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Heartware Limited

A pipeline of products



Wilson HTM
INVESTMENT GROUP

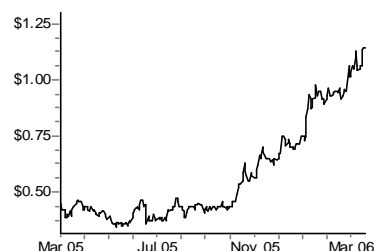
29 March 2006

\$1.14

BUY

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Price Performance



Security/Capital Details

ASX Code	HTW
Market Cap	\$178 M
Issued Shares	156.1 M
Avg Mth T'over	3.36 M
12 Mth High – Low	\$1.23 - \$0.34

Key Data/Ratios – FY 2006

Cash	\$14M
Cash burn	\$18M
Technology value	\$164M
Interest Cover	NA
ROE	-43.9%
EPS Growth	-37.8%
PEG Ratio	0.19 x
NTA / Share	\$ -0.02
DCF	\$ 1.14
12 Mth Price Target	\$ 2.11

BUY: Total return +10% or more over a 12 month period

HOLD: Total return expected to be between +10% to -10% over a 12-month period

SELL: Total return expected to be -10% or more over a 12 month period

TOTAL RETURN OR TSR = capital growth in share price + expected dividend yield in that period

Recommendation

We initiate coverage with a BUY recommendation and 12-month price target of \$2.11. The company has consistently met its development goals culminating last week in the first human implant of its HVAD device. We believe the company's third generation technology gives it an advantage over its competitors, as it is able to be miniaturise products, allowing the company to develop a pipeline of products. If trials in Australia and Europe are successful, the company is expected to begin generating commercial revenues in 2H07. A high rate of recruitment of volunteers during clinical trials will indicate a high degree of acceptance by physicians.

Key Points

- We initiate coverage of HTW with a BUY recommendation, and a 12 month price target of \$2.11.
- Since listing in January 2005, the company has consistently met its development goals, culminating last week in the first human implant of its HVAD left ventricular device. This implant was noticeable by the fact that it took only 85 minutes to perform, compared with a norm of 4-6 hours. We believe this is testament to the small size of the device, which is a direct result of the devices design and technological advantage.
- This implant was the first in its clinical trial program for CE Mark and TGA approval. The company will need to implant approximately 20 patients in this trial to demonstrate safety and efficacy.
- The company has approval to carry out implants at four hospitals in Europe and Australia. The first implant was carried out in Vienna, Austria.
- Enrolment for this trial is expected to be completed by the end of 2006, and if successful, approval for both bridge-to-transplant (BTT) and destination therapy (DT) in Europe and Australia could be expected in 2H07, allowing for commercial sales to begin. We expect the company to begin pilot clinical trials in the US in 4Q06 and to be completed by the end of June 2007.
- Rate of recruitment is a key determinant of physician acceptance of new technology, and the benchmark is expected to be the 50 patients per quarter currently being recruited by industry leader Thoratec (US) in clinical trials for its new LVAD.
- HTW has a significant competitive advantage over its competitors, in that its third generation device allows for miniaturisation and a pipeline of products.
- The company currently has \$14M in cash, and is expected to burn through approximately \$18M in FY06. The company will therefore need to raise cash to fund its operations, although it does receive reimbursement for implanted units.
- We value the company at \$1.14 per share, with a price target of \$2.11 in 12 months time, to be catalysed by continuous news flow of additional implants in Europe, US and Australia

HeartWare Limited

Introduction

HeartWare (HTW) was listed on the ASX in January 2005 after raising \$33M. Since listing, the company's share price has increased by 114% to 120 cps. The company is based in the US and has a market capitalisation of approximately \$187M.

The company recently made a major advance in its clinical development of its HVAD, by successfully implanting its first human volunteer. The surgical procedure took only 85 minutes, significantly less than the industry norm which is closer to 4-6 hours.

HTW's Products

HTW is developing a range of left ventricular assist devices (LVADs). These LVAD's are:

- HVAD
- MVAD
- PedVAD

In terms of development, the HVAD is the most advanced, followed by the MVAD and then the PedVAD.

HVAD

Since the IPO the company has made significant progress in getting their HVAD to clinical trials. The HVAD has a volume of only 45 cc and a mass of 145 grams.

Figure 1: HTW's HVAD



Source: HTW



The company has completed all pre-clinical trial work to enable them to begin clinical trials in Australia and Europe. We believe the company is on track to implant 20 patients with the HVAD by the end of 2006 at 4 hospitals:

- Royal Perth in Australia
- Vienna General Hospital in Austria
- Harefield in the UK
- Medical University in Hanover Germany

We estimate that these 20 implants will cost the company approximately \$3M.

The clinical end-point of this trial will be 180 days survival or survival until transplant if before 180 days.

The company also aims to begin recruiting patients in 4Q06 in the US for the US feasibility trial. Enrolment for this trial is expected to be completed by the end of March 2007.

