



## ASX ANNOUNCEMENT

12 August 2008

### HeartWare presentation at Canaccord Adams Global Growth Conference

**Framingham, MA and Sydney, Australia, 12 August 2008:** HeartWare Limited (ASX: HTW) advises that it will be participating in the Canaccord Adams Global Growth Conference, to be held in Boston from 12<sup>th</sup> – 14<sup>th</sup> August 2008.

Doug Godshall, President and Chief Executive Officer will present a company update at 9:30am on Wednesday 13<sup>th</sup> August 2008 (U.S. Eastern time).

A webcast of the presentation will be available through the conference website at [http://www.corporate-ir.net/ireye/conflobby.zhtml?ticker=HTW.AX&item\\_id=1887733](http://www.corporate-ir.net/ireye/conflobby.zhtml?ticker=HTW.AX&item_id=1887733) or through the HeartWare website at [www.heartware.com](http://www.heartware.com). A copy of the presentation is attached.

#### About HeartWare

HeartWare develops and manufactures miniaturized implantable heart pumps, or Left Ventricular Assist Devices (LVADs), to treat patients suffering from advanced heart failure. The Company is developing smaller and less invasive pumps which it believes will be the key to unlocking the potential of a large and underserved market. The HeartWare<sup>®</sup> LVAD is the only full-output pump designed to be implanted in the chest, avoiding the abdominal surgery generally required to implant competing devices. The device is currently the subject of an international clinical trial involving five investigational centres in Europe and Australia. The Company has received conditional approval from the US FDA to commence a pivotal clinical trial in the United States for a Bridge-to-Transplant indication.

For further information:

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

Howard Leibman

Director Corporate Development

HeartWare Limited

Email. [howard.leibman@heartware.com.au](mailto:howard.leibman@heartware.com.au)

Tel. +61 2 9238 2064

US Investor Relations

Matt Clawson

Partner

Allen & Caron, Inc.

Email. [matt@allencaron.com](mailto:matt@allencaron.com)

Tel. +1 949 474 4300

# HeartWare Limited (ASX:HTW)



- » **Corporate Update**  
*August 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.

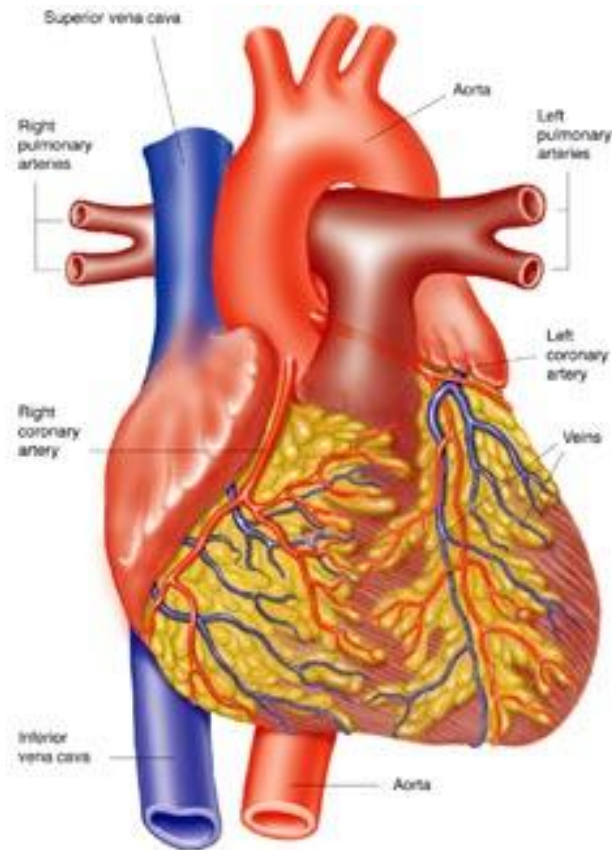
# Overview

- **HeartWare is developing the world's smallest implantable pumps for the treatment of advanced heart failure**
- **Heart failure is 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**
  - » *International clinical trial showing survival >91% at average follow up of 243 days*
  - » *41 implants; >9,700 implant days*
- **CE mark and first sales anticipated by end of 2008**
- **US clinical trials to commence imminently**
- **Promising progress of next generation products**

