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Sunshine Heart (SHC)

The sun also rises

Recommendation
Spec Buy (Initiation)
Price
$0.047
Target (12 months)
$0.14

Expected Return	
Capital growth	**198%**
Dividend yield	**0**
Total expected return	**198%**

Company Data & Ratios	
Enterprise value	**$43.2m**
Market cap	**$56.5m**
Issued capital	**1,203.2m**
Free float	**100%**
Avg. daily vol. (52wk)	**0.58m**
12 month price range	**$0.022-$0.063**
GICS sector	
Healthcare Equipment and Services	

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.04	0.05	0.03
Absolute (%)	17.50	-9.62	85.94
Rel market (%)	22.16	2.71	99.97

This report initiates Bell Potter Securities' coverage of Sunshine Heart.

An effective device for mid-stage heart failure

Sunshine Heart is developing the C-Pulse System, an implantable medical heart assist device for the treatment of mid-stage heart failure. The device, a balloon cuff that wraps around the ascending aorta, has performed very well in a feasibility study in Australia and New Zealand as well as in a US pilot trial in terms of treating the symptoms of heart failure. We expect a CE Marking of the device next year. FDA approval of the device is likely in 2015/16 after a US pivotal trial of the device.

C-Pulse has strong advantages over LVADs

Currently LVADs are growing in popularity as a heart assist device for 'Class IV' late stage heart failure patients, who represent around 5% of the heart failure population. However C-Pulse has several advantages over LVADs. The device is non-blood contacting and therefore brings much less risk of blood clotting. Patients can disconnect for brief periods of time. C-Pulse is easier to implant into the patient and therefore likely to appeal to a much larger physician group. Also, the device is likely to be much less expensive than LVADs. Consequently we see widespread adoption of the device in NYHA Class III, which is around 30% of the heart failure population.

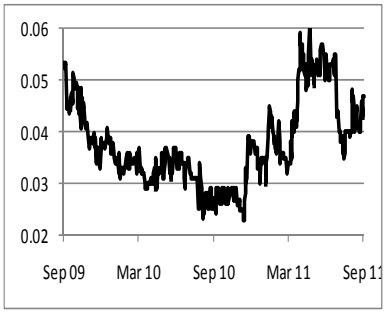
Sunshine Heart has a good leadership team

We have a high regard for the current management at Sunshine Heart under CEO Dave Rosa, who has been instrumental in completing C-Pulse's US pilot trial. We like the commercial approach that Rosa and his colleagues have taken since 2009.

Investment view – The sun is rising for Sunshine Heart

We value Sunshine Heart on a probability-weighted DCF valuation at 14 cents per CDI base case and 21 cents per CDI optimistic case, fully diluted for a A$50m capital raising. Our 14 cent price target sits at the low point of this valuation range. We anticipate Sunshine Heart being re-rated by the market as commercial interest builds in C-Pulse as a treatment alternative for Class III heart failure patients.

Absolute Price



SOURCE: IRESS

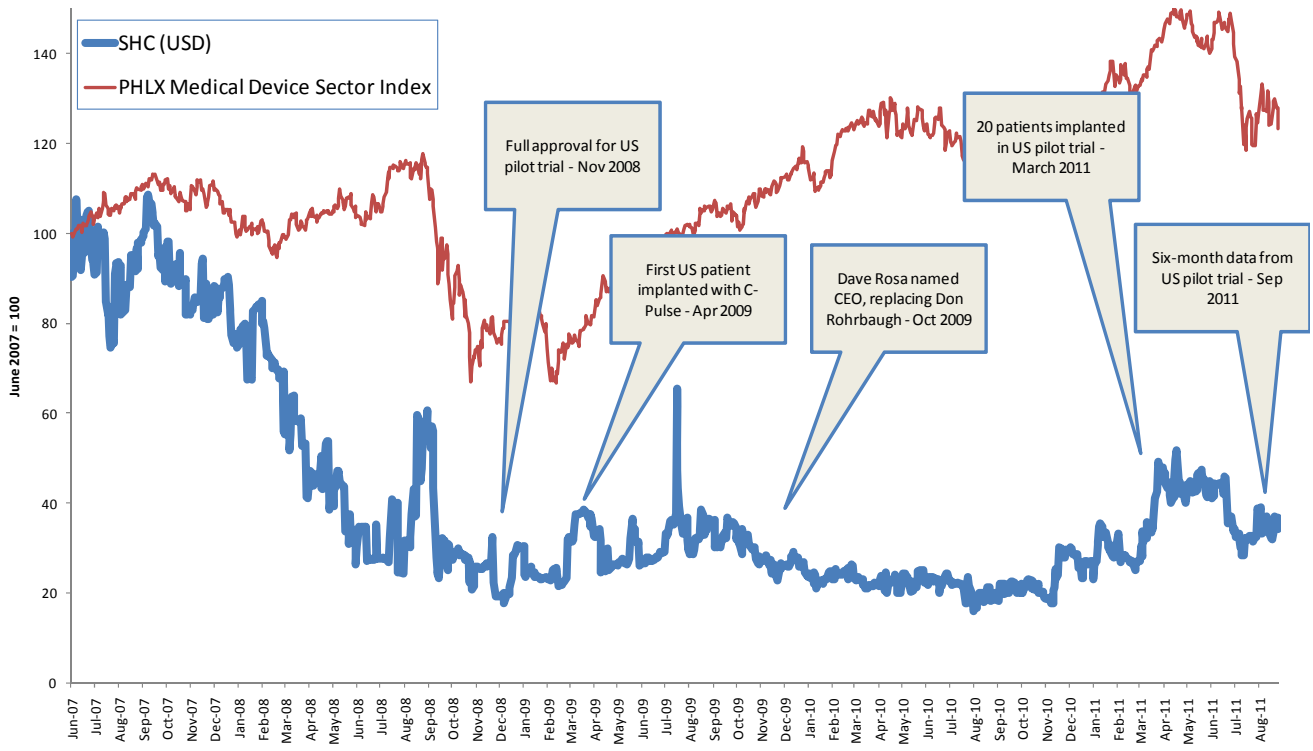
Earnings Forecast

Year end 30 June	2011a	2012f	2013f	2014f
Sales (A$m)	0	0	6	21
EBITDA (reported) (A$m)	-12	-15	-30	-17
NPAT (reported) (A$m)	-11	-15	-28	-16
EPS (cps)	-1.1	-1.0	-1.1	-0.6
EPS growth (%)	N/A	N/A	N/A	N/A
PER (x)	-4.2	-4.9	-4.4	-7.6
EV/EBITDA (x)	-4.8	-3.7	-1.9	-3.3
Dividend (¢ps)	0	0	0	0
Yield (%)	0.0%	0.0%	0.0%	0.0%
ROE (%)	-196%	-31%	-134%	-327%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Sunshine Heart – The sun also rises

Figure 1 – Major developments for Sunshine Heart since 2007



SOURCE: SUNSHINE HEART, BELL POTTER SECURITIES

"C-Pulse is highly innovative and implanted with a simple, low-risk minimally invasive surgical procedure. The device has the potential to offer a new therapy option for the treatment of moderate heart failure".

- Dr. Benjamin Sun, Chief, Division of Cardiothoracic Surgery and Director, Cardiac Transplantation and Mechanical Support at Ohio State University Medical Center, Columbus, Ohio, speaking in 2009.

Introducing Sunshine Heart, ASX: SHC

Sunshine Heart is a medical device development company based in Eden Prairie, Mn. The company's C-Pulse product is an implantable heart assist device for the treatment of mid-to-late stage heart failure. The device performed well in a first-in-man study trial in Australia and New Zealand and a pilot trial in the US. On the strength of this data the company expects to file for CE Mark, as well as initiate a US pivotal trial, in 2012.

2-4% of Western world adult populations have heart failure

What is heart failure? Heart failure is the progressive inability of the heart to pump properly due to weakened heart muscle. Whether it started from coronary artery disease[1] and led via one or more heart attacks[2] to *ischemic heart failure*[3], or from high blood pressure or from a number of other cardiovascular problems, leading to *non-ischemic heart failure*[4], heart failure manifests itself as more and more tiredness, pain and shortness of breath on the part of the patient whenever he or she engages in physical activity. Over the course of five to ten years the heart failure patient progresses from early stage 'NYHA Class I' heart failure through to late stage 'Class IV'. Heart failure represents a large market opportunity, given prevalence of ~2-4% of Western world adult populations.

What is C-Pulse? The core of the C-Pulse device is a balloon cuff which wraps around the ascending aorta (the blood superhighway that carries the red stuff out of the heart and on to the rest of the body) and inflates and deflates in time with heart filling and pumping, respectively. This counterpulsation action acts to force blood out of the ascending aorta, thereby assisting the heart to pump blood more efficiently. A sensing lead attached to the heart feeds the heart's electrical signals back to a battery-powered driver which is external to the body, and this driver in turn inflates and deflates the cuff through an air tube.

Why does the C-Pulse represent an improvement over existing heart failure treatments? The emergence of the left-ventricular assist device (LVAD) has been one of the more promising developments in heart failure over the last decade. LVADs are electromechanical pumps that implant inside the left ventricle, the chamber of the heart that pumps blood out to the body. LVADs work very well in terms of treating (but not reversing) the symptoms of heart failure. However they can be difficult to surgically implant and the pump itself is blood contacting, leaving the patient in danger of life-threatening blood clots. In addition, the device can't be 'switched off'. Moreover they are expensive, with the pump alone costing >US$120,000 in the US. Consequently they have been largely the preserve of Class IV heart failure patients which only constitute around 5% of the heart failure population. C-Pulse, by contrast, is much easier to implant, is non-blood contacting and can be switched off if necessary. It is also expected to be much less expensive than LVADs. For all these reasons C-Pulse is considered suitable for the much larger Class III patient population, which is more like 30% of the total.

If C-Pulse is so good why does Sunshine Heart only have an enterprise value of less than A$50m? Sunshine Heart has significantly underperformed in share price terms against comparable med-tech companies because of the slowness to recruit for its US pilot trial of C-Pulse (see Appendix II). However a new management team under CEO Dave Rosa, who joined the company in late 2009, worked with various physician groups to recruit the requisite 20 patients, and favourable data from these patients has now been released. We believe the data can act as a catalyst to help re-rate Sunshine Heart, since it permits both CE Marking of the device (on advice from Sunshine Heart's Notifed Body) as well as initiation of a US pivotal trial next year.

[1] That is, the build-up of fatty deposits inside the coronary arteries, leading to occlusion or blockage which deprives oxygen to heart muscle.

[2] More properly, 'acute myocardial infarctions'.

[3] Ischemia comes from Greek words meaning 'restriction of blood'.

[4] Non-ischemic heart failure, or 'dilated cardiomyopathy' (the heart becomes enlarged as it weakens), is heart failure that results from conditions such as hypertension, rheumatic heart disease, alcoholism and atrial fibrillation.

C-Pulse has performed in the clinic

In September 2011 Sunshine Heart reported to the market that its 20-patient US pilot trial of C-Pulse appeared to have gone well. At >6 months[5] the investigators found that:

- *All but one patient either improved or maintained NYHA class* – we assume the bias is towards improvement in class given the anecdotal evidence to date[6];
- *Two patients were disconnected permanently due to the absence of heart failure symptoms* – these patients appear to have been 'bridged to recovery';
- *Overall improvements were realised, as measured by quality of life scores, six-minute walk times, ejection fractions, and reductions in medications;*
- *No neurologic events were reported*, important given the stroke risk traditionally associated with LVADs;
- *There was only one instance of post operative, non-device related bleeding*, again, important given the bleeding risk of LVADs;
- *The median length of hospital stay for the patients was 8 days*, which was favourable when compared to hospital stays for LVAD patients that are often twice as long[7].

All but two of the patients recruited were Class III patients, for whom there are no heart assist options at present like LVADs[8], and all had either ICDs or CRT-D devices implanted, suggesting that C-Pulse is potentially synergistic with these devices as well.

The US pilot trial data will be published at the prestigious TCT conference in November

Sunshine Heart will present the full pilot data on 8 November in San Francisco at TCT 2011, the annual 'Transcatheter Cardiovascular Therapeutics' meeting, which is the world's largest scientific symposium for interventional cardiovascular medicine specialists[9]. We think the milestone of pilot trial data will help re-rate Sunshine Heart:

Implantation via minimally invasive surgery considerably strengthens the commercial case for C-Pulse

- *The data will likely put the company on track for CE Marking of its device next year*, with Sunshine Heart's European Notified Body having indicated that US pilot data will be acceptable for approval;
- *Sunshine Heart's report suggests that C-Pulse can compete with LVADs*, particularly since the device is now implantable via minimally invasive surgery – the need for an incision comparable to that used for a pacemaker makes the decision to implant a C-pulse at Class III heart failure a whole lot easier;
- *The publicity of the data at TCT will allow widespread exposure of C-Pulse* in the global interventional cardiology community, helping to drive further recruitment to established C-Pulse trial sites under a Continuous Access Protocol approved in April 2011[10], as well as helping to recruit sites for the US pivotal trial;
- The people involved in the trial - most notably Dr. Mark Slaughter of the University of Louisville[11] and Dr Bill Abraham of Ohio State University[12], whose institution reported the early results which Sunshine has submitted to the market - will likely help the C-Pulse approach to be taken seriously.