MVAD and PedVad

The MVAD is the next generation product which is designed to produce full cardiac output albeit one tenth the size of the HVAD. Animal trials of the MVAD have begun and have moved from acute testing to long term testing.

The PedVAD is based upon MVAD technology but is aimed at the paediatric market.

LVAD Market

The heart failure market can be segmented into the following four classes, as defined by the New York Heart Association (NYHA). These range from Class I to Class IV, and depend on severity of symptoms.

Table 1: NYHA Descriptions

Class	Definition
I	No limitation of physical activity; ordinary physical activity does not cause undue fatigue
II	Slight limitation of physical activity; comfortable at rest, but ordinary physical activity results in fatigue
III	Marked limitation of physical activity; comfortable at rest, but less than ordinary activity causes fatigue
IV	Unable to carry on any physical activity without symptoms; symptoms are present even at rest and increase if any physical activity is undertaken

Source: WHTM

Recommended therapy for each class is :

- Class I: exercise, stop smoking, ACE inhibitors
- Class II: As above plus Beta blockers
- Class III: As above plus salt restriction, diuretics, Digitalis
- Class IV: As above plus mechanical assist devices, transplant, continuous IV infusions, hospice care.

There are approximately 2M people in the US in Stage III and Stage IV heart failure. Many are suitable for a heart transplant, yet only around 2,000 heart transplants take place in the US p.a. due to a lack of donors.

While there are a number of mechanical devices, the most widely used are LVADs – Left Ventricular Assist Devices. There are numerous categories of LVADs, and these categories are a function of:

- Regulatory regime in a specific country
- Type of system



US Market for LVADs

The US Food and Drug Administration (FDA) has defined two indications for cardiac assist devices – Bridge-To-Transplant (BTT) and Destination Therapy (DT).

BTT Market

There are a number of devices approved for use in the BTT market. In 1995 Thoratec became the first company to receive FDA approval to market a ventricular assist device as a Bridge-to-Transplant for qualifying heart failure patients on the waiting list to receive a donor heart transplant. Thoratec has greater than an 80% share of the BTT market globally, and in excess of 90% in the US. The maximum size of the BTT market is defined by the number of patients on the heart transplant list, and the number of patients on this list has been steadily declining since 2000 due to improved management of heart failure patients and greater use of implantable cardiac defibrillators and cardiac resynchronisation therapeutic devices.

Statistics from UNOS, the United Network for Organ Sharing indicate that the number of patients on the waiting list for a new heart has declined by more than 25% over the last 5 years to approximately 3,000 people today. However, the proportion of patients on the list receiving VAD devices has increased. Approximately 900 BTT patients in the US received an LVAD in 2005 – a market penetration of approximately 30%. It is therefore clear that the BTT market is becoming a niche market dominated by Thoratec, particularly when one takes into account advances Thoratec is making in development of its HeartMate II device.

A major assumption in concluding that the BTT market is becoming a niche market, is that the FDA continues to discriminate between BTT and DT (discussed later).

DT Market

The DT market in the US came about as a result of the REMATCH trial (Randomised Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure). The 22-site trial demonstrated that long-term left ventricular assist device (LVAD) implantation doubled one year survival compared with optimal medical management. Two-year survival also improved significantly. However, after two years, survival was severely impeded by complications, particularly infection and device failure.

The device used in this trial was the Heartmate XVE LVAD, manufactured by Thoratec, and the results allowed the FDA to approve the Heartmate XVE device to be in patients not deemed candidates for heart transplant.

The American Heart Association estimates that there are around 4.9M Americans living with heart failure, with 550,000 new cases p.a. Of those 4.9M, approximately 245,000 (5%) are believed to suffer from Class IV heart failure. The addressable market is therefore significantly larger than the BTT market, even if only 10% of the Class IV patients are suitable for an implant. Given that Thoratec sells its LVAD for approximately US\$65,000, this translates into a US\$1.5B market in the US alone.

The regulatory pathway for each market in the US is very different. Given that Thoratec's Heartmate XVE device is the only approved LVAD for DT in the US market, all new DT devices have to be compared with the Heartmate in a randomised clinical trial.

For the BTT market, a manufacturer has to prove the device is safe after a clinical trial. The end points are typically safety and efficacy 180 days after implant.

Rest of World Market

We estimate that the US makes up approximately 50% of the global market. The major players in the rest of the world include:

- Japan
- UK
- Germany
- Italy



- Spain
- France

The European market differs significantly from the US in that it does not discriminate between DT and BTT. The regulatory pathway is significantly simpler than that for the US.

All that is required to obtain regulatory approval in the EU (CE Mark) and Australia (TGA approval) are clinical trials demonstrating safety and effectiveness in patients 6 months after being implanted.

HTW – Development program

Europe and Australia

On 22 March, HeartWare's HVAD device was implanted for the first time in a human patient. The implant took place at the Vienna General Hospital. This implant is the first of a total of 20 implants required to demonstrate safety and effectiveness of the device to the satisfaction of the European and Australian regulatory authorities. The results of this trial are expected to allow for HTW to apply for CE Mark and TGA approval. Enrolment in the trial is expected to be completed by the end of 2006. If successful, approval for both BTT and DT in Europe and Australia could be expected in 2H07 allowing for commercial sales to begin.

