

HEARTWARE LIMITED

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

11 July 2008
BY E-LODGE MENT

Dear Sir / Madam

Extraordinary General 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 Extraordinary General Meeting.

The EGM is being held at the Company's auditors, Grant Thornton, at Level 17, 383 Kent Street, Sydney, commencing at 10am.

Yours faithfully

David McIntyre
Chief Financial Officer &
Company Secretary

HeartWare Limited (ASX:HTW)



Extraordinary General Meeting

11 July 2008

» **Corporate Update**

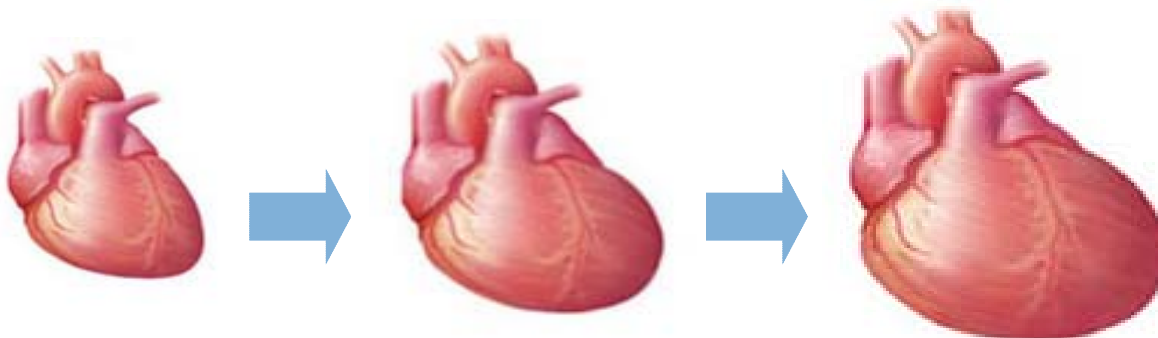
» **David McIntyre**
Chief Financial Officer

Topics

- Market Opportunity Recap
- Business Updates
 - » International Clinical Trial
 - » US Clinical Trial
 - » Pipeline Products
- Milestones

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

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 1

The HeartWare Left Ventricular Assist System

- Miniaturized implantable blood pump (50cc / 140g)
- The only centrifugal pump designed to be implanted in the chest, directly adjacent to the heart
- Capable of producing up to 10 L/Min 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

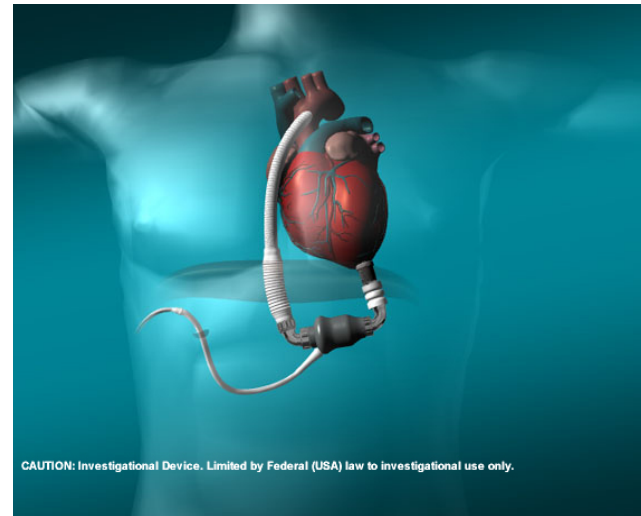


Pericardial placement – a key differentiator

Pericardial (HeartWare)



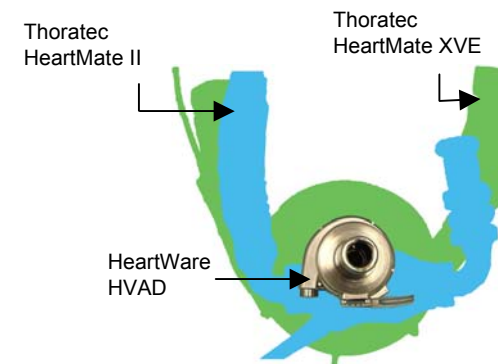
Abdominal (Others)



CAUTION: Investigational Device. Limited by Federal (USA) law to investigational use only.

