *HeartWare entering EU 2H 2008*
- Experience: **transplant programs more experienced**
  - » *Outcomes improving worldwide*
- Economics: **US reimbursement increased every year since 2004**
- Destination Therapy: **implants up 3X from 2005-2007**
- Data: **significantly better than historical experience**
  - » *Survival past 6 months stable and now resembling transplant outcomes*
- Transplant availability: **waiting times extending worldwide**

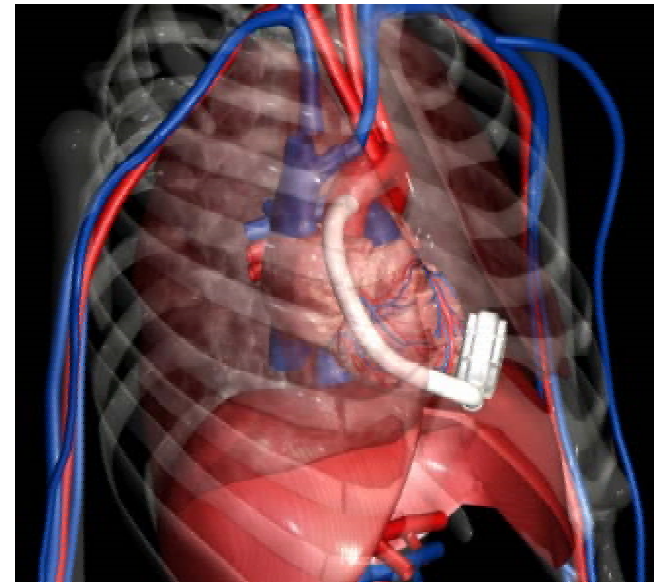


# HeartWare's advantages resonating worldwide

Abdominal (Others)



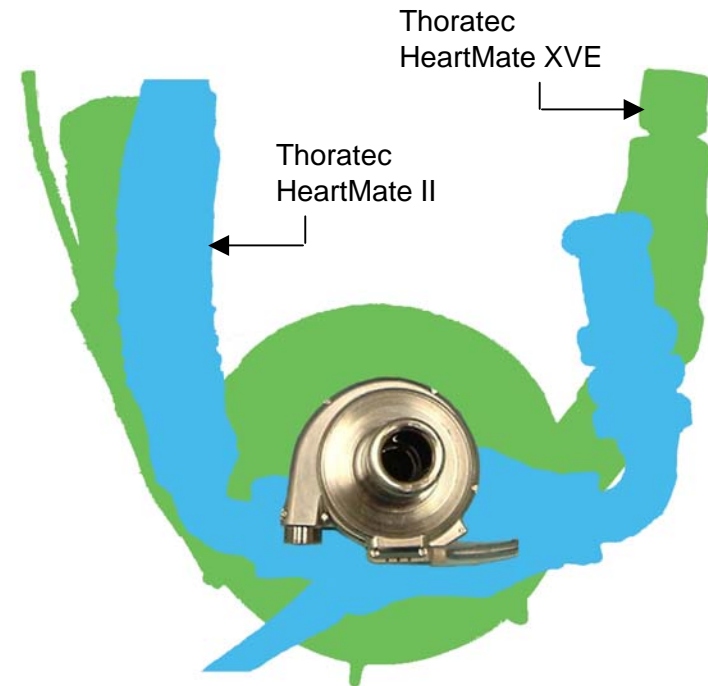
Pericardial (HeartWare)