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



# Heart Failure



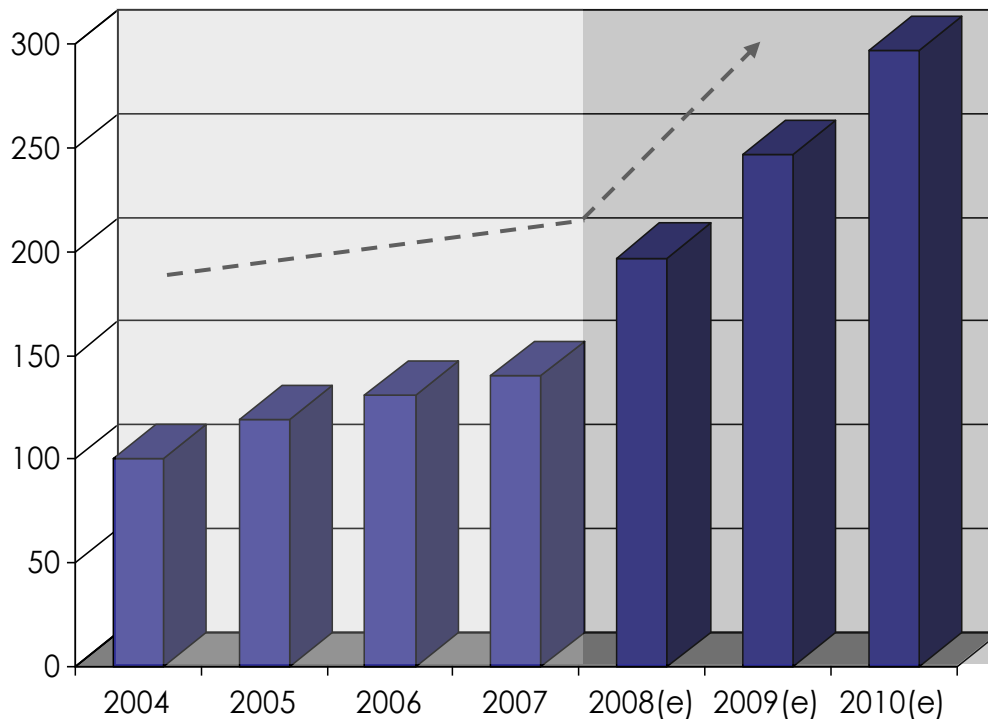
- A degenerative and terminal disease
- Affects over 20 million people globally (5+ million in the US)
  - » 1 million new cases diagnosed every year
  - » 300,000 deaths per year in the US
- At least 1 million patients in NYHA Class IV, the end-stage of the disease
- In the US, heart failure represents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

# 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; (~2,200 per year in the US)*
  - » *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
  - » *Data continues to improve and demonstrate long term benefits*

