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

23 May 2007 **BY E-LODGEMENT**

Dear Sir / Madam

Annual General Meeting Presentation Material

In accordance with ASX Listing Rule 3.13.3 the Company provides a copy of the material that will be delivered today at the Company's Annual General Meeting.

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

The AGM may also be viewed by webcast at the Company's website (www.heartware.com.au).

Yours faithfully

David McIntyre

Chief Financial Officer &

Company Secretary

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 HVADTM 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 HVADTM 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 HVADTM 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 HVADTM is performing as well or better than expected
- Our investigators consider the pump to provide clear and obvious advantages relative to competing LVADs



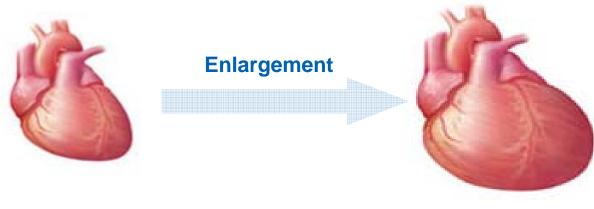
Operational Update

- 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



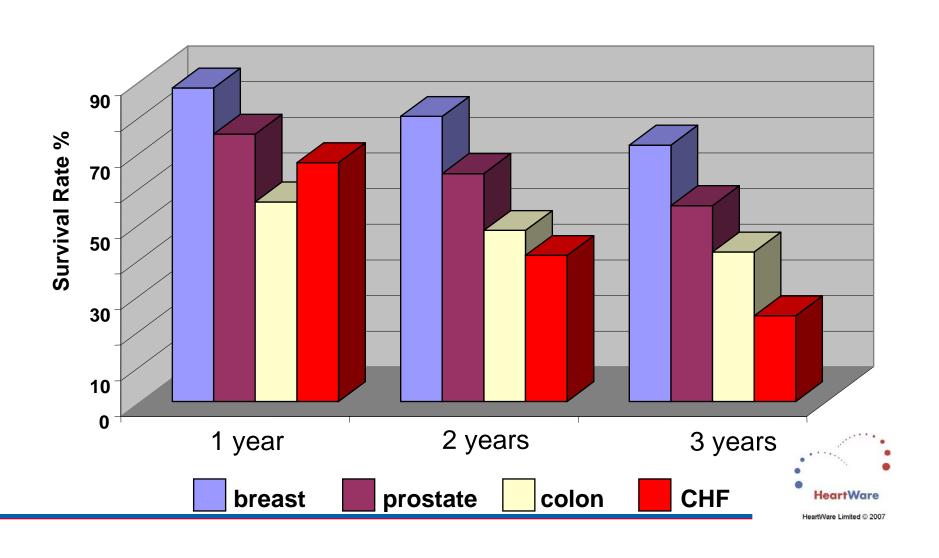
Heart Failure is a dramatic issue for society

- 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





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



LVAD's are the only viable option for most

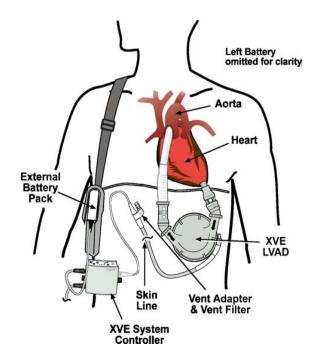
- Heart transplantation remains the gold standard of treatment
 - » Fewer than 4,000 donor hearts available each year
 - » Many patients not suitable for transplantation
- Alternative therapies don't work
 - » Drugs & pacing do not halt disease progression
 - » Surgical techniques and other devices have 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

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

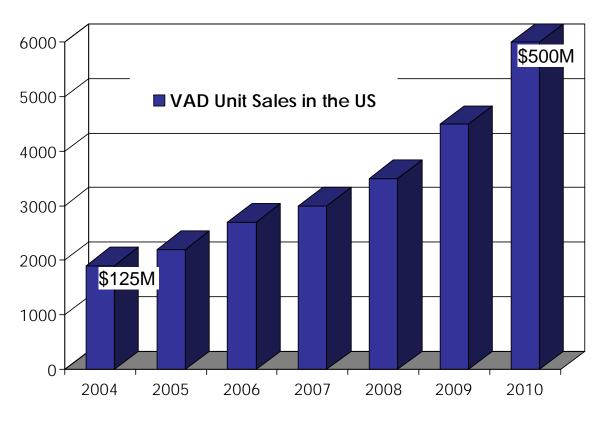


Reprinted with permission from Thoratec Corporation

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



The LVAD market is poised to accelerate



- >12% pa compound growth in past 3 years with <u>no new</u> <u>technology since 1998</u>
- 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 Siniaws Hans B. Lehmkuhl, MD; Roland Hetze

Background—Since our first successful left ventricular assist device (LVA dilated cardiomyopathy (IDCM) in 1995, an additional 31 IDCM pati Echocardiographic evaluations during repeated "off-pump" trials were the years of experience, we assessed the reliability of our weaning criteria in

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

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

MECHANICAL CIRCULATORY SUPPORT

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

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 Ro and James W. Long, MD, PhD^b

