

# HeartWare Limited (ASX:HTW)



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

» *March 2007*



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# Forward Looking Statements

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# Investment highlights

- HeartWare is commercialising the world's smallest heart pumps for the treatment of advanced heart failure
  - » *12 years in development - \$100m invested*
  - » *Successful human implants – March 2006 to date*
  - » *Anticipated revenues - within 12 months*
- International CE mark trial on track
  - » *Promising initial clinical results*
  - » *8 implants conducted across 3 centres > 1200 implant days*
  - » *Pumps in inventory and additional 2 centres trained*
  - » *CE mark and commercial sales by early 2008*
- US trials imminent
  - » *Anticipate lodging IDE in Q3 2007 with implants late 2007 / early 2008*
- Operationally well positioned
  - » *High quality management team – 70 staff in total*
  - » *Manufacturing upgrades complete*
- Promising results of next generation products
  - » *MVAD™ in acute animal studies and IV VAD at design stage*



# Snapshot - Goals and achievements of the last 6 months

Goal	Achievement	
<b>Clinical</b>		
Resume implants	Two implants in Perth (October 2006) with four additional since then	✓
All international trial centres open	Implants conducted at three centres (Vienna, Perth and Hanover) and training complete at Harefield Fifth centre trained and screening patients – pending ethics approval	✓
Complete 20 implants by June 2007	Eight implants conducted – 20 implants by June is achievable	In progress
<b>Operational</b>		
Improve manufacturing yields	7 sterile pumps in February, dramatic yield improvements Inventory on hand to complete international trial	✓
Complete quality systems upgrade	Systems upgraded and mock audit conducted with very positive report	✓
Expand supplier network	Additional suppliers for critical components. More to be secured	In progress
Continue development of new products	Advances with MVAD (animal studies) and IV Vad (prototyping) and TETs	In progress
<b>Team</b>		
Key hires complete	Jen Foley appointed VP Clinical & Regulatory Jane Reedy appointed VP Marketing - roll out European sales	✓
<b>Corporate</b>		
Improve shareholder communication	Implemented regular newsletter + 2 investor road shows in 5 months	✓
Expand breadth of Board	Experienced US director (Bob Stockman) appointed	✓



# 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:



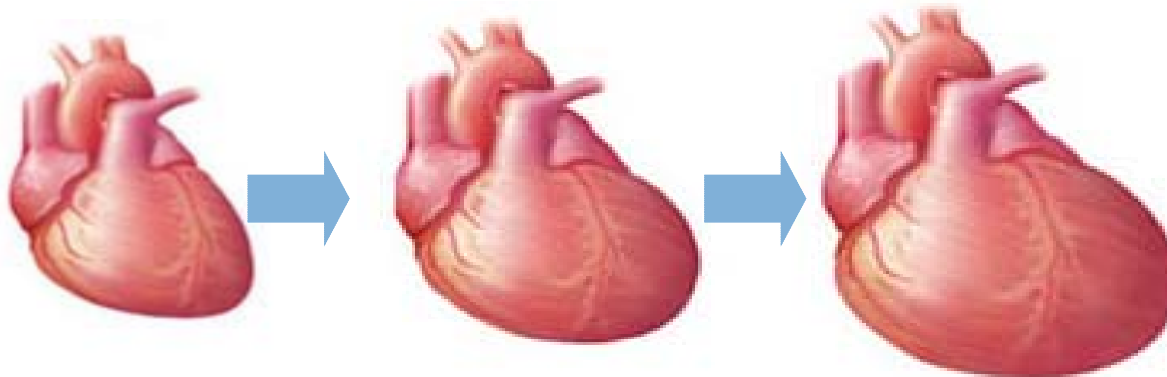
HeartWare's first patient, approximately 6 and 9 months following surgery at Vienna General Hospital in March 2006