Reprinted with permission from Thoratec Corporation

# Size REALLY matters

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



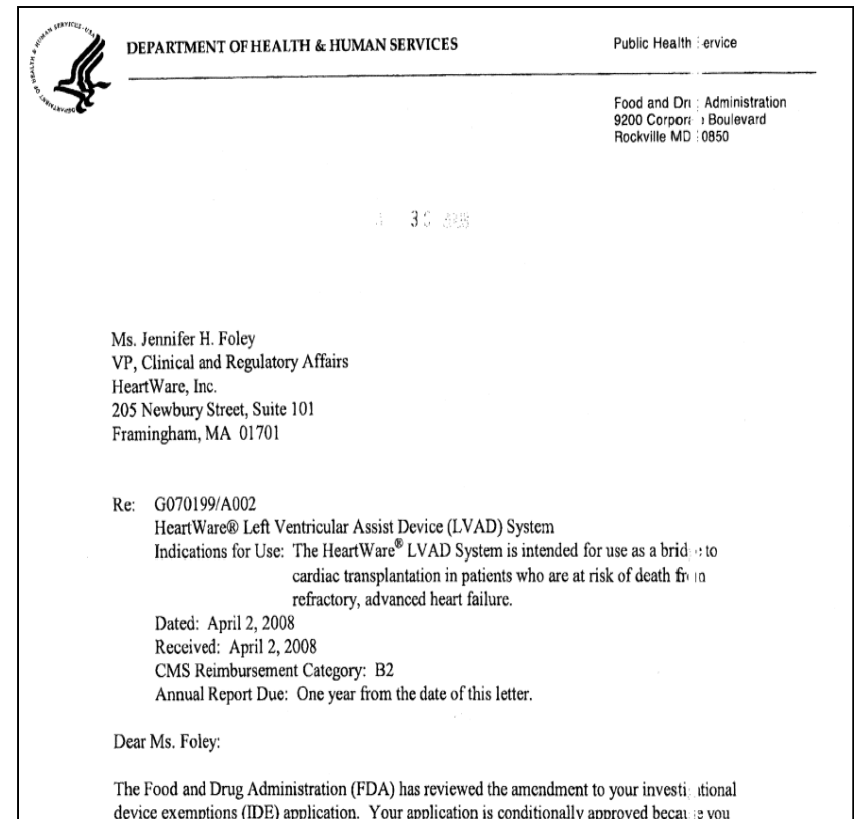
# Entire system required to win

	Surgeons	Cardiologists	Patients
Factors	<p>Easy to implant</p> <p>Avoid pump pocket</p> <p>Minimal re-intervention</p>	<p>Minimal “fiddle factor”</p> <p>Infrequent re-admissions</p> <p>“Out of sight out of mind”</p>	<p>Intuitive peripherals</p> <p>Low complication rates</p> <p>Good battery life</p> <p>“Normal” life</p>
HeartWare			



# US IDE trial

- Received conditional approval for BTT protocol on May 1
- Novel trial design
  - » Utilizing NIH funded control arm (Intermacs Registry)
  - » First Bridge study to be permitted “survival” as endpoint versus “listed for transplant”
  - » Immediate patient discharge permitted
  - » No safety phase required; straight to pivotal
- Initial sites identified, processing documentation and training underway
  - » First patient likely June / July



# International CE Mark clinical trial

- Trial enrolment completed August 2007 (20 patients)
- Extension approved to allow up to 50 patients (currently 32)
- Primary endpoint is survival to 180 days or transplant
- Submission of Technical Dossier expected 2H 2008

Centre	Country	Implants
Vienna General Hospital	Austria	8
Royal Perth Hospital	Australia	4
Hannover Medical Center	Germany	12
Harefield Hospital	UK	2
St Vincents Hospital, Sydney	Australia	6

