

# HEARTWARE LIMITED

ABN 34 111 970 257



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Manager of Company Announcements  
ASX Limited  
Level 6  
20 Bridge Street  
SYDNEY NSW 2000

22 October 2008  
**BY E-LODGEMENT**

Dear Sir / Madam

## **Redomiciliation Meetings**

In accordance with ASX Listing Rule 3.13.3 the Company provides a copy of the presentation materials that are to be delivered today at the meetings of Shareholders, Optionholders and Performance Rights holders in connection with the proposed redomiciliation of the Company to the United States.

These meetings are being held at the Adelaide Room, Sofitel Sydney Wentworth Hotel, 61-101 Philip Street, Sydney commencing at 10am.

A copy of the Information Memorandum is available on the Company's website.

Yours faithfully

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

# HeartWare Limited (ASX:HTW)

Leading a small revolution



**CEO Presentation  
Mr Doug Godshall**

22 October 2008

# 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.

## 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. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation those described in "Item 1A. Risk Factors" in our Annual Report on Form 10-K filed with the Securities Exchange Commission ("SEC") on February 28, 2008, and those described in other reports filed from time to time with the SEC or the ASX.

## 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.

# Agenda

- Redomiciliation
- Corporate Update
  - » *US & International Clinical Trial Update*
  - » *Operations Update*
  - » *Future Products Update*
  - » *Milestones*

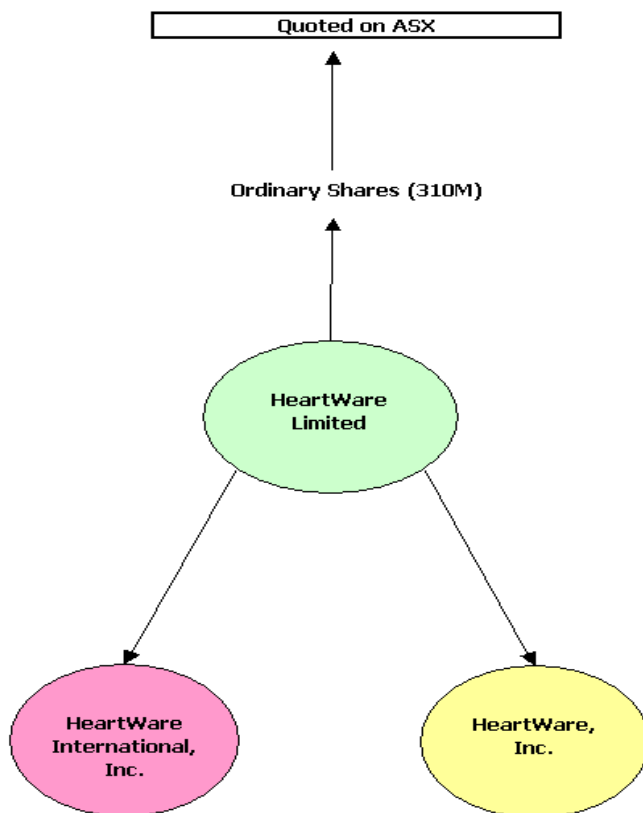
# Redomiciliation - Overview

- The HeartWare Group will redomicile – or reincorporate – in the United States of America
- HeartWare International, Inc (a US-based Delaware corporation) will become the ultimate parent company of the HeartWare Group
- HeartWare International will replace HeartWare Limited as the ASX listed entity with HeartWare International “CDIs” being quoted for trading on the ASX
- 3 separate schemes of arrangement:
  - » *Share Scheme – Ordinary Shares are exchanged for HeartWare International CDIs or HeartWare International Common Stock*
  - » *Option Scheme – ESOP options exchanged for HeartWare International Options*
  - » *Performance Rights Scheme – Performance Rights exchanged for restricted stock units in HeartWare International*
- Standalone options exchanged for HeartWare International options

## Redomiciliation - Continued

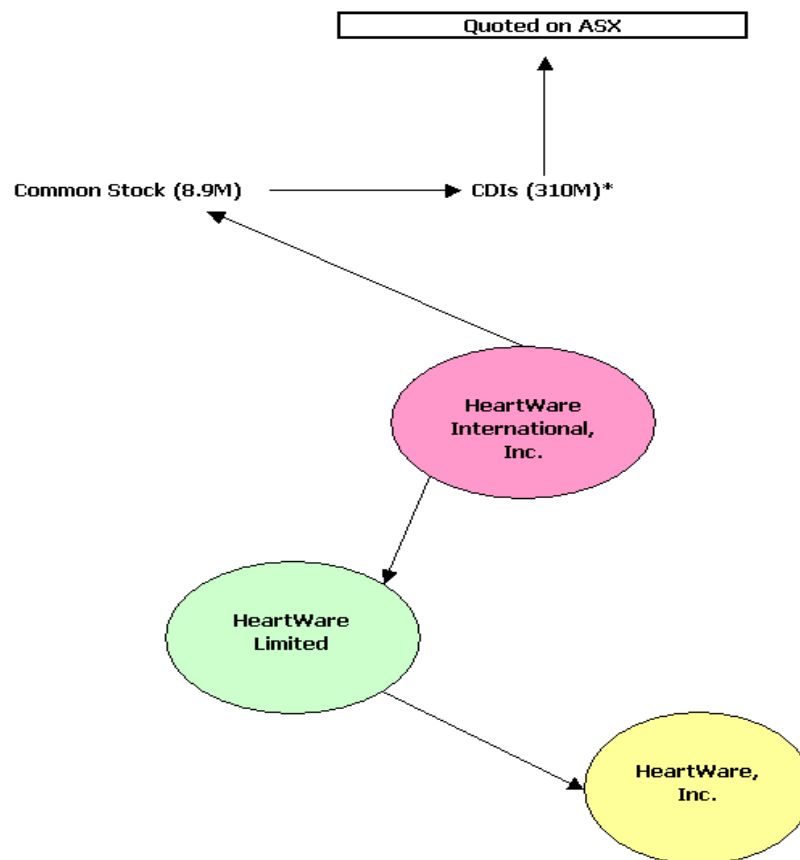
- Shareholders have the same economic interest in HeartWare before and after the transaction
- Shareholders will receive:
  - » *1 HeartWare International CDI per Ordinary Share held; OR*
  - » *1 HeartWare International Common Stock for every 35 Ordinary Shares held*
- CDIs and Common Stock are interchangeable BUT only CDIs will be tradeable on the ASX
- Trading price of “HeartWare” on the ASX is expected to be unchanged pre and post redomiciliation
- Potential advantages and disadvantages cited on pages 14 and 15 to the Information Memorandum and discussed by the Independent Expert