# VAD's: a 25 year overnight success

**Thoratec Worldwide VAD Sales (\$M)**

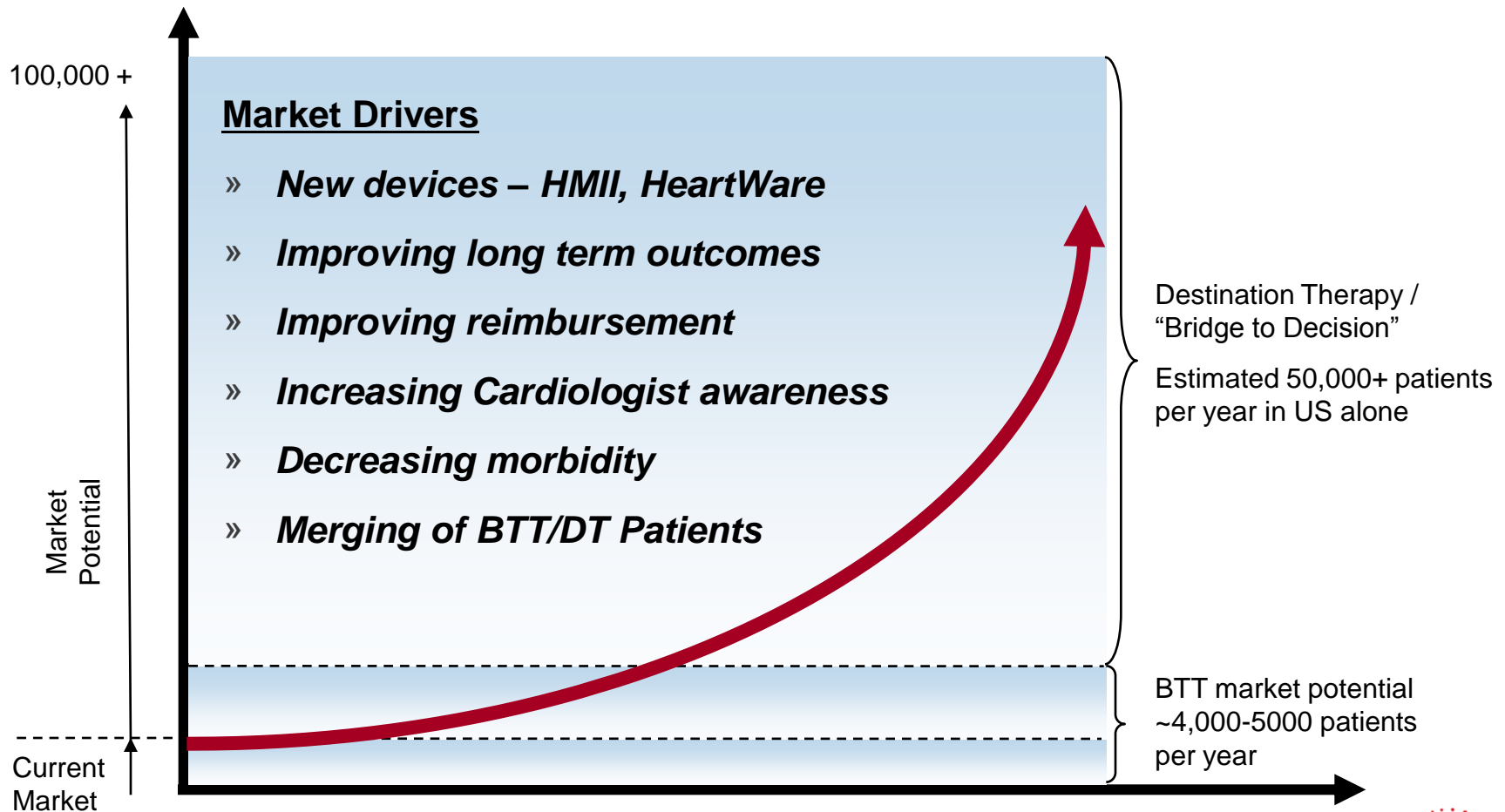


Source: Canaccord Adams Aug. 1, 2008 report

- Historic compound growth rate >12% pa despite no new technology
- 2008 inflection in market growth
  - » *HeartMate II – the first new pump approved since 1998*
  - » *Early adoption rate signaling strong demand*
- Waiting list expanded '06 & '07 – the first time since 1995

