

HeartWare Limited (ASX:HTW)



» **Doug Godshall**
*Chief Executive
Officer*

» **Annual General Meeting**
23 May 2007



Agenda

- Clinical Trial Update
- Operational Update
- Our Market Opportunity
- Our Future
- Milestones and Timeline
- Financial Snapshot



Saving and transforming quality of life

Before the procedure:

- » *Couldn't sleep lying down*
- » *Couldn't digest food*
- » *Constantly cold*
- » *Could barely walk up stairs*
- » *Took several minutes to tie his shoes*
- » *Was "waiting to die..."*

6 Months Later:



9 Months Later:



HeartWare's first patient, approximately 6 and 9 months following surgery at Vienna General Hospital in March 2006

The HVAD™ Clinical Trial

- Exceptional early results
 - » 13 patients implanted
 - » 12 patients surviving
 - » ~2,000 days of cumulative support
 - » 3 patients successfully transplanted
 - » 5 patients successfully passed endpoint
- All 5 centers enrolling patients
 - » Vienna
 - » Perth
 - » Hannover
 - » Harefield
 - » St Vincent's



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



What our investigators say

- “The surgery took ...significantly less than the time typically required to implant other devices.”

Dr George Wieselthaler, Vienna General Hospital, March 2006

- “... eliminating the need for abdominal surgery and minimizing both bleeding and infection risks.”

Dr Gerry O’Driscoll, Royal Perth Hospital, October 2006

- “... reduces the complexity of the surgical procedure and presents clear and distinct clinical advantages.”

Dr Martin Strüber, Hannover Medical Center, January 2007

- “I am convinced that this pump marks a significant step forward in the treatment of end stage heart failure.”

Dr Paul Jansz, St Vincent’s Hospital Sydney, April 2007



Our observations after 13 patients

- The HVAD™ survival data to date is unprecedented for an early experience
 - » *Thoratec HeartMate II data has established the benchmark at 75% survival to 180 days*
 - » *Of HeartWare's first 13 patients, 12 are alive and doing well.*
- Extrapolation of our data suggests clinical results that would be unparalleled in the sector
- The HVAD™ is performing as well or better than expected
- Our investigators consider the pump to provide clear and obvious advantages relative to competing LVADs



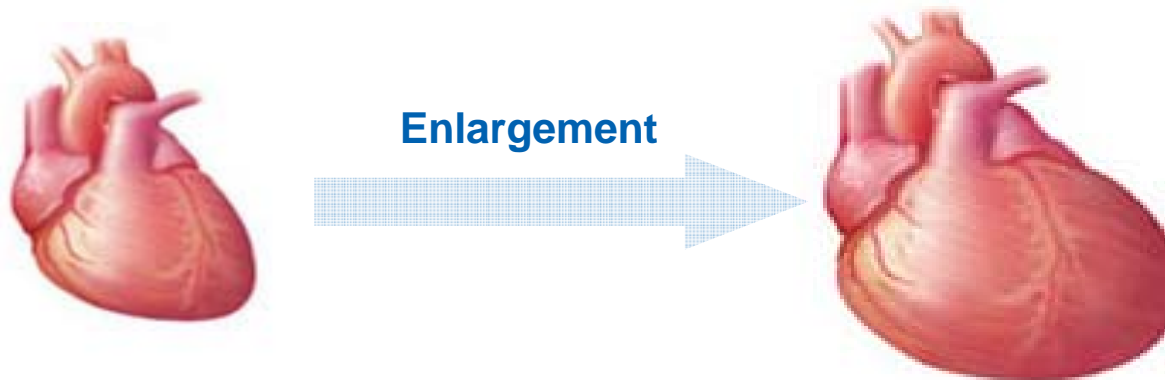
Operational Update

- Completing the transition from an R&D organization to a medical device manufacturing operation
 - » *Significant investment in systems, fixtures and equipment upgrades*
 - » *Not finished yet but tremendous progress*
- Successful upgrade of Quality System
 - » *Independent mock audit complete and Pre-audit conducted by Notified Body*
 - » *ISO accreditation anticipated during Q3 2007*
- Have moved focus to upgrading supplier performance
- Conducting strategic analysis of all critical technologies and processes
 - » *Dual Source suppliers, vertically integrate where control is essential, eliminating human variability*



Heart Failure is a dramatic issue for society

- A degenerative and terminal disease
- Affects over 10 million people globally (5 million in the US)
 - » *1 million new cases diagnosed every year*
 - » *Affects 1% of population under 50 years old*
 - » *Affects over 15% of population over 75 years old*
 - » *300,000 U.S. deaths per annum*
- At least 1 million patients in NYHA Class IV, the end-stage of the disease
- Enormous cost to society
 - » *Estimated U.S. cost of \$30B in 2006 - most expensive disease for Medicare*