### Current Structure



<b>Parent Entity</b>	HeartWare Limited
<b>Type of Shares on Issue</b>	Ordinary Shares
<b>Number of Shares on Issue</b>	310,356,839
<b>Type of Shares Quoted on ASX</b>	Ordinary Shares
<b>Number of Shares (Ordinary) Quoted on ASX</b>	310,356,839
<b>ASX Share Price</b>	\$A0.55 (1)
<b>Number of Options<sup>^</sup> on Issue</b>	29,546,464
<b>Weighted Average Exercise Price of Options<sup>^</sup></b>	A\$0.71

### Proposed Structure



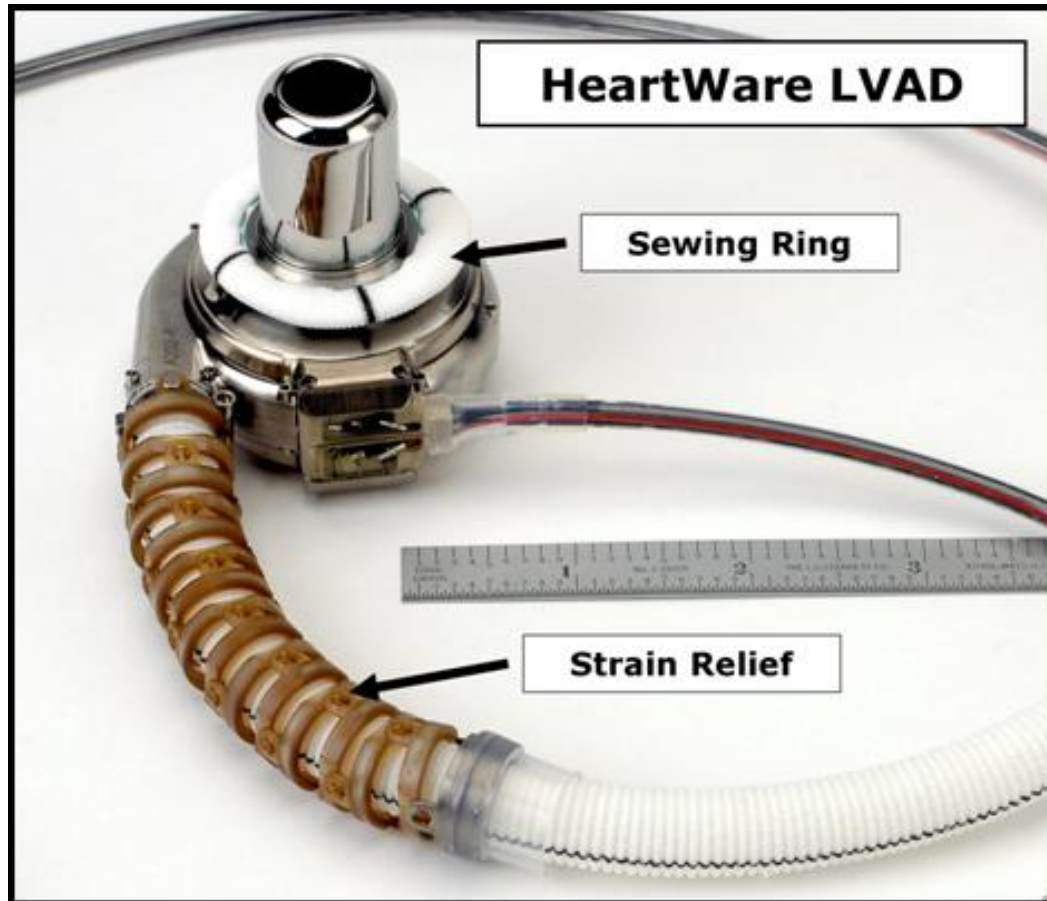
<b>Parent Entity</b>	HeartWare International, Inc.
<b>Type of Shares on Issue</b>	Common Stock
<b>Number of Shares on Issue</b>	8,867,338
<b>Type of Shares Quoted on ASX</b>	CDIs
<b>Number of Shares (CDIs) Quoted on ASX</b>	310,356,839 (2)
<b>ASX Share Price</b>	\$A0.55 (3)
<b>Number of Options<sup>^</sup> on Issue</b>	844,185
<b>Weighted Average Exercise Price of Options<sup>^</sup></b>	A\$24.85

# Summary - Redomiciliation

- Redomiciliation will reduce costs, complications and the overall burden associated with being a dual public company “in the United States and Australia”
- HeartWare will become a US public company that is listed on the ASX
- Paves the way for a primary listing on NASDAQ
- The Board of Directors unanimously support the redomiciliation of HeartWare to the United States
- BDO Kendalls determined that redomiciliation “is in the Best Interests of the Equity Interest Holders of HeartWare”.