United States

As discussed earlier the regulatory regime in the US is considerably different from the rest of the world. As such we expect the company to begin a 10-patient feasibility BTT trial in the US in Q406, followed by "pivotal" BTT and DT trials expected to begin in 2H07.

BTT Trials in the US

BTT trials would entail implanting 120 volunteers and determining safety and effectiveness 180 days after implant. HTW expect this trial to be complete by the end of 2008, allowing for regulatory submission to be made by early 2008. If approved one would expect commercial sales to begin in Q408.

DT Trials in the US

Under current FDA guidelines trials for a new device for DT therapy have to be conducted via a randomised structure comparing the new device with an approved device. As the only approved device at the moment in the US is Thoratec's HeartMate XVE, the control arm of the study would have to use this device.

Many industry players, including cardiologists and cardiac surgeons object to structuring a trial in this manner on ethical grounds as the HeartMate XVE has a short lifetime as demonstrated in the REMATCH trial, of only 1-2 years.

Some practitioners believe a trial should be done comparing a new device with drug therapy, essentially a REMATCH trial. However, as it has already been shown that a device can offer better outcomes over drug therapy objections can once again be made to such a trial on ethical grounds.

There has been increasing resistance from physicians regarding structure of DT trials. Discussions with industry players indicate that the FDA is considering changes to its requirements for DT clinical trials. Comments by the CEO of Thoratec recently indicate that changes are expected by the end of 2006 or early in 2007.

A change in FDA requirements by that date would fit in well with HTW's aim to begin its DT trial in mid-07. HTW is therefore not in the position of having to delay their trial or possibly change the structure mid-way through the trial if the FDA changes its requirements.

HTW Development Timeline

HTW's development timeline for the HVAD is shown in Table 2.

**Table 2: HTW Development Timeline**

	1Q06	2Q06	3Q06	4Q06	1Q07	2Q07	3Q07	4Q07	1Q08	2Q08	3Q08	4Q08
EU and TGA path	First human implant. Start EU and Aust. trial			Complete EU and Aust. trial			TGA approval and CE Mark	Commercial sales in Europe and Australia				
US pilot trial			Submit IDE to FDA	Begin US pilot trial		Complete US pilot trial						
US BTT pathway							Begin US BTT trial					Complete US BTT trial
US DT pathway							Begin US DT trial					

Source: WHTM and HTW

Considerable news flow is therefore expected over the next 12-18 months:

- Progressive enrolment of 20 patient CE mark trial across a minimum of four international investigational centres
- Submission of Investigational Device Exemption (IDE) application to the FDA, allowing for a pilot trial to begin (by end of September 2006)
- Start of US pilot trial (by end of December 2006)
- Complete EU and Australian trial (by end of December 2006)
- Completion of US Pilot Trial (by March 2007) and subsequent start of US pivotal trial
- Obtain CE Mark and TGA approval (by end of September 2007)
- First commercial sales (by end of December 2007)

While each of the above is a critical point in the company's development, the major area of uncertainty is the rate at which patients can be recruited into the various trials. As discussed above, the rate of recruitment is a key indicator of acceptance by gatekeepers – cardiologists and cardiac surgeons. HTW's rate of recruitment will undoubtedly be compared with that of Thoratec's 50 per quarter - the approximate current rate of enrolment in the trial for their Heartmate II device.



Competition

HTW has 2 major competitors – Thoratec and Ventracor.

Thoratec

Thoratec has a market capitalisation of US\$1B, and earned revenues in FY05 of approximately US\$200M. The company has the only LVAD on the market approved for DT, and as such enjoys a considerable competitive advantage. Under current FDA guidelines, all new products need to be compared with Thoratec’s Heartmate XVE device in a randomised trial before being approved for use.

Thoratec is currently trialling a new LVAD, HeartMate II, for DT. It is a second generation device