[5] That is, after the last-recruited patient had survived six months with the C-Pulse. Some patients in the trial had been supported by the device since April 2009. Only one patient died, from an aortic disruption resulting from re-sternotomy surgery to treat a procedure-related infection.

[6] See, for example, http://www.youtube.com/watch?v=AhpdTe62mFo, profiling Faye Prather, an early pilot trial patient from Kentucky. In the Australia and New Zealand first-in-man trial all five patients, who were late stage and generally weren't on the device for long, nonetheless improved by 1 NYHA class.

[7] As we note further down in this report, the use during the trial of minimally invasive surgery cut hospital stay down to just 3-4 days.

[8] The other two were Class IV patients.

[9] See www.tctconference.com. Around 12,000 people attend this meeting.

[10] As part of the FDA's effort to encourage further usage of heart assist devices in the US market, the Agency in April 2011 approved an IDE Supplement which allowed the centres that had participated in the pilot trial to treat more patients beyond the 20 that were included in the trial. An additional 20 patients were permitted. We assume that if these 20 places are filled the FDA will permit further recruitment beyond this. Sunshine has yet to take advantage of these Continuous Access places, but continues to implant patients at McGill University Health Centre in Montreal, where the company is conducting a separate coronary perfusion study (see NCT01176370 at www.clinicaltrials.gov).

[11] He was Principal Investigator in HeartWare's highly successful US Bridge to Transplant trial, which reported data at the American Heart Association meeting in November 2010.

[12] Dr Abraham has been named as one of the Best Doctors in America (www.bestdoctors.com).

Nine reasons to like Sunshine Heart

1) **The C-Pulse device is an effective treatment for heart failure**. Sunshine Heart has demonstrated that C-Pulse can treat, and in some cases reverse the symptoms of heart failure, with less hospitalisations in the treated patients. The device has completed its US pilot trial, and this milestone allows the company to file for CE Mark approval of the device, as well as prepare for the US pivotal.

2) **The heart failure market is large and growing.** With 2-4% of Western world adult populations suffering heart failure and the patient numbers growing every year thanks to the high prevalence of cardiovascular disease, the number of potential C-Pulse recipients is large.

3) **LVADs have pioneered the market for C-Pulse**. Since the 2008 FDA approval of Thoratec's Heartmate II device, LVADs have been gaining greater and greater acceptance from the cardiology community, helped by the fact that drug therapy is relatively ineffective and heart transplantation is rare. We think the success of LVADs paves the way for C-Pulse as a 'next generation' heart assist device.

4) **C-Pulse has advantages over LVADs**. Currently LVADs are used almost exclusively in 'Class IV' late stage heart failure patients, who represent around 5% of the heart failure population. However C-Pulse has several advantages over LVADs. The device is non-blood contacting and therefore brings less risk of blood clotting and also can be disconnected for temporary periods of time. It is easier to implant into the patient and therefore likely to appeal to a much larger physician group. Also, the device is likely to be much less expensive than LVADs. Consequently we see widespread adoption of the device in Class III patients, which is more like 30% of the heart failure population.

Sunshine Heart can file for CE Marking of C-Pulse this year

5) **Sunshine Heart is getting ready to file for CE Mark approval of C-Pulse**. With the US pilot trial now complete, Sunshine Heart has received guidance from its EU Notified Body that it can file for European approval based on this data. We see C-Pulse gaining its CE Mark by late 2012.

6) **A US pivotal trial of C-Pulse is being prepared.** Sunshine Heart is currently preparing to initiate a US pivotal trial which we think will initiate in 2012. We think this puts C-Pulse on track for a PMA filing in 2015 and product launch by 2016. As with other heart assist devices we expect Sunshine Heart will be reimbursed for devices implanted in this trial.

7) **The fully implantable development programme holds promise**. Sunshine Heart has developed a prototype of a fully-implantable C-Pulse system which it believes it can continue testing next year outside the US. We believe this system can further build the appeal of the device.

8) **Sunshine Heart has a good leadership team**. We have a high regard for the current management at Sunshine Heart under CEO Dave Rosa, who has been instrumental in C-Pulse completing its US pilot trial. We like the commercial approach that Rosa and his colleagues have taken to preparing C-Pulse for widespread acceptance in the cardiology community.

9) **There is strong upside in the stock, on our numbers** We value Sunshine Heart on a probability-weighted DCF valuation at 14 cents base case and 21 cents optimistic case, fully diluted for a A$50m capital raising in order to fund European market development and the US pivotal trial. Our 14 cent price target sits at the low point of this valuation range. We anticipate Sunshine Heart being re-rated by the market as commercial interest builds in C-Pulse as a treatment alternative in Class III patients.

Valuing Sunshine Heart

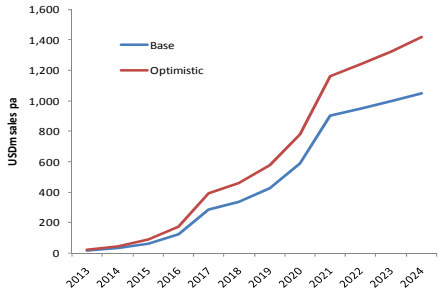
Base case 14 cents, optimistic case 21 cents. We value Sunshine Heart at 14 cents per CDI base case and 21 cents per CDI optimistic case using a probability-weighted DCF valuation, diluted for another A$50m equity raising[13] to fund the FDA trial of C-Pulse (A$35m) and C-Pulse's commercial launch in Europe (A$15m). Our target price of 14 cents per CDI sits at the low point of our DCF range.

Figure 2 - Our valuation of Sunshine Heart

	Base case (A$m)	Optimistic case
Valuation of C-Pulse (AUDm)	427.5	640.2
Less underlying R&D expense (AUDm)	-33.6	-33.6
Cash now (AUDm)	13.4	13.4
Cash from options and warrants (AUDm)	27.6	27.6
Total value (AUDm)	434.9	647.6
Total diluted CDIs (million)	3,023.2	3,023.2
Value per CDI	$0.144	$0.214
Valuation midpoint	$0.179	
Current CDI price	$0.047	
Upside to midpoint	280.9%	

SOURCE: BELL POTTER SECURITIES ESTIMATES

Figure 3 – Our assumed sales profile for C-Pulse



SOURCE BELL POTTER SECURITIES ESTIMATES

A model not based on device partnering. We assumed that the company did not partner C-Pulse but brought it to market by itself. We assumed only European and US sales and modelled C-Pulse using estimated sales levels reached at the point of maximum sales growth in year 5, after which sales only rise 5% pa (see chart above for an example). These sales levels were US$225m for Europe and US$550m for US base case, and US$350m for Europe / US$700m for US optimistic case. We also assumed:

- patent life out to 2024;
- 70% (base case) to 80% (optimistic case) gross margin on sales;
- a cost base for the marketing operation of around US$20-40m pa (base case) to US$60-120m (optimistic case, with high marketing costs driving higher sales);
- an 80% probability of clinical/ regulatory success;

We then calculated the NPV of the resulting cash flow at a 15% discount rate, adjusted for a 35% US tax rate, and valued the cash flows in Australian dollars using a long-run assumption for the AUDUSD of 0.85.

We expect CE Marking to help continue a re-rating of Sunshine Heart

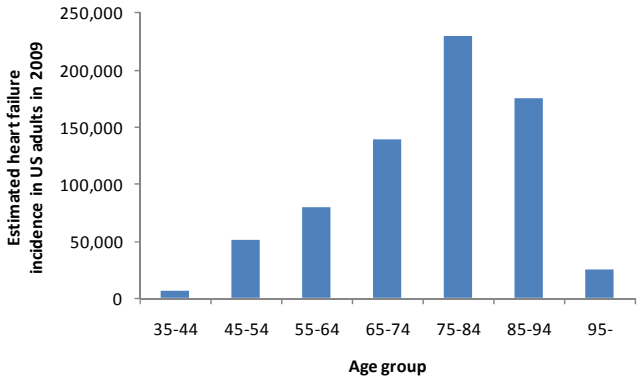
Solid news flow can help the stock reach our target price. We see the following developments as helping Sunshine Heart stock achieve our target price:

- Further implants from existing pilot trial centres under Continuous Access – 3Q11;
- Presentation of the US pilot trial data at TCT – 4Q11;
- Completion of development of single unit C-Pulse system – 4Q11;
- Filing for CE Mark – 1Q12;
- Initiation of US pivotal study – 1Q12;
- Recruitment of various sites into the US pivotal – 2Q12;
- CE Mark Approval – 3Q12.

[13] We assumed for modelling purposes that this raising would take place at 3.5 cents per share.

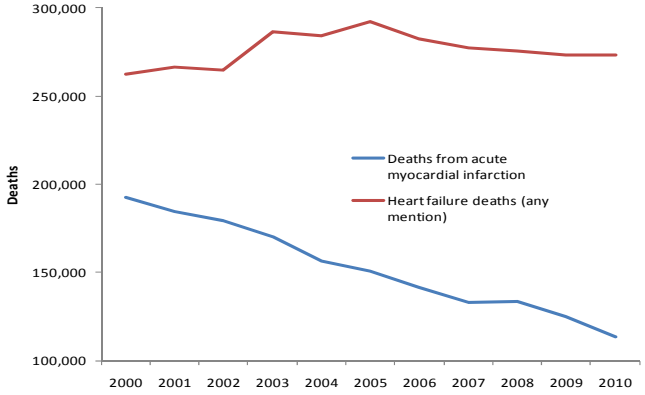
Heart failure is a significant market opportunity

Figure 4 – An aging population will experience more heart failure



SOURCE: NHLBI DATA FROM FRAMINGHAM HEART STUDY, ADJUSTED BY BELL POTTER SECURITIES

Figure 5 – Heart attack deaths down = heart failure deaths up



SOURCE: CDC NATIONAL VITAL STATISTICS REPORTS; AMERICAN HEART ASSOCIATION, HEART DISEASE AND STROKE STATISTICS UPDATES. NOTE 2008-2010 REPRESENTS BELL POTTER SECURITIES ESTIMATES.

There's a lot of heart failure out there. Heart failure may affect at least 5.7 million adult Americans or 2.4% of the adult population[14], which is a knock-on effect of the high prevalence of cardiovascular disease generally. Multiplying the US number by three or four may give a sense of the global patient size[15]. In Europe heart failure prevalence has been estimated at more like 3.0-3.5% of the adult population[16].

1.5-2.0m people in America may have NYHA Class III heart failure

Class III heart failure is a sizeable market in its own right. While estimates of the prevalence of heart failure by disease stage are sketchy, we estimate that around 24% of patients are NYHA Class I (no limitation of physical activity) and 42% are Class II (slight limitation of physical activity). These patients are generally only managed with drug therapy. We estimate Class III heart failure (marked limitation of physical activity) constitute another 30% of the patient population while Class IV patients (virtually no physical activity without discomfort) are only 4-5%. The Class III patient population is of particular interest to Sunshine Heart because these patients are becoming refractory to drug treatment and are helping grow the market for implanted devices called ICDs or CRT-Ds, but do not yet qualify for LVADs, which, for cost reasons, are the preserve of Class IV patients. There are probably something like 1.6 million Class III patients in the US alone.

Patient numbers are probably growing through increased survival. Heart failure incidence could run north of 700,000 new cases a year in the US[17], and is likely to rise in the years ahead given the aging population, the decreasing risk of dying from acute myocardial infarction[18], and increasing survival over time for heart failure patients[19]. In

[14] Source: American Heart Association, *Heart Disease and Stroke Statistics,* 2011 update, Table 9-1. The figures come from NHANEs 2005-2008 data, which is self-reported and therefore potentially under-estimates prevalence.

[15] In its 21/10/2010 investor presentation HeartWare suggests that heart failure 'affects over 20 million people globally'.

[16] Data on heart failure in Europe is sketchy. One common estimate is '14 million Europeans' (J Am Coll Cardiol, 2009; 53:1960-1964), which would be ~3.3% of the population of the EU27 over 14. A comparison of population-based heart failure prevalence in Framingham, Ma (NHLBI, 2006 Chart Book on Cardiovascular and Lung Diseases, Table 5-42) and in the Dutch city of Rotterdam (see Eur Heart J. 1999 Mar;20(6):447-55) suggests roughly comparable rates of heart failure prevalence (ie ~3.5%)

[17] Data from the Framingham Heart Study on incidence per person years for people over 35 (NHLBI, 2006 Chart Book on Cardiovascular and Lung Diseases, Table 4-28), if applied to the 2009 population structure of the US, yields this sort of incidence. The American Heart Association estimated 550,000 cases pa in the early 2000s (source: Heart Disease and Stroke Statistics 2005).

[18] There was a 35% reduction in death from acute myocardial infarction between 2000 and 2009 (Source: CDC National Vital Statistics reports) thanks primarily to devices such as stents, pacemakers and implanted defibrillators.

[19] Up to the 1980s median survival after the onset of heart failure was only 1.7 years in men and 3.2 years in women (see Circulation. 1993 Jul;88(1):107-15), however survival trends have gradually improved over time (see N Engl J Med. 2002 Oct 31;347(18):1397-402).

2007, only 277,000 deaths were registered in the US where heart failure was an issue at the time of death[20].