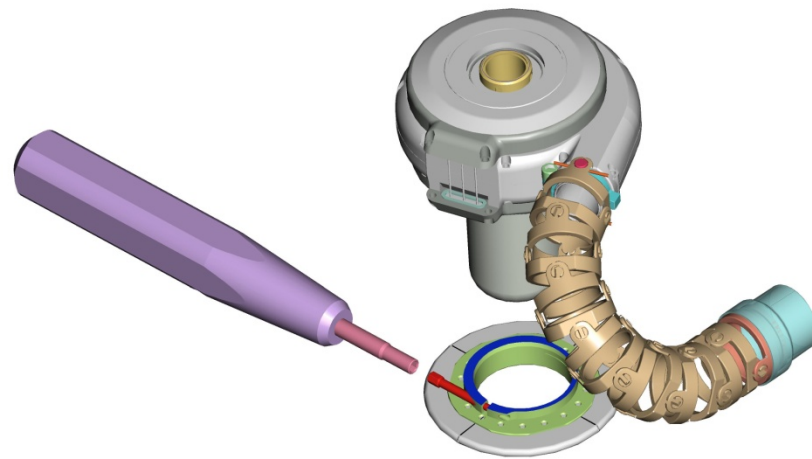
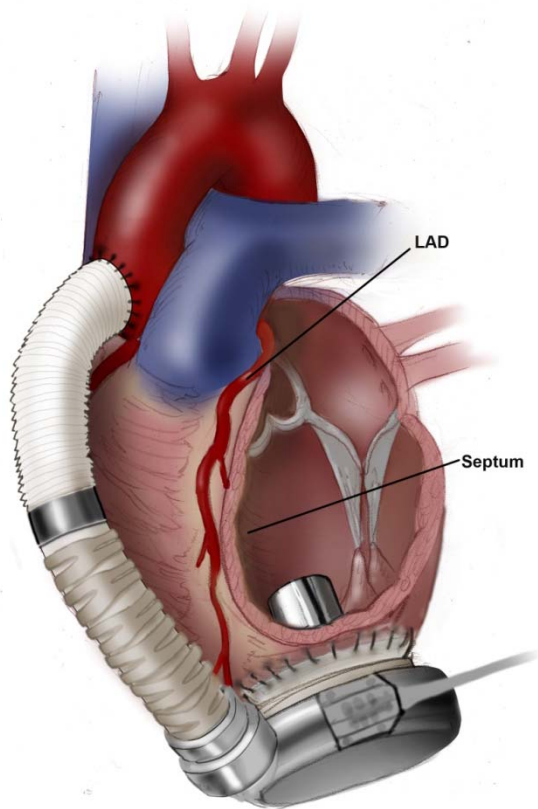
# Physical Characteristics



- *Centrifugal pump*
  - 50 cc
  - 140 grams
  - 2 inch outside diameter
- *Integrated inflow cannula*
- *10 mm outflow graft with articulating strain relief*
- *Thin, flexible driveline*
- *Custom sewing ring*

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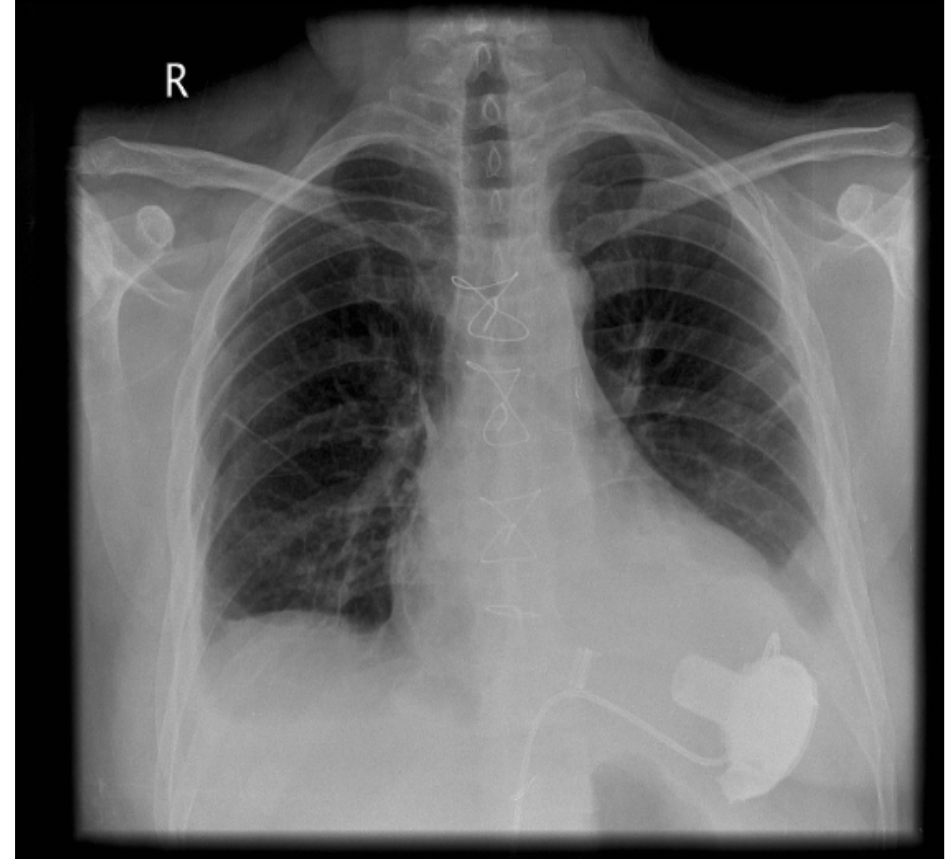
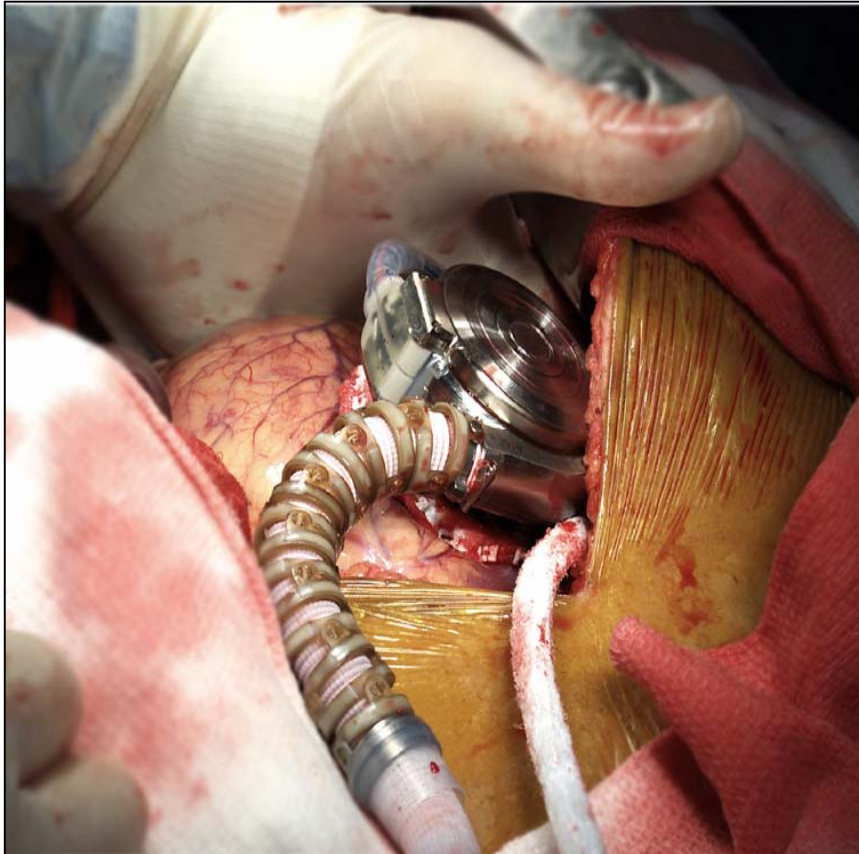
# Implanted in Pericardial Space