Background: The use of left ventricular assist dev therapy (end of life support), is an inc 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-



HeartWare Limited © 2007

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 HVADTM addresses the clinical need

The smallest full output pump available

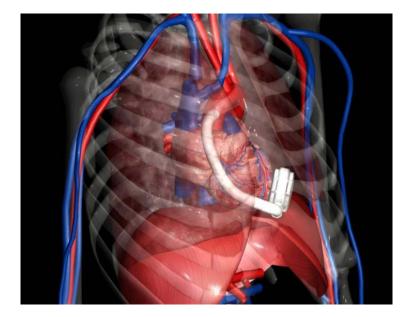
- » Thoracic placement no abdominal surgery
- » Shorter and less complex procedure (~ 1.5 hours) relative to competing devices
- » No pump pocket

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

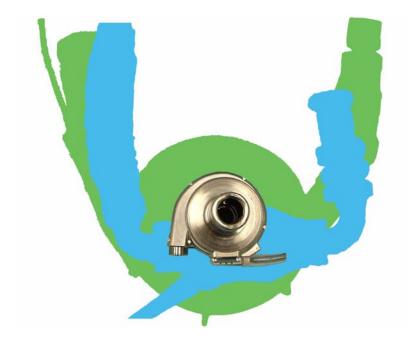


The HVADTM pump is implanted directly into the apex of the left ventricle



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				
Durability				
Efficiency				
Ease of Implant				



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

HVADTM

MVADTM

IV-VAD







Procedure	Surgical				
Flow	10 L/min				
Patient Class	Late Class I\				
Treatable Pop.	100,000				

Potential Market \$7bn

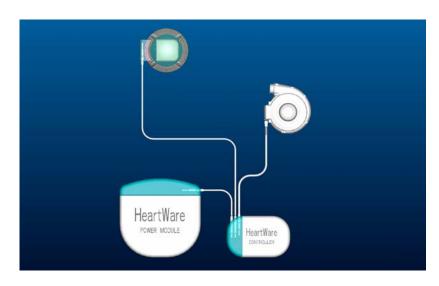
Minimally Invasive
10 L/min
Class IV
350,000
\$15bn

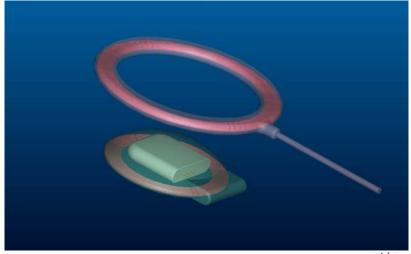
Catheter Delivery System
3 L/min
Class III / Early Class IV
1,000,000
\$30bn



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	х	x	x	x			X		x	x		x	
Axial Flow Pump									x	x			
Surgical Tools											х		
Intravascular Pump													х
										<u></u>			
Issued patents							Pending application Provisiona						

Project status and next milestones

- MVADTM 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
- HVADTM 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

Market Development <u>2010</u> **Cost Reduction** LAUNCH Capacity Scaling **MVAD US Trial** Build US Sales Org **TETs First Human Use** DT enrollment 2009 Refine Sales processes **BTT** enrollment Establish Int'l Operation **MVAD First Human Use** Select Vertical Integration **MVAD Int'l study** 2008 Clinical Processes **CE Mark** Manufacturing Yields **Commence Pivotol US Upgrade Quality System** 2007 **Complete Int'l Trial** Commence IDE

Expand Channels

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

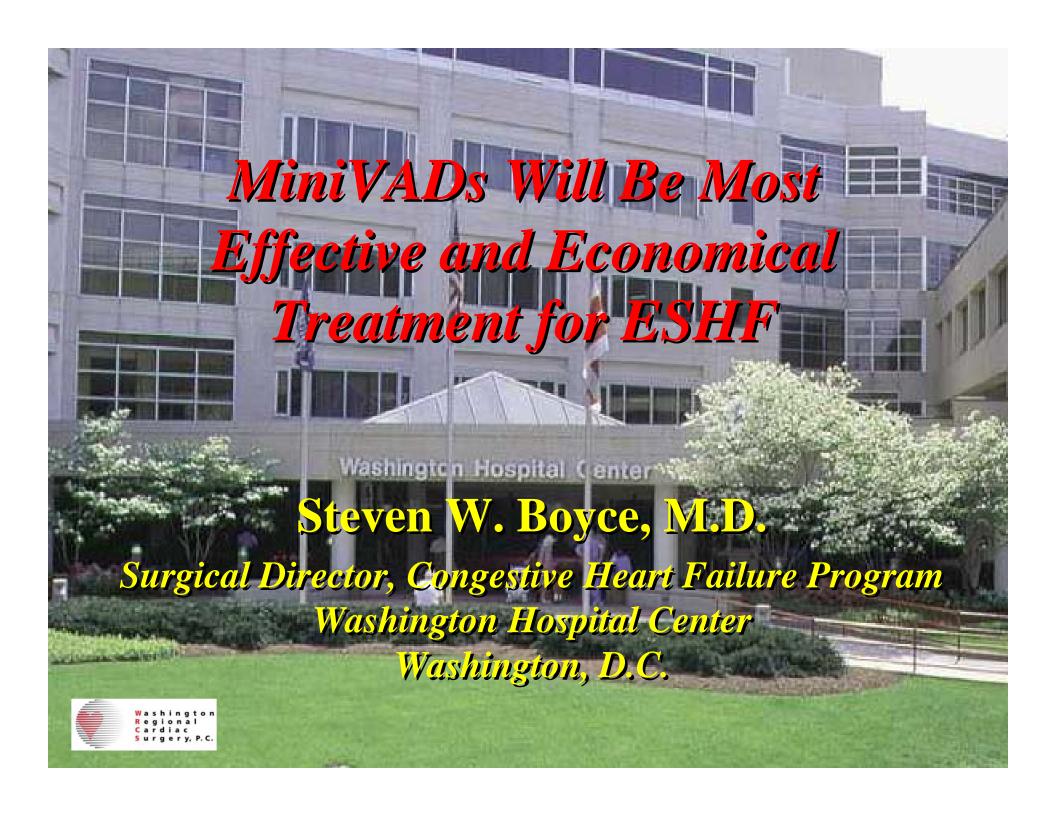
- Heart Failure is a disease of epidemic proportions
- LVADs are emerging as the only viable treatment option
- HeartWare has the most compelling LVAD in the clinic today <u>AND</u> the most advanced pipeline of future products