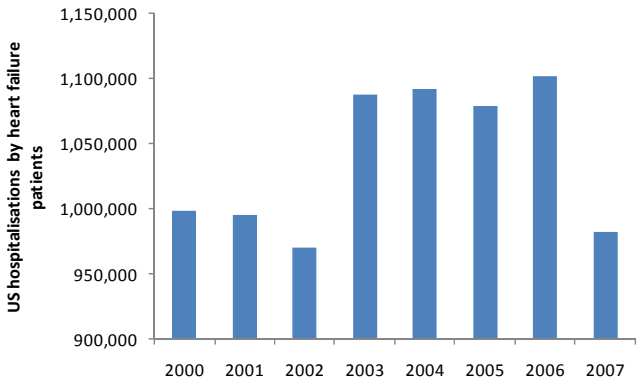
The pool of potential patients is large. As we note in Appendix III, a large proportion of Western world adult populations – in the order of 20-40% - are at risk of cardiovascular disease.

The costs of managing the disease are very high. Not only is the market for heart failure therapies large in terms of patients but the current standard of care leaves a lot to be desired both in terms of cost - heart failure costs the US healthcare system in the order of US$35bn pa in direct medical expenses[21] - and outcomes:

Heart failure hospitalisation is expensive

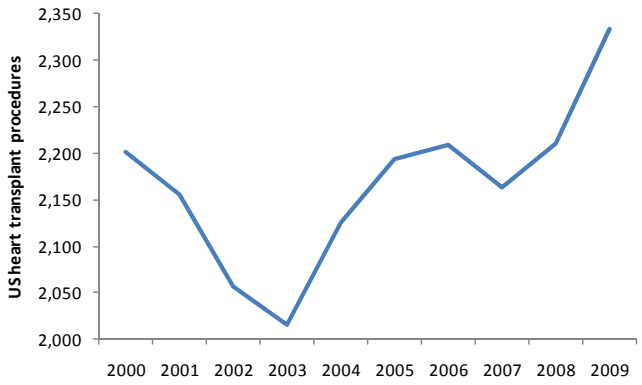
- *Rates of hospitalisation are high*. Even though rates of hospitalisation have been trending down[22], in 2007 Americans with heart failure still generated close to a million hospital discharges with average length of stay of 5 days[23]. Each hospitalisation costs around US$19,000[24], with costs probably rising 7% pa, and around a fifth of all discharged heart failure patients will be readmitted to hospital within 30 days[25], which is of serious concern to hospital operators because of the potential for CMS reimbursement to be cut[26].
- *Just about no-one gets a heart transplant*. Only around 2,200-2,300 heart transplants occur on average each year in the US[27]. The waiting list for a donor heart is always much larger (3,190 as at August 2010), and the median wait time for successful recipients over 18 years of age is 5.3 months[28]. Given that there are probably close to 300,000 Americans with late-stage Class IV heart failure, and 50,000-100,000 patients that could be considered eligible for a heart transplant[29], such a transplant is clearly not an option for the vast majority of patients, who don't even make it to a waiting list.

Figure 6 - Heart failure patients are frequently hospitalised



SOURCE: CDC, NATIONAL HOSPITAL DISCHARGE SURVEYS

Figure 7 – Heart transplants in the US are rare



ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK.

[20] Source: American Heart Association, *Heart Disease and Stroke Statistics,* 2011 update.

[21] Source: American Heart Association, *Heart Disease and Stroke Statistics*, 2010 update, Table 20-1. These costs have risen around 7% pa for the last seven years. Heart failure-related hospital visits increased 1.7% pa between 2000 and 2006, which was 45% faster than the growth of the US adult population. Around 37% of US Medicare's spending is on patients with heart failure (see Circulation. 2008;118:S_1030).

[22] See See Int J Cardiol. 2011 May 19;149(1):39-45. Epub 2010 Jan 13.

[23] Source: CDC, National Hospital Discharge Survey: 2007 Summary.

[24] Calculated using Naylor et. al. (J Am Geriatr Soc. 2004 May;52(5):675-84), updated using US CPI data on the cost of inpatient hospital services.

[25] See Circ Heart Fail. 2010 Jan;3(1):97-103. Epub 2009 Nov 10.

[26] CMS currently has the power to reduce, modify or deny payment for a hospital readmission within 30 days of discharge. From 2012, however, under provisions of PPACA (The Patient Protection and Affordable Care Act, the major healthcare reform law which President Obama signed into law in March 2010), CMS will be required to withhold payments for 'excessive' readmission rates.

[27] Transplant numbers were the same in 2000 and 2009 even though the US population grew 9% between those two years. Basically fewer people were dying - traffic fatalities were down and so were homicides – with hearts suitable for transplantation.

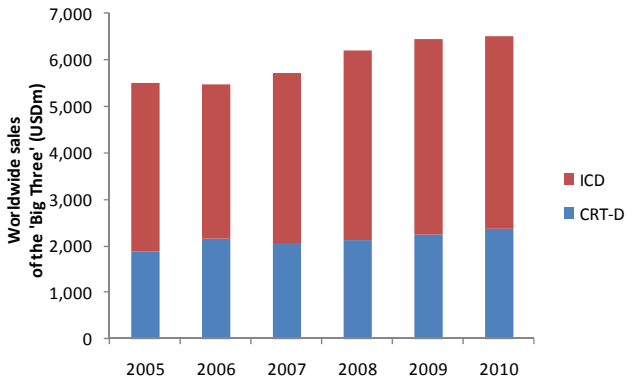
[28] Source: Organ Procurement and Transplantation Center. Data for waiting time is from 2003/04.

[29] Generally to be eligible for a heart transplant the patient needs to be under 65 and free of serious disease conditions other than heart failure. A prospective study of patients referred for evaluation to a Boston transplant centre found 19% of Class IV patients to be transplant-eligible and another 16% to be 'potentially eligible' (see J Am Coll Cardiol. 2004 Mar 3;43(5):794-802).

Thanks to heart failure, ICDs and CRT-Ds are now a >US$6bn market globally

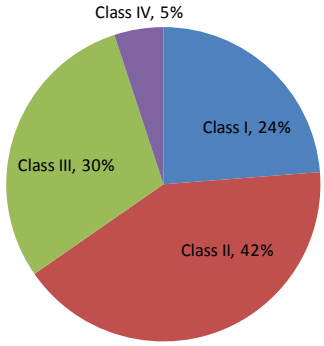
- *The drug market is large.* Heart failure is at least a US$3-4bn drug market in the US[30] driven mostly by off-patent products such as the ACE inhibitor lisinopril (the 2nd most prescribed generic in the US in 2010[31]), the diuretic furosemide (12th most prescribed[32]) and aspirin[33]. However these drugs have only modest efficacy and only provide symptomatic relief, with the patient progressively worsening over a median survival period of around eight years[34].
- *ICDs and CRT-Ds are growing in popularity*. The last ten years has seen the emergence of implantable defibrillation devices as an alternative for later-stage heart failure patients. ICDs, or Implantable Cardioverter Defibrillators, which send electrical signals to the heart to correct irregular heartbeat, began to be increasingly implanted in Class III patients from around 2005[35]. That followed on from the rise of CRT-D devices, which came on the market from 2001, designed to correct conduction defects as well as defibrillate the failing heart[36] and useful in around 20% of heart-failure patients[37]. With both ICDs and CRT-Ds cost effective for the extra year or two of life gained[38] the result has been a >US$6bn market globally for the big American medical device companies Medtronic, St Jude Medical and Boston Scientific.
- *Another large market is emerging for LVADs, but only for NYHA Class IV patients.* As we detail in the next section, LVADs are growing use in popularity as the first true heart assist device (that is, one that can rest the failing heart rather than just keep it pumping normally). However LVADs are currently for late-stage 'NYHA Class IV' heart failure patients, and these represent perhaps 4-5% of the heart failure population. This leaves earlier classes of patients without a device-based heart assist alternative, which Sunshine Heart believes it can provide.

Figure 8 – Heart failure has grown the market for defibrillators



SOURCE: FOR TOTAL SALES OF DEFIBRILLATION SYSTEMS, ST JUDE MEDICAL, MEDTRONIC, BOSTON SCIENTIFIC. FOR CRT-D SYSTEM SALES, BELL POTTER SECURITIES ESTIMATES.

Figure 9 - Most heart failure is in Classes II and III



SOURCE: EUR J HEART FAIL. 2004 OCT;6(6):795-800, 821-2; EUR J HEART FAIL. 2010 JAN;12(1):25-31; BELL POTTER SECURITIES.

[30] See for example American Heart Association Heart Disease and Stroke Statistics 2010, Table 20-1, which postulates US$3.8bn in 'home health care' costs of the 'drugs/other' variety in 2010. We corroborated this estimate using CHF drug cost data from Sokol et. al. (Med Care. 2005 Jun;43(6):521-30), updated with BLS prescription drug price inflation estimates.

[31] The innovator drug, Merck & Co's Prinivil, went generic in 2002.

[32] Even though this drug has been FDA approved since 1966.

[33] Some drugs used in heart failure are still on-patent. The ACE inhibitor Diovan enjoyed US $1.4bn in US sales in 2010 for Novartis, making it that country's 18th biggest selling brand drug. Meanwhile the beta blocker Coreg CR, from GSK, was No. 128 on the US branded list of best sellers, with US$250m in 2010 sales.

[34] See Circulation. 2006 Mar 21;113(11):1424-33. Epub 2006 Mar 13.

[35] Traditionally ICDs had been used mainly to treat ventricular arrhythmia or tachycardia. However two large scale trials, MADIT-II in 2002 (See N Engl J Med. 2002 Mar 21;346(12):877-83. Epub 2002 Mar 19) and SCD-HeFT in 2005 (N Engl J Med. 2005 Jan 20;352(3):225-37), established their utility in treating heart failure with low Ejection Fraction regardless of the presence or absence of arrhythmia/tachycardia.

[36] Cardiac Resynchronisation Therapy (CRT), also called 'Biventricular Pacing', involves the use of specialised pacemakers to re-coordinate the action of the right and left ventricles of the heart where an abnormality in the heart's electrical conducting system has caused the two ventricles to beat in an asynchronous fashion. CRT-D devices combine these pacemakers with a defibrillator.

[37].One large study in the UK evaluating the ability of ECG to guide therapy found 20% of suspected heart failure patients had QRS ≥120 ms, indicating a need for evaluation for Cardiac Resynchronisation Therapy (see Eur J Heart Fail. 2007 May;9(5):491-501. Epub 2007 Jan 9).

[38] For ICDs see Circulation. 2006 Jul 11;114(2):135-42. Epub 2006 Jul 3. For CRT-D see J Am Coll Cardiol. 2005 Dec 20;46(12):2311-21.

LVADs have pioneered the heart assist market

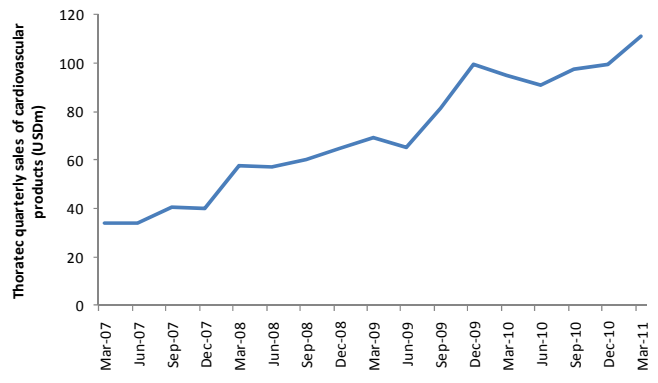
A device emerging into the cardiology mainstream. The emergence of the LVAD, or left-ventricular assist device, has been one of the more promising developments in heart failure over the last decade. LVADs are battery-operated mechanical pumps that, after being surgically implanted in the left ventricle, the chamber of the heart that pumps blood out to the body, are able to effectively take over the pumping function of the heart. After several decades of development, they now work effectively and reliably to reverse the symptoms of heart failure, and the LVAD space has now progressed to the point where favourable data and availability of reimbursement is driving uptake for two competing companies:

The LVAD market is still markedly underpenetrated

- Thoratec[39] whose Heartmate II LVAD became FDA-approved in April 2008 as a 'Bridge to Transplant'[40]. The data from the pivotal trial related to this approval was encouraging - all completing patients in the trial were 'NYHA Class IV' at baseline, but 85% of them improved to Class I or II while the other 15% at least improved to Class III. Heartmate II gained FDA 'Destination Therapy' approval in January 2010[41].
- Heartware[42], whose HVAD device, which is considerably lighter and smaller than HeartMate II and which, unlike HeartMate II, is implantable within the pericardial space next to the heart. HVAD gained European approval in 2009 and performed well in a US Bridge to Transplant trial for which data was released in November 2010. The PMA for HVAD was accepted by the FDA in March 2011.

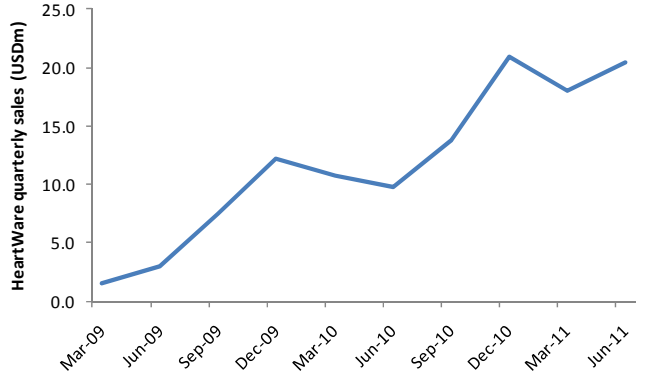
The commercial success of these companies – US$383m in 2010 revenue for Thoratec and US$55m for HeartWare – and the high growth rates has resulted in substantial market capitalisations, with Thoratec valued at US$1.92bn and HeartWare US$822m on Nasdaq[43] even though market penetration is still low[44].

