HeartWare International (ASX: HIN)

» **Corporate Update**
January 2009

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CEO

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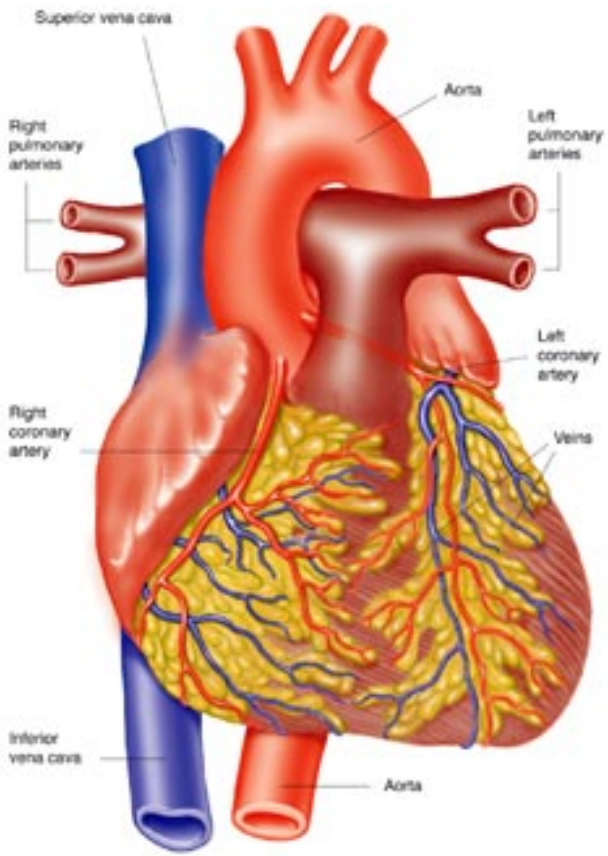
Overview

- HeartWare is developing the world's smallest implantable pumps for the treatment of advanced heart failure
- Heart failure is nearing epidemic with few good treatment options
- The HeartWare® HVAD is demonstrating promising clinical results
- CE mark and first European sales anticipated in February 09
- US clinical trials and US revenue have commenced
- Encouraging progress of next generation products
- Company has transitioned to US and NASDAQ listing is imminent

Heart Failure



Source: Circulation, AHA update, January 2008
Heart Failure Society of America / NHLBI

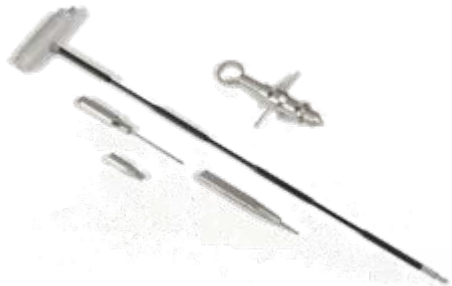
- A degenerative and terminal disease
- Affects over 20 million people globally (5+ million in the US)
  - » *1 million new cases diagnosed every year*
  - » *300,000 deaths per year in the US*
- At least 1 million patients in NYHA Class IV, the end-stage of the disease
- In the US, heart failure represents 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

All signs Point to Market Expansion

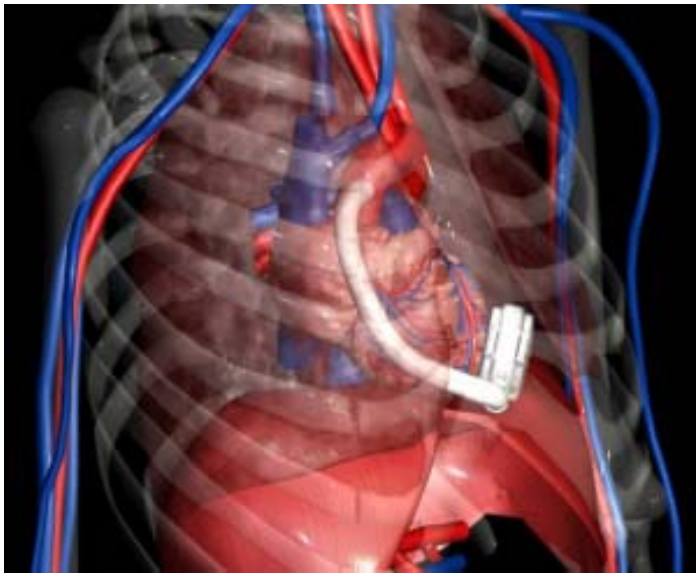
- Aging population
- Decreasing transplant availability
- Outcomes for VADS improving markedly
- VAD sizes decreasing (generally) and reliability improving
- Reimbursement stable to increasing
- MI survival improving; primary contributor to HF pool
- Market undergoing substantial growth with Heartmate II