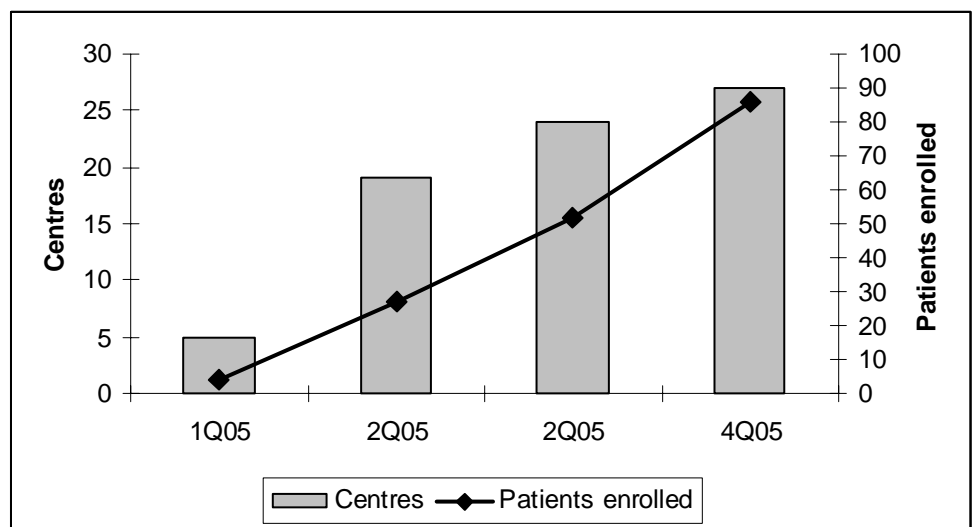
Thoratec’s HeartMate II

Thoratec’s HeartMate II has re-ignited interest in the LVAD industry and sector. After lacklustre demand for DT implants post-REMATCH, there has been renewed interest in LVADs from cardiologists, cardiac surgeons and patients. This has been for a number of reasons including:

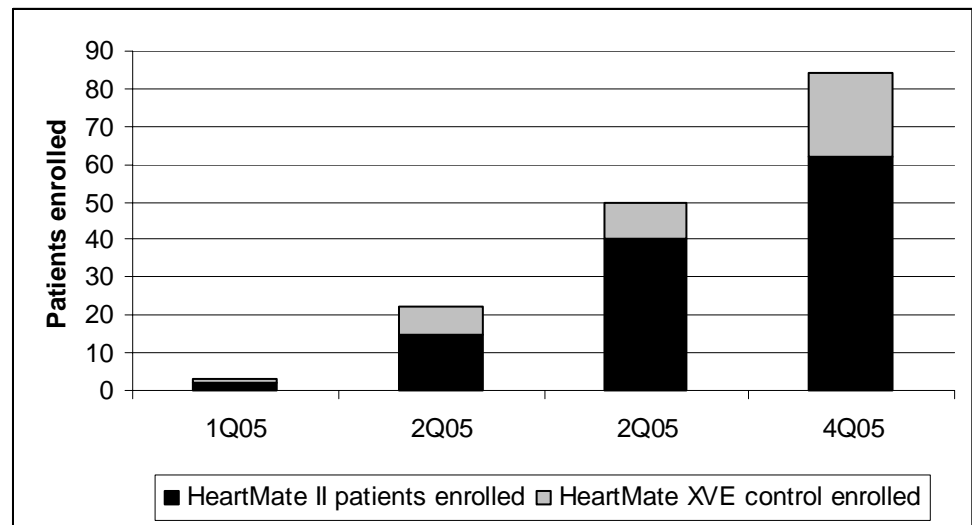
1. Increased reimbursement from CMS in the US (Medicare and Medicaid) for LVADs. In 2004 reimbursement for a procedure was increased from approximately US\$29,000 for a procedure to an effective US\$136,000 for a procedure. This goes towards the cost of the device, cost of surgery, hospital and post-hospitalisation care.
2. Market development by Thoratec has begun to bear fruit after an effective marketing/educational initiative (Heart Hope), designed to increase acceptance of DT among cardiologists, generate physician referrals and broaden patient awareness.
3. HeartMate II is a second generation device which has eliminated many of the shortcomings in the HeartMate XVE. After a rocky start the HeartMate II was improved and physician feedback has been good. The device is currently in US pivotal trials for BTT and DT and recruitment rates look to be extremely strong.

Patient enrolment rates for Thoratec’s HeartMate II BTT and DT trials are shown in Figures 2-3.

Figure 2: Thoratec’s BTT recruitment rate



Source: Thoratec

**Figure 3: Thoratec's DT recruitment rate**

Source: Thoratec

The rate of recruitment on an aggregated basis is some 50-60 patients per quarter. This has pleasantly surprised market watchers as it indicates greater acceptance by cardiologists of the HeartMate II as a treatment alternative, which would only be forthcoming if they believed it would be effective and safe.

The recruitment rate can therefore be seen as a benchmark for the industry. If a company is able to achieve a similar or greater rate, it could indicate greater acceptance by cardiologists and surgeons with all the implications of safety and effectiveness. However, if a company generates a lesser rate of recruitment it could be a warning that something is amiss.

Ventracor (VCR)

VCR is developing a third generation device that relies on hydrodynamic forces to produce a wearless impeller. It is a third generation device in that it is wearless. It is larger than HTW's HVAD and generally needs to be placed below the diaphragm. While the VentrAssist has been implanted in a child, this is probably an exception. To date over 50 patients have been implanted with the device in Australia, New Zealand, UK, Norway and the USA.

The company has made significant progress in its clinical trial program over the last 12 months. In Europe, enrolment targets under the CE Mark Trial were recently met, where 30 patients were implanted with the VentrAssist LVAD. CE Mark (EU approval) of the VentrAssist is now possible in Q406, but is more likely in Q107.

VCR's DT Timeline

VCR plans to submit a DT protocol to the FDA by around December 2006, allowing it to begin enrolment early in 2007. Such a trial under current FDA guidelines would require approximately 300 patients, in two distinct arms. Approximately 200 patients would be implanted with the VentrAssist, the balance with an approved LVAD – currently the HeartMate XVE, but possibly by that stage the HeartMate II.