Figure 10 – Thoratec is the LVAD market leader



SOURCE: THORATEC

Figure 11 – HeartWare is a strong No. 2 in LVADs



SOURCE: HEARTWARE

While LVADs are now regarded as a conventional therapy for heart failure, particularly since their reliability has greatly improved[45], they still come with four key drawbacks:

[39] Nasdaq: THOR; Pleasonton, Ca; www.thoratec.com.

[40] Meaning that the device could only be implanted into people awaiting a heart transplant.

[41] Where the LVAD is implanted into the patient permanently.

[42] Nasdaq: HTWR and ASX: HIN; Framingham, Ma; www.heartware.com.

[43] 21 September 2010 market close.

[44] Consider, for example, that if US heart failure incidence is 700,000 pa, Class IV incidence could be 35,000. However Thoratec only sold 2,500 pumps on the US market in 2010, which would represent ~7% penetration.

[45] Curr Opin Cardiol. 2009 Mar;24(2):184-9.

- *High cost.* US Medicare currently provides US$147,000 in minimum total reimbursement for an LVAD implantation[46], the majority of which goes for the device. This means that they are currently only reimbursed for Class IV patients, which as we noted above constitute around 5% of the total patient population[47];
- *Perceived lack of cost-effectiveness*. Following on from the high costs of the device, all studies to date have found LVADs to lack cost-effectiveness. In healthcare the benefits of a therapy are estimated using the Incremental Cost Effectiveness Ratio (ICER). This is the cost of switching treatments from the current standard of care to the new therapy, as given in costs per Quality-Adjusted Life Year (QALY)[48]. Traditionally in the US an ICER under US$50,000 per QALY was considered 'cost effective'[49] although in more recent years the threshold seems to have lifted to US$100,000 to account for healthcare inflation[50]. So far LVADs remain above that threshold although they are trending in the right direction – one recent study[51] estimated that they have come down from ~US$600,000 per QALY at the time of the 2001 REMATCH trial to ~US$120,000 per QALY for second generation devices such as HeartMate II[52]. Basically devices are becoming more efficient, while at the same time hospital costs are declining[53].

LVADs have high bleeding and stroke risk

- *Bleeding and thromboembolic risk.* Because the LVAD is blood-contacting, it brings a high risk of thromboembolism. This, in turn, is managed using antiplatelet therapy, which brings bleeding risk. So, for instance, of 250 patients in the ADVANCE Bridge to Transplant trial of HeartWare's HVAD device, the event rate for gastrointestinal bleeding was 0.22 per patient year, while the event rate for venous thrombosis and arterial embolism was around 0.09 per patient year[54]. Put another way, over the course of a year around a fifth of all patients experienced bleeding and one-tenth experienced life-threatening blood clots. Primarily because of bleeding, hospital readmission rates for LVAD patients are very high over the six months period post-implant[55].
- *Shortage of transplant skills*. Getting an LVAD into a patient's left ventricle is regarded as, literally, a bloody difficult proposition from a surgical perspective - something best done by a transplant surgeon. That these skills are in somewhat limited supply is indicated by the fact that there are only around 100 Medicare-approved VAD Destination Therapy facilities in the United States at the moment. This is potentially a limitation on the growth in LVAD take-up in the long-term.

It is these drawbacks that suggest to Sunshine that their device has an opportunity to compete alongside the LVADs, but targeting Class II and especially Class III patients, the latter of which, as we noted above, would constitute possibly 1.6 million patients in the US alone.

[46] Calculated using the MS-DRG 001 relative weight of 26.3441, multiplied by a national adjusted base payment rate (operating plus capital) of US$5,564.12 (for full 2.35% increase), which equals a US$147,108.42 base payment for the device. Source: CMS FY 2011 Acute IPPS Final Rules. When provider-specific adjustments are applied, actual payment will usually be higher than base payment amount. We estimate that the device represents the lion's share of Medicare's payment. Thoratec's average revenue per device system in 2010 has been ~US$118,000. The reason for this high reimbursement lies in part because the cost of a single heart transplant can be US$1m (Source: Milliman, *2011 US organ and tissue transplant costs estimates and discussion*).

[47] In August 2010 CMS rejected a request from Thoratec to extend cover to Class IIIb patients. This was in spite of the fact that such patients had been evaluated by that company's clinical programme. Class IIIa is no shortness of breath at rest, and Class IIIb is shortness of breath at rest that has recently started to occur. Once shortness of breath at rest has become commonplace the patient has arrived in Class IV.

[48] A 'quality adjusted' life year is one year of perfect health understood to be gained by the therapy. Two years of '50% health' are one QALY, as are three years of '30% health'. There is, the reader will appreciate, a certain subjectivity to such assessments.

[49] See Grosse SD, *Assessing cost-effectiveness in healthcare: history of the $50,000 per QALY threshold*, Expert Rev Pharmacoecon Outcomes Res. 2008 Apr;8(2):165-78.

[50] See BMJ. 2006 Mar 25;332(7543):699-703. Epub 2006 Feb 22.

[51] See Russo et al., J. Am. Coll. Cardiol. 2010;55;A18.E169.

[52] One reason for this remarkably better ICER is the fact that in the late 1990s and early 2000s the US medical management of late stage heart failure patients over the final two years of life cost an estimated US$156,000 (see Russo et. al., J Card Fail. 2008 Oct;14(8):651-8. Epub 2008 Jul 21). Consequently even a small lengthening in life expectancy with better quality LVADs helps magnify the ICER number when the cost of LVAD therapy is comparable (ie ~US$147,000 on 2011 Medicare reimbursement).

[53] For REMATCH in 2001 the typical hospital cost per patient was US$210,000 due to a 44 day length of stay (see Rose et. al., op. cit). By 2006 it was estimated that hospital costs were more like US$126,000 for a 33 day stay (see Miller et. al., *Hospital costs for left ventricular assist devices for Destination Therapy: lower costs for implantation in the post-REMATCH era,* J Heart Lung Transplant. 2006 Jul;25(7):778-84).

[54] Source: Presentation to ISHLT 2011 by Dr Mark Slaughter, HeartWare's principal investigator for HVAD, submitted to ASX 18/4/2011. As we noted above, Slaughter was also a principal investigator for C-Pulse's US pilot trial.

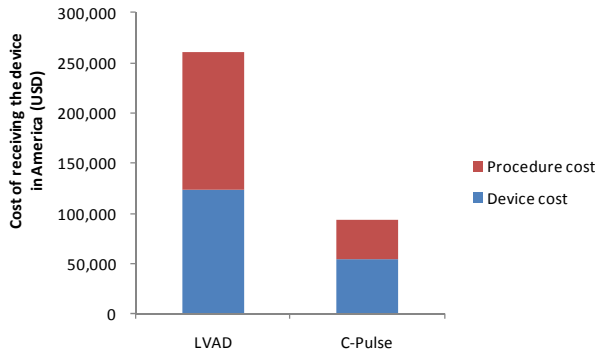
[55] See *Readmission rates with LVADs nearly 50% at six months* by Caroline Helwick, heartwire, 18/4/2011. This story related to an analysis of INTERMACS data presented at ISHLT 2011.

C-Pulse is the Next Big Thing in heart assist devices

C-Pulse may be competitive with LVADs on patient outcomes

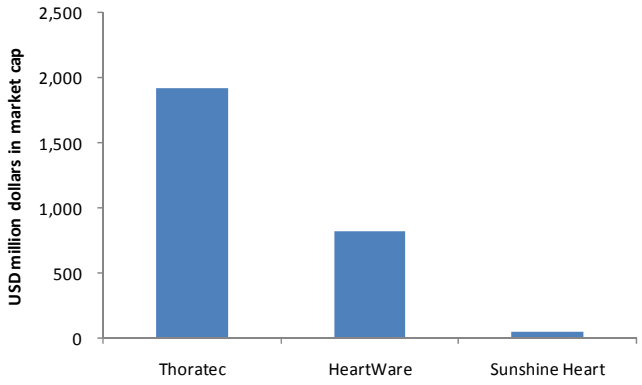
We see Sunshine Heart's C-Pulse device as the Next Big Thing in heart assist devices now that LVADs have started to establish themselves. As we noted above, LVADs are mechanical pumps that implant in the left ventricle and take over the pumping action of the heart. By contrast the C-Pulse is a balloon cuff wrapped around the ascending aorta which, by inflating and deflating counter to the heart's filling and pumping action, helps force blood out of the aorta to assist the heart to pump blood more efficiently. To understand why C-Pulse is a better device in many ways, with more potential commercial upside, consider:

Figure 12 –C-Pulse will be cost competitive with LVADs



SOURCE: SUNSHINE HEART, THORATEC, BELL POTTER SECURITIES ESTIMATES[56]

Figure 13 - Sunshine aspires to be the next HeartWare, at least



SOURCE: NASDAQ, ASX

C-Pulse is non-blood contacting

- *The skill-set required to implant is more widely available*. C-Pulse can be implanted in locations other than heart transplant centres and by surgeons of less skill than your average transplant doctor, suggesting the potential for greater availability than LVADs[57];
- *The device is relatively easy to implant, even with a sternotomy.* Originally all implantations of C-Pulse had taken place via a sternotomy, requiring a hospital stay of around 7-8 days. This was a markedly better outcome than for LVAD implantation where hospital stay can be more like three weeks[58];
- *The device is implantable via minimally invasive surgery*. This was demonstrated on six occasions in the US pilot trial, initially in June 2010 with a cuff that was pre-sutured so as to speed implantation[59] via a mini-sternotomy, and then in August 2010 when the device was implanted via a mini-thoracotomy. This reduced implantation procedure times down to around one hour[60] and average hospital stay down to 3-4 days.
- *C-Pulse is non-blood contacting*, eliminating the need for antiplatelet medication and therefore the potential for gastrointestinal bleeding that, as we noted in the previous section, is a characteristic of LVAD therapy;

[56] LVAD device costs estimated from Thoratec data and LVAD procedure costs estimated from Miller et. al. (J Heart Lung Transplant. 2006 Jul;25(7):778-84), adjusted for US inpatient hospital cost inflation and newer data on length of stays. C-Pulse device costs come from Sunshine Heart, with C-Pulse procedure costs approximated using the estimated cost of a CABG procedure (Arch Intern Med. 2010;170(14):1202-1208) adjusted for US inpatient hospital cost inflation. CABG is an appropriate comparator since procedure and recovery times are similar.

[57] That said, C-Pulse uptake would involve a change in the attitudes of the two types of people who look after patients with heart failure - cardiologists and cardiac surgeons. C-Pulse would be a boon for the latter because it would mean more business, but some of the thought leaders in cardiac surgery may not like the new device because it lets surgeons with less skill get in on the game. And cardiologists, traditionally drug-oriented, would have to accept the device before they started referring patients, raising the importance of clinical data.

[58] In one recent study which compared LVADs to heart transplant the average length of stay for the LVAD patients was 17.5 days. See Ann Thorac Surg. 2011 May;91(5):1330-3; discussion 1333-4. Epub 2011 Mar 24.

[59] The company intends to release this as its standard cuff product from late this year.

[60] By comparison the first implant in the Australia/NZ first-in-man study in May 2005 took 2.5 hours. While LVAD implantation times have also come down in recent years thanks to HeartWare's HVAD, procedure time for that device is more like 2-3 hours.

- *C-Pulse can be turned on and off without harm to the patient*, reducing concerns over device reliability that traditionally existed with LVADs[61], and also making activities like bathing or showering a whole lot easier.;
- *There is potential to use C-Pulse to rest the heart,* giving it a greater chance to 'reverse remodel' (ie undergo repairs) and thereby recover. There is demonstrated evidence that LVADS can do this[62], and C-Pulse would allow these benefits to be enjoyed by earlier stage patients. It's also reasonable to expect that C-Pulse would be used synergistically with stem cells now being contemplated for rebuilding of heart muscle in order to speed the recovery process[63].

C-Pulse is competitive with LVADs from a cost perspective

The company has been reimbursed for the majority of patients implanted under the US pilot trial. In the US CMS and the private insurers typically reimburse heart assist devices even if the device is only being used in clinical trials. C-Pulse has qualified for this reimbursement[64], which we regard as important in terms of the product's commercial future:

- *The device is being reimbursed under MS-DRG 001*. CMS reimburses hospital stays under a series of MS-DRG codes. LVADs are coded under MS-DRG 001, one of the most severe, allowing a high level of reimbursement, and C-Pulse was granted the same code.

Sunshine Heart is selling its C-Pulse systems for US$54,000 each

- *Reimbursement allows Sunshine Heart to set a competitive price*, with the company choosing to sell at US$54,000, thus providing a significant cost advantage to LVADs. This pricing helps raise the chances that C-Pulse will ultimately attract reimbursement for Class III patients and earlier.
- *There is potential for the healthcare economics to be favourable.* Lower device costs plus the lower length of hospital stay for implantation, as well as potentially lower hospitalisation rates for implanted patients going forward (see below), all suggest the possibility of a cost per QALY lower than US$100,000 or even US$50,000, which would drive strong device uptake.