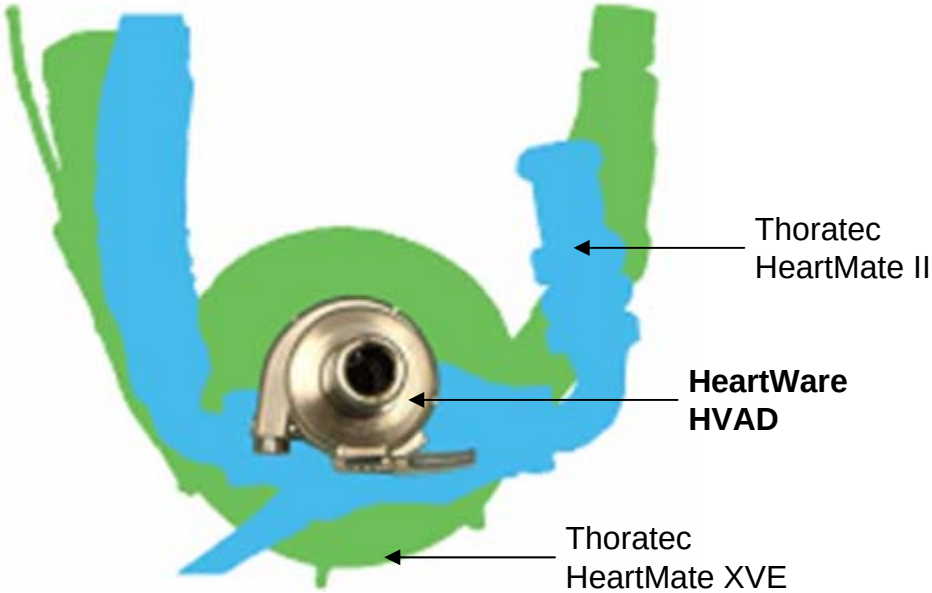
The HeartWare© Left Ventricular Assist System

- Miniaturized implantable blood pump (50cc / 145g)
- The only centrifugal pump designed to be implanted ***in the chest***, directly adjacent to the heart
- Designed to produce up to 10 liters 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





Potential Benefits:

- *No abdominal surgery*
- *No pump pocket*
- *Reduced Recovery time*
- *Reduced procedural invasiveness and complexity*
- *Shorter pump implant time*

International Clinical Trial Progress

- Enrollment complete: 50 patients – December 2, 2008
- Primary endpoint is survival to 180 days, transplant or recovery