It would appear that VCR is banking on the FDA changing its DT trial guidelines by the end of 2006. The line between BTT and DT is blurring – if someone is on the transplant list has an implant, and does not have a transplant – they become *de facto* DT recipients. If the FDA does not change its guidelines in time for VCR to submit its DT protocol, it runs the risk of losing development momentum.

We believe Thoratec has set the benchmark for recruitment against which all LVAD companies will be measured (50 per quarter). VCR commenced a US feasibility trial in mid-2005 and recently implanted their fifth patient out of a required ten. The first patient was implanted in July 2005, the fifth in December 2005. The company is recruiting volunteers through 5 centres in the US.

VCR Share Placement and Rights Issue

VCR has recently raised \$22.6M at a 20% discount to the closing price before the raising was announced, via a placement. The placement was the first component of an equity capital raising of up to approximately \$51.7M, via a placement and a renounceable rights issue. The new shares issued in the placement will be eligible to participate in the rights issue. Closing date for acceptances for the rights issue is 11 April 2006.

Comparisons between the major second and third generation LVADs under development or on market is shown in Table 3 for completeness.

Table 3: LVAD Comparisons

	Generation	Volume (cc)	Mass (g)	Pericardial placement	Wear less	Able to minituriase
Jarvik 2000	2	25	85			
MicroMed DeBakey	2	37	95			
Thoratec HeartMate II	2	63	281	No	No	No
WorldHeart HeartQuest	3(a)	155	540	No	No	No
Terumo DuraHeart	3(a)	150	420	No	No	No
Thoratec HeartMate III	3(a)	195	500	No	No	No
Berlin Incor	3(a)	60	200	No	No	No
Arrow CorAide	3(b)	200	300	No	Yes	No
Ventracor VentrAssist	3(c)	122	298	No	Yes	No
HeartWare HVAD	3(d)	45	145	Yes	Yes	Yes

- (a) active magnetic levitation
- (b) radial hydrodynamic support
- (c) magnetic levitation plus radial and axial hydrodynamic support
- (d) magnetic levitation plus axial hydrodynamic support

We believe this comparison clearly indicates the advantages HTW has over its competitors.

HTW Management

HeartWare is chaired by Mr Rob Thomas, the former Chairman of Citigroup Australia's Corporate and Investment Bank. Other directors include Seth Harrison MD, Managing Partner of Apple Tree Partners I.L.P. ("Apple Tree Partners"), a US venture capital firm, Dr Christine Bennett, formerly Chief Executive Officer of Research Australia Limited, and Dr Denis Wade AM, formerly Chairman of Johnson & Johnson Research Pty Limited.

HeartWare's Managing Director and CEO is Mr Stuart McConchie. Mr McConchie has over 25 years of medical device company experience including over 10 years in the heart failure device industry.



The Scientific Advisory Board consists of a number of highly experienced and internationally recognised experts in the cardiology and cardiac surgery fields:

- O. Howard 'Bud' Frazier MD (Chief of Transplant Services, Texas Heart Institute): who has implanted over 600 left ventricular assist devices. Dr Frazier is Chairman of the Advisory Board.
- Steven Boyce MD - Director of Heart Transplantation Washington Hospital Centre.
- Leslie Miller MD - Director Cardiovascular Division, University of Minnesota.
- Laman Gray Jr. MD - Director of Thoracic and Cardiovascular Surgery, University of Louisville.
- Mr Stephen Westaby - Cardiothoracic surgeon, John Radcliffe Hospital.
- Dr Georg Wieselthaler - Clinical Director of Mechanical Circulatory Support, Vienna General Hospital.

Intellectual Property

The Company has established an extensive patent portfolio with 14 patents issued by the US Patent and Trademark Office, and 10 international patents.

HeartWare's US and foreign issued patents and patent applications cover the fundamental technology underlying its haemodynamically and physiologically compatible full output, long term circulatory assist devices. The company has also filed an extensive additional suite of patent applications covering specific elements of its miniaturised "MVAD" technology.

Unit Sales Forecasts

The key issue for an LVAD company is the rate at which it is able to implant units in volunteers during trials. Of course the key endpoints of safety and effectiveness are the key determinants of success, but we believe that given the nature of the market, rate of uptake is a leading indicator of technological success.