Even at a lower cost than LVADs gross margins are expected to be high. Thanks to the low cost of materials – for example, the use of conventional pacemaker leads – Sunshine Heart expects that it can enjoy gross margins in the order of 80% through its own manufacturing of C-Pulse devices in Minnesota even at the lower reimbursement than LVADs. We have modelled 70% for conservatism's sake. It's reasonable to expect Sunshine to be able to move down the cost curve for C-Pulse as it manufactures more devices for use under Continuous Access.

C-Pulse will be commercially available from next year

C-Pulse's US pilot trial will be sufficient for CE Marking. In early 2011 Sunshine Heart's EU Notified Body[65] informed it that the US pilot trial data would be sufficient to file for a CE Mark of C-Pulse. The company intends to make such a filing soon – we expect 1Q12. We think CE Mark will be a significant commercial step forward for Sunshine Heart:

[61] LVADs today have a high record of reliability. However for the Thoratec HeartMate XVE device, which pioneered the LVAD space and was pretty much state-of-the-art until the FDA approval of HeartMate II in 2008, more than 70% of devices would fail within two years (see Circulation. 2007 Jul 31;116(5):497-505. Epub 2007 Jul 16).

[62] Circulation. 2011 Feb 1;123(4):381-90. Epub 2011 Jan 17.

[63] For more on this, see our 24/8/2011 research report on the Melbourne-based stem cell company Mesoblast (ASX: MSB, www.mesoblast.com) headlined '*The heart of the matter'*. Mesoblast will report Phase II data on the use of its Mesenchymal Precursor Cells in mid-stage heart failure at the American Heart Association meeting in November 2011.

[64] Medicare classifies medical devices being trialled under an IDE as either Category A (experimental) or Category B (nonexperimental/investigational) and can choose to reimburse Category B. The LVADs and now C-Pulse were placed in Category B. In the C-Pulse pilot trial three implantations were not reimbursed.

[65] A Notified Body, in the European Union, is an organisation that has been accredited by a Member State to assess whether a product meets certain preordained standards. Sunshine Heart is working with a Notified Body under the EU's Medical Device Directive, but hasn't named which body. For the Medical Device Directive there are around 80 Notified Bodies in all, including various national branches of the Swiss company SGS (www.sgs.com).

- Thoratec enjoyed US$68m in revenue in the year to June 2011 from 'international sales' of HeartMate II, with its systems being reimbursed at around US$94,000 each, not too far below the level of reimbursement in the US. Its competitor HeartWare's US$73m in revenue in the year to June 2011 for HVAD came primary from Europe, with US approval for Bridge to Transplant still pending;

Europe can be a big market for Sunshine Heart

- Europe is proving a strong growth market for defibrillation systems, with St Jude, Medtronic and Boston Scientific growing their 'rest of world' sales of ICDs and CRT-Ds by ~7% pa since 2005, to US$2.5bn.
- As we noted previously, in the EU alone there may be 14 million heart failure patients, of which 4-5 million could be Class III.
- CE Marking allows the company to seek approval in countries that honour the CE Mark system such as Australia and many jurisdictions in Asia;

We expect that Sunshine Heart will look to develop its own distribution for C-Pulse in Europe post CE marking, which we think will happen in mid-to-late 2012, with the device to launch in 2013 as reimbursement is secured.

A US pivotal trial is intended to start early next year

A 270 patient trial. While the final design of the trial is still being worked out, Sunshine Heart currently envisages 270 Class III and ambulatory Class IV patients being recruited over 30 sites and randomised to either C-Pulse or optimal drug therapy. We expect this trial will have a better experience than the slow-moving pilot study:

- The use of minimally invasive surgery to implant is likely to make recruitment easier;
- The trial is expected to have less restrictive inclusion/exclusion criteria;
- Sunshine Heart expects to go to centres that have strong patient flow and systems to refer patients, as well as less in the way of competition[66].
- The company will be trialling a single unit system of the C-Pulse that is lighter and smaller than its predecessor system (see below).

We expect this trial to cost US$35m and initiate in early 2012, complete recruitment in 2014, and generate 12-month data for a PMA filing in 2015. This would allow a 2016 product launch.

The primary endpoint in this trial will be a reduction in re-hospitalisation due to heart-failure related events[67]. If C-Pulse can meet this endpoint it will suggest strong value from a healthcare economics perspective beyond the lower device and implant procedure costs:

- We noted previously the high cost of heart failure hospitalisations;
- The rate of hospitalisation increases as heart failure progresses[68];
- Patients with low Ejection Fraction - which are likely to predominate in the C-Pulse trial - tend to be admitted to hospital more[69], tend to cost more while in hospital, and have higher readmission rates[70].

[66] A trial site in the pilot study, for example, was St Paul Heart Clinic in St. Paul, Mn (www.stphc.com) which is a cardiology practice that doesn't perform LVADS or heart transplants.

[67] This is a common endpoint for heart failure related trials. For example, the MADIT-CRT study, which established that CRT-Ds were effective in early stage heart failure patients, had death or first hospitalisation as its primary endpoint. See *N Engl J Med*. 2009 Oct 1;361(14):1329-38. Epub 2009 Sep 1.

[68] We estimated from Ahmed et. al. (Am Heart J. 2006 February; 151(2): 444–450) that perhaps 20% of all Class I patients in any one year to 25-26% of Class III and IV patients per year will be hospitalised for any cause, with worsening heart failure as a percentage of all cause hospitalisation rising from 23% of Class I patients to 44% of Class IV patients.

[69] Patients with Ejection Fraction below 42 are far more likely to be Class III than Class II and have higher rates of hospitalisations - See Circulation. 2005 Dec 13;112(24):3738-44. Epub 2005 Dec 5.

[70] See Clin Cardiol. 1999 Mar;22(3):184-90.

The C-Pulse technology is getting better

Sunshine is working on a 'one unit system'. The US pilot trial was conducted using what Sunshine Heart calls its 'two unit system', in which the device driver and the battery pack are worn external to the patient in separate units. This system may be effective, but it was considered too large, heavy (ie around 3.6 kilograms, that is eight pounds) and noisy, and we think this impacted recruitment for the trial[71]. Under Dave Rosa's leadership from 2009 the company moved forward on a 'single unit system' in which the battery pack and device driver were combined into a smaller, lighter unit, albeit one still worn externally. This is currently being developed by the Melbourne-based Hydrix, a software and electronic design consultancy, and it is expected that this system will be the one used in the pivotal trial, although some pilot trial patients that have met their six month endpoint will be offered the new driver as well[72].

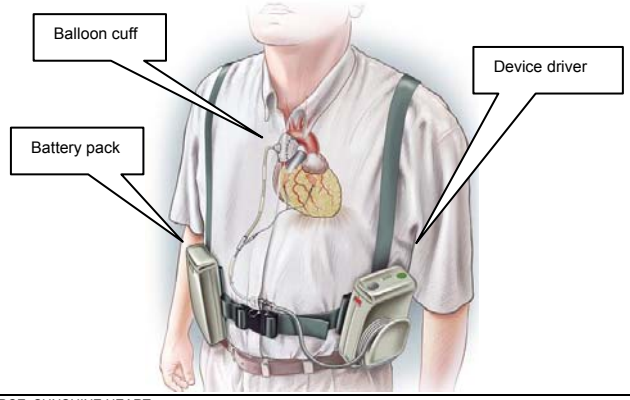
Sunshine Heart wants to eliminate driveline infections with its next generation C-Pulse

Sunshine Heart is also working on a fully-implantable system, for which a feasibility study was completed in June 2011[73]. This system would see:

- the power source remaining external to the body but the device driver being implanted and powered using transcutaneous energy transfer[74]. This would eliminate the driveline hole in the abdomen, which has been a traditional source of infections for LVADs as well as for C-Pulse implantees[75];
- a driver unit that can connect directly to a patient's pacemaker should that patient already have one - this would eliminate the need for the doctor to have to install a second set of leads[76].

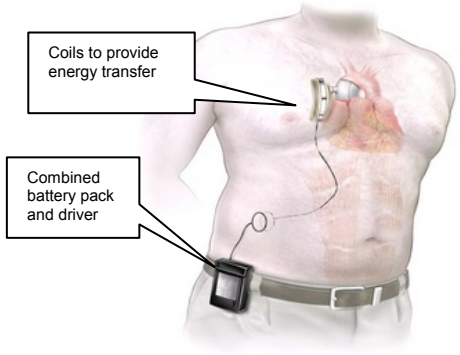
Sunshine Heart believes it can start testing its fully implantable system outside the US from next year[77]. For the US pivotal the company will stick with the single unit system so as to avoid missing endpoints, which could happen should sufficient bugs show up in the fully-implantable system during its early experience with patients.

Figure 14 - The C-Pulse two-unit system worked well, but was considered unwieldy



SOURCE: SUNSHINE HEART

Figure 15 – The C-Pulse fully implantable system will likely be much more acceptable to the patient



SOURCE: SUNSHINE HEART

[71] That said, it was better than the device driver used for the Australia and New Zealand first-in-man trial, which was housed in a unit the size of a suitcase – see Sunshine Heart's 16/5/2007 announcement on completion of the two-unit system, which contains a picture.

[72] Sunshine Heart does not envisage having to run a clinical trial in Europe for the single unit driver before filing an amendment to its CE Mark.

[73] See Sunshine Heart announcement of 9/6/2011. Sunshine Heart's original intellectual property envisaged a fully implantable system.

[74] This technology, which would enables the transfer of power across the skin without piercing it, involves a primary coil placed outside the skin opposite a secondary coil located beneath the skin. When the primary coil is excited by an external power source, a high-frequency electromagnetic field is created which excites the secondary coil, initiating an electric current.

[75] See, for example, *A new beat* by Christopher Snowbeck, St Paul Pioneer Press, 23/12/2010, which profiles a trial patient who suffered an infection. Ahead of the fully implantable system Sunshine Heart has come up with the so-called 'C-Patch' which goes over and around the tubing that exits the skin. By better securing the driveline, it may help minimise infections.

[76] This compatibility would also allow the pulsation rate of the device to be altered depending on the heart rate, so that the heart isn't provided with more support than it needs – such extra support would simply thus stress the heart after it has begun to show signs of recovery.

[77] Sunshine Heart expects to have to run only a very small trial of its fully implantable system driver before filing an amendment to its CE Mark.

Commercial leadership

Dave Rosa has turned the fortunes of Sunshine Heart around

We have a high opinion of the new leadership team at Sunshine Heart:

CEO **Dave Rosa** brings years of experience working with large medical device companies, having been (2004-2008) a marketing VP in St Jude Medical's Cardiac Surgery and Cardiology businesses and, before that (1995-1999) a product manager for Boston Scientific's Scimed unit, which had developed a new generation angioplasty balloon catheter[78]. Rosa also has start-up experience having been (1999-2004) a key member of the team that attempted to build A-Med Systems, a privately-held California company working on a percutaneous ventricular assist device. This company was shut down in 2005[79] and while not a success, it gave Rosa valuable experience in dealing with commercial partners, regulators, financiers and technology development people. We think Rosa's team-building skills as well as his knowledge of the cardiovascular device space and particularly his relationships with cardiologists will be instrumental in helping Sunshine Heart grow its business in Europe as well as progress through C-Pulse's US pivotal. Rosa has already contributed to Sunshine Heart's success by moving the company to Minnesota's Twin Cities, a metro area known for its expertise in medical devices where proven talent in this area is relatively easy to find.

Medical Director **Dr Will Peters** brings a high level of technical expertise, having invented the C-Pulse technology in the late 1990s. Peters also brings corporate memory, having stayed with the company since its founding.

VP of R&D **Kevin Bassett** brings valuable experience in cardiovascular device developments through six years at Acorn Cardiovascular (2004-2010), before which he consulted to the drug and medical device industries. Acorn will have taught Bassett a good deal about US regulatory requirements[80].

VP of Clinical and Regulatory **Debra Kridner** brings many years on the clinical and regulatory side of the big cardiovascular device business, with stints at St Jude Medical and Medtronic. She has also worked at Medsource, a contract medical device manufacturer.

CFO **Jeff Mathiesen** brings financial disciplines to the group, having served in senior finance roles in a number of technology-based, high growth companies over the years.

The Sunshine Heart board, which includes Rosa and Peters, has the range of skills needed to build a successful medical device company. It features two venture capitalists (Chairman **Nick Callinan**, founder of the Advent group, and **Dr Geoff Brooke** of major shareholder GBS Ventures). **Donal O'Dwyer** who led J&J's Cordis unit when it gained FDA approval for the first drug-eluting stent in 2003. The Minneapolis-based **Paul Buckman** brings high-level executive experience in the medical device industry, having run the cardiovascular division of both St Jude Medical[81] and Boston Scientific as well as having founded and built up the endovascular device company EV3 before selling it to Covidien in 2010 for US$2.6bn. A similar high-level executive on the Sunshine board is **Greg Waller**, who was CFO of Sybron Dental Specialties before that company's US$2.6bn sale to Danaher in 2006.

[78] Rosa joined Scimed the year after Boston Scientific had bought the company for US$1.4bn. Scimed formed the basis for Boston Scientific's cardiovascular division. During his time at Boston Scientific Rosa was instrumental in turning around the company's intravascular ultrasound business, which had come with the 1994 acquisition of CVIS.