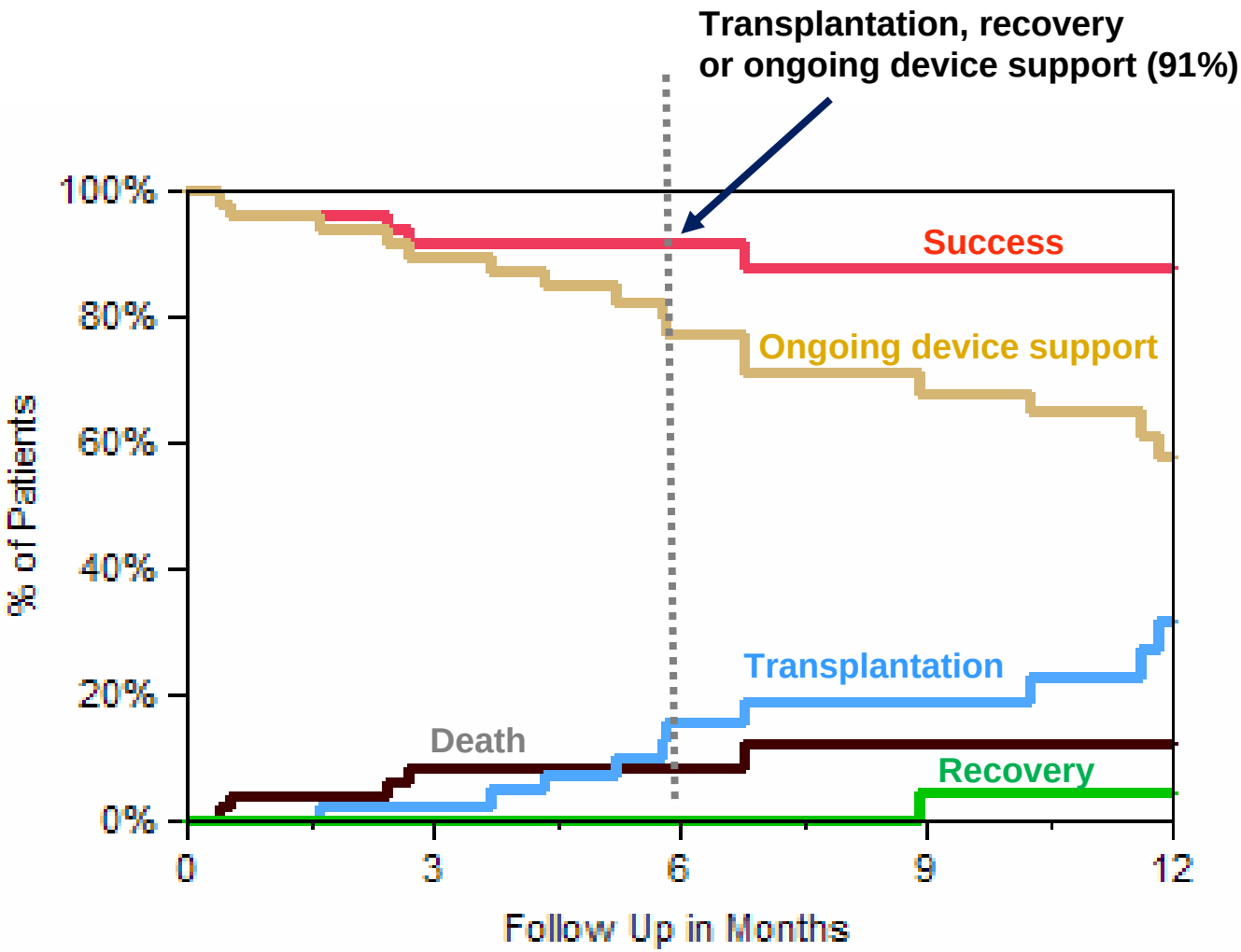
Centers	# Patients
Vienna General Hospital, Austria **Georg Wieselthaler, Henrich Schima**	**10**
Royal Perth Hospital, Australia **Gerry O'Driscoll, Rob Larbalestier, Lawrence Dembo**	**8**
Hannover Medical Center, Germany **Martin Strueber, Christian Kuehn, Anna Myer**	**19**
Harefield Hospital, UK **Asghar Khaghani, Emma Birks, Gilles Dreyfus**	**3**
St. Vincent's Hospital, Australia **Paul Jansz, Philip Spratt**	**10**

Update as of January 5, 2009

Enrolled	50
Alive	45
Transplanted	14
Recovered	3
Deceased within study period*	4
Longest in Use	23.6 months
Total LVAD Support	37.3 pt-yrs

*1 patient died after achieving primary endpoint

All Outcomes at 180 Days (n=50)



Outcomes (n=50)

