



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

30 July 2009  
**BY E-LODGE MENT**

Dear Sir / Madam

**Annual Meeting Presentation**

In accordance with ASX Listing Rule 3.13.3 the Company provides a copy of the presentation that is to be delivered today at the Company's Annual Meeting.

The Annual Meeting is being held at The Westin Sydney, 1 Martin Place, Sydney commencing at 9am (Sydney time) and may be viewed via the Company's website (see the link under Corporation Presentations).

Yours faithfully

A handwritten signature in blue ink, appearing to read "D McIntyre".

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

# HeartWare International

NASDAQ: HTWR  
ASX: HIN



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# Disclaimer

## Not an Offer of Securities

This presentation regarding HeartWare International, Inc. ("HeartWare", "we" or "us" ) is for informational purposes only. This presentation does not constitute nor does it contain an offer to sell or an invitation to buy or subscribe for securities of HeartWare. The securities described herein, if any, may not be offered or sold in the United States absent registration or an exemption from registration, and any offering of the securities by HeartWare will only be made by means of a prospectus or a private placement memorandum.

## Information Regarding HeartWare

We are subject to the periodic reporting requirements of the Securities and Exchange Act of 1934, as amended, and, accordingly, file with and/or furnish to the United States Securities and Exchange Commission ("SEC") the following forms: Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statement. Our shares are listed for quotation on the NASDAQ Stock Market LLC and the Australian Securities Exchange ("ASX") under the trading symbols "HTWR" and "HIN", respectively. Our corporate website is [www.heartware.com](http://www.heartware.com).

## Forward-Looking Statements

This presentation contains forward-looking statements that are based on our management's beliefs, assumptions and expectations and on information currently available to our management. Generally, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements, which generally are not historical in nature. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation, our expectations regarding (a) the completion of the proposed acquisition of us by Thoratec Corporation; (b) regulatory submissions and approvals; (c) our clinical trials, including enrollment in our clinical trials; (d) our intellectual property position; (e) our perceived ability to develop and commercialize our existing and new products; our estimates regarding our capital requirements.

The forward-looking statements reflect our current view about future events and are subject to risks, uncertainties and assumptions. Accordingly, you should not place undue reliance on our forward-looking statements. Except as required by law, 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. We may not actually achieve the plans, projections or expectations disclosed in our forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation those described in Part I, "Item 1A. Risk Factors" of our Form 10-K for the year ended December 31, 2008 and elsewhere in this presentation and those described from time to time in our subsequent reports filed with the SEC and ASX.

For instance, the following important factors could prevent us from achieving our goals and cause the assumptions underlying the forward-looking statements and the actual results to differ materially from those expressed in or implied by those forward looking statements: (a) inability to fund ongoing operations, including raising additional capital to support further development and growth; (b) inability to recruit, retain and motivate appropriately qualified employees; (c) unsatisfactory or uncompetitive clinical outcomes for our products (e.g. high stroke, device failure or adverse event rates); (d) lack of physician acceptance or adoption of our products; and, (e) inability to achieve and maintain regulatory approvals and consents (e.g. ISO, FDA etc). Additional information concerning our risk factors and uncertainties is contained in our filings with the SEC and ASX.

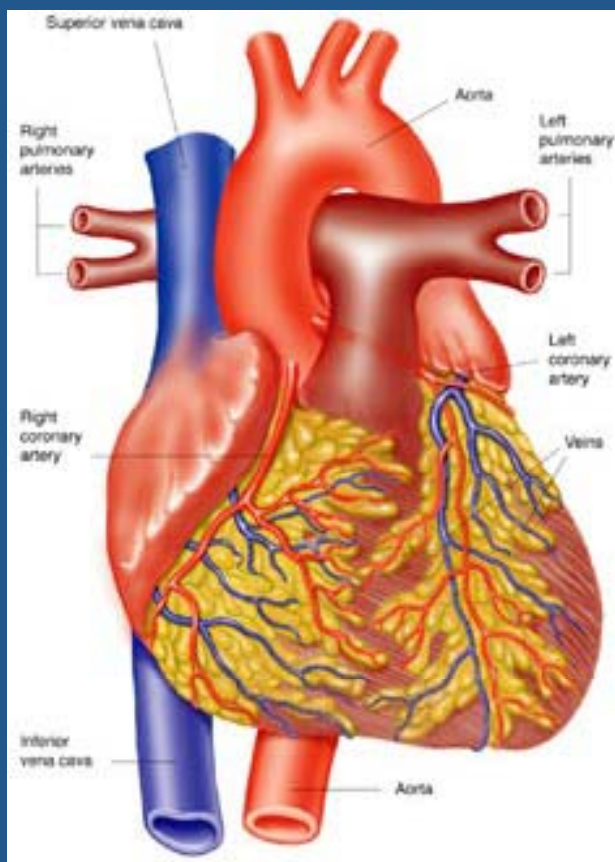
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# Agenda