[79] A-Med's device was designed to be midway between a conventional LVAD and a low cost balloon pump, with the ease of surgical implantation of the latter and the ventricular assist capability of the former. It was also expected to sell for about a tenth of the price of an LVAD, and had been used clinically (see Ital Heart J. 2001 Jul;2(7):502-6). Management took the decision to close A-Med after the FDA turned down a humanitarian use designation. Around US$30m in venture capital had been invested in the company. The embolic protection business was sold to Edwards Lifesciences, while the VAD technology was sold to Guidant, two transactions which we think reflect creditably on Rosa.

[80] Acorn developed the CorCap device, a mesh designed to treat heart failure by supporting the heart and preventing its dilation as the disease progresses. The device gained European approval but failed to gain FDA approval in spite of a favourable clinical experience (see J Thorac Cardiovasc Surg. 2011 Jul 13. [Epub ahead of print]). This was largely due to changing FDA requirements as to clinical trial structure and acceptable data. Acorn Cardiovascular was more or less shut down in 2010 after having raised US$110m in venture capital.

[81] Where he worked with Dave Rosa.

The risks

Medical device development is risky. The stocks of medical device companies without revenue streams from product sales or ongoing service revenue should always be regarded as speculative in nature. The fact that the intellectual property base of most medical device companies lies in science not generally regarded as accessible to the layman adds further to the riskiness with which such companies ought to be regarded. Investors are advised to be cognisant of these risks before buying Sunshine Heart or any other medical device development stock.

Sunshine Heart is not without risk. We see seven major risks specifically related to Sunshine Heart as a company and a stock:

1 **Clinical risk** – There is the risk that Sunshine Heart's US pivotal trial of C-Pulse could fail to reach its endpoints.

2 **Regulatory risk** – There is the risk that the EMA may delay European approval of C-Pulse or that the FDA may ask for more patients in the US pivotal than Sunshine Heart had expected.

Timing risk has historically dogged Sunshine Heart

3 **Timing risk** – There is the risk that Sunshine Heart could take much longer to organise its US pivotal and then recruit and treat patients than the timing we have postulated in this note.

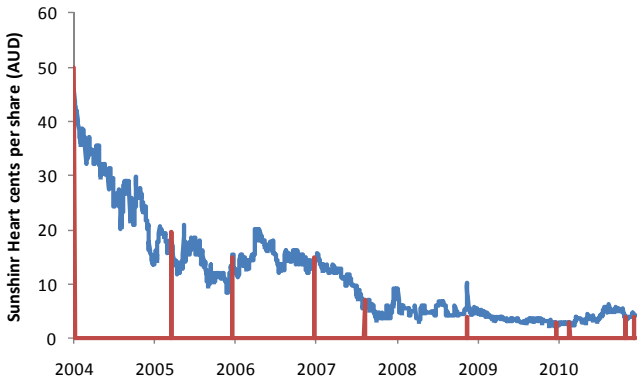
4 **Partnering risk** – There is the risk that Sunshine Heart's prospective partners either in product distribution or in an M&A deal may strike too hard a bargain for Sunshine Heart shareholders to enjoy a strong return.

5 **IP risk** – There is the risk that Sunshine Heart could find itself locked in dispute over patent infringement should its intellectual property be found to lean too heavily on unrelated or unlicensed predecessor science.

6 **Manufacturing scale-up risk** – There is the risk that as Sunshine Heart scales up its manufacturing processes in order to be able to make C-Pulse systems sufficient for the US pivotal trial that this scale-up process could interfere with the company's clinical programme.

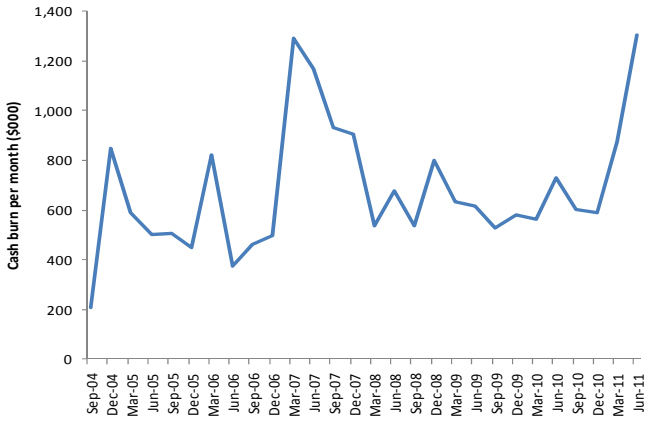
7 **Burn rate** – Sunshine Heart has raised around A$74m since IPO and for the last twelve months has burned around $840,000 per month. The company will likely have to make further capital raisings to fund its cash burn.

Figure 16 – Sunshine Heart has undertaken ten major capital raisings since 2004



SOURCE: SUNSHINE HEART

Figure 17 – Sunshine Heart's burn rate, 2004-2011



SOURCE: SUNSHINE HEART

Appendix I – Sunshine Heart's capital structure

The stock. Sunshine Heart is currently only traded on the ASX as CDIs even though the company is incorporated and headquartered in the US. In August 2011 the company advised shareholders of its plans to establish a dual listing on Nasdaq.

Major shareholders. Currently the major shareholders of the company are the Australian venture capital groups CM Capital (22.9%) and GBS Ventures (19.9%) and the Montreal-based Sectoral Asset Management (5.2%).

Figure 18 – Sunshine Heart's current capital structure

Shares (ASX Code SHC)	1,203,178,786	Price (c)	4.7
Options/warrants	391,429,966	Undiluted cap ($m)	56.5
Total diluted shares	1,594,608,752	F.D. Cap ($m)	74.9

Options and warrants	Number	Exercise price	Expiry date	Cash (AUDm)
Employee options	89,904,719	$0.177	23/07/2016	15.9
Warrants	60,624,227	$0.066	3/08/2015	4.0
Placement options	240,901,020	$0.032	30/11/2014	7.7
Total	391,429,966	$0.071	25/05/2015	27.6

SOURCE: SUNSHINE HEART. NOTE, OPTION AND WARRANT NUMBERS REPRESENT ESTIMATED AVERAGES

Figure 19 – Sunshine Heart's major capital raisings since 2004[82]

Date	Shares	% of current shares on issue	Price per share	Amount raised (AUDm)	Type of raising	Capitalisation at raising price (AUDm)
Sep-04	30.0	2.5%	$0.500	$15.00	IPO	$32.5
Dec-05	16.9	1.4%	$0.195	$3.30	Placement	$16.0
Sep-06	92.0	7.6%	$0.150	$13.80	Placement plus 3:10 options	$26.1
Sep-07	40.0	3.3%	$0.150	$6.00	Placement plus 2:5 options	$32.1
May-08	77.8	6.5%	$0.070	$5.45	4:11 rights issue	$20.4
Aug-09	245.2	20.4%	$0.040	$9.81	Placement plus 3:5 rights	$21.5
Sep-10	133.4	11.1%	$0.028	$3.74	Placement plus 1:2 options	$18.8
Nov-10	340.3	28.3%	$0.028	$9.53	5:7 rights issue	$28.4
Jul-11	114.4	9.5%	$0.040	$4.58	Placement plus 3:10 warrants	$45.3
Sep-11	69.9	5.8%	$0.040	$2.80	Placement plus 3:10 warrants	$48.1
Total	1159.9	96.4%	$0.064	$73.99		

SOURCE: SUNSHINE HEART

Sunshine Heart's average capital raising price has been 6.4 cents

[82] The company has also received $4.7m in government grants since 2003.

Appendix II – The C-Pulse technology

Background to the technology

C-Pulse is aortic counterpulsation, but outside the aorta. Back in the late 1990s a young New Zealand heart surgeon then living in Melbourne named Dr Will Peters, fresh from having developed an endovascular cardiopulmonary bypass system for minimally invasive cardiac surgery[83], which was commercialised by a California-based company called Heartport[84], had a bright idea on heart assist devices. He came to the conclusion that a good pathway to mechanically assisting the failing heart, while avoiding the issues of blood contact and heavy-duty surgery, lay at a point outside the heart, and in particular on the ascending aorta. Way back in the late '60s heart doctors had figured out that a balloon within the descending aorta, inflated and deflated counter to the heart itself, could be used to temporarily ease the strain on a heart pumping inefficiently[85]. Peters proposed to transfer the aortic counterpulsation approach to the outside of the ascending aorta with a balloon-style aortic 'cuff' that was inflated and deflated by an electronic driver taking its cue from the heart's electrical impulses. People had been working on extra-aortic counterpulsation since the 1960s but Peters' device - named C-Pulse to refer to its counterpulsation ability – was the first to deal with the technical issues that had killed the idea up to that time[86]. Peters sought in the design process to create a counterpulsation balloon that imposed the minimal possible strain on the ascending aorta – C-Pulse doesn't 'squeeze' the aorta so much as compress it on one side via a 'thumb print', reducing the possibility that the vessel would be gradually worn down (although not ruptured) by too many squeezes. The resulting device gives the patient a 'double pulse' – the normal pulse and the C-pulse pulse.

Most heart failure patients could benefit from extra-aortic counterpulsation. Peters' approach would contra-indicate only one major group of patients – those with calcification of the ascending aorta. That could be around 15-20% of the total[87].

The animal and early human data showed that the concept worked, 1999-2004. By 2004 Peters' C-Pulse, development of which had been funded by Sunshine Heart[88] from 1999, had been wrapped around the aortae of:

- *Pigs* - C-Pulse devices implanted in six pigs saw blood flow to heart muscle increase by 63%[89].
- *Sheep* - C-Pulse devices implanted in 26 adult sheep functioned continuously for 10 months. This study dealt with a concern that many observers of the heart assist space would have – that compression of the aorta around 70 times per minute could fatigue it over time. Examination of sheep aortae at one, two, five and 10 months showed that the inner layers of the artery were completely normal. Expected minor changes to the tissue of the artery wall were seen in all sheep, but signs of tissue repair were evident at the 10 month point[90]. We understand that examination of the aortae of patients being explanted for heart transplantation has demonstrated a similar effect.

C-Pulse's balloon cuff doesn't seem to damage the ascending aorta

[83] See J Thorac Cardiovasc Surg. 1996 Mar;111(3):567-73.

[84] Acquired by J&J in 2001 for US$81m.

[85] The father of this approach was the American cardiac surgeon Dr Adrian Kantrowitz (1918-2008) – see JAMA. 1968 Jan 8;203(2):113-8 – who in 1967 performed the world's first pediatric heart transplant operation.

[86] Such as the need to implant devices via sternotomy, concern over blood clot formation, and issues regarding surgical anastomosis between the pump device and the aorta. See Ann Thorac Surg 1992;53:30-37.

[87] In its 2004 prospectus Sunshine Heart states that 'extensive literature on the incidence of significant atheroma and calcification in the ascending aorta places the figure at 15% to 20%'. We note, however, the work of Eisen et. al. (Circulation. 2008 Sep 23;118(13):1328-34. Epub 2008 Sep 8), who prospectively studied 361 patients with stable angina and found that 11% had calcification of the ascending aorta and 37% calcification of both the ascending and descending aorta at baseline.

[88] So called because Peters was visiting Sunshine Beach near Noosa in Qld when he started to figure out the design of what became C-Pulse.

[89] See Heart Lung Circ. 2005 Sep;14(3):178-86. Epub 2005 Jul 25.

[90] Source: Sunshine Heart announcement, 25/10/2004. The observations of aortic health were similar to those observed earlier in pigs.

- *Humans (for about 20 minutes)* – In six people undergoing coronary artery bypass surgery temporary implantation of a C-Pulse resulted in an average 67% increase in blood flow to the heart muscle in the implanted patients ($p<0.05$). There was also a 31% reduction in left ventricular wall stress, that is, the amount of pressure being applied to the wall of the ventricle ($p<0.05$), and a 13% improvement in fractional area change, which is a measure of the pumping ability of the heart ($P<0.005$) [91].

Bench testing demonstrated that the cuff was robust. Before initiating clinical trials of the device Sunshine Heart performed benchtop fatigue testing of the cuffs to show that they could last for four years even after inflating and deflating at 70 times per minute. C-Pulse passed this test with flying colours.

The first-in-man trial provided encouraging evidence of efficacy, 2005-2007. A first-in-man trial of C-Pulse in Australia and New Zealand was initiated in May 2005. This trial proved to be disappointing to investors in terms of the time it took to generate a result. The trial started around five months later than expected, and a full seven months after Sunshine Heart's IPO, with the company intending to implant ten devices. In the end only five patients were implanted before results were first presented in August 2007[92], and three of these patients had infectious complications, with two explanting at only five and seven weeks respectively. The results, however, were still encouraging:

- all patients improved by 1 NYHA class;
- there were improvements in blood flow, as measured by invasive haemodynamic monitoring, in three patients;
- one patient maintained good blood flow at six months post-implant, but suffered infective complications after this.

Sunshine Heart's engineers looked at the infection issue and designed a new cuff to minimise infection risk before taking the device into its US pilot trial.