Average Duration of support	**272 ± 189 (12- 698 days)**
Total duration of Support	**37.3 years (13597 days)**
Length of Hospitalization	**42.2 ± 19.3 days (14-110 days)**
Patients Discharged	**43/50 (3 still in hospital)**
Transplanted	**14 (47 - 558 days-mean 254)**
Recovered/Weaned	**3 (267, 424 and 541 days)**
Ongoing Supported by Pump	**28**
> 180 days	**19**
< 180 days	**9**
Died	**5 (12, 15, 73, 81, 203 days)**

Serious Adverse Events (SAE)

Within 180 day study endpoint

Complications	Patients	Events	Event Rate (per patient year)
Infections (all)	6	6	0.30
Driveline exit site infection	2	2	0.10
Sepsis	2	2	0.10
Wound	2	2	0.10
Bleeding	8	9	0.45
Postoperative	7	8	0.40
GI Bleed	1	1	0.05
CNS Events	1	1	0.05
Ischemic Stroke *	1	1	0.05

* Fully recovered

Serious Adverse Events (SAE)

After 180 day study endpoint

Complications	Patients	Events	Event Rate (per patient year)
Infections (all)	5	8	0.48
Driveline exit site infection	5	6	0.36
Bleeding	2	3	0.18
GI Bleed	1	1	0.06
Epistaxis (nose bleed)	1	2	0.12
CNS Events	3	4	0.24
Hemorrhagic CVA	2	2	0.12
TIA	1	2	0.12

Baseline Characteristics Context

	HVAD	HM II
	N = 50	**N=133**
Age	51 ± 13	50.1 ± 13.1
Race	100% Caucasian	69% Caucasian
Gender	86% male	79% male
BMI (m^2)	26.6 ± 5.4	26.8 ± 5.9
Isch CM	40%	37%
LVEF (%)	20.5 ± 7.9	16.3 ± 5.7
CI L/m^2	1.96 ± 0.57	2.0 ± 0.6
creatinine (mg/dL)	1.3 ± 0.5	1.4 ± 0.5
BUN (mg/dL)	13.7 ± 8.3	31.4 ± 17.6
Bilirubin (mg/dl)	1.39 ± 0.87	1.2 ± 0.8
Hct	36.5 + 6.5	34.8 ± 5.2
IV inotropes	97%	89%
ICD	68%	74%

Sources:
HVAD – HeartWare 002 International Clinical Trial
Heartmate II - Use of a Continuous Flow Device in Patients Awaiting Heart Transplantation. Miller LW et al NEJM 357: 846-849, 2007

Key Outcomes

	HVAD N=50
All bleeding (events/patient year)	0.37
All infections (events/patient year)	0.5
All neurologic (events/patient year)	0.22
Survival/Transplanted (<180 days)	90%**
Survival/Transplanted (12 months)	88%**
Average duration of support	272
% Transplanted @ 180 days	10%

** 9 patient alive but haven't reached endpoint

Other data comparable to other continuous flow devices

Clinical Experience in First 50 Patients

- Success to primary endpoint: 91%
- Hemodynamic improvements highly significant
- Improved functional class and activity levels
- Improved neurocognitive functions
- Improved QoL
- AE rate trends are in range with historic literature
- Pericardial placement appears feasible
- Device malfunctions low and only 1 failure recorded
  - » *Failure occurred in one of exchanged pumps with manufacturing tolerance issue (Q1 2007)*

US clinical trial underway

- Granted full IDE approval from FDA in September 2008
- 150 patients at a maximum 28 centers
  - » *No longer restricted to stop at 10 centers*
- 6 Implants at Washington Hospital Center and Jewish Hospital (Louisville)
- 2 additional centers now active
  - » *8-10 by January 31*
- 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

First revenues - EU

CE Mark anticipated SOON

- » *Informed in December by Notified Body that there are no open concerns and all reviewers recommending approval; strictly administrative procedures now*
- » *Triggers the start of commercial sales throughout European Union*

- Commercial rollout through 2009
  - » *Direct sales strategy.*
  - » *HeartWare personnel and infrastructure already established in Europe*
  - » *Strong interest throughout the continent*
  - » *TGA submission in Australia to follow*