- Opportunity “refresher”
- 2008 / 2009 look back
- Clinical Update – International & USA
- Market / Opportunity Update
- Product Pipeline
- Operations Update
- Corporate Update
  - Merger status
  - Upcoming Milestones

# 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

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# The HeartWare® Ventricular Assist System

- HVAD™ miniaturized implantable blood pump
  - 50cc / 140g, 50mm outside diameter
  - About the size of a “D” battery
- Up to 10 liters of flow
- Advanced Impeller is the only moving part
  - Hybrid magnetic / hydrodynamic suspension
  - Wear-less system
- Dual motors designed to provide power efficiency and redundancy
- Thin (4.2 mm), flexible driveline with fatigue resistant cables



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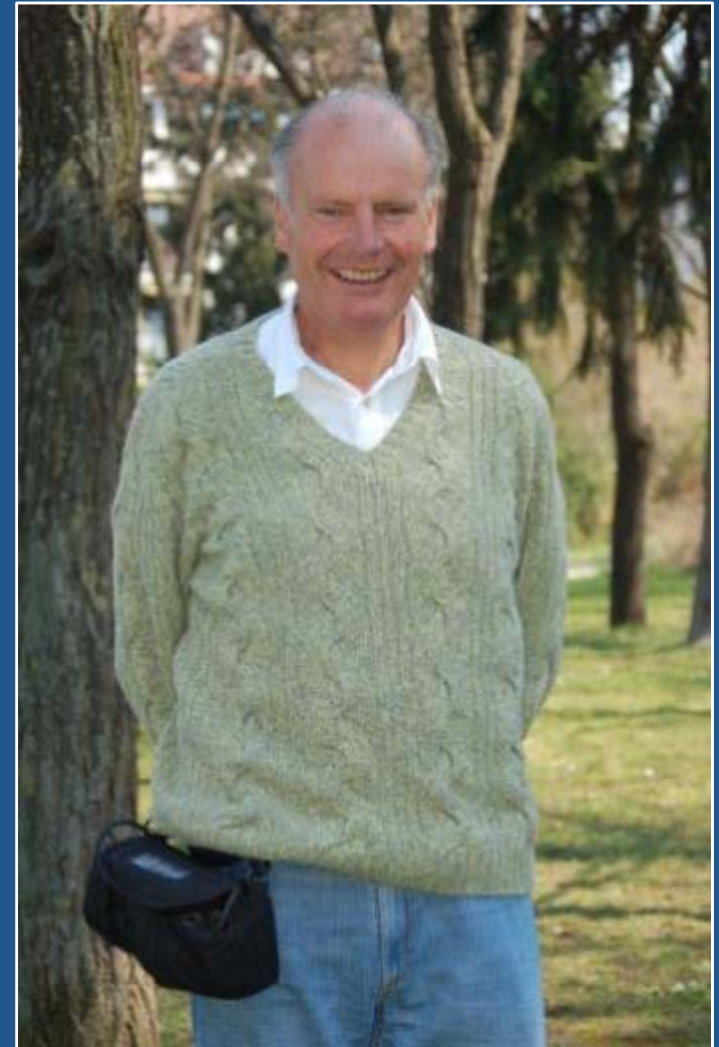
# HeartWare Peripheral Equipment