Reprinted with permission from Thoratec Corporation

- » *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*



International clinical trial - overview

- Trial enrolment completed August 2007 (20 patients)
- 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	4
Hannover Medical Center	Germany	Dr Martin Strüber	16
Harefield Hospital	UK	Dr Asghar Khaghani	3
St Vincents Hospital, Sydney	Australia	Dr Paul Jansz	9
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International clinical trial – status update

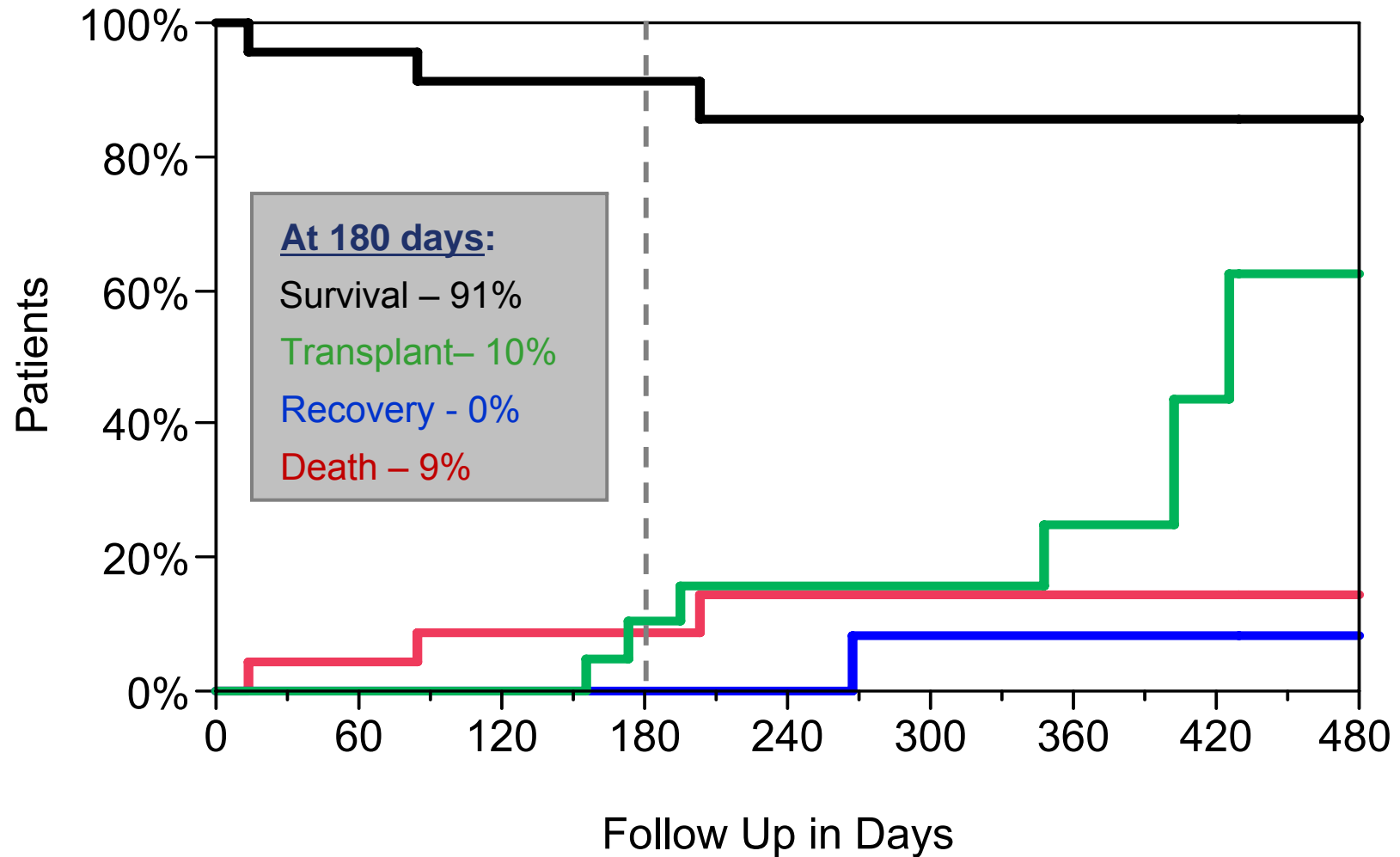
- 40 patients enrolled to date
- Cumulative support – approx 9,000 days (24+ yrs)
- Average support - 225 days per patient
- >91% survival (of first 28 patients, 26 have successfully passed trial endpoint)
- Total transplants to date - 9
- Average support days per transplant – 283 days
- Recovery patients - 2
- Longest supported patient - 558 days
- Patients supported >12 months - 10



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

International clinical trial


- data for first 23 patients presented at ISHLT



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

US clinical trial - overview

- Received conditional approval for BTT protocol on 1 May 2008
- No safety phase required; directly to pivotal
- 150 patients at a maximum 28 centers
- Utilizing NIH funded control arm (Intermacs Registry)
- Immediate patient discharge permitted
- Expect first patient July / August