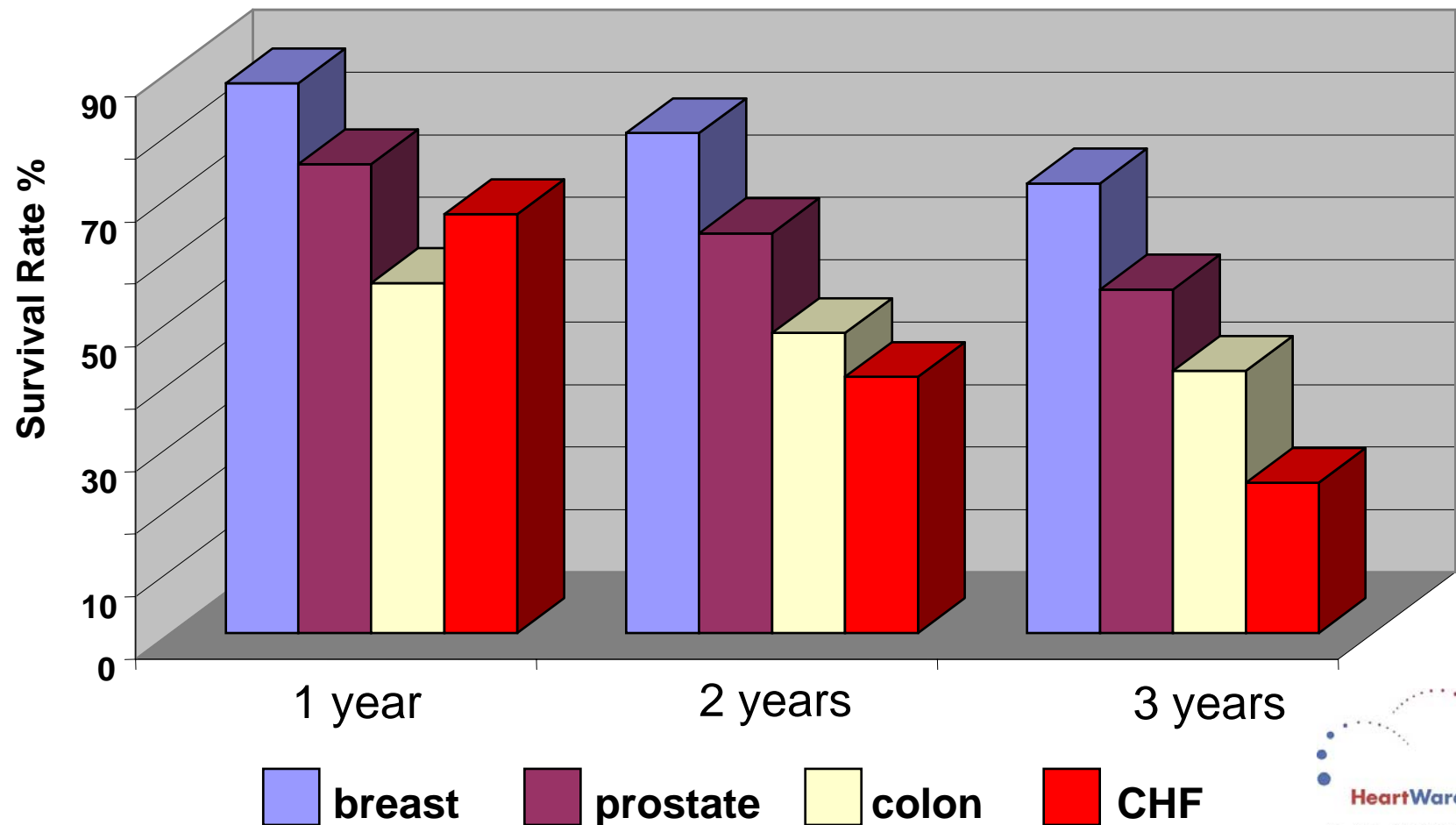


Source: Circulation, AHA update, February 14, 2006
Heart Failure Society of America/NHLBI



HeartWare Limited © 2006

Mortality rate comparison: NYHA Class IV Heart Failure –v- Malignant Tumors



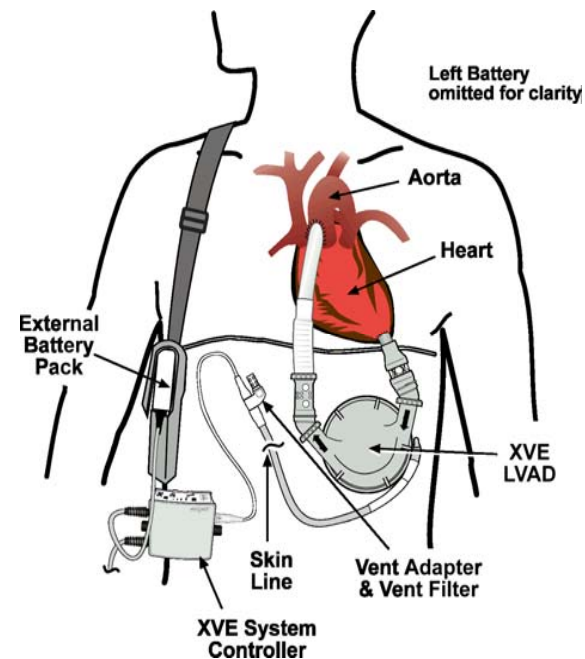
LVAD's are the only viable option for most

- Heart transplantation remains the *gold standard* of treatment
 - » *Fewer than 4,000 donor hearts available each year*
 - » *Many patients not suitable for transplantation*
- Alternative therapies don't work
 - » *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 is the only therapy that can fully rehabilitate patients from NYHA class IV to class I
 - » *Data continues to improve and demonstrate long term benefits*
- NIH estimates 100,000 US patients per year could benefit from LVADs
 - » *Medicare & Medicaid reimbursement – US\$136,000 for implant (~US\$75,000 for device)*
 - » **\$7B potential market**



The market has been constrained by sub-optimal technology

- Large device size
- Invasive surgery
- Risk of infection
- Adverse G.I. effects
- Limited durability
- Risk of stroke due to blood clots