Touch screen Hospital Monitor  
with pump parameters & flow  
waveforms



Controller with LCD  
display, audible alarms  
and 30 day data storage

2 small, Lithium ION  
Batteries last 12  
hours

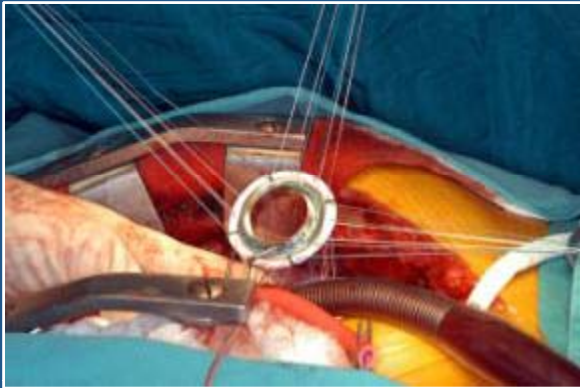


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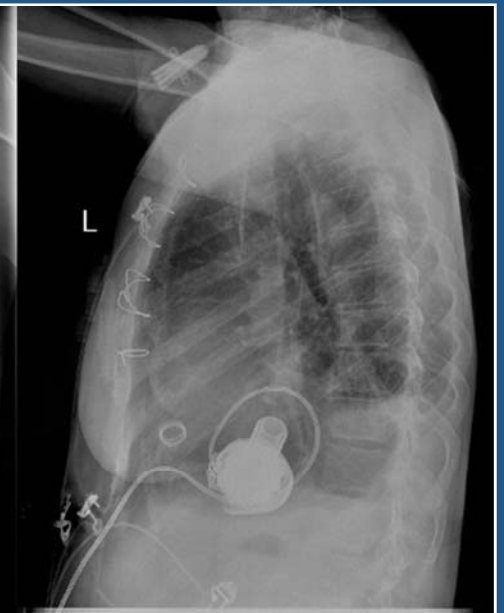
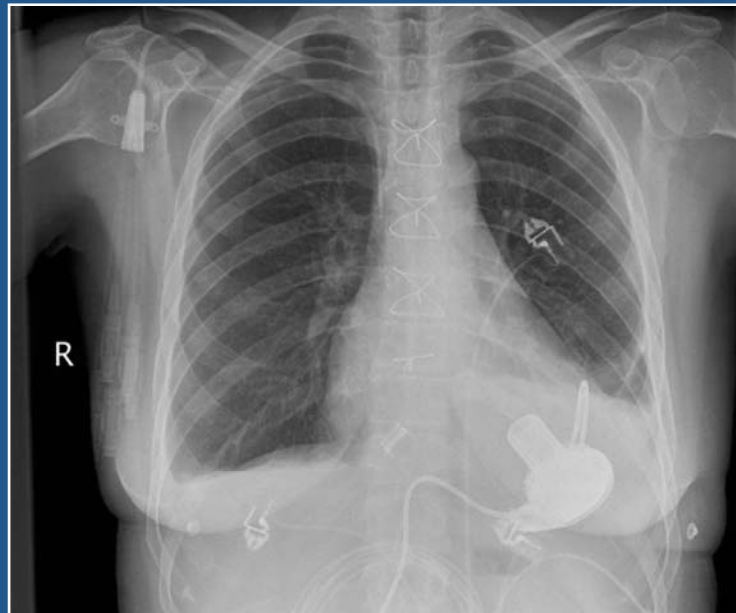
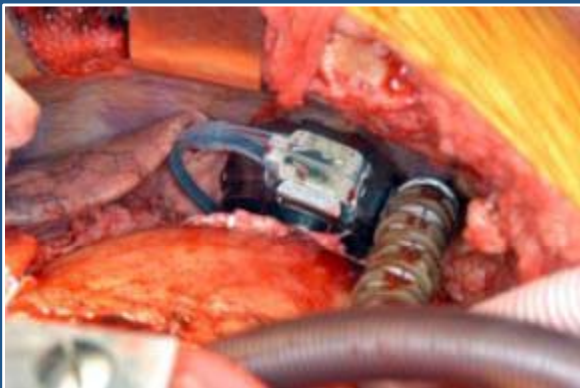


# Small Size = Pericardial Placement

*A Key Advantage resonating globally*



- No abdominal surgery
- No pump pocket
- Potential to expand treatable patients
- Could reduce blood loss
- Potential for short implant time