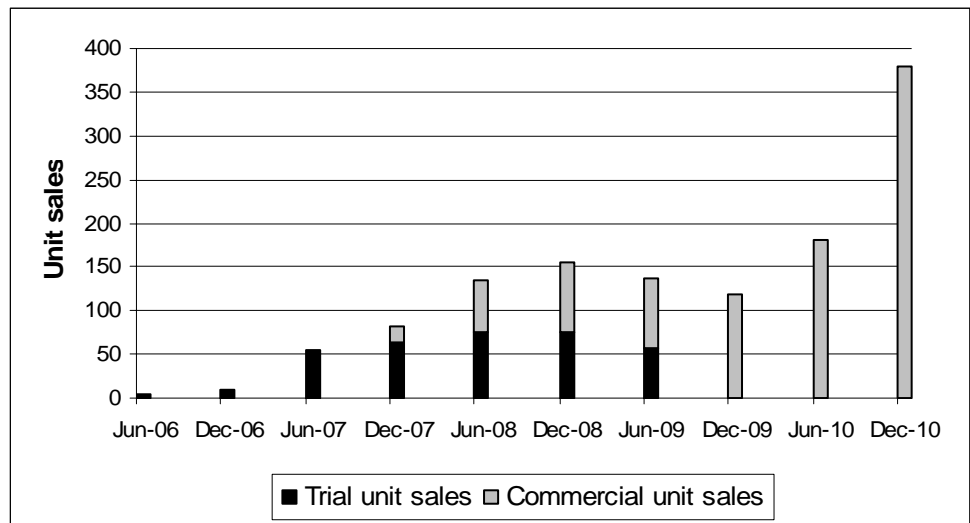
The nature of the market – strong adoption by key opinion leaders on the back of technological success, means that the product virtually markets itself.

As discussed earlier, the company is expected to be able to implant in 4 centres in the near future. We view the number of centres as critical to the timely recruitment of patients and completion of trials.

Our forecast unit sales (implants) for both clinical trials and commercial sales are shown in Figure 4.



Figure 4: Forecast HVAD Unit Sales



Source: WHTM

Decline in unit sales in 2H09 is reflective of conservative nature of our forecasts. If the product is approved for the DT market in the US we would expect uptake to be rapid, reaching approximately 375 units in 2H10. This compares with the 100 per 6 months that Thoratec is currently achieving in clinical trials.

Based on these forecasts we believe HTW will burn through approximately \$18M in FY06 and a further \$12M in FY07. The reduced cash requirement is a function of reimbursement the company receives for units in clinical trials in the US.

We estimate that the company will receive an average reimbursement of US\$65,000 per implant. Once again to be on the conservative side we assume that only 80% of these implants are reimbursed.

Valuation

Thoratec, the market leader, trades at a historical sales multiple of approximately 5x. However it is important to realise that Thoratec has 2 major divisions – VADs and ITC. The ITC division (International Technidyne Corporation) markets point-of-care blood diagnostic test systems. These products are sold in the hospital, physician, long-term care etc. markets. The division is essentially a cash cow for the company, albeit with low margins, and makes up approximately 36% of revenue. The market appears to be valuing Thoratec on a multiple of LVAD sales. Thus after accounting for ITC revenues, Thoratec is trading on a revenue multiple closer to 7.8x.

Placing HTW on a 7.8x sales multiple based on FY10 revenues (as that is when we expect the HVAD to be generating sales for all indications), discounting back at 15%, and applying an 80% probability of successfully commercialising the HVAD, we arrive at a valuation of \$161M or 104 cps.

Table 4: Sales Multiple Valuation

FY10 Revenue (\$M)	49.86
7.8x (\$M)	388.93
15% discount rate (\$M)	222.37
80% probability (\$M)	177.90
Value per share (\$)	1.14

Source: WHTM

The share is currently trading at 118 cps, implying the MVAD, PedVAD and miniaturisation technology is only worth 11 cps or \$16.6M.

Table 5: Implied Value of MVAD etc

	cps	\$(M)	
Current price	114	177.95	
HVAD	103	161.38	
MVAD, PedVAD etc	11	16.57	implied value

Source: WHTM

Comparing HTW with VCR's valuation, it is clear that the technology (EV) is valued equally (Table 5). On balance we estimate that HTW is approximately 6-9 months behind VCR in terms of bringing the HVAD to market. However, 9 months ago, VCR had a market capitalisation of approximately \$240M. The peak valuation for the company in the last 12 months was post its first European implant (May 2005), boosting the company's market capitalisation to approximately \$300M.

Table 6: Comparison with VCR and Thoratec

	M. Cap (M)	Revenues (A\$) (ttm)	Cash (M)	EV (\$)	LVAD Sales multiple
Thoratec (US\$)	1,000.0	129.0	211.0	789.0	7.8
VCR (\$)*	222.0	0.5	66.0	156.0	444.0
HTW (\$)	174.0	0.0	13.0	161.0	na

Source: WHTM, IQ Capital

* At price of recent capital raising

The comparative valuations above ignore a key advantage we believe HTW has over both Thoratec and VCR, and that is the pipeline of products and the ability to miniaturise the HVAD technology. We believe that this not only gives HTW a competitive advantage, but should also allow HTW to expand the market.

The analysis arguably also does not reflect the potentially significant competitive advantages that the HeartWare HVAD might demonstrate over all competing devices. This should enable HeartWare to capture a relatively healthy market share, even before its next generation technologies are introduced.

DCF Valuation

Our cash flow model is shown in Table 7.