**Integrated inflow cannula and novel sewing ring designed to expedite the implant procedure**

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## Implanted in Pericardial Space



“...you simply let the heart go and both the heart and the pump disappear into the chest...”

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# Patient and Hospital Equipment

2 battery packs last approximately 10 hours

Battery Packs and Charger

Clinical Monitor



Intuitive touch screen monitor



Wearable Controller

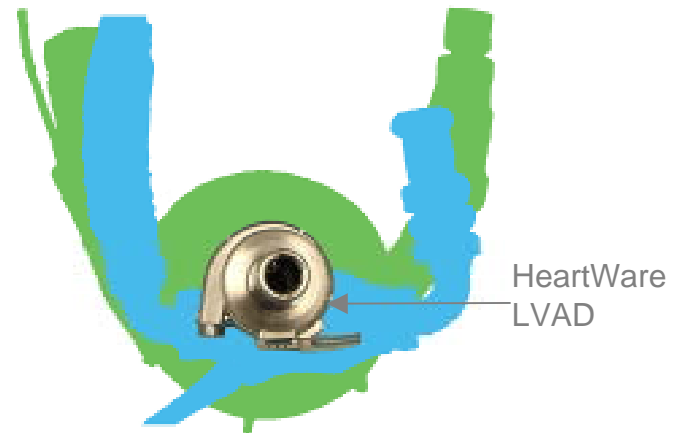
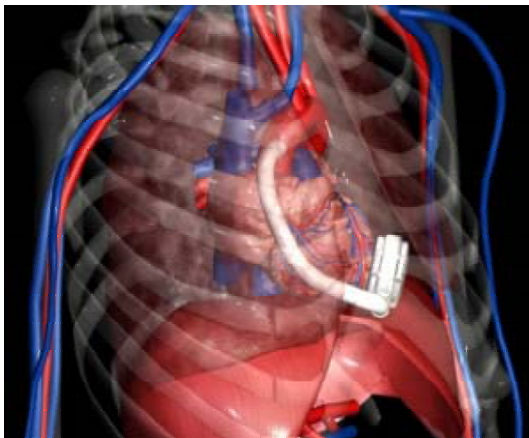
2 line LCD display, power connections, & log files

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# Comment

- This pump offers something that no other pump offers. It has the potential to make an important difference for our patients and on the market.

» O. H. (Bud) Frazier M.D.; at HeartWare Investigators' meeting held on 10 October 2008



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# US Clinical Trial Underway

- Granted full IDE approval from FDA in September 2008
- 150 patients at a maximum 28 centers
- First US implant at Washington Hospital Centre
- 6 additional centers trained
- 2 others have received IRB
- Strong interest from leading transplant centres
- 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

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# International Clinical Trial Update as of October 10, 2008

<b>Enrolled</b>	<b>45</b>
<b>Alive on pump or transplanted</b>	<b>40</b>
<b>Transplanted</b>	<b>12</b>
<b>Recovered</b>	<b>3</b>
<b>Deceased</b>	<b>5*</b>
<b>Longest in Use</b>	<b>22 months</b>
<b>Total LVAD Support</b>	<b>30.6 pt/yrs</b>