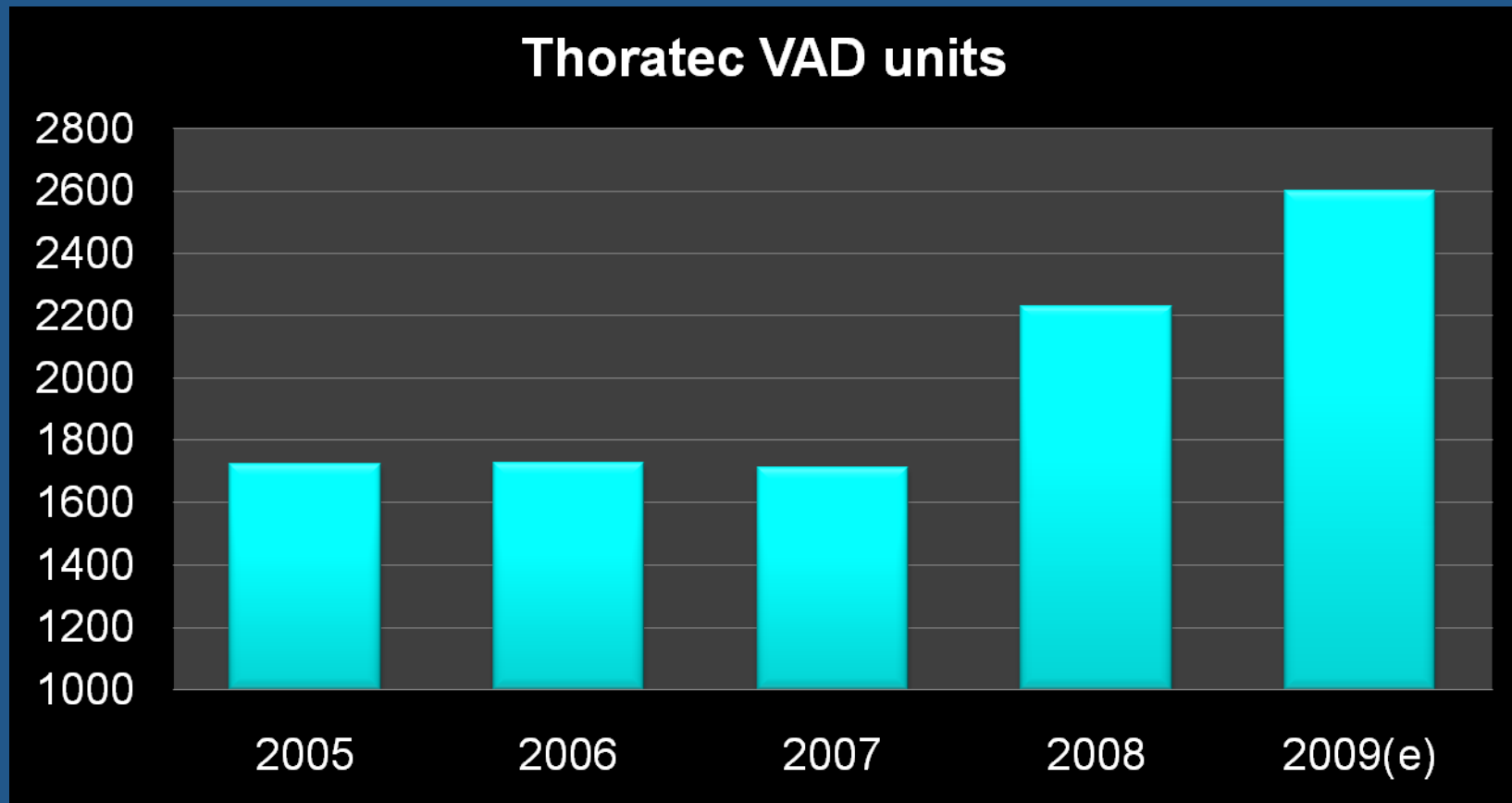


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**HeartWare**



# Backdrop: Market Growing Dramatically



VAD opportunity vastly underpenetrated due to technology shortcomings prior to 2008

Data Source: US analyst reports

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# Since Last AGM

- VAD market growth continues to exceed expectations
- International trial enrollment completed
- Patient follow-up completed with 90% survival in 50 patients
- CE mark received
- IDE approved in US
- US trial commenced and enrollment accelerating
- First commercial revenue – EU, USA and Australia
- ISO re-audit successful
- Redomiciled to US
- NASDAQ listing completed
- Entered into Merger agreement with Thoratec
- Made significant progress on pipeline technologies

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# International Trial Clinical Highlights

(n = 50)

Overall survival at 180 days	90%
Total duration of pump support	49.1 years
Average pump support	358 days
Average days on pump at time of transplant	283 days
Longest support time	882 days
Patients transplanted at 180 days	14%
Six month survival after transplant	94%
Survival in 60 and older subgroup (n =14)	93%
Significant improvements pre-implant vs. post implant hemodynamic parameters	PAP, PCWP, CI/VAD Flow Index



Presented by G. O'Driscoll, M.D. – July 31, 2009

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# International Trial Device Performance

(n = 50)

Successful pericardial placements	100%
Reduction in re-hospitalizations post implants*	80%
Average pump flow and power	6.2 L 4.8 w
Recorded <u>single</u> Battery support time	6 hrs
Peri-operative survival	96%
Shortest cardiac bypass time	21 min
Mechanical pump failures	0%
Driveline cable fractures	0%