# Opportunity for significant long term growth

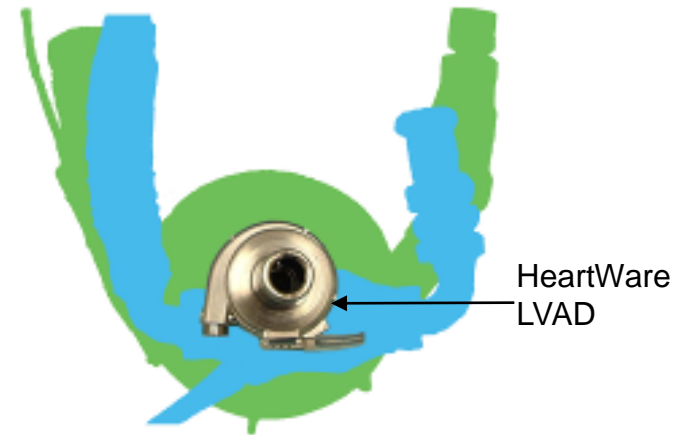
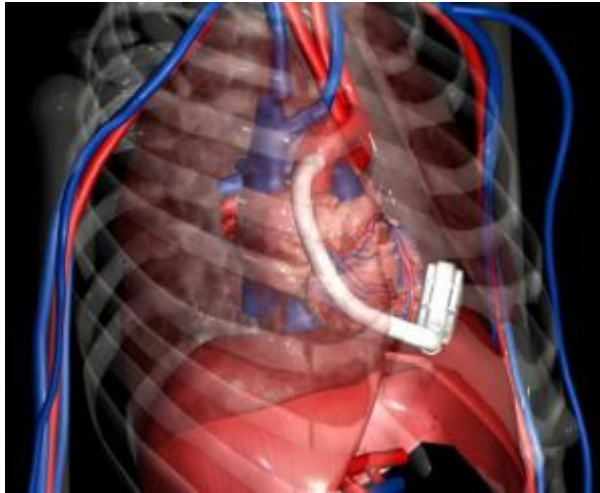
Potential VAD Patients per Year





# Pericardial placement – Offers potential benefits

## Pericardial



---

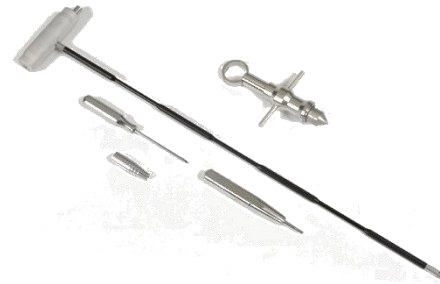
### Potential Benefits:

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

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

# The HeartWare<sup>®</sup> 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



Caution – Investigational Device, Limited by United States Law to Investigational Use<sup>®</sup>



# International clinical trial progress to date

- 41 patients enrolled to date
- Extension approved to allow up to 50 patients
- Primary endpoint is survival to 180 days or transplant
- Submission of Technical Dossier expected Q3 2008, CE mark anticipated Q4 2008

Centre	Country	Principal Investigator	Implants
Vienna General Hospital	Austria	Dr Georg Wieselthaler	8
Royal Perth Hospital	Australia	Dr Gerry O'Driscoll	5
Hannover Medical Center	Germany	Dr Martin Strüber	16
Harefield Hospital	UK	Dr Asghar Khaghani	3
St Vincents Hospital, Sydney	Australia	Dr Paul Jansz	9
			<hr/> 41