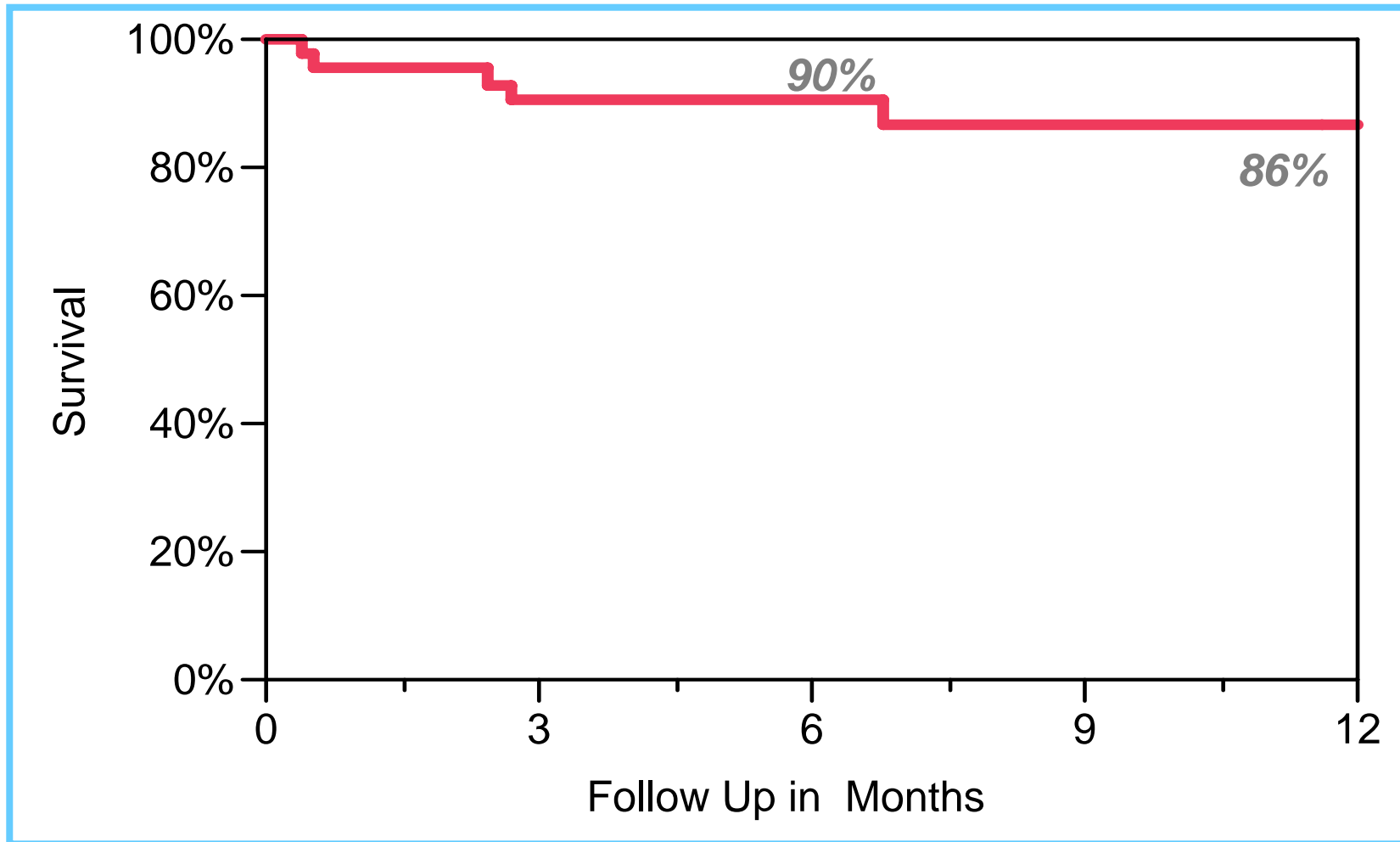
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\*1 patient died on POD 203 after reaching primary endpoint

Adverse events/complications consistent with reported events in 1<sup>st</sup> 23 patients (ISHLT April 2008)

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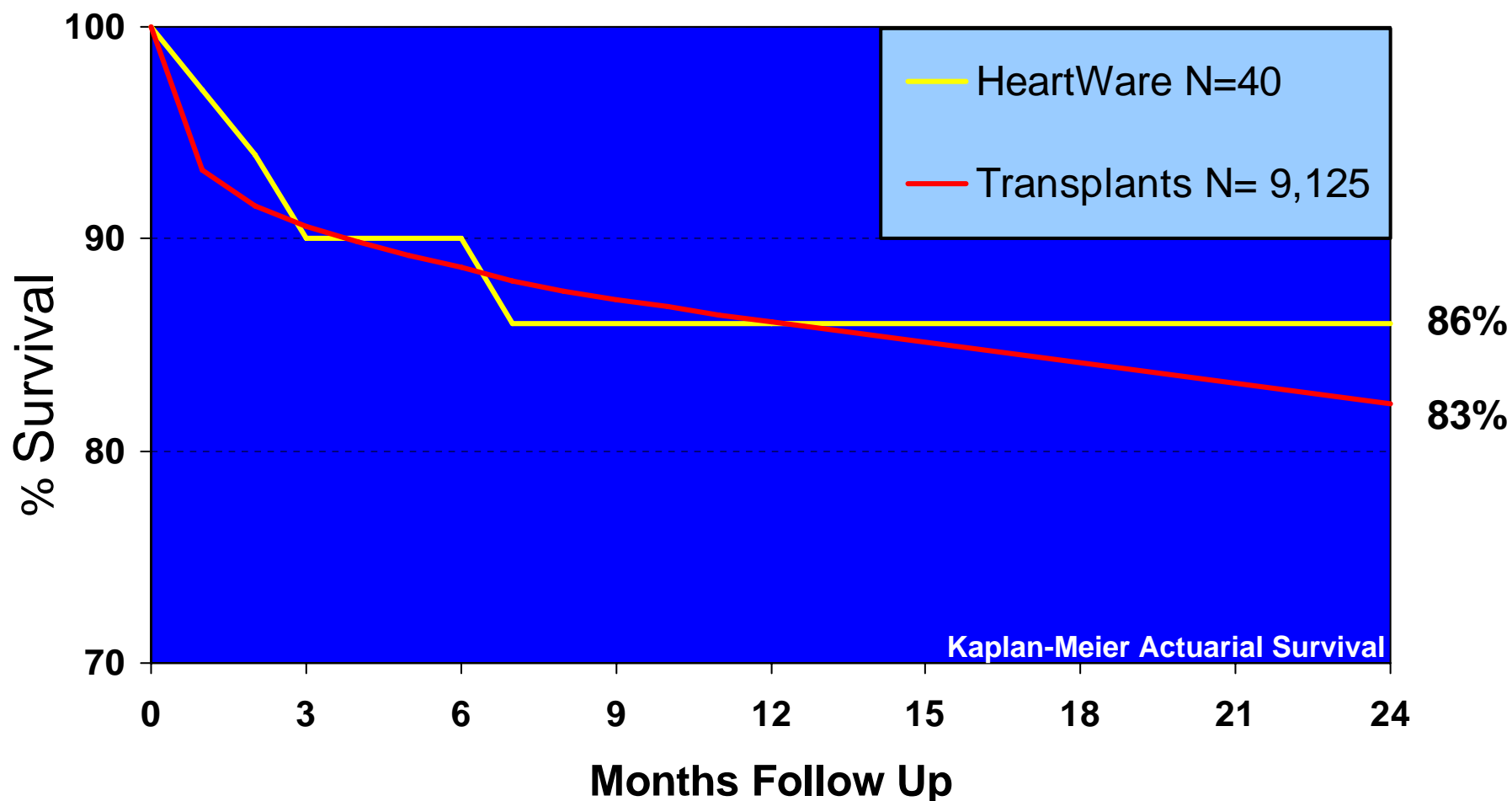
# Kaplan-Meier: Interim Report (N = 45)