Reprinted with permission from Thoratec Corporation

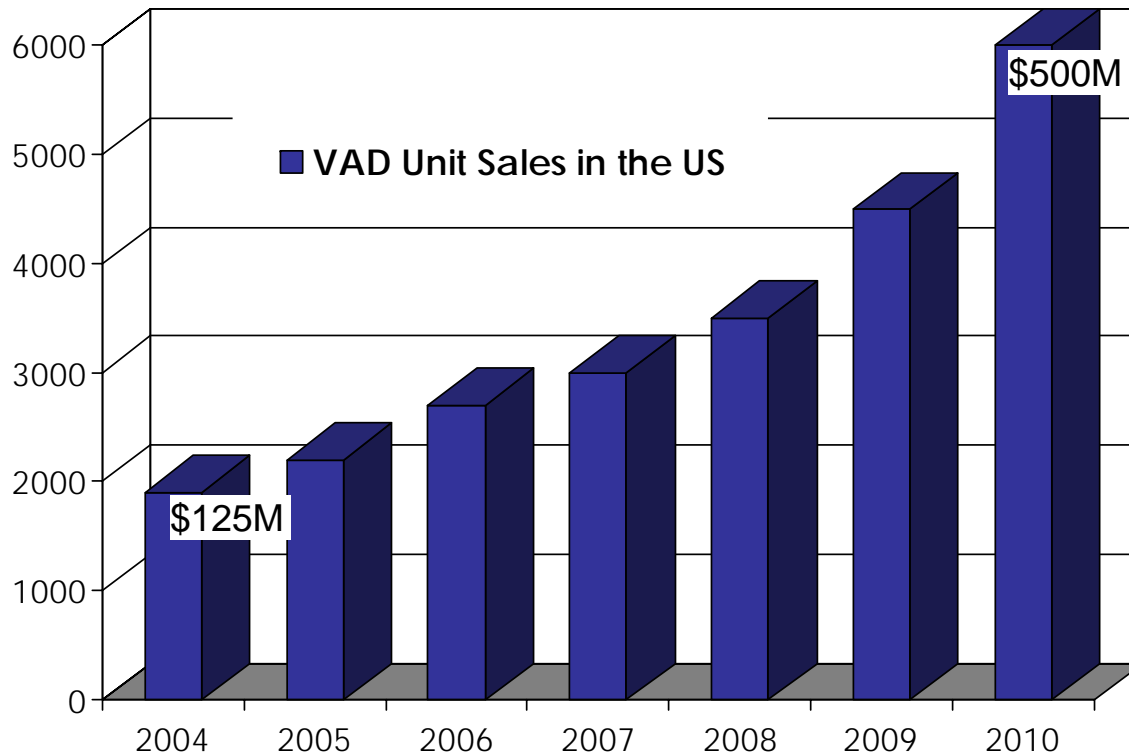
The Thoratec HeartMate XVE - the only VAD with FDA approval for Destination Therapy

Source: NHLBI Working Group, April 2005:
Limitations of Currently Available VADs



HeartWare Limited © 2007

The LVAD market is poised to accelerate



- >12% pa compound growth in past 3 years with no new technology since 1998
- 2007 will see the first new pump; Thoratec's Heartmate II

Source: 2006 Frost and Sullivan, US Congestive Heart Failure Device Markets; and HeartWare internal projections



Clinical validation continues to grow

Long-Term Results in Patients With Idiopathic Dilated Cardiomyopathy After Weaning From Left Ventricular Assist Devices

Michael Dandel, MD; Yuguo Weng, MD, PhD; Henryk Siniawski, MD; Hans B. Lehmkühl, MD; Roland Hetzer, MD

Background—Since our first successful left ventricular assist device (LVAD) implantation for idiopathic dilated cardiomyopathy (IDCM) in 1995, an additional 31 IDCM patients have been treated. Echocardiographic evaluations during repeated “off-pump” trials were the primary criteria for weaning. In this study, we assessed the reliability of our weaning criteria in patients with long-term experience.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Left Ventricular Assist Device and Drug Therapy for the Reversal of Heart Failure

D. Tansley, F.R.C.S.,
George, M.R.C.S., B.Sc.,
J. Burke, F.R.C.Path.,
Khaghani, F.R.C.S.,
F.R.S.

MECHANICAL CIRCULATORY SUPPORT

Hospital Costs for Left Ventricular Assist Devices for Destination Therapy: Lower Costs for Implantation in the Post-REMATCH Era

Leslie W. Miller, MD,^a Karl E. Nelson, RN, MBA,^b Robert J. Shroeder, MD, PhD,^c and James W. Long, MD, PhD^b

Background: The use of left ventricular assist device (LVAD) for destination therapy (end of life support), is an increasingly common clinical scenario.

Change in Quality of Life From After Left Ventricular Assist Device Implantation to After Heart Transplantation

Left ventricular assist devices: an alternative to medical therapy for end-stage heart failure

Branislav Radovancevic, MD, Bojan Vrtovec, MD, and O.H. Frazier, MD

Although aggressive medical therapy and ultimately cardiac transplantation have long been the therapeutic mainstays for

Heart failure has been defined as “a complex clinical syndrome that can result from any structural or func-



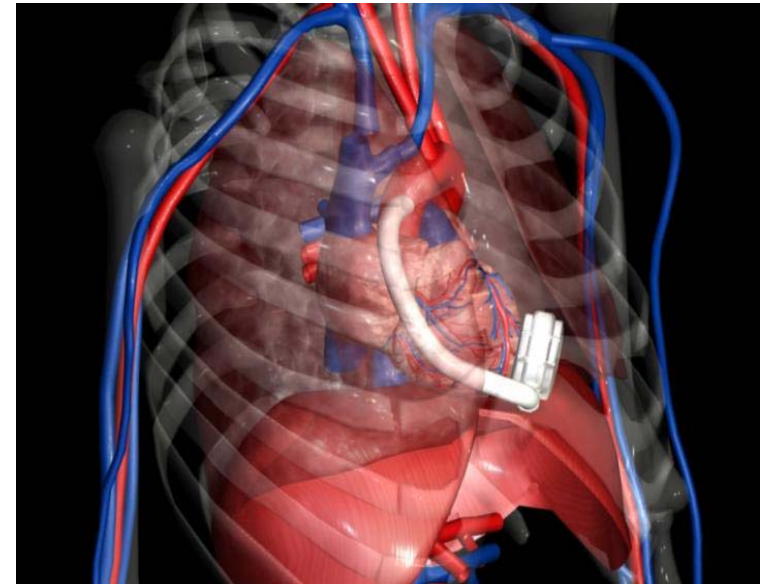
Other positive developments

- Thoratec shut down next generation platform – Heartmate III
- Arrow shut down Coraide program
- Multi-center trial initiated to investigate “recovery” indication
- International market growing rapidly
- FDA approved first non-traditional destination therapy trial design
- Medicare expanded reimbursement to include non-transplant centers