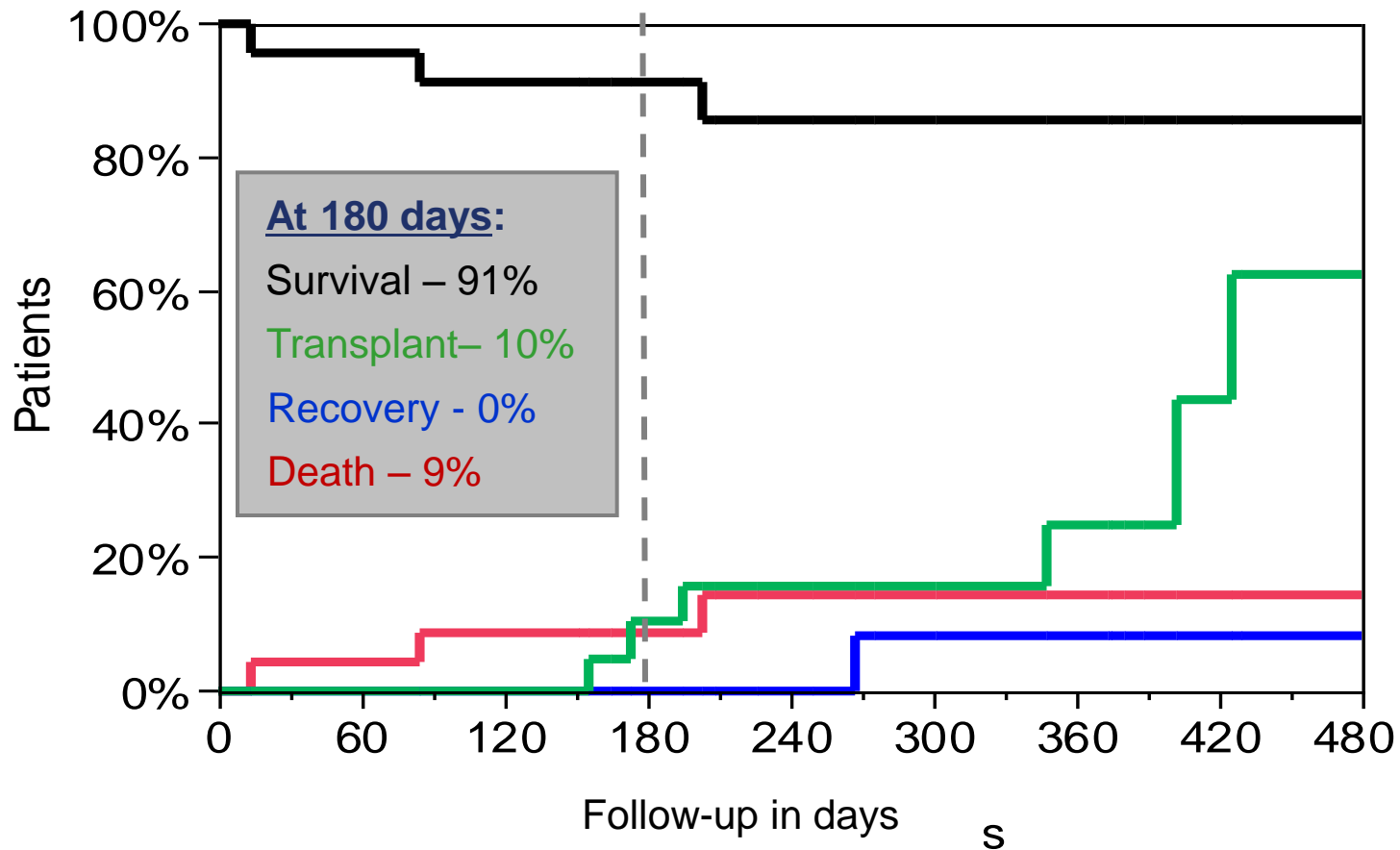
# Promising early data

- 41 patients enrolled
- Cumulative support - 9,730 days (~27 yrs)
- Average support - 243 days per patient
- >91% survival (of first 29 patients, 27 have successfully passed trial endpoint)
- Total transplants to date - 10
- Average support days pre transplant - 275
- Recovery patients - 2
- Longest supported patient - 558 days
- Patients supported >12 months – 11
- Adverse events in range with historical publications



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

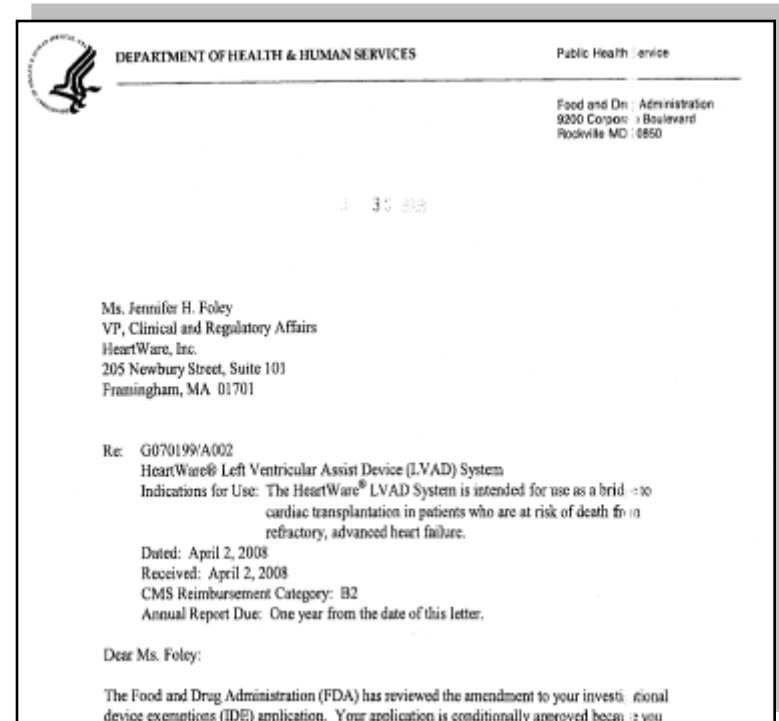
# Outcomes at 180 Days



Presented by G Wieselthaler, MD at the ISHLT Annual Meeting, Boston, MA, April 12, 2008  
Data from first 23 patients enrolled in HeartWare clinical trial