*The right pump at the right time*



# 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



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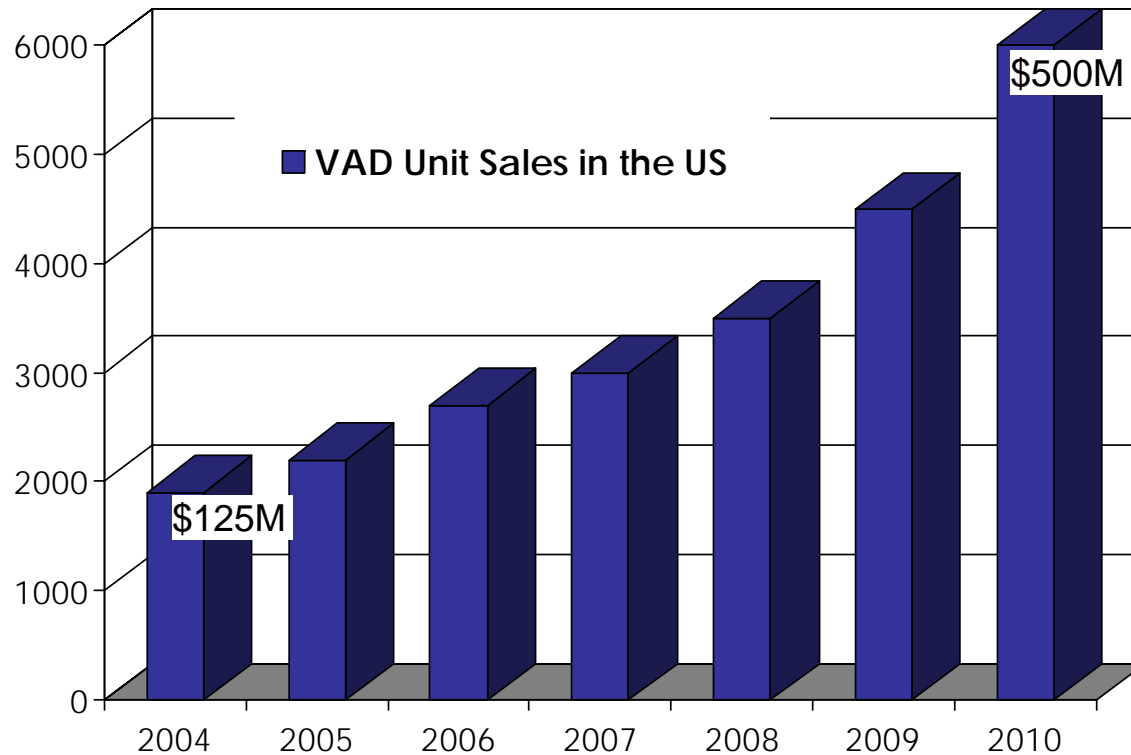
# LVAD's are the only viable option for most

- 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**





# Market is growing and poised to accelerate



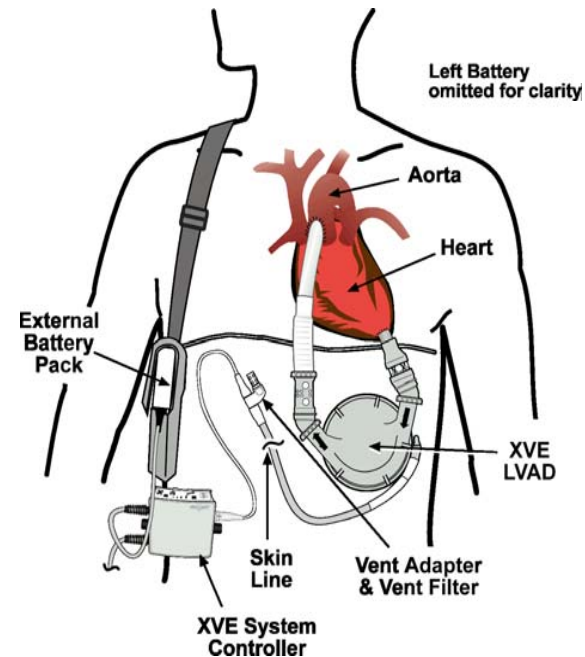
- >12% pa compound growth in past 3 years with no new technology since 1998