The US pilot trial recruited quickly after Dave Rosa joined the company

The US pilot trial provided strong evidence of efficacy, 2009-2011. As with the first-in-man study, Sunshine Heart's 20-patient US pilot study of C-Pulse was dogged by timing issues. The company submitted its IDE in June 2007, but the pilot trial did not receive conditional approval until September 2008[93] and full approval in November 2008[94]. The first patient was not implanted until April 2009 and only four patients had been implanted by the time Dave Rosa became CEO in October 2009[95]. Under Rosa, however, the pace of the trial quickened, with new sites signed up[96] and existing sites recruiting more, helped by some changes to the trial's inclusion/exclusion criteria. The 20th patient was enrolled in March 2011, allowing the company to report favourable early results in September 2011 which we note on page 4 of this report.

The intellectual property around C-Pulse

Sunshine Heart's core intellectual property is covered by 13 published patent applications

1 **Heart assist devices, systems and methods**, WO 2000/076288[97] (Priority date 10/6/1999; Invented by Will Peters, Crispin Marsh[98], Geoff White[99], Paget Milsom[100], Hans Henrichsen[101], Rolf Unger and Colin Sullivan[102].)

[91] See Circulation. 2005 Aug 30;112(9 Suppl):I26-31.

[92] At the Annual Scientific Meeting of the Cardiac Society of Australia and New Zealand. The data was not published in a peer-reviewed journal until December 2010 - see J Heart Lung Transplant. 2010 Dec;29(12):1427-32. For a case report of one of the patients see Ann Thorac Surg. 2008 Jun;85(6):2122-5.

[93] The trial was approved but the FDA required minor changes to the trial protocol as well as altered processes for patient record keeping and device labelling.

[94] See NCT00815880 at www.clinicaltrials.gov.

[95] Part of the problem was ironing out bugs in the two unit system – we understand the first two patients required 21 return visits in order to successfully eradicate the bugs.

[96] These included Saint Luke's Hospital in Kansas City, Mo, whose Mid America Heart and Vascular Institute ended up as the leading enroller for the trial. McGill University Health Centre in Montreal was signed up earlier this year (see *New heart pump aims to cut stroke risk* by Bradley Bouzane, Postmedia News, 13/2/2011).

[97] This patent was granted in the US as No. 6,808,484 in October 2004 and as No. 7,357,771 in April 2008.

[98] Crispin Marsh is a Sydney-based patent attorney who was a co-founder of Sunshine Heart with Will Peters in 1999. He retired from the Sunshine Heart board in 2011.

[99] Dr Geoff White is Head of the Department of Vascular Surgery at Royal Prince Alfred Hospital in Sydney.

This patent application covers the basic design of the C-Pulse system.

2 **Heart assist devices, systems and methods**, WO 2002/024255[103] (Priority date 22/9/2000; Invented by Will Peters, Crispin Marsh, Geoff White, Hans Henrichsen and David Snow)

This patent application covers the mechanism for removal of the cuff of the C-Pulse, being a wire that can be pulled to release one end of the cuff from the aorta, after which it can be pulled back into the catheter.

3 **A fluid pressure generating means**, WO 2003/011365[104] (Priority date 30/7/2001; Invented by Will Peters, Hans Henrichsen and Peter Watterson[105])

This patent application covers the pump of the C-Pulse, whose purpose is the inflate and deflate the balloon cuff, preferably using helium gas.

4 **A method of performing a coronary artery bypass operation on a patient's beating heart**, WO 2003/028787 (Priority date 28/9/2001; Invented by Will Peters)

Coronary Artery Bypass Graft, or 'CABG'[106], more commonly known as 'heart bypass' surgery, is a surgical treatment for coronary artery disease that has been performed since the 1960s. In the mid-2000s it represented a large market opportunity, with ~350,000 CABGs performed in US hospitals in 2003[107], even though the procedure was in decline[108]. CABG is a lengthy procedure – generally 4 to 6 hours – and traditionally the procedure has involved stopping the heart and providing blood supply to the rest of the body via cardiopulmonary bypass (CPB), an artificial circulation system. In the 1990s doctors were performing more 'off pump' CABGs in which the heart was left beating, arguing that the clinical outcomes are better than 'on-pump' CABG[109]. WO 2003/028787 covers the use of C-Pulse in performing off-pump CABG, the device being useful for patients who have poor coronary performance such as patients with unstable angina.

5 **An intraluminal inflatable counter-pulsation heart assist device**, WO 2004/045676 (Priority date 15/11/2002; Invented by Will Peters, Hans Henricksen, Scott Miller and Rodney Parkin)

This patent application covers the use of an intra-aortic balloon packaged within a stent to act as a heart assist device.

6 **Heart assist device utilising aortic deformation**, WO 2004/045677[110] (Priority date 15/11/2002; Invented by Will Peters and Scott Miller)

This patent application covers the use of the C-Pulse as an intra-aortic counterpulsation device, but with only part of the circumference of the aorta being compressed by the balloon.

7 **A wrap**, WO 2005/041783[111] (Priority date 30/10/2003; Invented by Will Peters, Scott Miller and Gemma De Plater)

This patent application covers the elastic wrap which holds the balloon onto the aorta.

[100] Dr Paget Milsom is a cardiac surgeon at Auckland City Hospital in New Zealand.

[101] Hans Henrichsen is today a consulting engineer through his family company, 3H Engineering in Wollongong, NSW. While at the Australian Centre for Advanced Medical Technology at the University of Sydney, he helped design the outsides of C-Pulse's fluid compressor as well as the cuff.

[102] Dr Colin Sullivan was a pioneer of CPAP therapy for the treatment of obstructive sleep apnea in the 1980s.

[103] This patent was granted in Europe as EP 1 318 848 in July 2008.

[104] This patent was granted in the US as Nos. 7,306,558 (December 2007), 7,740,575 (June 2010) and 8,002,691 (August 2011).

[105] Dr Peter Watterson, of the Faculty of Engineering at the University of Technology, Sydney, is an authority on electromagnetism. He was instrumental in the process of integrating the motor and bearing into the impeller of VentrAssist, a heart assist device which the ASX-listed Ventracor trialled for a number of years before the company was shut down in 2009 due to lack of funding.

[106] Pronounced 'cabbage', as in, the cultivated plant, *Brassica oleracea*.

[107] Source: Agency for Healthcare Research and Quality, Procedures in U.S. Hospitals, 2003.

[108] The US rate per head of the adult population declined 38% between 2001 and 2008 due in part to the increasing popularity of stenting. See JAMA. 2011 May 4;305(17):1769-76.

[109] More recent evidence has suggested no superiority for off-pump CABG – see N Engl J Med. 2009 Nov 5;361(19):1827-37.

[110] This patent was granted in the US as No. 7,347,811 in March 2008.

[111] This patent was granted in the US as No. 7,862,499 in January 2011.

8 **Methods and devices for tensioning a wrap around a blood vessel**, WO 2005/041781 (Priority date 30/10/2003; Invented by Will Peters, Scott Miller and Gemma Au-Yeung)

This patent application covers the way in which the wrap from WO 2005/041783 is secured onto the aorta. It involves a buckle which allows one part of the cuff to pass through another after it has been wrapped around the aorta, with the buckle holding the two ends of the cuff in place until they can be sutured together.

9 **Extra-aortic patch**, WO 2005/042063 (Priority date 30/10/2003; Invented by Will Peters)

This patent application covers the use of use of a balloon compressing only part of the aorta, as per WO 2004/045677, but where the balloon cuff is applied externally.

10 **Percutaneous gas-line**, WO 2005/042082[112] (Priority date 31/10/2003; Invented by Will Peters)

This patent application covers the gas line which inflates and deflates the C-Pulse balloon, with the device driver worn externally.

11 **Synchronisation control system**, WO 2005/042089[113] (Priority date 31/10/2003; Invented by Will Peters and Rodney Parkin)

This patent application covers C-Pulse device driver, which is activated by detecting the two audible 'heart sounds', S1 (produced by the closing of the mitral and tricuspid valves) and S2 (produced by the closing of the aortic and the pulmonary valves). After detection of S1 the driver deflates the balloon, while detection of S2 sees the drive inflate the balloon.

12 **Actuator for a heart assist device**, WO 2005/044338[114] (Priority date 11/11/2003; Invented by Scott Miller)

This patent application covers an improved balloon/wrap combination for C-Pulse, in which the wrap restrains the 'flexure region' of the balloon (ie the outer edges of the balloon's oval shape) from outward displacement upon inflation, but not on inward displacement during deflation. This is important because the flexure region is constantly moving during inflation and deflation, and excessive restraint would cause the balloon to wear out and ultimately fail.

13 **An improved wrap for a heart assist device**, WO 2008/022379 (Priority date 21/8/2006; Invented by Gemma De Plater and Scott Miller)

This patent application covers a better wrap to hold the C-Pulse balloon in place, with slits in the centre of the wrap allowing better anatomical fit over the balloon and the aorta.

[112] This patent was granted in the US as No. 7,887,478 in February 2011.

[113] This patent was granted in the US as No. 7,765,003 in July 2010.

[114] This patent was granted in the US as No. 7,955,248 in June 2011.

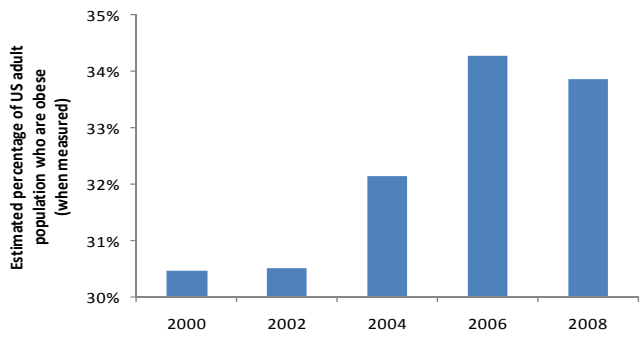
Appendix III – Heart failure risk is high

19% of American adults smoke. A lot of them will end up in heart failure

Prevalence of heart failure is driving strong uptake of LVADs, even though the market is still at an early stage. We argue that the potential patient pool for LVADs and for C-Pulse when it gains regulatory approval is set to continue growing strongly since the number of adults *at risk* of cardiovascular disease in the future is also significant:

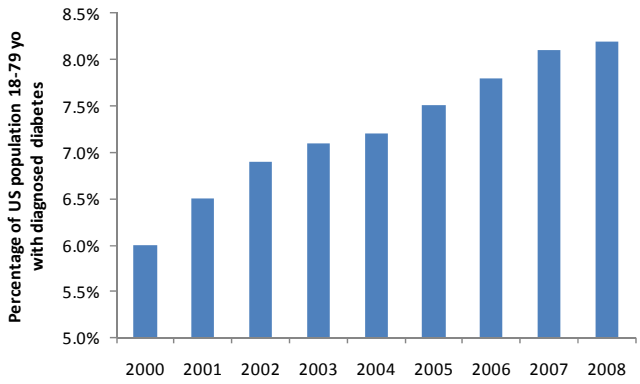
- 19% of American adults and 26% of European adults smoke[115];
- Only 35% of Americans and 40% of Europeans engage in regular leisure time physical activity[116];
- 32% of Americans have LDL (ie 'bad' cholesterol) greater than 130 mg/dL, which is considered 'borderline high' (>160 is 'high'), while 34% of Americans have high blood pressure (ie systolic pressure > 140 mm Hg[117]);
- 35% of American adults are considered 'pre-diabetic'[118];
- Around 17% of European adults and 34% of American adults are estimated to be obese[119].

Figure 20 – Measured obesity in the US may have peaked, but at over 30% of the adult population



SOURCE: CDC, NHANES DATA

Figure 21 – US diabetes prevalence has also been rising



SOURCE: CDC

The market will grow as the population ages

US data indicates that the prevalence of cardiovascular disease rises with age, with a notable jump in people over the age of 60[120]. Consequently, as Western world populations have seen their median ages increasing they have also seen rising prevalence of cardiovascular disease, and this trend is likely to continue.

[115] Sources: For US, National Health Interview Survey 2010. For Europe, WHO/Europe Health for All database, figures for 2009.

[116] Source: For US, National Health Interview Survey 2010. For Europe, EU 'Eurobarometer' Survey No. 246, conducted in 2005.

[117] Source: American Heart Association's *Heart Disease and Stroke Statistics* 2011 update, Tables 7-1 and 13-1.

[118] Source: NHANES data on or fasting glucose or A1C levels. 12.3% of Americans 20-79 years old are diabetic, and 9% of Europeans (Source: International Diabetes Federation estimates for 2010).

[119] BMI >30. Source for Europe: WHO infobase survey data for 2010, which suggests a US adult obesity rate of 46%. Source for US: NHANES data for 2008, based on actual measurement rather than self-reporting.

[120] For American men prevalence rises from 40% of 40-59 year olds (both sexes) to 73-74% of 60-79 year olds. Source: American Heart Association's *Heart Disease and Stroke Statistics* 2010 update.

Appendix IV – A Sunshine Heart glossary

Actuator - A mechanical device that converts energy into motion.

Ambulatory – Medical care given to patients who do not need to be admitted to a hospital.

Angina – Chest pains associated with coronary heart disease. Stable angina has a regular pattern that only occurs if the heart is working harder than usual. Unstable angina doesn't follow a pattern, can occur without physical exertion, and in 10-20% of cases is the prelude to a heart attack.

Antiplatelet therapy – The use of drugs that inhibit blood clots such as the BMS/Sanofi drug Plavix, or aspirin.

Aorta - The large artery that carries blood from the left ventricle of the heart to branch arteries.

Atria – The two upper chambers of the heart.