# US clinical trial – imminent start

- Received conditional approval for BTT protocol
- Allowed to commence pivotal trial
- 150 patients at a maximum 28 centers
- Utilizing NIH funded control arm (Intermacs Registry)
- Immediate patient discharge permitted
- Site training underway
- Expect first patient August / September
- IRB approval received Wash. Hosp. Ctr.



# Product pipeline – pump miniaturization

HVAD™



MVAD™



IV-VAD

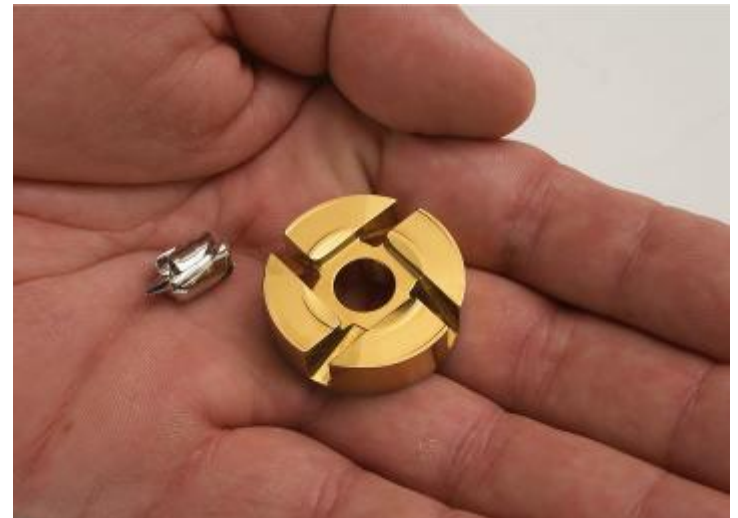
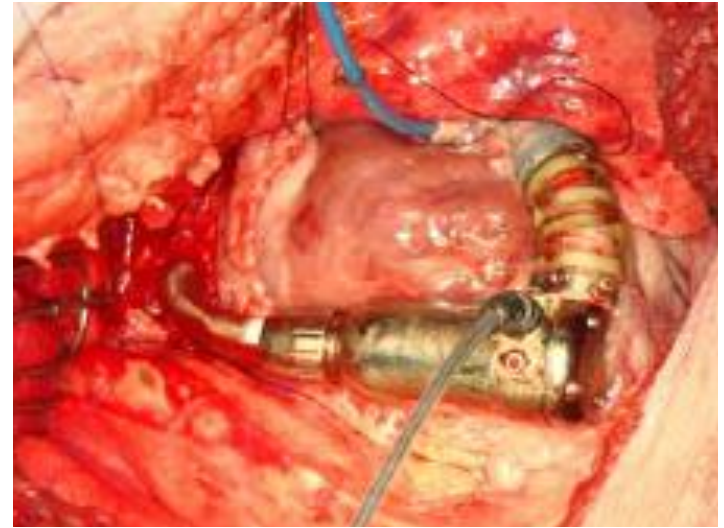


<b>Procedure</b>	Surgical	Minimally Invasive	Catheter Delivery System
<b>Flow</b>	10 L/min	7 L/min	3 L/min
<b>Patient Class</b>	Late Class IV	Class III & IV	Class III
<b>Treatable Pop.</b>	100,000	350,000	1,000,000
<b>Current status:</b>	IDE	Preclinical studies	Prototype and exploratory