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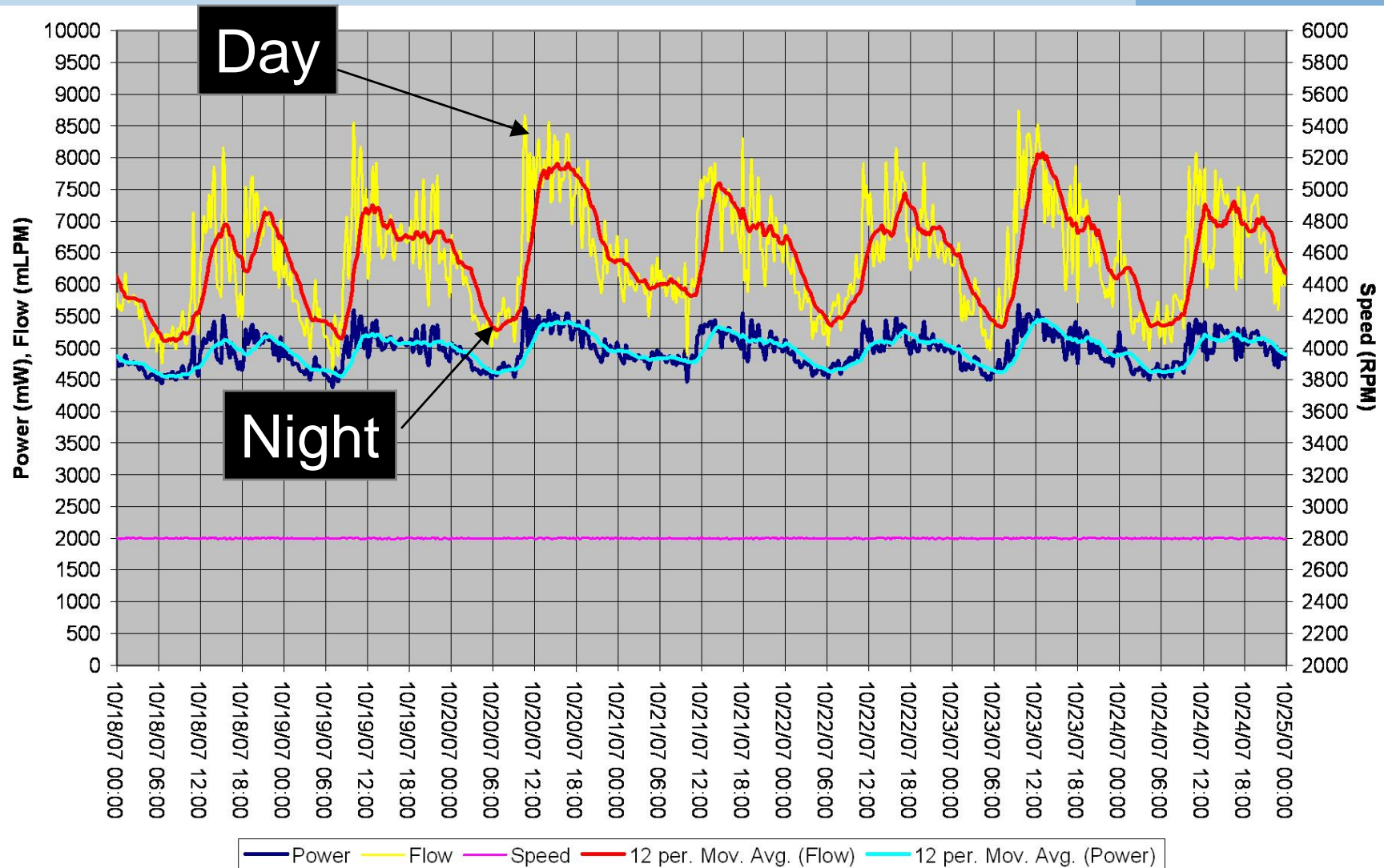
# International Trial Survival vs. Heart Transplantation



Transplants: 2002 – 6/2005 J Heart Lung Transplant 2007;26: 769-781

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# HeartWare LVAD Flow: Enables Circadian Rhythm



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# LVAD Market Dynamics Very Favorable

- Patient population continues to grow
- VAD's are suddenly an attractive sector
- Market growth has exceeded almost all expectations
  - » *Thoratec up 44% Q2 over Q2 '07*
  - » *26 new centers started implanting in Q2 in US*
  - » *Cardiology meetings which were previously neutral to negative on VAD's, now positive*
  - » *Even bearish analysts projecting 40% growth '08-'10*
- Data from all companies improving; reinforcing merits of VAD therapy
- Considerable interest in HeartWare worldwide
  - » *Multiple sites in EU waiting for CE mark and very high level of enthusiasm amongst US investigators*