	DEPARTMENT OF HEALTH & HUMAN SERVICES	Public Health Service
	Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850	
30 APR 2008		
Ms. Jennifer H. Foley VP, Clinical and Regulatory Affairs HeartWare, Inc. 205 Newbury Street, Suite 101 Framingham, MA 01701		
Re: G070199/A002 HeartWare® Left Ventricular Assist Device (LVAD) System Indications for Use: The HeartWare® LVAD System is intended for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory, advanced heart failure.		
Dated: April 2, 2008 Received: April 2, 2008 CMS Reimbursement Category: B2 Annual Report Due: One year from the date of this letter.		
Dear Ms. Foley:		
The Food and Drug Administration (FDA) has reviewed the amendment to your investigational device exemptions (IDE) application. Your application is conditionally approved because you		

US clinical trial – initial sites

- Finalizing clinical trial contract arrangements with 10+ lead centres
- CMS reimbursement running in parallel
- Very few remaining conditions with conditional IDE
- 3 sites trained
- 4 additional sites scheduled for training over next 6 weeks

Centre	Principal Investigator	Site Training Status
Texas Heart Institute	Dr. Bud Frazier	Training complete
University of Michigan	Dr. Francis Pagani	Training complete
Ohio State University	Dr. Benjamin Sun	Training complete

Product pipeline – pump miniaturization

HVAD™



MVAD™



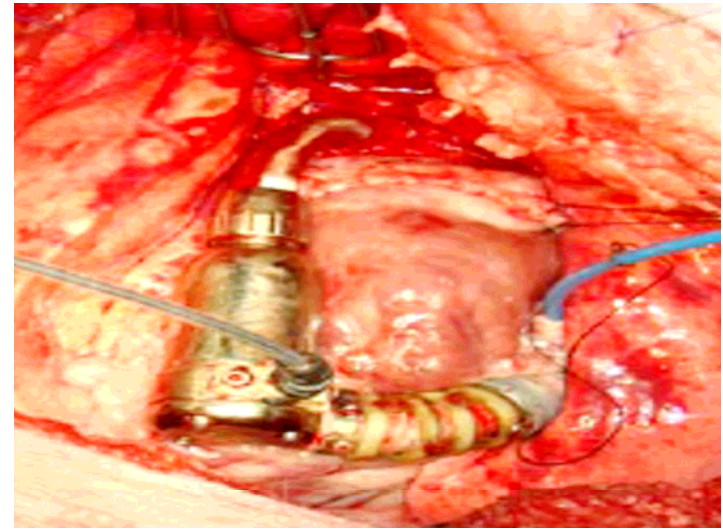
IV-VAD



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

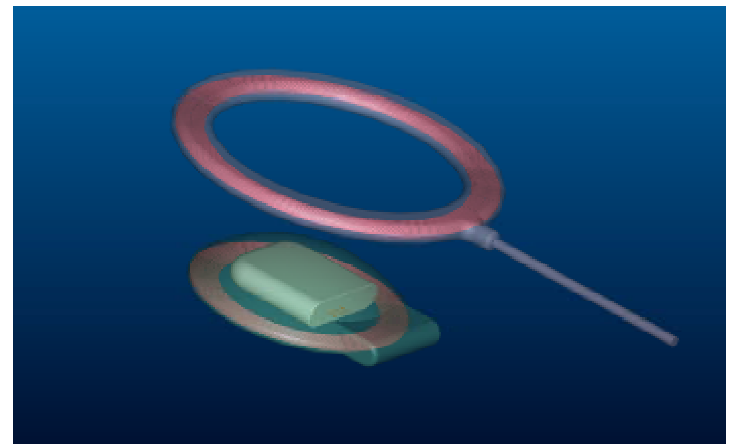
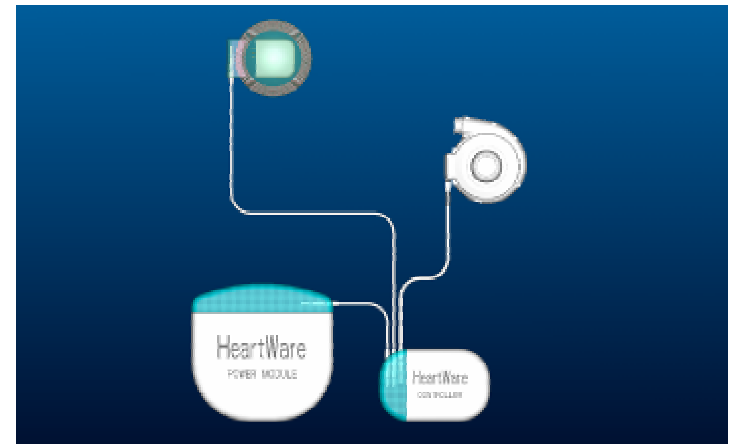
MVAD showing promise and versatility

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



Product pipeline – TET System

- 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; now refining performance attributes*



Key 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	✓
Capital raising	Q2 2008	✓
Commission new manufacturing facility	Q3 2008	On Target
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	Q3 2008	On Target
First revenue	Q3 2008	On Target



Thank You