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

# MVAD showing its potential

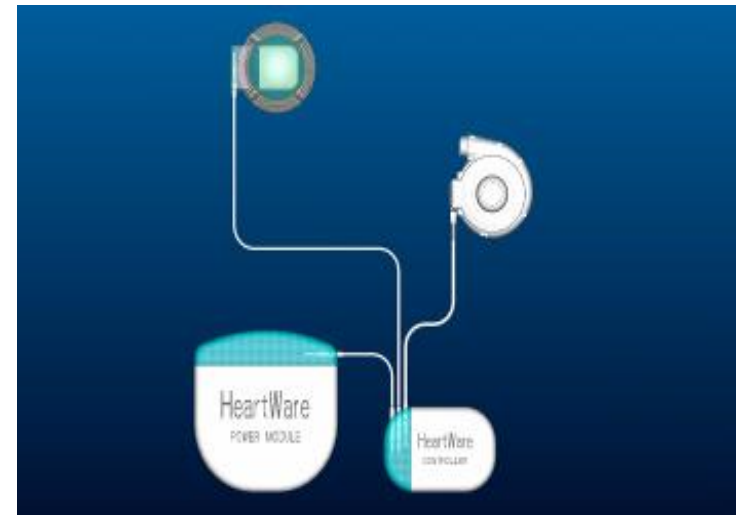
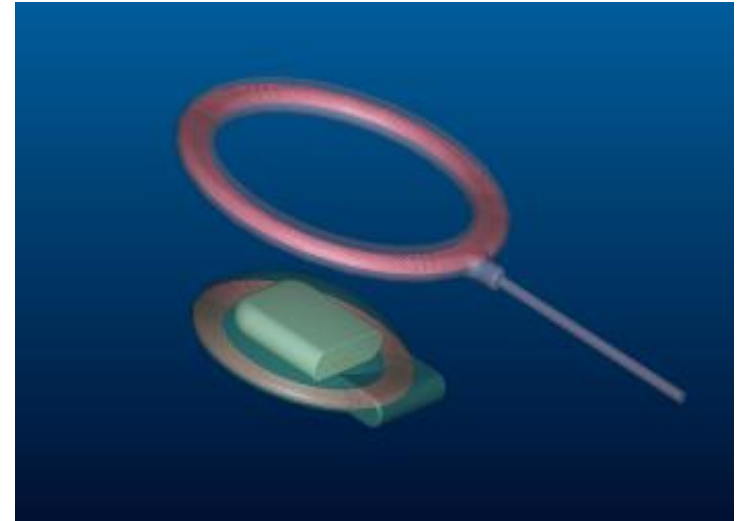
- Developing implant techniques that avoid sternotomy
  - » *Extremely encouraging preclinical results*
- Goals are
  - » *Small incision*
  - » *Decrease complications*
  - » *Increase number of patients who can benefit*
- Will select “winner” in 2008
  - » *Full project kick off in 2009*





# Product pipeline – TET System

- Transcutaneous Energy Transfer showing significant progress
  - » *Designed to enable transfer of energy and information across the skin*
  - » *Replaces driveline cable and eliminates risk of driveline complications*
  - » *Designed to enable patient to be untethered from the charging system for extended periods*
  - » *Pre-clinical testing meeting design targets*



# Upcoming milestones

<b>Milestone</b>	<b>Timing</b>	<b>Status</b>
Extension of International Trial to allow additional implants	Q4 2007	✓
Conditional IDE Approval	Q2 2008	✓
Commencement of US Clinical Trial	Q3 2008	On Target
First Revenue	Q3 2008	On Target
Submission of Technical Dossier to Competent Authority	Q3 2008	On Target
Receipt of CE Mark	Q4 2008	On Target
Redomiciliation of Parent Company from AUS to US	2H 2008	On Target

# Financial snapshot (\$AU)

- Cash on hand \$42.6M (31 July)
- Burn rate \$2-2.5M per month
- First revenue Anticipated Q3 2008
- Shares on issue 310M
- Market Cap \$165M
- Number of employees 102
- Top 20 shareholders > 75% of shares
- US Ownership > 80%

# Summary

- Heart Failure is a disease of epidemic proportions
- The LVAD market is growing and poised for rapid acceleration
- HeartWare is well positioned to benefit from market growth now and will be the primary driver of dramatic growth in the future