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



# Market has grown despite sub-optimal technology today

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



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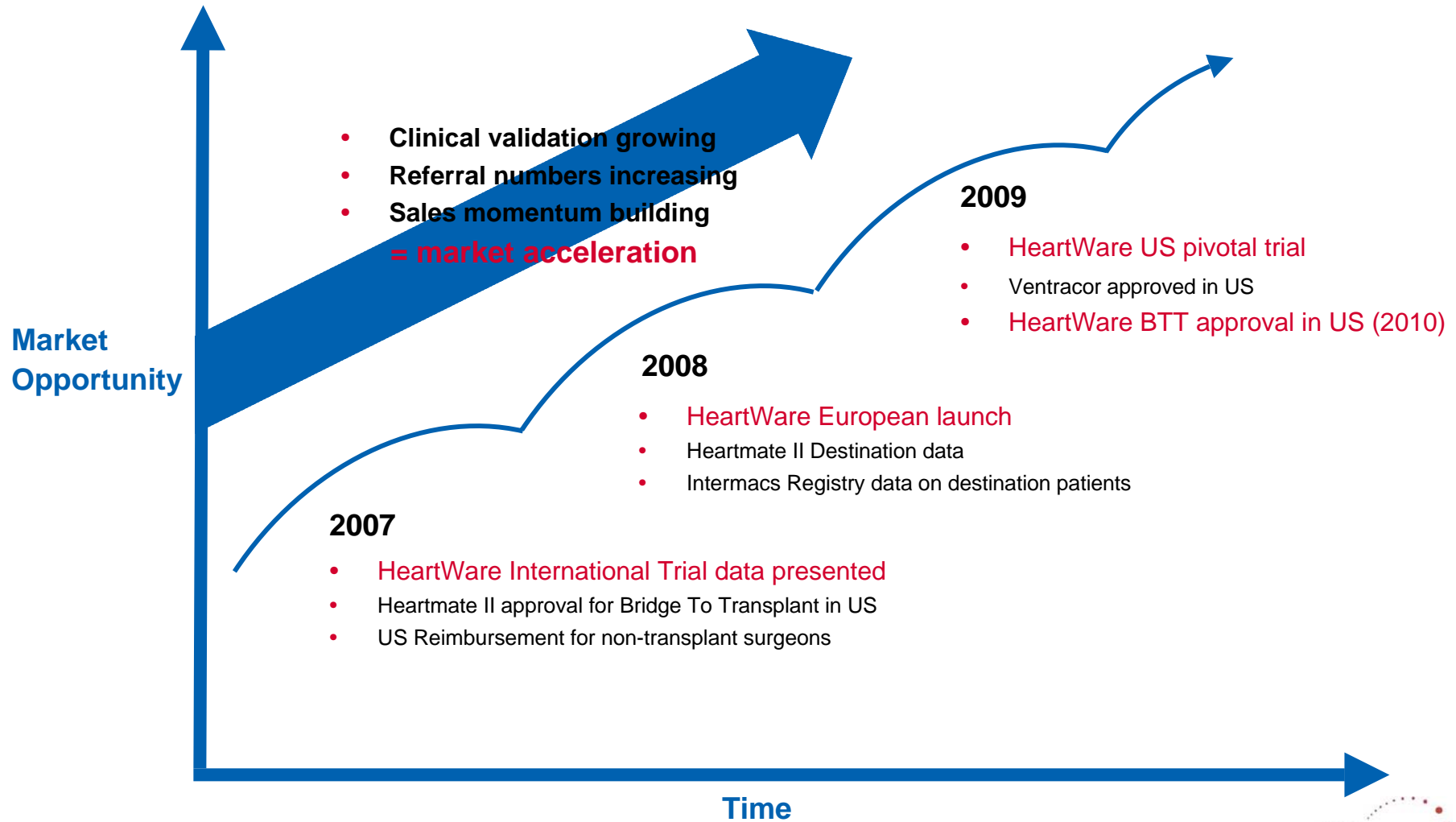
The Thoratec HeartMate XVE - the only VAD with FDA approval for Destination Therapy

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



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# Multiple market catalysts in the near term



# Promising clinical results

- 8 implants / 3 centers / >1200 days
  - » *Vienna, Perth, Hannover*
- Successful completion of primary study endpoint (180 days) for first 2 patients
  - » *Nearing 1 year*
- Rapid implant procedure and post-operative recovery
- First 7 patients discharged\*
- Excellent clinical outcomes
- 2 new centres trained and actively screening patients
- Pre-IDE meeting with FDA pending



Dr George Wieselthaler at Vienna General Hospital with HeartWare's first patient

\* Most recent patient still recovering from surgery



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# Positive physician response

- “The surgery took only 85 minutes, significantly less than the time typically required to implant other devices.”

*Dr George Wieselthaler, Vienna General Hospital, March 2006*

- “The pump’s small size facilitates implantation above the diaphragm, eliminating the need for abdominal surgery and minimizing both bleeding and infection risks. These factors should translate into improved outcomes for our patients.”