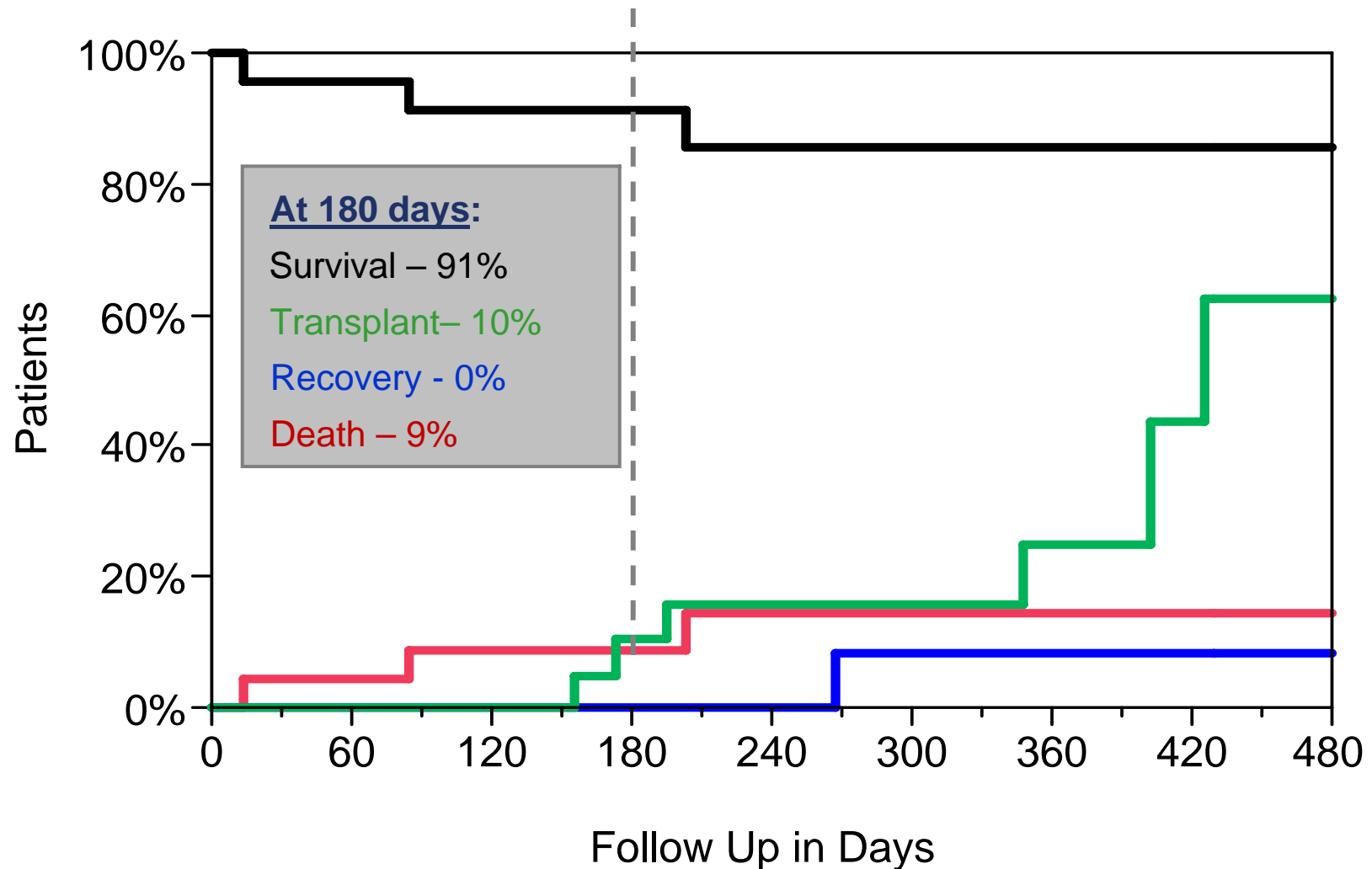
# Promising clinical results

- 91% Survival presented at ISHLT
- 32 implants
- Cumulative support >7500 days (20+ yrs)
- Average duration of support >230 days per patient
- Successful completion of primary endpoint for 23 patients
- Only 6 transplants to date
- 1 successful “recovery” patient
- 8 of first 13 supported > 1 year
- Longest implant at 530 days