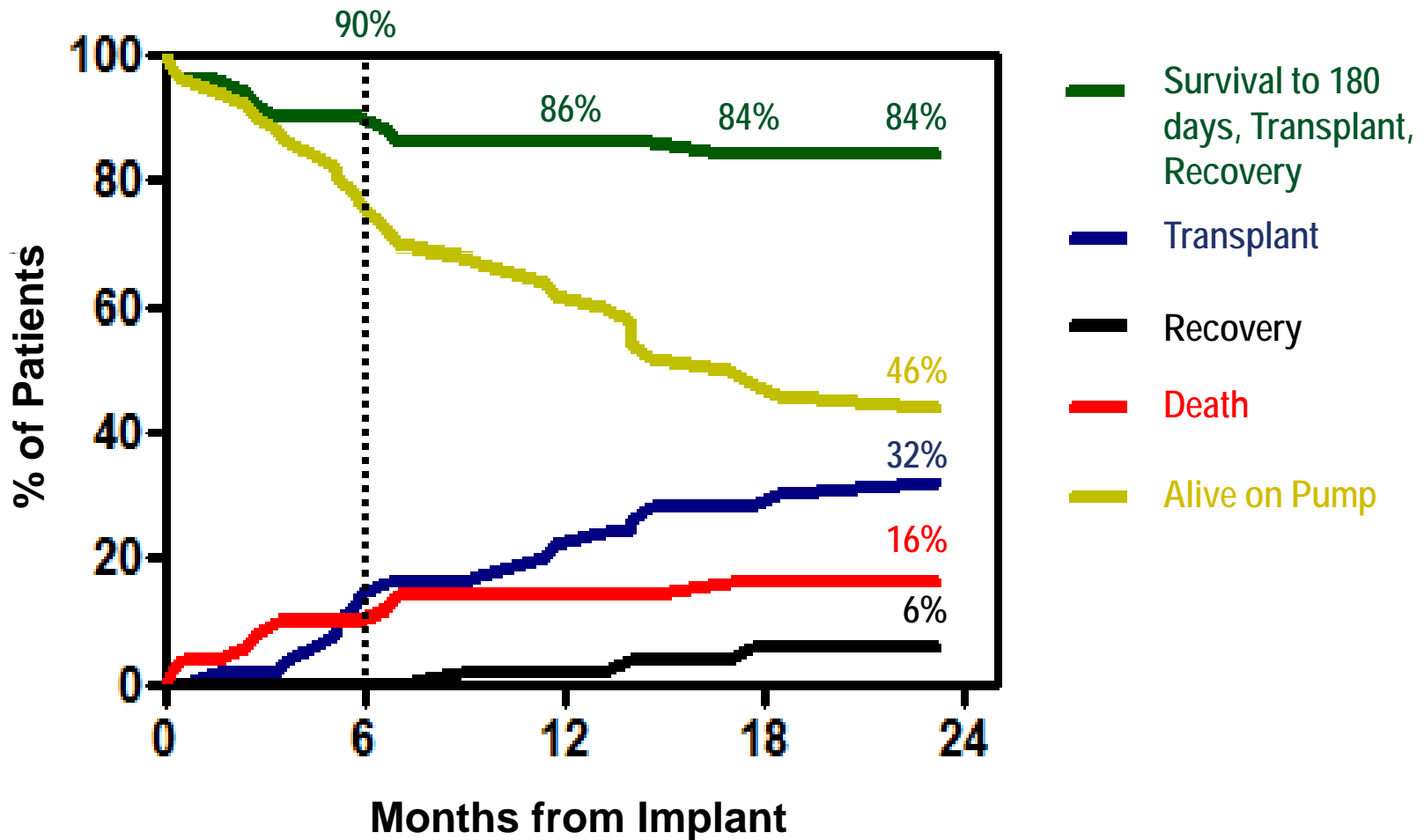
\* Compared admissions during 12 months pre-implant versus 12 months post-implant. February 2009 data analysis from MDCI, North Attleboro, MA.

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# International Trial Competing Outcomes (n = 50)



Presented by G. O'Driscoll, M.D. – July 31, 2009

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# Clinical Experience Summary

- First in human clinical trial demonstrated effective hemodynamic support and improvement in functional status and QOL
- Experience reinforces the efficacy of the design, implant technique, and long term patient support capabilities of the system
- Acceptable risk profile for serious adverse events
  - Stroke, pump exchange, bleeding, infections in line with and in some cases suggested improvement over historical VAD studies
- More clinical experience to come from commercial launch and BTT trial in the US

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# International Rollout on Plan