Bridge to Transplant – Use of a heart assist device to bridge a heart failure patient through to cardiac transplantation.

Cardiovascular disease – The various medical conditions that affect the heart and the blood vessels, of which one is heart failure.

Category B – A Medicare classification in which a device is deemed to be 'nonexperimental/investigational' and therefore eligible for reimbursement during a clinical trial.

CDI – Short for CHESS Depositary Interests, a type of security used by the Australian Securities Exchange (ASX) to allow stocks of international companies to trade in Australia. CHESS is the ASX's Clearing House Electronic Subregister System, which manages the settlement of transactions executed on the ASX.

CE marking – The process of gaining European approval for a medical device. CE stands for *Conformité Européenne.*

CMS – The Centers for Medicare and Medicaid Services (CMS), which is the US Federal agency that runs Medicare and helps coordinate Medicaid.

Continuous Access Protocol – FDA approval of continuing use of a device by patients or doctors who have participated in a clinical trial.

Counterpulsation – Pumping of the heart counter to its natural rhythm in order to improve cardiac output.

Cardiac Resynchronisation Therapy (CRT) - The use of specialised pacemakers to re-coordinate the action of the right and left ventricles of the heart where an abnormality in the heart's electrical conducting system has caused the two ventricles to beat in an asynchronous fashion. Also called 'Biventricular Pacing'.

Catheter - A tube that can be inserted into a body cavity, duct, or vessel to allow drainage, injection of fluids, or implantation of devices.

CRT-D – A pacemaker device that performs 'Cardiac Resynchronisation Therapy' in which the pacemaker is combined with a defibrillator.

C-Pulse - An external aortic counterpulsation support system being commercialised by Sunshine Heart.

Destination Therapy (DT) – Use of a heart assist device as a permanent implant in a heart failure patient rather than as a Bridge to Transplant.

Defibrillator – Devices which treat ventricular or atrial fibrillation, which is where the heart muscle has a quivering motion rather than normal pumping action as a result of disorganised electrical signals. The electrical signals from defibrillators correct this by shocking the heart back into its normal rhythm.

Ejection Fraction – See LVEF.

EMA – The European Medicines Agency, Europe's answer to the FDA.

Explant – Removal of a medical device from the body.

Fatigue testing – Testing of a medical device to determine its resistance to stress.

First-in-man study – Clinical work on a device at the earliest stage of its development to establish proof of concept.

Haemodynamic monitoring – Measurement of the level of blood movement, often using sensors in the bloodstream (called invasive haemodynamic monitoring).

Heart assist device – A medical device that assists the heart in its natural pumping action.

Heart failure – A condition where the heart is unable to pump adequate amounts of blood around the body. There are four classes of heart failure (see NYHA class). Heart failure is sometimes called congestive heart failure or CHF due to congestion in the lungs being one of its symptoms.

ICD – Short for Implantable Cardioverter Defibrillator, a device which send electrical signals to the heart to correct irregular heartbeat.

IDE – Short for Investigational Device Exemption, FDA permission for a clinical trial of a medical device to proceed.

INTERMACS – Short for Interagency Registry for Mechanically Assisted Circulatory Support, INTERMACS is a US registry for patients who are receiving mechanical circulatory support device therapy.

Intraaortic ballon pump - A polyethylene balloon that sits in the aorta and counterpulsates in order to improve the heart's pumping capacity.

ISHLT – The International Society for Heart and Lung Transplantation, whose annual meeting is held every April.

Left Ventricular Assist Device - A mechanical device that can assist in the pumping of blood through the left ventricle of the heart.

LVAD – Short for Left Ventricular Assist Device**.**

LVEF – Short for Left Ventricular Ejection Fraction (EF), a measure of the capacity at which the heart is pumping, calculated by percentage of blood ejected with each contraction of the left ventricle. A normal LVEF is 55% to 70%.

Minimally invasive – Surgery that is carried out by entering the body through the skin with the smallest damage possible.

MS-DRG – Short for Medicare Severity-based Diagnosis-Related Group, the diagnostic group under which a hospital stay is coded for reimbursement purposes by CMS. C-Pulse is coded under MS-DRG 001, one of the most severe, allowing a high level of reimbursement.

Notified Body - In the European Union, an organisation that has been accredited by a Member State to assess whether a product meets certain preordained standards. Companies seeking EU approval of medical devices use a Notified Body approved under the Union's Medical Device Directive.

NYHA Class – One of four classes of heart failure patients as determined by the New York Heart Association, ranging from 'Class I' heart failure (you barely notice it) through Class II

(occasionally you find it hard to do things), then Class III (you can't do much at all) and finally to Class IV (Death's Door). Diagnosis of NYHA Class is highly subjective.

PHLX Medical Device Sector Index – A stock price index (Bloomberg symbol MXZ) composed of companies engaged in the development and manufacturing of device-based therapies and surgical devices.

Pericardial – Located in the vicinity of the pericardium, which is the bilayered serous membrane surrounding the heart.

PMA – Short for Premarket Approval, FDA approval to market a new medical device where there is no functional equivalent that was approved before 1976.

Pilot study – An early stage clinical trial to establish proof of concept.

Pivotal study - A clinical trial in humans to test efficacy in a large sample.

Pre-sutured – A C-Pulse balloon cuff in which the sutures (that is, stitches) are pre-placed on one of the tabs of the cuff, prior to wrapping.

Refractory – Resistant to treatment.

Unstable angina – See angina.

Sternotomy - A surgical procedure involving incisions in the breastbone.

Thoracotomy – A surgical procedure involving incisions made on the right or left side of the chest between the ribs. Such procedures are considered less invasive than a sternotomy.

Thromboembolism - A condition in which a blood clot forms inside a blood vessel or the heart and then breaks off and travels inside the bloodstream to plug another blood vessel, causing organ damage.

Ventricle – One of the heart's two pumping chambers (left or right).

Sunshine Heart

COMPANY DESCRIPTION

Sunshine Heart is a medical device development company based in Eden Prairie, Mn. The company's C-Pulse product is an implantable heart assist device for the treatment of mid-to-late stage heart failure. The device performed well in a pilot trial in Australia and New Zealand and is currently in a pilot trial in the US. The company expects to initiate a pivotal trial of the device for CE Marking next year, before initiating a US pivotal trial.

INVESTMENT STRATEGY

We see Sunshine Heart being revalued on the basis of clinical data from its 20-patient US pilot trial of C-Pulse, as well as CE Marking of the device, expected in early 2012. We also see Sunshine benefiting from early sales of the device in Europe as well as moves towards initiation of a US pivotal trial, expected to complete after 2014, allowing launch of the product in the US by around 2016.

VALUATION

We value Sunshine Heart at 14 cents per CDI base case and 21 cents per CDI optimistic case using a probability-weighted DCF-based valuation. Our target price of 14 cents at the low point of our valuation range.

RISKS

We see the main risk in Sunshine Heart as being regulatory risk – ie that product approval in Europe, which we expect in 2012, is delayed. There is also clinical risk from the upcoming US pivotal trial. A third risk is that prospective partners either in product distribution or in an M&A deal may strike too hard a bargain for Sunshine Heart shareholders to enjoy a strong return. A fourth risk relates to scale up – as Sunshine attempts to manufacture sufficient C-Pulse systems for the FDA trial, the scale-up process could interfere with the company's clinical programme.

Sunshine Heart
as at 22 September 2011

Recommendation	Spec Buy
Price	$0.047
Target (12 months)	$0.14

Table 1 - Financial summary

Sunshine Heart (SHX) — **Share price (A$) $0.047**
As at 22 September 2011 — **Market cap (A$m) 56.5**

Profit and Loss

Y/e June 30 (A$m)	2010a	2011a	2012f	2013f	2014f
Revenue	0	0	0	6	21
EBITDA	**-7**	**-12**	**-15**	**-30**	**-17**
Depreciation	0	0	0	0	0
Amortisation	0	0	0	0	0
EBIT	**-7**	**-12**	**-15**	**-30**	**-17**
Net interest Expense	0	0	0	2	1
Pre-tax profit	-7	-11	-15	-28	-16
Tax	1	0	0	0	0
Reported Net Profit	-7	-11	-15	-28	-16
Less minority interests	0	0	0	0	0
Net profit to shareholders	**-7**	**-11**	**-15**	**-28**	**-16**

Cashflow

Y/e June 30	2010a	2011a	2012f	2013f	2014f
NPAT plus discontinued ops.	-7	-11	-15	-28	-16
Non-cash items	0	0	0	0	0
Working capital	-1	1	0	-1	-1
Other operating cash flow	0	0	0	0	0
Operating cashflow	**-7**	**-10**	**-15**	**-28**	**-16**
Capex	0	0	0	0	0
Investments	0	0	0	0	0
Other investing cash flow	0	0	0	0	0
Investing cashflow	**0**	**0**	**0**	**0**	**0**
Change in borrowings	0	0	0	0	0
Equity raised	9	12	57	0	0
Dividends paid	0	0	0	0	0
Other financing cash flow	0	0	0	0	0
Financing cashflow	**9**	**12**	**57**	**0**	**0**
Net change in cash	**2**	**2**	**43**	**-28**	**-17**
Cash at end of period*	4	6	49	21	4
* Includes effect of exchange rate fluctuations on cash balance					
Free cash flow	**-7**	**-10**	**-15**	**-28**	**-17**

Balance sheet

Y/e June 30	2010a	2011a	2012f	2013f	2014f
Cash	4	6	49	21	4
Current receivables	0	0	0	1	1
Inventories	0	0	0	0	1
Other current assets	1	0	0	0	0
Current assets	**5**	**6**	**49**	**22**	**6**
PPE	0	0	0	0	0
Non-current receivables	0	0	0	0	0
Intangible assets	0	0	0	0	0
Other non-current assets	0	0	0	0	0
Non-current assets	**0**	**0**	**0**	**0**	**0**
Total assets	**5**	**6**	**49**	**22**	**6**
Payables	0	0	0	1	1
Debt	0	0	0	0	0
Provisions	0	0	0	0	0
Other liabilities	0	0	0	0	0
Total liabilities	1	1	1	1	1
Shareholders' equity	5	6	49	21	5
Minorities	0	0	0	0	0
Total shareholders funds	**5**	**6**	**49**	**21**	**5**
Total funds employed	**5**	**6**	**49**	**22**	**6**
W/A shares on issue	177	1,014	1,560	2,632	2,632

Valuation data

Y/e June 30	2010a	2011a	2012f	2013f	2014f
Net profit ($m)	-6.5	-11.5	-15.0	-28.0	-16.4
EPS (c)	-3.7	-1.1	-1.0	-1.1	-0.6
EPS growth (%)	N/A	N/A	N/A	N/A	N/A
P/E ratio (x)	-1.3	-4.2	-4.9	-4.4	-7.6
CFPS (c)	-4.1	-1.0	-0.9	-1.1	-0.6
Price/CF (x)	-1.1	-4.7	-5.0	-4.4	-7.5
DPS (c)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	0%	0%	0%	0%	0%
EV/EBITDA	-7.6	-4.8	-3.7	-1.9	-3.3
EV/EBIT	-7.5	-4.8	-3.6	-1.8	-3.2

Share price now	$0.047
Target price (12 mth):	$0.140
Premium (discount) to price	197.9%
Recommendation:	Spec Buy

Profitability ratios

Y/e June 30	2010a	2011a	2012f	2013f	2014f
EBITDA/revenue (%)	N/A	N/A	N/A	N/A	N/A
EBIT/revenue (%)	N/A	N/A	N/A	N/A	N/A
Return on assets (%)	-124.1%	-179.5%	-30.6%	-128.7%	-270.0%
Return on equity (%)	-138.2%	-195.9%	-30.9%	-133.5%	-326.9%
Return on funds empl'd (%)	-138.2%	-195.9%	-30.9%	-133.5%	-326.9%
Dividend cover (x)	N/A	N/A	N/A	N/A	N/A
Effective tax rate (%)	10.7%	0.0%	0.0%	0.0%	0.0%

Liquidity and leverage ratios

Y/e June 30	2010a	2011a	2012f	2013f	2014f
Net debt/(cash) ($m)	-4	-6	-49	-21	-4
Net debt/equity (%)	-83.4%	-102.8%	-100.4%	-98.5%	-83.2%
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	9.5	11.7	91.0	27.4	5.7

Interims

Y/e June 30 ($m)	2H10a	1H11a	2H11a	1H12f	2H12f
Revenue	0	0	0	0	0
EBITDA	**-4**	**-5**	**-7**	**-6**	**-10**
Depreciation	0	0	0	0	0
Amortisation	0	0	0	0	0
EBIT	**-4**	**-5**	**-7**	**-6**	**-10**
Net interest Expense	0	0	0	0	0
Pre-tax profit	-4	-5	-6	-5	-10
Tax	1	0	0	0	0
Reported Net Profit	-3	-5	-6	-5	-10
Less minority interests	0	0	0	0	0
Net profit to shareholders	-3	-5	-6	-5	-10

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Spec Buy: Expect >30% total return on a 12 month view but carries significantly higher risk than its sector

Buy: Expect >15% total return on a 12 month view

Accumulate: Expect total return between 5% and 15% on a 12 month view

Hold: Expect total return between -5% and 5% on a 12 month view

Reduce: Expect total return between -15% and -5% on a 12 month view

Sell: Expect <-15% total return on a 12 month view

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