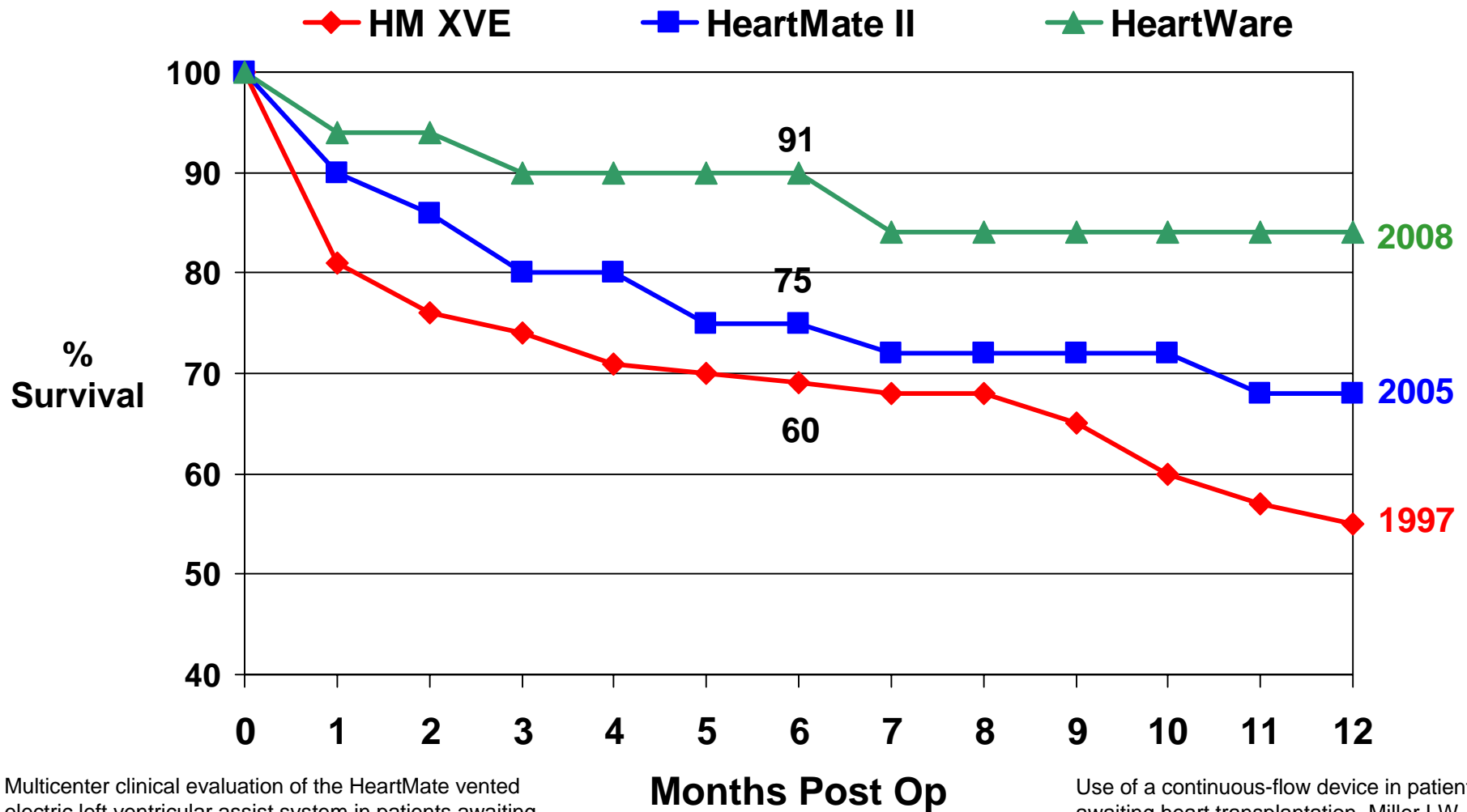
Dr George Wieselthaler, Principal Investigator at Vienna General Hospital, with three of his HeartWare patients

# Outcomes at 180 Days for First 23 Implants



\*Presented by G Wieselthaler, MD at the ISHLT Annual Meeting, Boston, MA, April 12, 2008

# BTT: Improvement in Survival over time



Multicenter clinical evaluation of the HeartMate vented electric left ventricular assist system in patients awaiting heart transplantation. Frazier OH, Rose EA, Oz MC et al. J Thor Cardiovasc Surg 2001:122

Use of a continuous-flow device in patients awaiting heart transplantation. Miller LW, Pagani FD, Russell SD et al. N Engl J Med. 2007 Aug 30.



# What do HeartWare patients do post implant?

- Sing opera
- Play tennis
- Play soccer
- Travel
- Return to work
- Raise their families
- Practice Law
- Play in chess tournaments
- Walk the dog
- Live normal lives