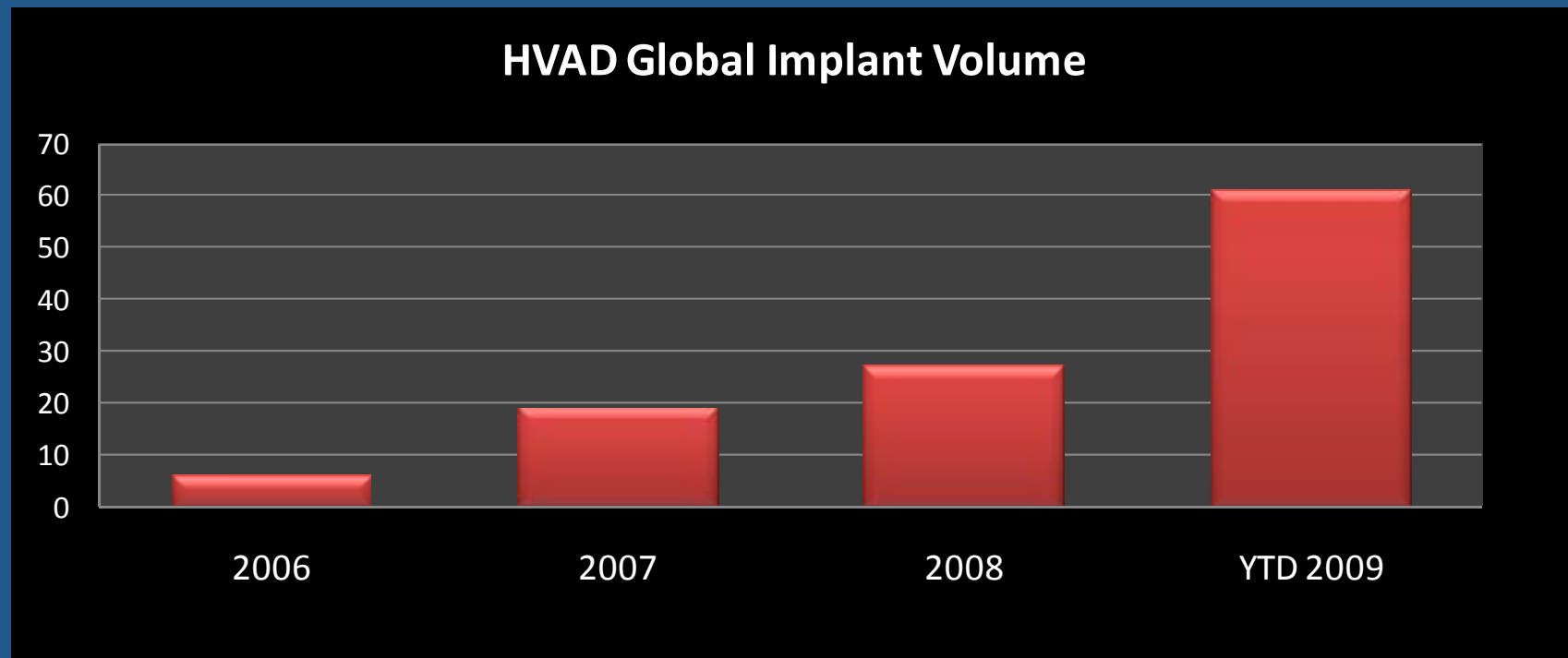
- Phase I: Convert Int'l trial sites into “Customers” in first 3 months
  - Complete
- Phase II: Expand beyond trial sites in second 3 months
  - 10 sites trained and 3 others scheduled
- Phase III: Build infrastructure and move to “Full Launch” in Q4 2009
  - Now expanding EU capabilities to meet accelerating demand.
- Reception very strong throughout EU



# US IDE Progress Strong

- Trial enrollment accelerating and now approximately 1/3 enrolled
  - Enrollment completion still expected by April 2010
- Implants completed at 12 of 16 sites with product
  - Important lesson: sites took 2-3 months post start up to begin implanting
  - Twenty sites will be initiated by end of Q3
- Demand from sites to join trial far exceeds permitted openings under IDE
- Hiring additional Clinical Specialists to accelerate addition of new sites and to manage increasing implant rate
- Destination Therapy trial design to be reviewed with FDA in Q3