Pipeline: Exceeding Expectations

- **Three MVAD designs all proving effective in pre clinical studies**
- **Will pick a winner within the next 6 months and move towards clinic**

Version 1: MVAD Trans-Apical

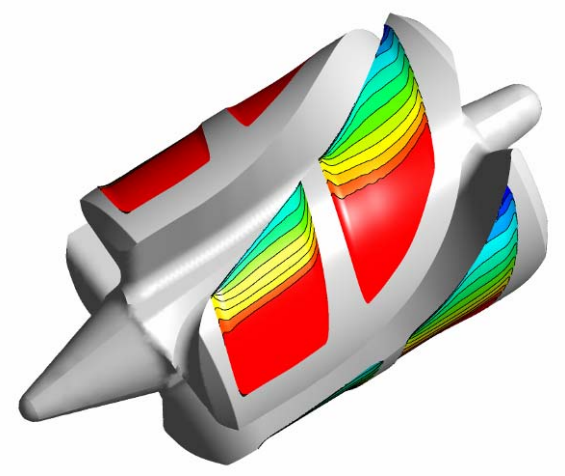
Left Thoracotomy or Sternotomy

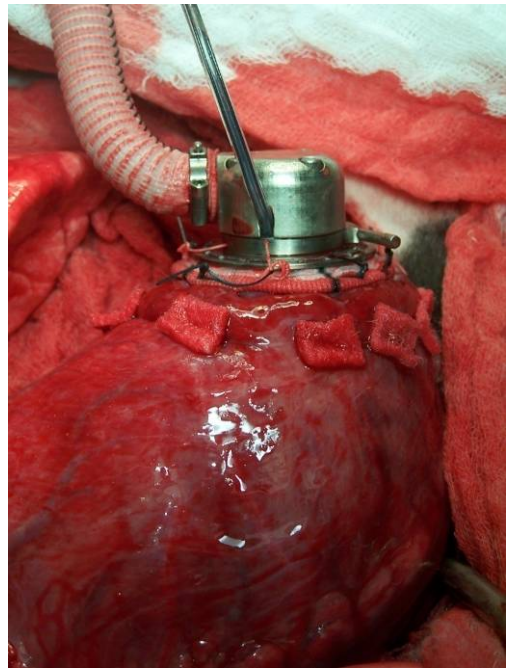
Up to10 liters per minute of flow

Exceptional fluid dynamics

1/3 the size of HVAD

11 In-Vivo Studies: platform “works”





Version 2: “VCAN” Right Thoracotomy

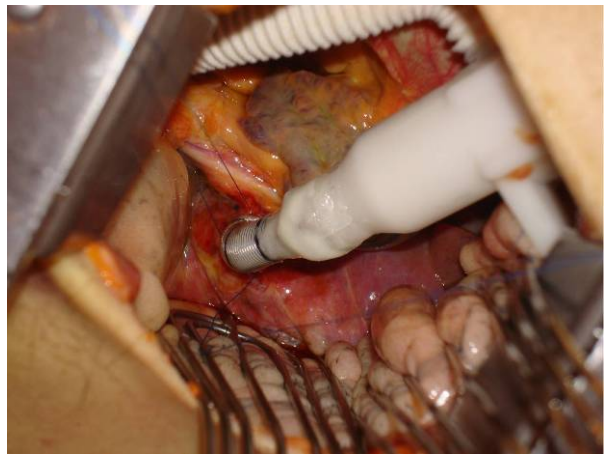
Right Thoracotomy

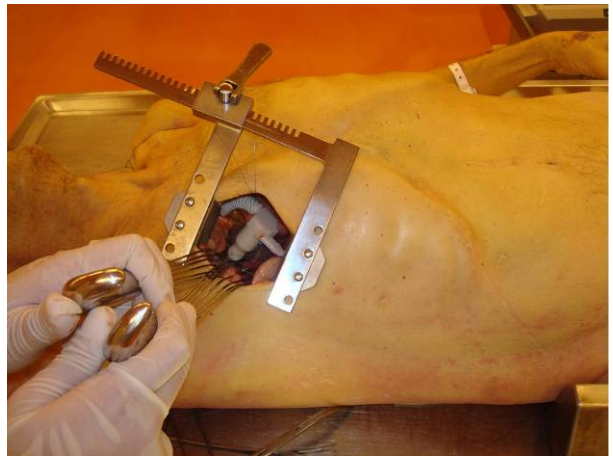
One incision for implant and anastomosis