The HeartWare HVAD™ addresses the clinical need

- **The smallest full output pump available**
 - » *Thoracic placement – no abdominal surgery*
 - » *Shorter and less complex procedure (~ 1.5 hours) relative to competing devices*
 - » *No pump pocket*
- **Excellent blood flow characteristics**
 - » *Minimal haemolysis*
- **Long term reliability**
 - » *One moving part, no mechanical bearings, wear-less suspension*
 - » *Dual motor stators*
 - » *Designed for 10+ years of pump performance*

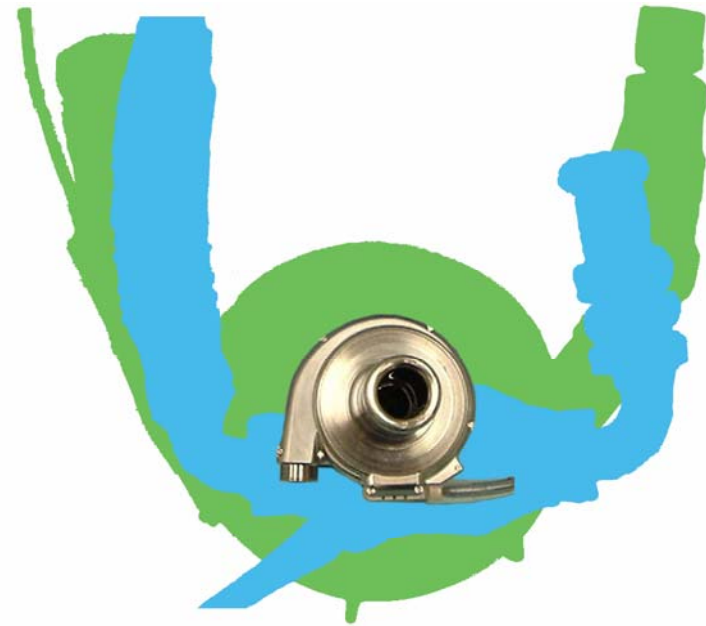


The HVAD™ pump is implanted directly into the apex of the left ventricle



Size REALLY matters

- The HeartWare HVAD™ pump is the only full output LVAD implantable within the pericardial space in all patients
 - » *No abdominal surgery*
 - » *No pump pocket infections*
 - » *No GI distress related to abdominal wall pressure*
 - » *Reduced procedural invasiveness and complexity*
 - » *Very short pump implant time*
 - » *Low procedural morbidity*
 - » *Reduced recovery time*



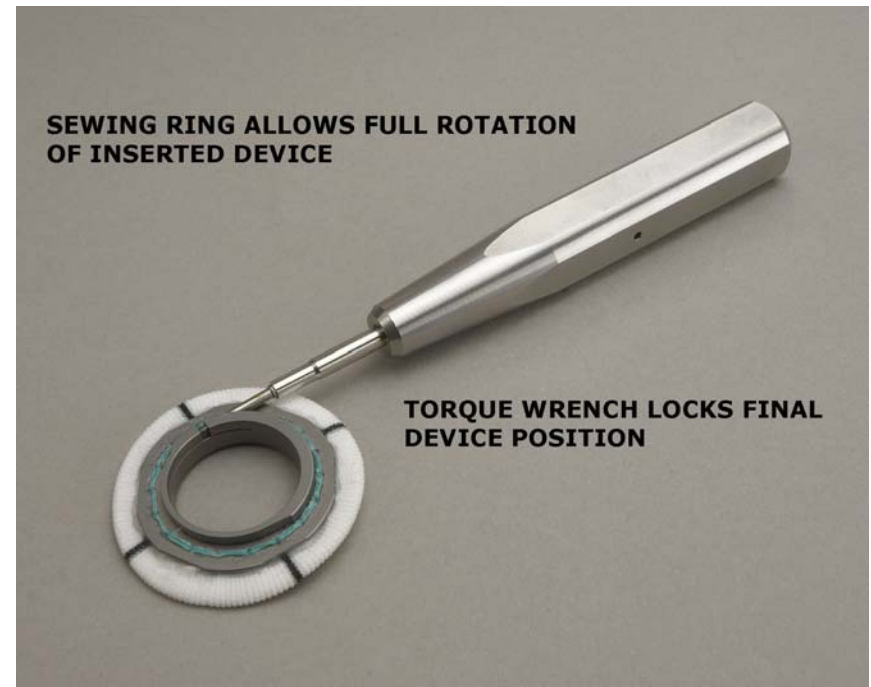
HeartWare stacks up well vs. other full output systems

	Mechanical Bearings	Electro-Magnetic	Passive Bearing	HVAD™ Pump
Anatomic Location	Red	Red	Red	Green
Durability	Yellow	Yellow	Green	Green
Efficiency	Red	Yellow	Green	Green
Ease of Implant	Yellow	Red	Yellow	Green



What wins in medical devices?