Right Pump, Right Time, Right Team



Thank You





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





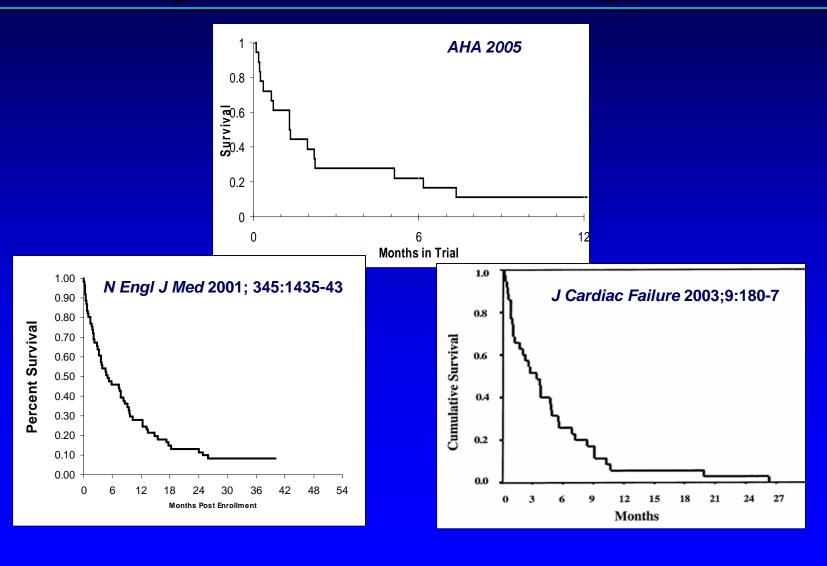
4.9 Million*

End-Stage Heart Failure *Morbidity and Mortality*

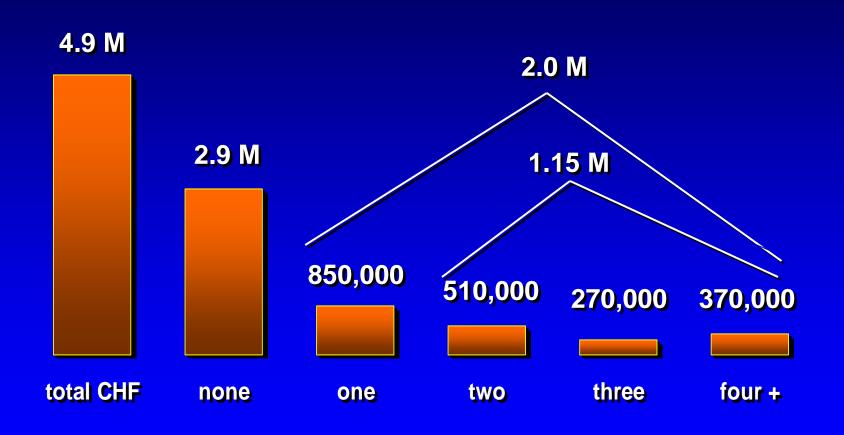
- Stage D HF has 30-78% mortality/yr, with only 30% being sudden death (Davis, et al. Am J Hospice and Palliative Medicine. 22 (3); May/June 2005: 211-22).
- COSI* Study of 36 inotrope-dependent stage D HF pts: 46 rehosp, median survival 3.4 mos, with 6% one year survival (Hershberger RE, et al. J Card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



Survival of Stage D Patients Optimal Medical Therapy



End-Stage Heart Failure One Year Hospital Admissions





HeartWare Limited (ASX:HTW)



» ANNUAL GENERAL MEETING

» 23 MAY 2007





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



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



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



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 reelection as a Director, be re-elected and confirmed as a Non-Executive Director



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