Up to 7 liters per minute

No pump pocket

13 In-Vivo studies





Version 3: Longhorn

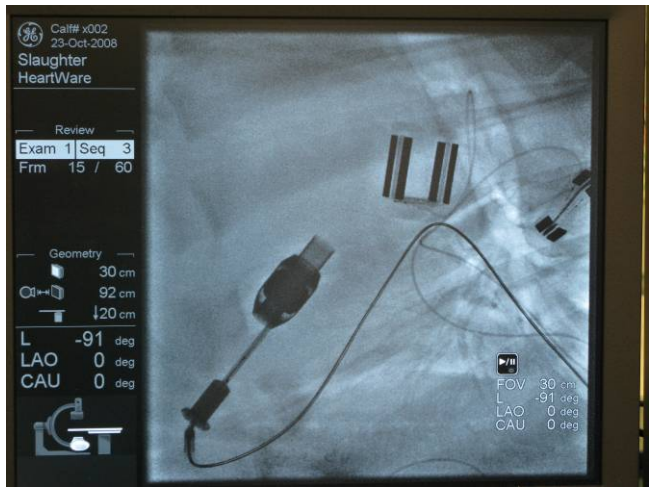
Subcostal Incision: NO anastomosis

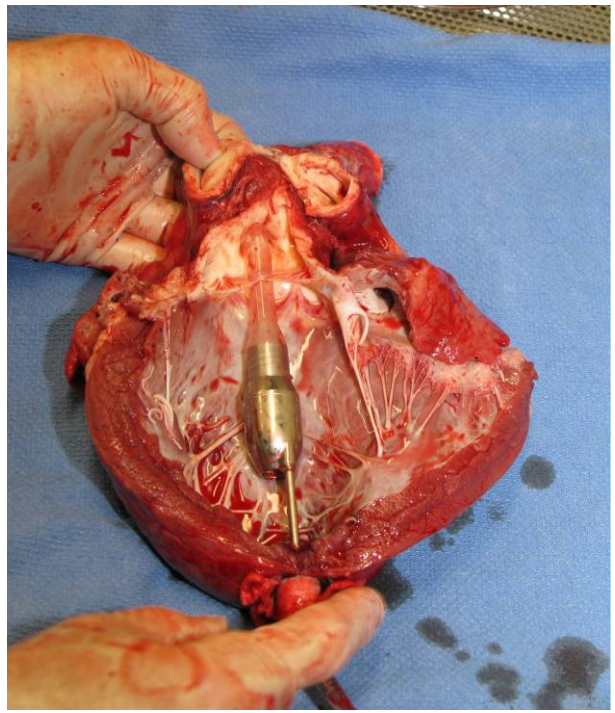
Up to 7 liters per minute

“30 Minutes Skin to Skin”

Acute In-Vivo studies very successful

Average M.D. reaction: WOW





Upcoming Milestones in 2009

Milestone	**Timing**
Receipt of CE Mark	January/February
NASDAQ Listing (HTWR)	January/February
European Revenue	February
10 Sites Enrolling in US	February
Submit TGA (Australia)	Q1
20 Sites Enrolling in US	Q2
Full Data Presentation	April (ISHLT)
Commence Destination Therapy Trial	2H ‘09
Complete BTT enrolment in US	Q4 ‘09/Q1 ‘10

Financial snapshot ($USD)

• Cash on hand	$31M (30 Sept)
• Burn rate	$2.5M per month
• First revenue	Sept 2008
• Shares on issue	310M
• Market Cap	$100M
• Number of employees	112
• Top 20 shareholders	> 75% of shares
• US Ownership	> 80%

Thank You