Table 7: Cash Flow Model

	2006(E)	2007(E)	2008(E)	2009(E)	2010(E)
Unit sales	14	139	291	257	560
unit sales % growth		892.9%	109.4%	-11.7%	117.9%
Revenues (\$M)	0.997	10.258	23.222	21.868	49.863
Gross profit (\$M)	0.748	7.693	17.416	16.401	37.397
SG&A (\$M)	15.000	15.912	17.210	18.615	20.134
R&D (\$M)	1.906	3.230	2.456	2.482	2.510
EBITDA (\$M)	-16.158	-11.449	-2.250	-4.696	14.753
Interest (\$M)	0.269	-0.072	-0.072	-0.072	-0.072
PBT (\$M)	-15.889	-11.522	-2.322	-4.768	14.681
Change in W.C. (\$M)	-1.579	-5.587	-5.200	2.564	-18.521
FCF (\$M)	-17.469	-17.109	-7.522	-2.204	-3.839

Source: WHTM

The company has approximately \$13.8M in cash (as at end of December 2005). We expect they will burn through approximately \$18M in 2006, thus a capital raising is inevitable, as foreshadowed in their IPO prospectus.

Our DCF variables are shown in Table 8, arriving at a valuation of 187 cps.

Table 8: DCF Valuation

beta	1
Probability of reaching market	80%
Discount rate	15%
Terminal rate	5%
NPV 2015 (\$M)	91.70
Perpetuity (\$M)	273.52
Value	365.22
80% probability	292.18
Value per share	1.87

Source: WHTM

The 15% discount rate is probably a little high, given the fact that the company has achieved everything it set out to do in their prospectus – on time. The 80% probability of the HVAD reaching the market, we believe is fair given that only a single implant has taken place. Some may argue that it is too high, but we believe the fact that first implant was performed in only 85 minutes of surgery to be extremely positive.

Value Enhancing Events and Newsflow

The most important value enhancing event in the next 12 months is the completion of the EU and Australian clinical trials. This is expected by the end of December 2006. Submission of an IDE to the FDA by the end of September 2006 is crucial as a precursor to the start of the US pilot trial. Completion of the EU and Australian trials sets the stage for TGA approval and CE Mark which would then be expected in 3Q07, followed by commercial sales soon thereafter.

Successful completion of the EU and Australian clinical trials would see us increase our probability of the HVAD reaching the market from 80% to 90%, increasing our DCF valuation to at least 211 cps.

We continue to emphasise the importance of recruitment rate as an indicator of acceptance by physicians as to the probable success of a product. Therefore each



successful recruitment is likely to be a value accretive event, more so if the rate of implantation allows the company to keep to or beat its timeline.

Conclusion

Since listing the company has achieved everything it planned to do, including its first human implant by the end of March 2006. The fact that the procedure took only 85 minutes is extremely impressive.

We believe the company has a significant competitive advantage over its competitors in terms of its technology. We believe their technology allows the company to develop a product not only smaller and more robust than other LVADs, but also to develop a pipeline of products.

On a DCF basis the share appears significantly undervalued, with a strong pipeline of news flow expected. We therefore initiate coverage with a BUY recommendation with a 12 month price target of \$2.11.

Heartware Limited (HTW : \$1.14)

INVESTMENT FUNDAMENTALS

Yr Ending Dec	2004A	2005A	2006E	2007E	2008E
EPS Reported (c)		-9.4	-13.6	-11.7	-10.9
EPS Normalised (c)		-9.9	-13.6	-11.7	-10.9
EPS Growth (%)	N/A	N/A	-44.6%	14.0%	7.2%
PER Normalised (x)		-11.5	-8.4	-9.7	-10.5
DPS (c)	0.0	0.0	0.0	0.0	0.0
Payout (%)		0.0%	0.0%	0.0%	0.0%
Yield (%)		0.0%	0.0%	0.0%	0.0%
Franking (%)	0%	0%	0%	0%	0%

VALUATION DATA

Yr Ending Dec	2004A	2005A	2006E	2007E	2008E
EV / EBITA (x)		-12.0	-11.0	-15.1	-18.0
EV / EBITDA (x)		-12.3	-11.4	-15.7	-19.5
CFPS (c)		-7.3	-11.2	-11.2	-8.1
Price / CF		-15.6	-10.2	-10.2	-14.1
Book Value / Share (\$)		0.4	0.2	0.1	0.0
Price / Book (x)		3.0	4.7	9.1	69.5

PROFIT & LOSS (\$m)

Yr Ending Dec	2004A	2005A	2006E	2007E	2008E
Sales Revenue	0.0	0.0	0.0	0.4	2.0
EBITDA	0.0	-13.5	-16.1	-12.8	-11.1
Depreciation	0.0	0.3	0.5	0.5	0.9
EBITA	0.0	-13.8	-16.7	-13.3	-12.0
Amortisation	0.0	2.4	4.9	4.9	4.9
EBIT	0.0	-16.3	-21.5	-18.2	-16.9
Net Interest Expense	0.0	-0.9	-0.3	0.1	0.1
Pre-tax Profit	0.0	-14.7	-21.3	-18.3	-17.0
Tax	0.0	0.0	0.0	0.0	0.0
Tax rate (%)		0.0%	0.0%	0.0%	0.0%
Minorities / pref divs	0.0	0.0	0.0	0.0	0.0
Equity accounted NPAT	0.0	0.0	0.0	0.0	0.0
Net Profit	0.0	-14.7	-21.3	-18.3	-17.0
Abn's / Extraord's	0.0	0.0	0.0	0.0	0.0
Reported Net Profit	0.0	-14.7	-21.3	-18.3	-17.0
Revenue Growth (%)	N/A	N/A	N/A	N/A	340.0%
EBIT Growth (%)	N/A	N/A	-32.4%	15.4%	7.2%
NPAT Growth (%)	N/A	N/A	-44.8%	14.0%	7.2%