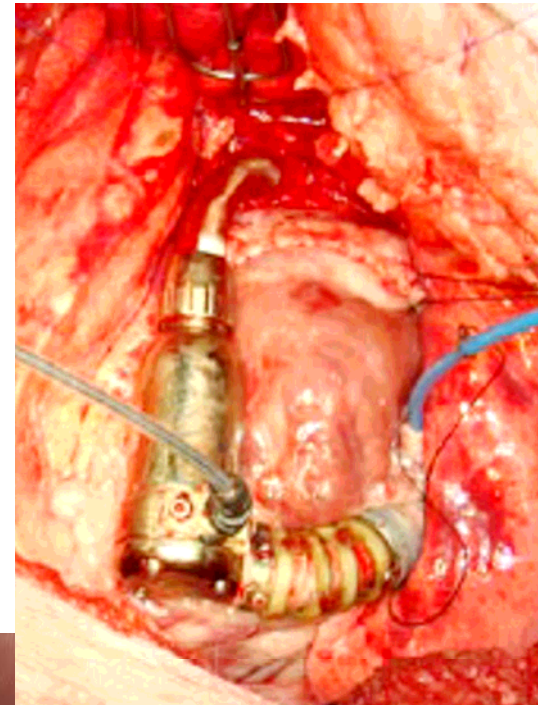
# Getting bigger by getting smaller



<b>Procedure</b>	Surgical	Minimally Invasive	Catheter Delivery System
<b>Flow</b>	10 L/min	7 L/min	3 L/min
<b>Patient Class</b>	Late Class IV	Class III & IV	Class III
<b>Treatable Pop.</b>	100,000	350,000	1,000,000
<b>Current status:</b>	IDE	Preclinical studies	Prototype and exploratory

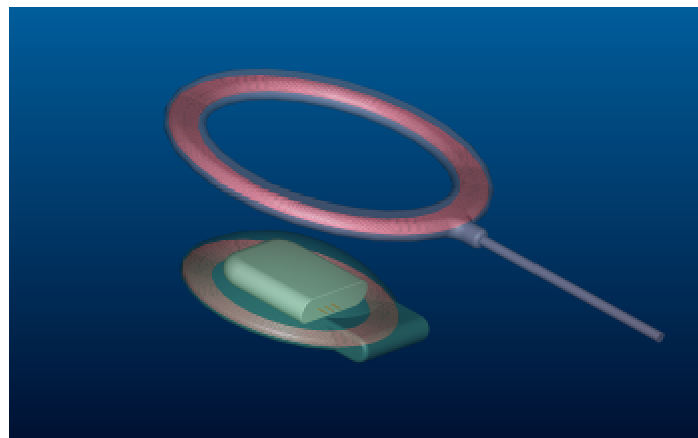
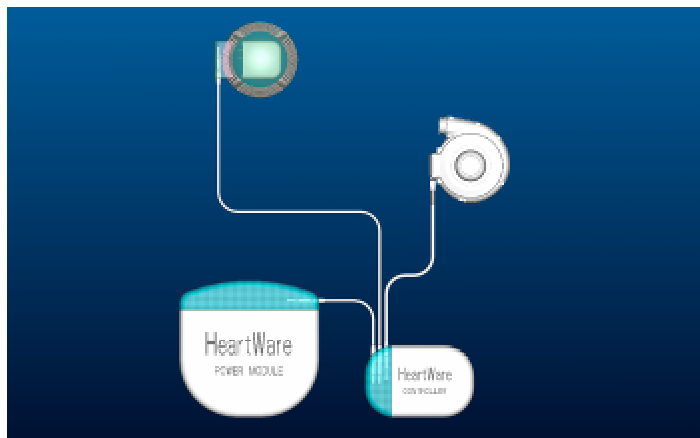
# MVAD showing promise and versatility

- Developing implant techniques that avoid sternotomy
  - » *MVAD seems to work wherever we place it*
- Goals are:
  1. *Small incision*
  2. *Decrease complications*
  3. *Increase number of patients who can benefit*
- Will select “winner” in 2008
  - » *Full project kick off in 2009*
- First implant likely < 24 months



# The next major advance: TETS

- Transcutaneous Energy Transfer showing significant progress
  - » *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*
  - » *Successfully demonstrated feasibility; refining performance attributes*



# Key Upcoming Milestones

Milestone	Timing	Status
Submissions of IDE to US FDA	Q4 2007	✓
Extension of International Trial to allow additional implants	Q4 2007	✓
Approval to Commence US trial	Q2 2008	✓
Submission of Technical Dossier to Competent Authority	2H 2008	On Target
Receipt of CE Mark (European Regulatory Approval)	2H 2008	On Target
Commencement of US Clinical Trial	Q2 2008	On Target
First revenue	Q2 2008	On Target

# Financial snapshot

- Cash on hand ~ AU\$24.9M (31, March)
- Burn rate ~ AU\$2-2.2M per month
- First revenue Anticipated mid 2008
- Shares on issue ~ 248M
- Market Cap ~ \$120M
- Number of employees 92
- Top 20 shareholders >75% of shares

# Summary

- Heart Failure is a disease of epidemic proportions
- Market acceleration is underway
- HeartWare is well positioned to benefit from market growth now and will be the primary driver of dramatic growth in the future
- Commercialization to commence in mid-2008



**HEARTWARE LIMITED  
2008 ANNUAL GENERAL MEETING  
CHAIRMAN'S ADDRESS**

Annual General Meeting of Shareholders to be held at the offices of the Company's auditors, Grant Thornton, Level 17, 383 Kent Street, Sydney, New South Wales at 10.30am on Friday 9 May 2008.