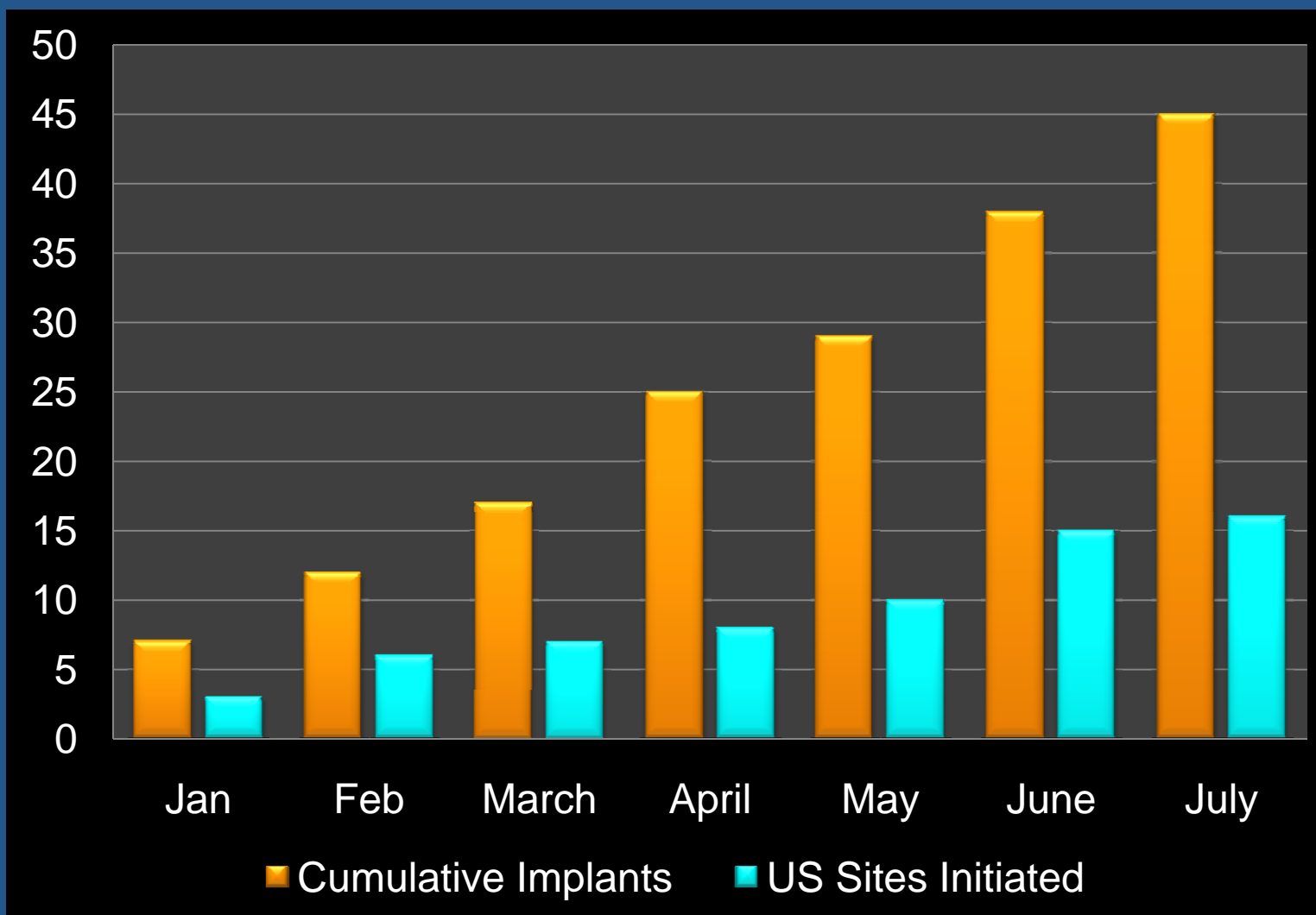
# Global Ramp is Underway



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# US IDE Implants and Sites Initiated



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# Clinical Momentum Driving Financials

- Revenue
  - Q1 2009 – US\$1.4 million
  - Q2 2009 – US\$3.0 million
  - 1H 2009 – US\$4.4 million
- Month of July 2009 – US\$1.6 million in revenue expected
- Revenue footprint growing in US and EU
  - Addition of 7-10 new sites in next 60 days
- Q2 / 2H 2009 financials released August 12

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# MVAD Platform

- Wide bladed, axial flow technology allows significant miniaturization
- Full range of outputs achievable
- Wear-less impeller suspension
- Simplified manufacturing
- Versatile, configurable and scalable
- Enables HeartWare's strategic objective of decreasing invasiveness and morbidity without decreasing efficacy

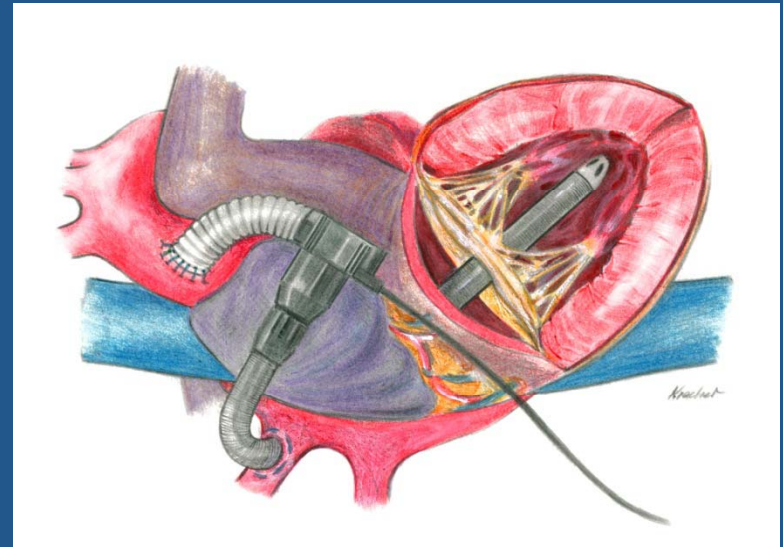


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# Trans-mitral, mini-right thoracotomy (VCAN)

- Mini-right thoracotomy
- Implant and anastomosis through single incision
- Outflow graft connected to ascending aorta
- Conducting series of chronic implant studies