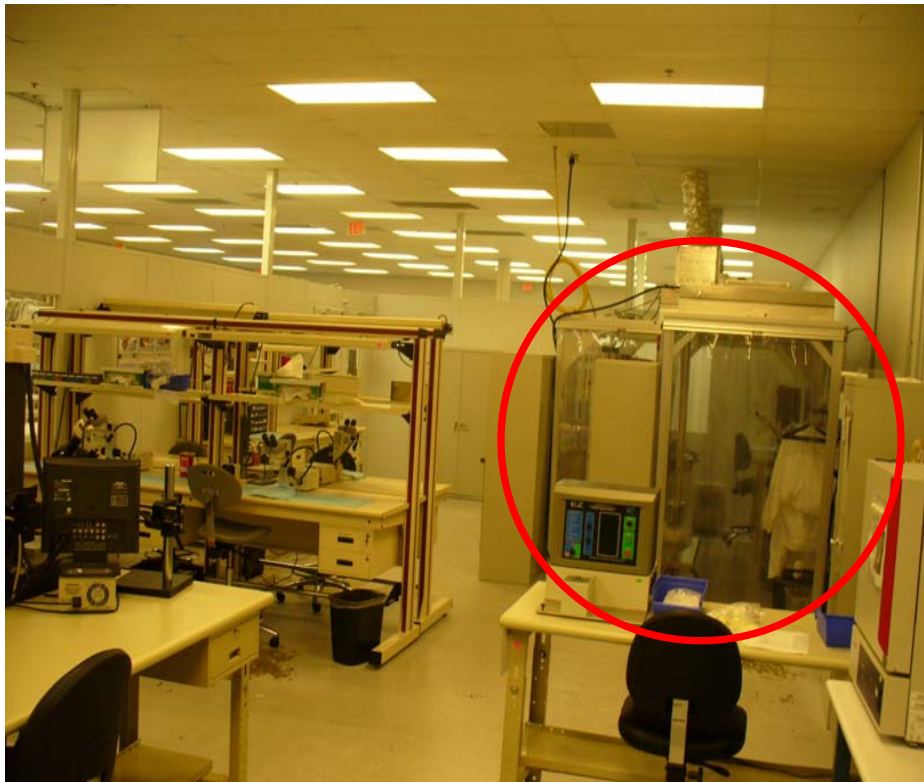
# Operational Update

- Capacity expansion and capability requirements identified during 2007
  - » *Requirement #1 – General facility upgrade*
  - » *Requirement #2 – Expanded clean room capability*
  - » *Requirement #3 – Validation / verification of all equipment and processes*
  - » *Requirement #4 – Yield and throughput improvement*
  - » *Requirement #5 – Improved inventory and supplier management*
  - » *Requirement #6 - Increasing number of highly skilled operators*

# 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

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## In 2008 We Established Foundation for 2009+

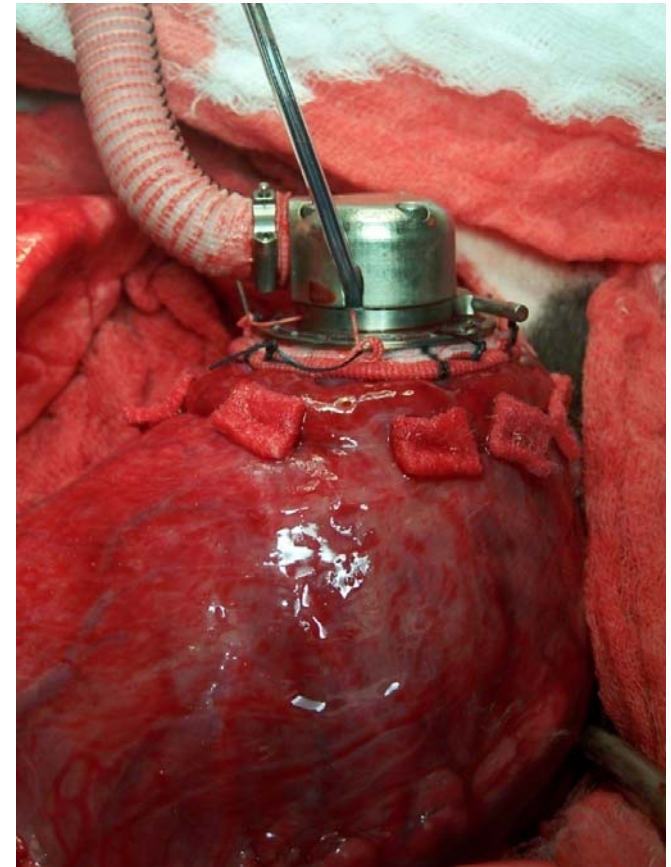
- ✓ Validation / verification of equipment and processes
- ✓ Relocation to “state-of-the-art” clean room in Miami Lakes
- ✓ Quality system upgrade
- ✓ Received ISO 13485 Certification
- ✓ Expanded capacity/reduced cycle time in receiving and inspection
- ✓ Partnered closely with key suppliers
- ✓ Ramped up in-house inventory depth
- ✓ Significant enhancement of operator and engineering capabilities
- ✓ Doubled number of operators on manufacturing floor
- ✓ Analyzed and identified action plans for:
  - ✓ *High impact yield loss activities*
  - ✓ *Redundancy shortfalls*
  - ✓ *Process and related “bottlenecks”*