- ✓ *Easier to Use*
- ✓ *Lower complications*
- ✓ *Less invasive procedure*
- ✓ *Shorter recovery time*
- ✓ *Shorter procedure time*
- ✓ *Smaller devices with similar outcomes*
- ✓ *Simple, reproducible procedure*
- ✓ *Easily understood benefits*
- ✓ *Fast Follower*



Focusing on 2 key platforms

- Pumps
 - » *Optimize HVAD performance by tightening specifications and refining processes*
 - » *Exploring new opportunities to significantly improve production yields and decrease cost*
 - » *Acceleration of miniaturization pipeline immediately following submission of HVAD™ System IDE*
- Electronics
 - » *Establishing self sufficiency in software and hardware design*
 - » *Creating best of class peripheral system*
 - » *Advanced prototyping of implantable electronics*



Getting bigger by getting smaller

HVAD™



MVAD™



IV-VAD

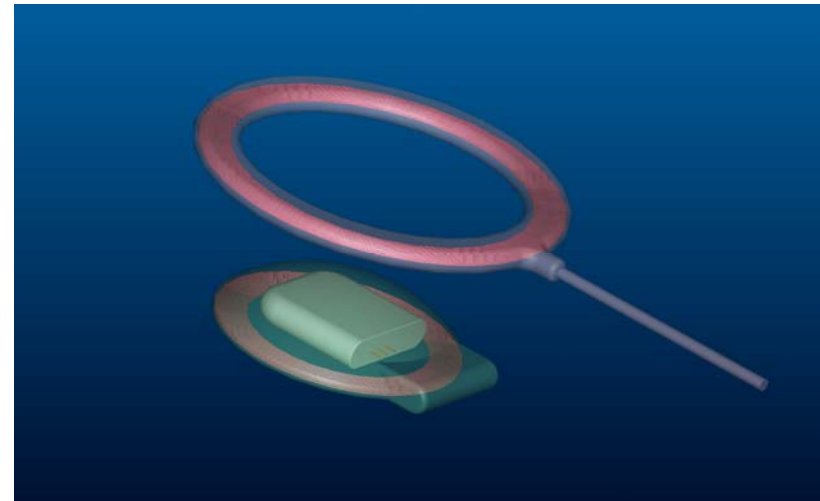
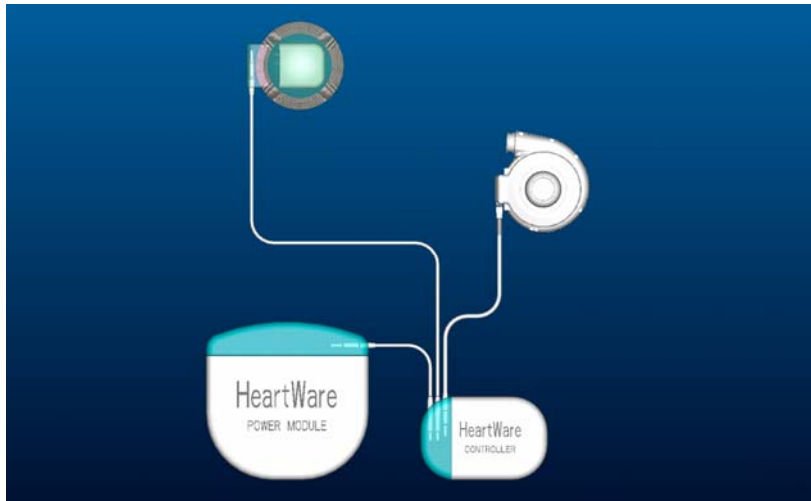


Procedure	Surgical	Minimally Invasive	Catheter Delivery System
Flow	10 L/min	10 L/min	3 L/min
Patient Class	Late Class IV	Class IV	Class III / Early Class IV
Treatable Pop.	100,000	350,000	1,000,000
Potential Market	\$7bn	\$15bn	\$30bn



The next major advancement: TETS

- Transcutaneous Energy Transfer
 - » Enables transfer of energy and information across the skin
 - » Replaces driveline cable
 - » Eliminates risk of driveline complications
 - » Enables patient to enjoy an improved quality of life by being un-tethered for extended periods
 - » TETS system compatible with HVAD™ pump, MVAD™ pump and IV-VAD platforms



Intellectual Property Portfolio

- 20 years of patent protection, and counting
 - » 15 granted patents in the US and 17 applications pending
 - » 29 patents granted internationally and 15 applications pending

Patent Expiration Dates

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
Rotary Blood Pump	X	X	X	X			X		X	X		X	
Axial Flow Pump									X	X			
Surgical Tools											X		
Intravascular Pump													X

} Issued patents
 } Pending application
 } Provisional

Project status and next milestones

- **MVAD™ pump preclinical development progressing well**
 - » *Acute animal studies demonstrate pump haemocompatibility comparable to HVAD™*
 - » *Current focus is to develop a minimally invasive implant procedure and associated surgical tools*
 - » *3 separate studies conducted this year evaluating implantation without sternotomy*
 - » *Chronic implants in next 12 months*
- **HVAD™ pump**
 - » *Right ventricle preclinical studies being planned for late 07 to expand indication to biventricular support*
- **Transcutaneous Energy Transfer System (TETS) at working prototype stage**
 - » *Proof of concept and early prototype achieved for fully implantable electronics and peripherals*
 - » *Higher power experiments and advanced prototyping in next 6 months*