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

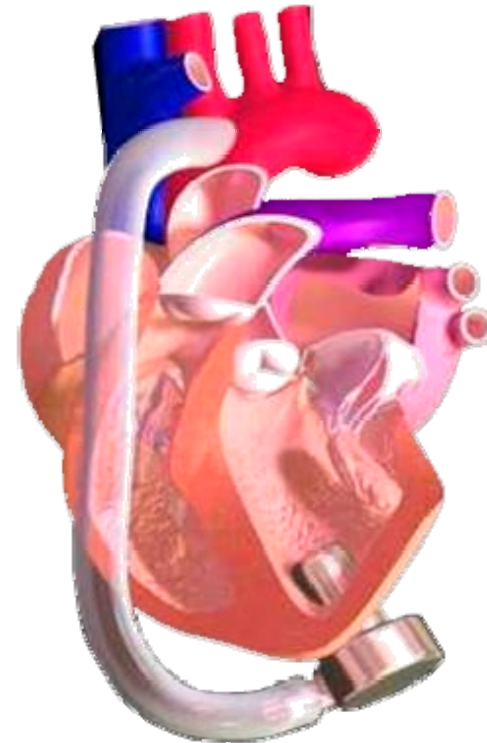
- “The pump’s small size, placement above the diaphragm and innovative cannulation technique significantly reduce the complexity of the surgical procedure and present clear and distinct clinical advantages.”

*Dr Martin Strüber, Hannover Medical Center, January 2007*



# HVAD™ addresses patient needs

- The ***smallest*** full output pump available
  - » *Thoracic placement – no abdominal surgery*
  - » *Shorter and less complex procedure (~ 1.5 hours) relative to competing devices*
- **Improved 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*

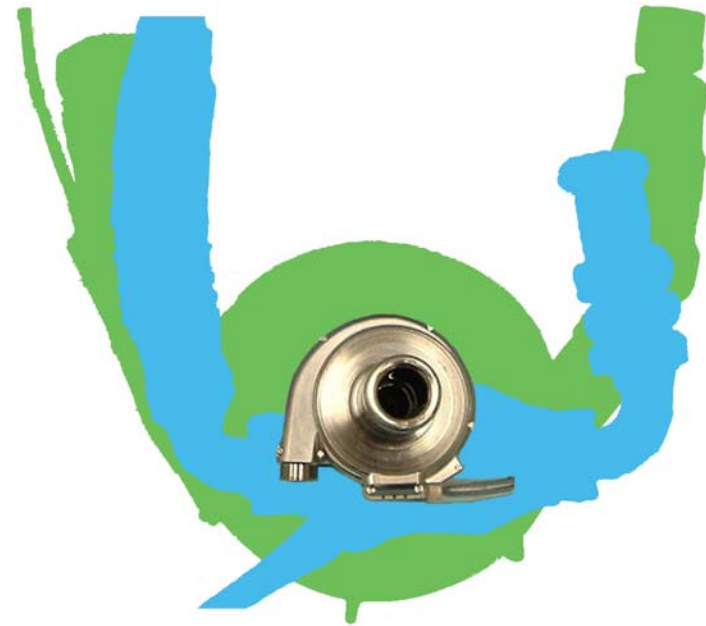


The HVAD™ pump is implanted directly into the apex of the left ventricle



# 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 postoperative drains*
  - » *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*