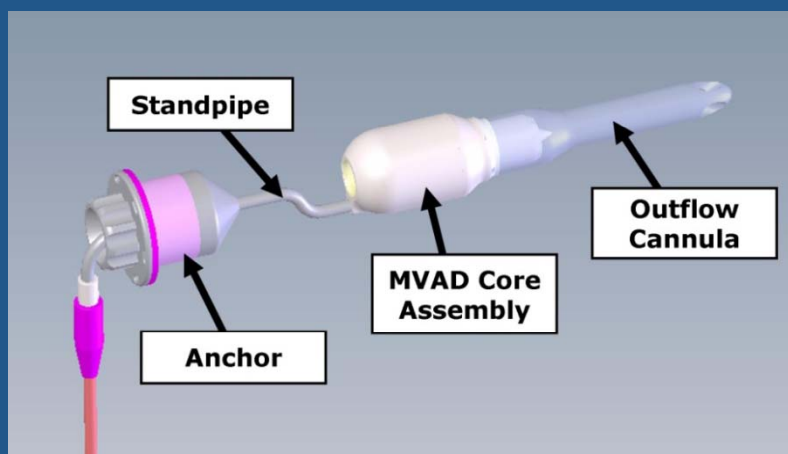
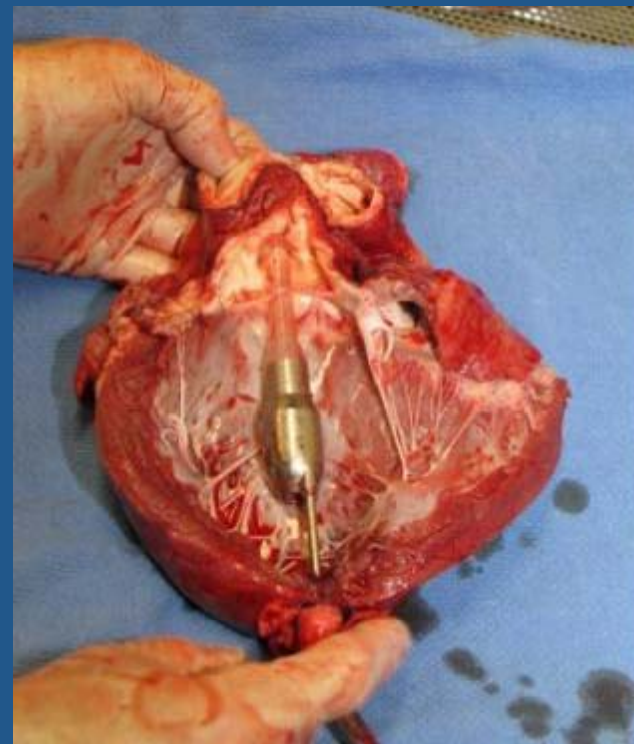


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# Trans-apical, intra-ventricular

- Trans-apical insertion
- Outflow cannula crosses the aortic valve
  - Eliminates outflow graft and anastomosis
- Results of 30 day pre-clinical implants impressive
  - No evidence of valve trauma
- Preparing first chronic studies Q4
- Targeting GLP's 1H 2010



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# Operations: No Longer a Bottleneck

- Significant progress made addressing 3 major bottlenecks in late 2008/early 2009
  - Dramatically improved yields and reduced scrap
- Pump production team now able to produce 30+ pumps per month
- Given projected demand of 2 trials in US and expanding international sales, no constraint anticipated in foreseeable future
- In process of establishing second source suppliers of critical components
- Evaluating option of bringing certain critical components in house to control quality, reduce lead time and cost

# Thoratec Transaction Status

- Entered into Merger Agreement with Thoratec on Feb 12
- Received “Second Request” from US Federal Trade Commission (“FTC”) on March 26
  - Both HeartWare and Thoratec have complied with the Second Request
- HeartWare and Thoratec have met several times with the FTC to discuss the benefits of the transaction, but there can be no assurances that the FTC will approve the merger
- FTC review process is ongoing and an FTC decision is anticipated by mid-August
  - Only the Commissioners can vote to authorize FTC to clear transaction or to seek to block the transaction by filing for a preliminary injunction in a US Federal District Court
- The HeartWare stockholders have yet to vote on the merger, and we expect to schedule a special meeting of our stockholders for that purpose after the HeartWare/Thoratec proxy-registration statement is finalized

# Other Upcoming Transaction Events

- The Merger Agreement can be terminated by either party after July 31, if the merger has not closed by then, unless either party extends the termination date to October 31 in connection with seeking FTC clearance
- Following July 31, HeartWare may draw down up to \$20M of its convertible loan facility with Thoratec
  - Currently, HeartWare may draw down up to \$12M of the convertible loan facility
- HeartWare will continue to update its stockholders of any significant developments relating to the merger, including any decision by it or Thoratec relating to the termination date of the Merger Agreement, including whether to extend the July 31 termination date, and of any decision by the FTC whether to clear or seek to block the merger

# What's Next?

Milestone	Status
CE Marking	✓
NASDAQ Listing	✓
International Revenue	✓
10 US Sites Enrolling	✓
TGA Submission	✓
Thoratec Transaction	?
10 International Sites Implanting	Q3 2009
20 US Sites Initiated	Q3 2009
Full 28 US BTT Sites Initiated	Q4 2009

Milestone	Status
100 US Implants	Q4 2009
Chronic Longhorn Study	Q4 2009
Chronic VCAN Study	Q4 2009
Select MVAD "winner"	Q1 2010
Commence MVAD GLPs	Q2 2010
Complete BTT Enrollment	Q2 2010
Commence US DT trial	1H 2010

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# Thank You



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