---

On Monday we announced conditional FDA approval to begin our US trials of the Heartware Left Ventricular Assist System. This is a most significant milestone for Heartware. The trial design is very favorable and we plan to complete the enrolment of all 150 patients in 2009. We of course receive revenues from the use of our devices in this trial.

I wanted to touch on the industry background and for any Heartware shareholder the recent annual International Society of Heart and Lung Transplantation Conference was enormously rewarding. Here was the most tangible evidence and verification to date that mechanical circulatory support systems such as ventricular assist devices (VADs) are an effective means of treating Congestive Heart Failure.

A very positive picture emerged. Life expectancy on mechanical circulatory support has improved substantially, and studies with longer follow up are emerging with positive results. Continuous flow pumps were shown to produce at least similar benefits compared with pulsatile pumps, and were much more reliable. Indeed evidence of device failure at ISHLT was rare. Infection rates are also being reduced substantially as better patient care protocols are developed through greater device experience.

We believe improved results will lead to increased expansion of implant centres and higher implant numbers which should ultimately lead to a further improvement in outcomes as greater implant experience generally drives survival rates higher.

What remains? Attention by doctors is now turning to quality of life factors, better peripherals and ultimately an ability to have batteries and controllers





implanted internally. We will also see continued developments in the use of drug and stem cell therapies to facilitate heart muscle function recovery, most likely in conjunction with assist devices.

VADs are becoming more cost effective compared with the cost of maintaining patients on pharmaceuticals and ultimately should lead to a reduced cost burden on the health system. Finally cardiologists will gain greater confidence to send patients for VADs much earlier than they are currently doing which again will provide better patient outcomes.

In summary we have an early stage but viable medical device industry with extraordinary supply demand characteristics meeting one of society's greatest health needs.

It was within this background that our clinical trial results were presented for our first 23 patients. Our CEO, Doug Godshall will cover these in more detail but suffice to say, that even accepting the small sample size, the results were exceptional. The bar however will continue to be raised and we have a lot to achieve to stay in front.

These results have been achieved due to an exceptional group of individuals. On behalf of all shareholders I would like to thank Doug and his team for their efforts. Their ability to cope with unexpected challenges, transform from an R&D centric organisation to a device manufacturer, and develop new concepts in parallel continues to surprise.

I would also like to thank the Board for all their support. It is not easy to oversee such a dynamic company with Directors split between two continents. In recognition of the fact that we believe we will become a major medical device company centred in the United States with prospects of a US IPO in 2009, the Board has sought additional experienced US based Directors. To attract so successful and well credentialed a healthcare executive as Tim Barberich is a testament to the potential of this company and we welcome him aboard.

To allow greater access to the US capital market, and also reduce significant administration cost, Heartware's current intention is to redomicile to the United States in the second half of 2008 subject to satisfaction of relevant legal requirements. If this occurs, shareholders will be asked to vote on a Scheme of Arrangement later this year. There will be no practical change for Australian shareholders but we anticipate the move will lead to greater US institutional interest.



2008/9 will be a challenging but exciting period, the start of our US trials, CE Mark, TGA submission, first revenues and settling into our new facilities. And of course further development of both our fully implantable “TET” system as well as the MVAD, our next generation pump. This extraordinary device has a volume of less than 15cc, can be used as either a low flow support device or as a full output pump and comprises only 12 components, allowing it to be quickly and easily assembled.

Finally a sincere thank you to all our shareholders. The Company, its Board and our employees appreciate the your continued support us through what have been difficult market conditions for developing companies such as HeartWare. We are there to save human lives so we will always be burdened with the highest standards of quality control and the need for measured expansion. Your Board remains very excited by the potential it sees over the next few years.