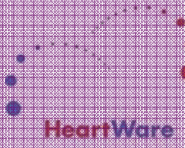
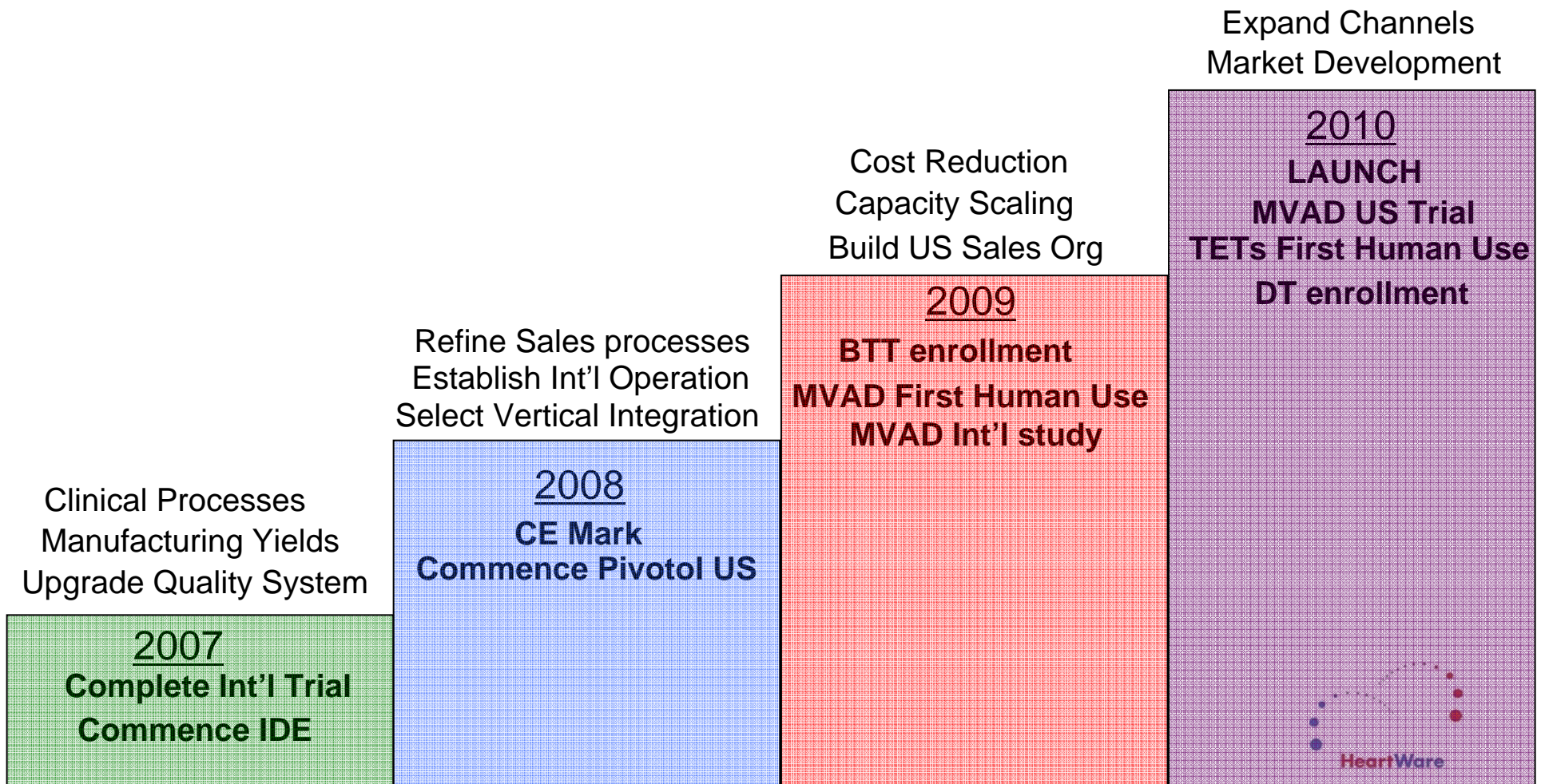


Operational plans for the next 12 months

- **Clinical**
 - » *Complete International trial enrollment – Q3 2007*
 - » *Submit regulatory filing to European Notified Body - Q4 2007*
 - » *Submit IDE application to FDA – Q3 2007*
 - » *Implant first patient in US Trial – Q4 2007*
 - » *CE mark and European commercial launch – Q1 2008*
- **Manufacturing**
 - » *Complete quality audit and gain ISO13485 certification – Q3 2007*
 - » *Increase production capacity to > 15 pumps per month – Q4 2007*
- **Marketing**
 - » *Establish International sales and marketing infrastructure – Q4 2007*
- **Corporate**
 - » *List ADR on NASDAQ Exchange – Q3 2007*



Progressing towards market leadership



Financial position

- Cash on hand AU\$15.4M (at 31 March 07)
- Burn Rate ~AU\$2M per month
- First revenue Anticipated early 2008
- Shares on issue ~ 186M
- Market Cap AU\$140M
- Number of employees 70
- Apple Tree Partners 49% of outstanding shares
- Top 20 shareholders 73% of outstanding shares

Based on share price of \$0.75

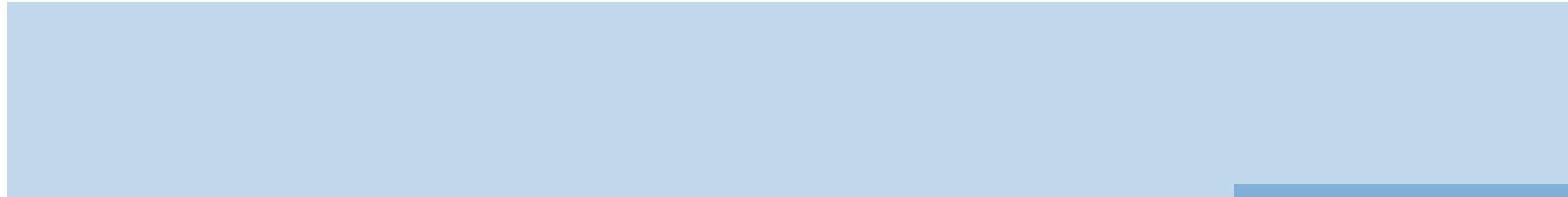


Summary

- Heart Failure is a disease of epidemic proportions
- LVADs are emerging as the only viable treatment option
- HeartWare has the most compelling LVAD in the clinic today AND the most advanced pipeline of future products

Right Pump, Right Time, Right Team





Thank You



A photograph of the Washington Hospital Center building, a large multi-story structure with many windows. In the foreground, there is a green lawn and some trees. The text is overlaid on the image.

***MiniVADs Will Be Most
Effective and Economical
Treatment for ESHF***

Steven W. Boyce, M.D.