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# MVAD's Promise Growing

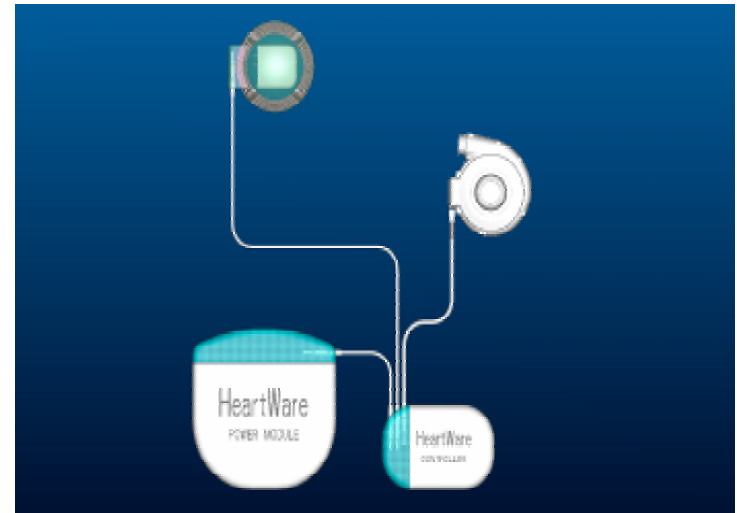
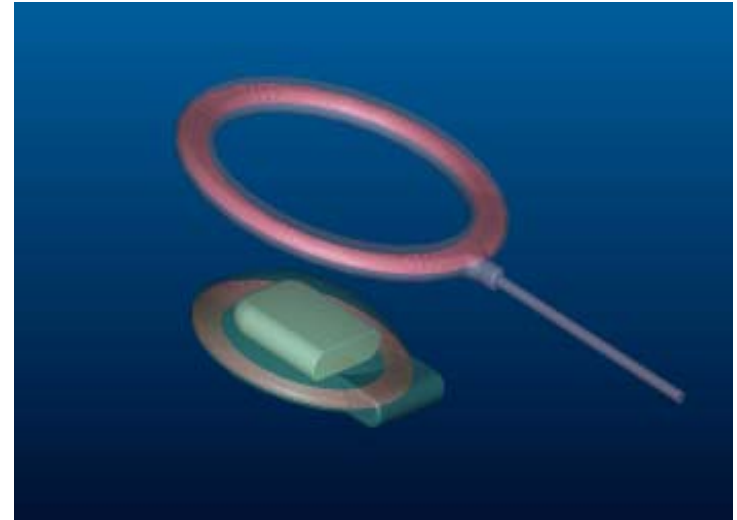
- 3 distinct surgical implantation approaches have emerged
  - » *Trans apical (pictured)*
  - » *Less invasive full flow (7 liters+)*
  - » *Less invasive partial flow (3-4 liters)*
- Physician feedback / interest very high
  - » *“WOW” is most common comment*
  - » *Received high praise at ISRBP*
- Configurability / versatility, ease-of-use and manufacturability evident
- 20+ animals studies in Germany, Austria and the United States
  - » *Additional chronic studies slated for Q4*
- Comparable hemodynamics to HeartWare LVAD



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# 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*



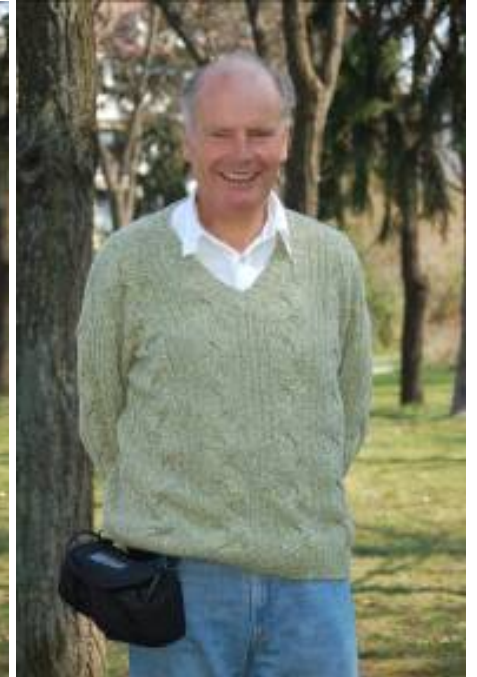
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# Milestone Review

<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	On Target
Submit TGA	Q1 2009	On Target
Commence Destination Therapy Trial	Mid 2009	On Target

# Thank You



# Share Scheme Meeting

*'That pursuant to, and in accordance with section 411 of the Corporations Act 2001, the arrangement proposed between the Company and the holders of its fully paid ordinary shares (the **Share Scheme**), the terms of which are described in the Information Memorandum, is agreed to and the board of directors of the Company is authorised to agree to such alterations or conditions as are thought fit by the Court and, subject to approval of the Share Scheme by the Court, to implement the Share Scheme with any such alterations or conditions'.*

Proxies For:	149,950,550	[78]
Proxies Against:	82,929	[8]
Proxies Open in Total:	7,486,554	[29]
- Proxies Open (Chairman)	7,297,221*	[26]

\* To be voted in favour of the resolution

# Option Scheme Meeting

*'That pursuant to, and in accordance with section 411 of the Corporations Act 2001, the arrangement proposed between the Company and the holders of options to acquire fully paid ordinary shares issued under the HeartWare Limited Employee Share Option Plan (**Option Scheme**), the terms of which are described in the Information Memorandum, is agreed to and the board of directors of the Company is authorised to agree to such alterations or conditions as are thought fit by the Court and, subject to approval of the Option Scheme by the Court, to implement the Option Scheme with any such alterations or conditions'.*

Proxies For:	3,364,204	[9]
Proxies Against:	-	[-]
Proxies Open in Total:	475,000	[1]
- Proxies Open (Chairman)	-*	[-]

\* To be voted in favour of the resolution

# Performance Rights Scheme Meeting

*'That pursuant to, and in accordance with section 411 of the Corporations Act 2001, the arrangement proposed between the Company and the holders of performance rights granted under the HeartWare Limited Performance Rights Plan ( **Performance Rights Scheme**), the terms of which are described in the Information Memorandum, is agreed to and the board of directors of the Company is authorised to agree to such alterations or conditions as are thought fit by the Court and, subject to approval of the Performance Rights Scheme by the Court, to implement the Performance Rights Scheme with any such alterations or conditions'.*

Proxies For:	600,000	[2]
Proxies Against:	-	[-]
Proxies Open in Total:	-	[-]
- Proxies Open (Chairman)	-*	[-]

\* To be voted in favour of the resolution

# Extraordinary General Meeting of Shareholders

*'That, for the purposes of section 162(m) and 422 of the US Internal Revenue Code (as amended) and for all other purposes, approval is given to the HeartWare International 2008 Stock Incentive Plan as described in section 8 and Appendix 11 of the Information Memorandum accompanying this notice of Extraordinary General Meeting'.*

Proxies For:	126,680,956	[76]
Proxies Against:	21,415,954	[9]
Proxies Open in Total:	7,478,099	[29]
- Proxies Open (Chairman)	7,278,766*	[25]

\* To be voted in favour of the resolution



Thank You