PROFITABILITY RATIOS

Yr Ending Dec	2004A	2005A	2006E	2007E	2008E
EBIT / Sales (%)					-862.9%
ROA (%)	N/A	-67.2%	-45.9%	-40.2%	-38.3%
ROE (%)	N/A	-49.7%	-43.9%	-63.8%	-153.1%
ROFE (%)	N/A	-59.1%	-36.9%	-30.8%	-28.5%

INTERIMS (\$m)

Half Yr	May 05	Dec 05	Jun 06	Dec 06	Jun 07
Yr Ending Dec	1H A	2H A	1H E	2H E	1H E
Sales Revenue	0.0	0.0	0.0	0.0	0.0
EBIT	-5.2	-11.1	-10.7	-10.9	-9.1
Net Profit	-4.1	-10.6	-10.4	-10.8	-9.2
EBIT / Sales (%)					

BALANCE SHEET (\$m)

Yr Ending Dec	2004A	2005A	2006E	2007E	2008E
Cash	0.0	13.7	0.0	0.0	0.0
Receivables	0.0	0.2	0.7	4.8	6.3
Inventories	0.0	0.0	1.2	1.9	1.6
Other	0.0	26.9	0.3	0.3	0.3
Current Assets	0.0	14.2	2.3	7.1	8.2
Net PPE	0.0	1.8	1.8	1.8	2.9
Investments	0.0	0.0	0.0	0.0	0.0
Intangibles	0.0	46.2	41.3	36.4	31.5
Other	0.0	0.0	0.0	0.0	0.0
Non-current Assets	0.0	48.0	43.1	38.2	34.4
Total Assets	0.0	62.1	45.4	45.3	42.6
Current Payables	0.0	1.4	1.6	1.9	1.6
Current Debt	0.0	0.0	4.3	22.2	36.8
Non-Current Debt	0.0	1.4	1.4	1.4	1.4
Provisions	0.0	0.1	0.1	0.1	0.1
Other	0.0	0.1	0.1	0.1	0.1
Total Liabilities	0.0	3.1	7.6	25.8	40.1
Equity	0.0	73.8	73.8	73.8	73.8
Reserves	0.0	-0.1	-0.1	-0.1	-0.1
Retained Profits	0.0	-14.7	-36.0	-54.2	-71.2
Minorities	0.0	0.0	0.0	0.0	0.0
Total Equity	0.0	59.1	37.8	19.5	2.6
Total Funds Employed	0.0	46.8	43.5	43.2	40.8

LIQUIDITY & LEVERAGE RATIOS

Yr Ending Dec	2004A	2005A	2006E	2007E	2008E
Net Debt (Cash) (\$m)	0.0	-12.2	5.7	23.7	38.3
Net Debt / Equity (%)		-20.7%	15.2%	121.2%	1,496.3
Interest Cover (x)		-625.8	-598.2	-252.9	-234.7
Debt / CashFlow (x)		-0.1	-0.3	-1.4	-3.0

CASHFLOW (\$m)

Yr Ending Dec	2004A	2005A	2006E	2007E	2008E
EBIT	0.0	-16.3	-21.5	-18.2	-16.9
Dep'n and Amort'n	0.0	2.8	5.4	5.4	5.8
Net Int Rec'd (Paid)	0.0	0.9	0.3	-0.1	-0.1
Tax Paid	0.0	0.0	0.0	0.0	0.0
Dec / (Inc) W'kg Cap	0.0	1.3	-1.6	-4.5	-1.4
Other	0.0	-0.1	0.0	0.0	0.0
Operating Cash Flow	0.0	-11.4	-17.5	-17.4	-12.6
Capital Expenditure	0.0	-4.9	-0.5	-0.5	-2.0
Asset Sales	0.0	0.0	0.0	0.0	0.0
Investments	0.0	0.0	0.0	0.0	0.0
Other Inv. Flows	0.0	0.2	0.0	0.0	0.0
Investing Cash Flow	0.0	-4.7	-0.5	-0.5	-2.0
Equity Raised	0.0	32.5	0.0	0.0	0.0
Inc / (Dec) in Loans	0.0	0.0	0.0	0.0	0.0
Dividends Paid	0.0	0.0	0.0	0.0	0.0
Other Fin. Flows	0.0	-2.7	0.0	0.0	0.0
Financing Cash Flow	0.0	29.8	0.0	0.0	0.0
Net Cash Flow	0.0	13.7	-18.0	-17.9	-14.6

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