Surgical Director, Congestive Heart Failure Program

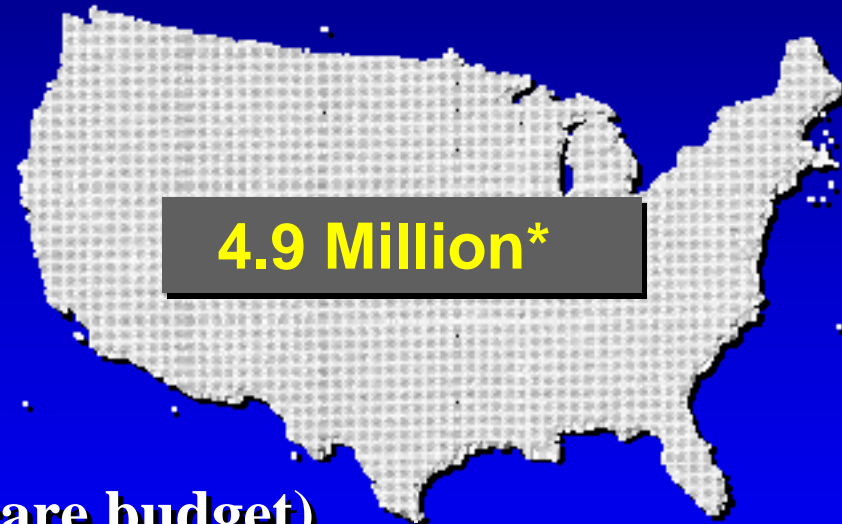
Washington Hospital Center

Washington, D.C.

End-Stage Heart Failure

The Epidemic

- **Nearly 5 million people in USA currently diagnosed with CHF (15 million worldwide)**
 - 1 million NYHA III
 - 0.5 million NYHA IV
- **550,000 new cases/year**
- **Over 287,000 deaths/yr**
- **CHF is the #1 DRG (\$52 B or > 5% of the healthcare budget)**
- **WHO predicts CHF will be the leading cause of mortality in the world by 2010**



**Heart and Stroke: American Heart Association, 1997*

End-Stage Heart Failure

Morbidity and Mortality

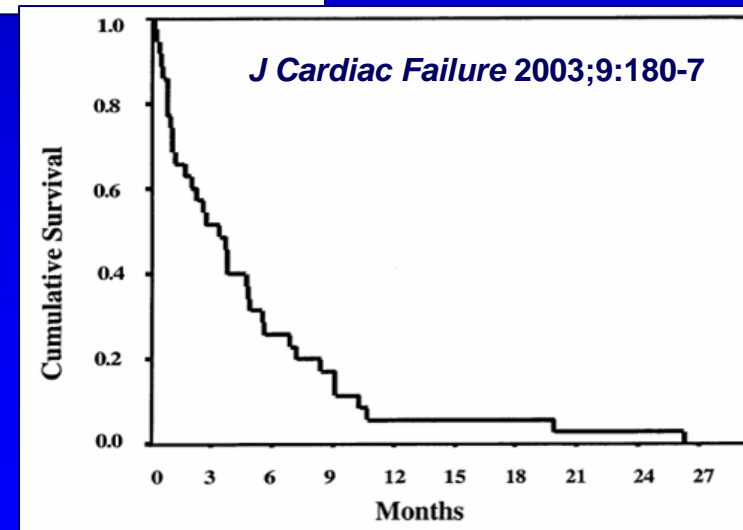
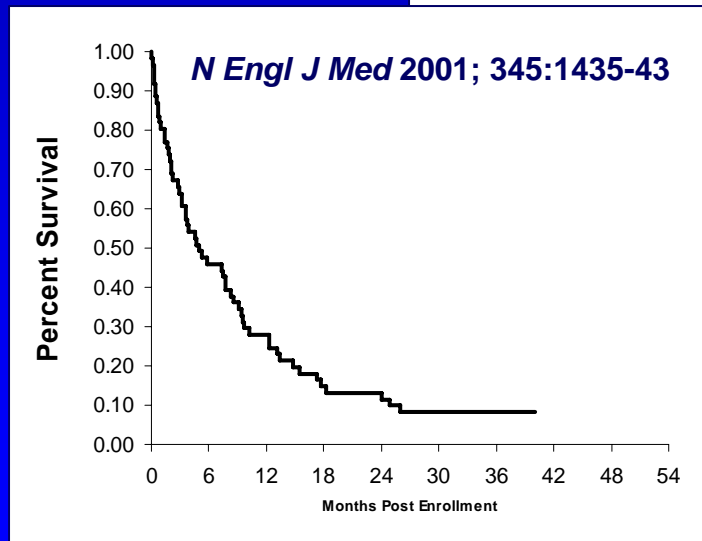
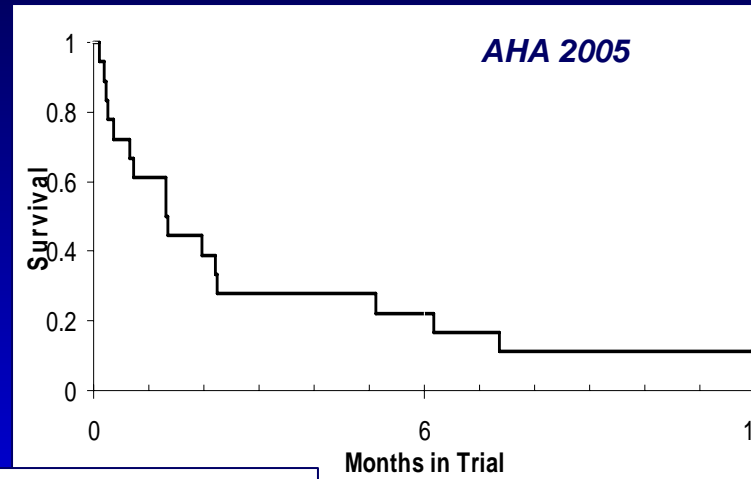
- **Stage D HF has 30-78% mortality/yr, with only 30% being sudden death**
(Davis, et al. Am J Hospice and Palliative Medicine. 22 (3); May/June 2005: 211-22).
- **COSI* Study of 36 inotrope-dependent stage D HF pts: 46 re hosp, median survival 3.4 mos, with 6% one year survival**
(Hershberger RE, et al. J Card Fail. 2003 Jun; 9(3): 188-91).