# Our pipeline - getting bigger by getting smaller

**HVAD™**



**MVAD™**



**IV-VAD™**



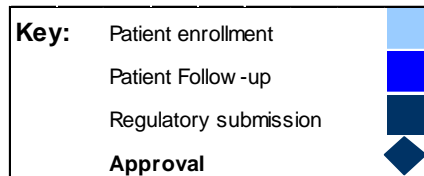
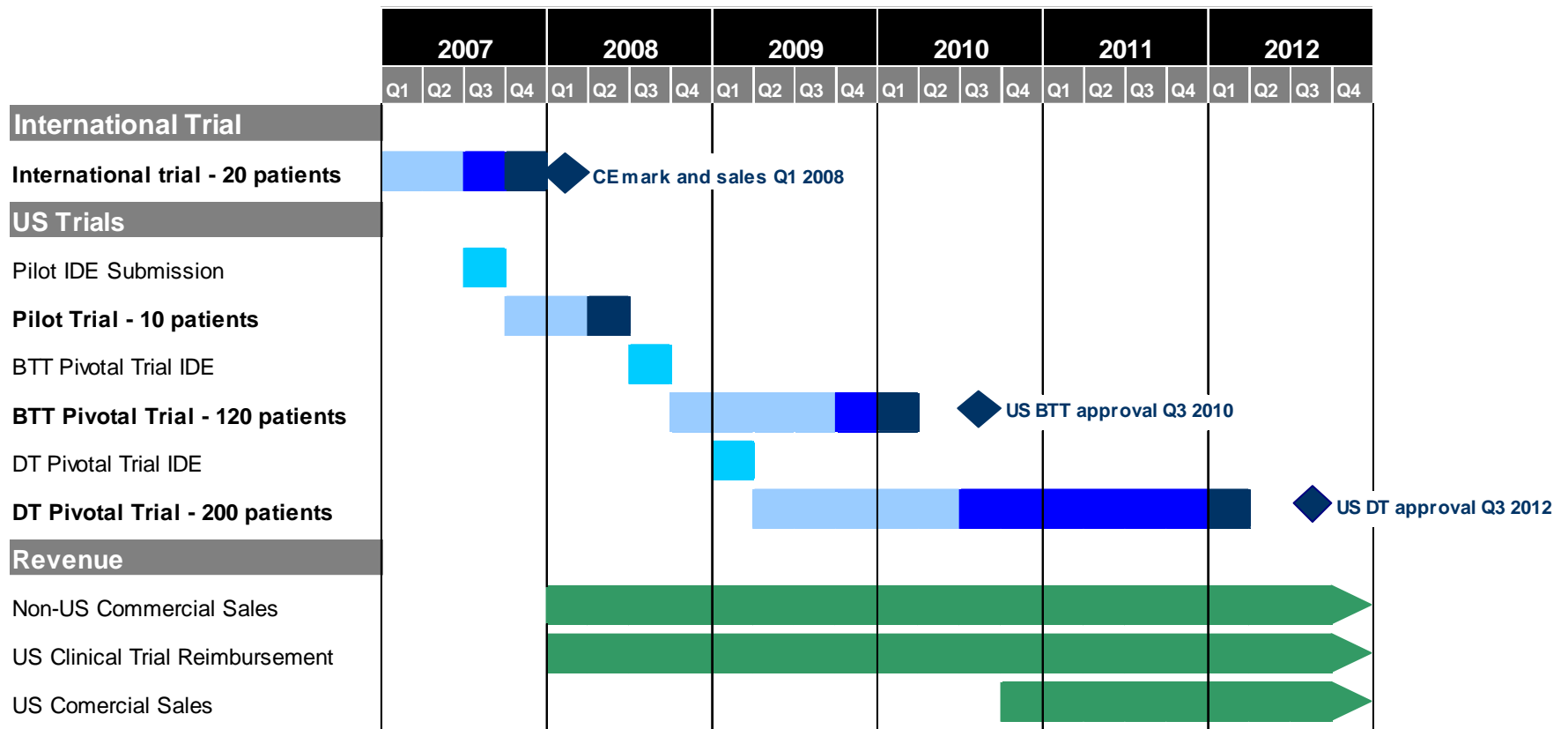
<b>Procedure</b>	Surgical	Minimally Invasive	Iliac Incision
<b>Flow</b>	10 L/min	10 L/min	3 L/min
<b>Patient Class</b>	Late Class IV	Class IV	Class III / Early Class IV
<b>Treatable Population</b>	100,000	300,000	1,000,000

15 granted US patents, 16 pending US applications, multiple international patents





# HVAD™ timeline to market



Dates are indicative and can vary depending on regulatory requirements and trial outcomes



# The year ahead

- **Clinical**
  - » *Commence implants at final two clinical trial Centres – April 2007*
  - » *Present Interim Data at ISHLT Symposium – April 2007*
  - » *Complete International trial enrollment – June 2007*
  - » *Submit regulatory filing to European Notified Body - Q3 2007*
  - » *Submit IDE application to FDA – Q3 2007*
  - » *Implant first patient in US – Q4 2007*
  - » ***CE mark and European commercial launch – Q1 2008***
- **Operational**
  - » *Complete quality audit and gain ISO13485 certification – Q3 2007*
  - » *Increase production capacity to > 20 pumps per month – Q4 2007*
  - » ***Establish sales infrastructure for Europe – Q4 2007***
- **Corporate**
  - » *SEC filing and US Securities compliant – April 2007*
  - » *Address financing requirements – 2007*
- **Development**
  - » *Develop MVAD™ less invasive implant procedure – 2H 2007*
  - » *Develop TETS to functional prototype stage – 2H 2007*



## Financial snapshot

- Cash on hand \$21M (at 31 Dec 06)
- Burn Rate \$2 M / month
- First revenue Anticipated early 2008
- Shares on issue ~ 186M
- Market Cap ~ \$115 M
- Number of employees 70
- Apple Tree Partners 49% of outstanding shares
- Top 20 shareholders 73% of outstanding shares



# HeartWare...

- Right Pump: The most compelling LVAD technology portfolio
- Right Time: A market poised for substantial growth
- Right Team: Proven management, strong operating backgrounds