* *COSI: Continuous Outpatient Support with Inotropes*

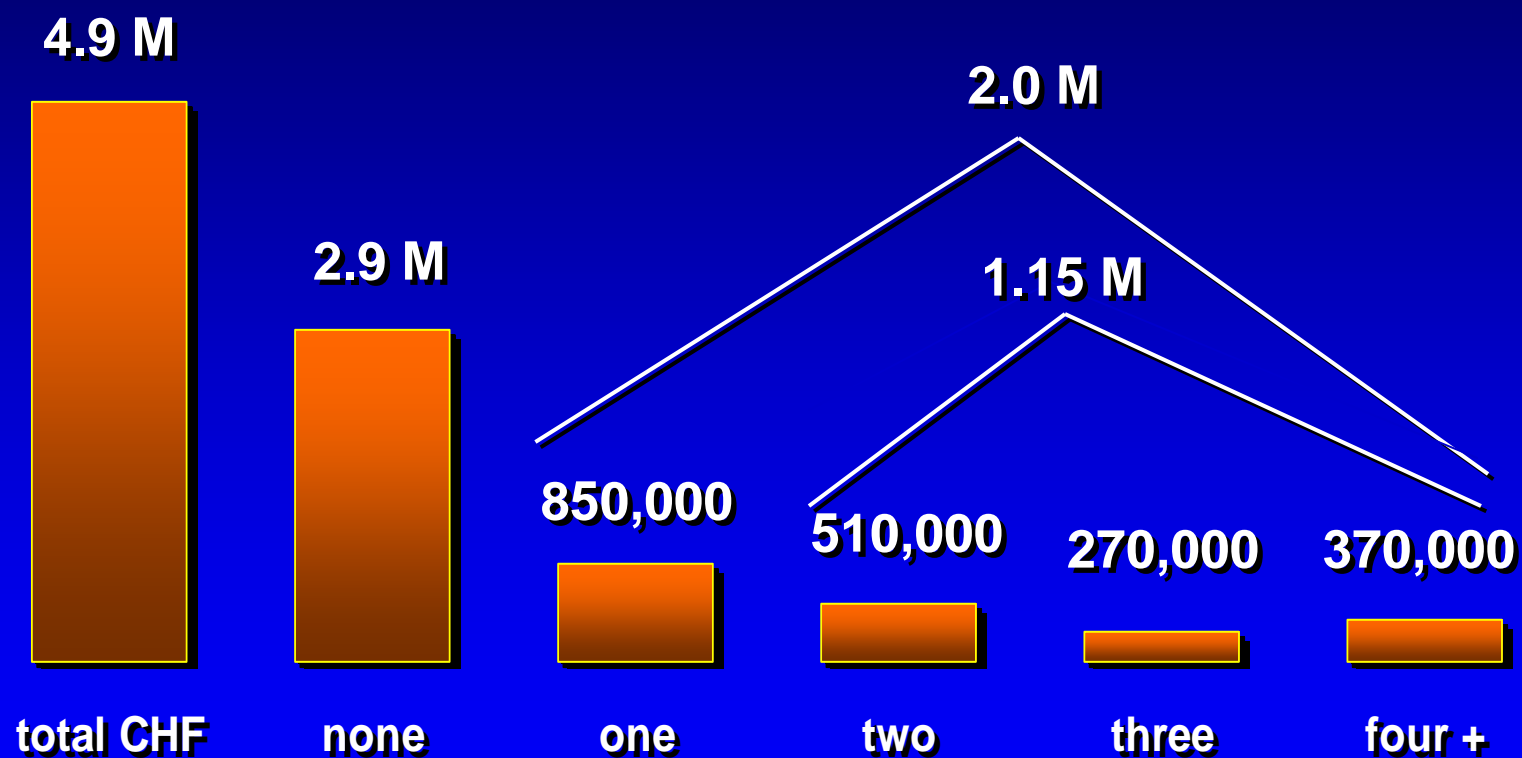
Survival of Stage D Patients

Optimal Medical Therapy



End-Stage Heart Failure

One Year Hospital Admissions



Market Insights. San Francisco: 1998; Cardiology Roundtable Analysis

HeartWare Limited (ASX:HTW)



» ANNUAL GENERAL MEETING

» 23 MAY 2007



Resolution No. 1



That the Remuneration Report (which forms part of the Directors' Report) for the year ended 31 December 2006 be adopted

Resolution No. 2



That Dr Denis Wade AM, who retires by rotation in accordance with the Company's Constitution, and being eligible offers himself for re-election as a Director, be re-elected as a Non-Executive Director

Resolution No. 3



That Dr Seth Harrison, who retires by rotation in accordance with the Company's Constitution, and being eligible offers himself for re-election as a Director, be re-elected as a Non-Executive Director

Resolution No. 4



That Mr Robert Stockman, who was appointed as a Director by the Board of the Company in accordance with the Company's Constitution with effect from 11 December 2006, and being eligible offers himself for re-election as a Director, be re-elected and confirmed as a Non-Executive Director

Resolution No. 5



That the appointment of Mr Douglas Godshall, who was appointed as Managing Director by the Board of the Company in accordance with the Company's Constitution with effect from 28 October 2006, be confirmed for the purposes of the Company's Constitution