

10 August 2011

Buy

Important: The above recommendation has been made on a 12 month view and may not suit your investment needs or timeframe. The basis it is prepared on is summarised on the last page of this report. **PLEASE CONTACT YOUR ADVISER TO DISCUSS THIS GENERAL RECOMMENDATION BEFORE ACTING ON IT.**

High Volatility

Target price
A\$0.07

Price
A\$0.04

Market capitalisation
A\$65.2m

SHC1108010

Priced at close of business 9 August 2011.
Source: IRESS

Sunshine Heart Inc

Positioning for next step

A key milestone approaches with the results of the 20 patient feasibility trial due in September. We are confident the results will be positive and expect the share price to re-rate closer to our target. Compared to peers SHC is compelling value. Buy maintained.

Sunshine Heart Inc - Milestone Table

Event	Timing	Impact
FDA Feasibility Trial - Finish recruitment	Achieved	Positive
FDA Feasibility Trial – Six month follow up	2HCY11	Positive
FDA Pivotal Trial Commence	1QCY12	Positive
CE Mark Approval	4QCY11	Positive
FDA Pivotal Trial Complete	1QCY14	Very Positive
Pivotal Trial Follow Up/Results	2QCY15	Positive
PMA application	3QCY15	Very Positive
Commercial Sales C-Pulse	1QCY16	Very Positive

Source: RBS Morgans & Company Data

FY11 result better than expected and funding underway

SHC posted a net loss of A\$11.6m for FY11, which was better than our forecast loss of A\$13.8m. The main difference relates to a lower R&D spend than we had forecast. SHC finished the year with A\$6.0m in cash. A capital raising is underway which is being conducted in two tranches, Tranche 1 raised A\$4.6m and was subscribed to by US based investors. Tranche 2 is subject to an extra-ordinary general meeting to be held on 18th August 2011 and potentially could raise up to A\$9.6m. RBS Morgans Corporate is joint lead manager to the issue and may receive fees in this regard. The funds will enable SHC to report the results of the 20 patient feasibility trial (expected in September) and prepare for a larger pivotal trial which is expected to commence in 1QCY12. Additional funding will be required to complete this trial.

On a comparative basis stock looks compelling

The most interesting comparison is a review of Heartware's (HIN) market capitalisation when it released the results of its 23 patient feasibility trial for its heart assist device. In April 2008, HIN noted that its device to treat Class IV heart failure patients had achieved a 6 month survival rate of 91%, and at that time had a market cap of approx A\$110m. Given SHC is due to release the feasibility trial result within two months and currently has a fully diluted market cap of A\$65m, in our view it is likely that SHC will be valued more in line with HIN's relative market cap, if the results are positive.

Investment View: Buy maintained – Price Target A\$0.07

We have made changes to our forecasts, reflecting the current capital raising and better aligning clinical trial costs with timelines. Our DCF valuation has reduced slightly to A\$0.09 (was A\$0.10) and we have maintained our short term price target of A\$0.07. The near term milestone to focus on is the results of the Feasibility Trial due in September. The key risk lies in securing adequate funding to maintain momentum for the pivotal trial. Buy maintained.

Analysts

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FY 11 result, changes to forecasts and capital raising

SHC posted a net loss of A\$11.6m for FY11, which was better than our forecast loss of A\$13.8m. The main difference relates to a lower R&D spend than we had forecast. SHC finished the year with A\$6.0m in cash.

A capital raising is underway which is being conducted in two tranches, Tranche 1 raised A\$4.6m at A\$0.04 and was subscribed to by US based investors. For each share purchased, investors will receive one warrant to purchase 0.3 shares of common stock at an exercise price of A\$0.056 per share (4-year term). Tranche 2 is subject to an extra-ordinary general meeting to be held on 18th August 2011 and potentially could raise up to A\$9.6m and will issued on the same terms. RBS Morgans Corporate is joint lead manager to the issue and may receive fees in this regard. The funds will be used to support SHC's continuing activities to obtain approvals to market its C-Pulse Heart Assist System, which include reporting the results of the 20 patient feasibility trial (expected in September) and preparing for a larger pivotal which is expected to commence in 1QCY12. Additional funding will be required to complete this pivotal trial.

In terms of forecasts we have increased our loss estimates by \$A2.2m to A\$15.4m, by \$1.8m to A\$14.7m and by A\$12.3m to A\$12.3m in FY12, FY13 and FY14 respectively. The changes reflect a better alignment of clinical trial costs with the timing of the anticipated pivotal trial protocol.

Key Milestones

As always the share price performance is usually directly correlated with achievement of key milestones. We have detailed in Table 1 the key milestones to focus on. In March 2011, SHC completed the recruitment of its 20th patient in the feasibility trial, and the results after a six month follow up are due in September 2011. We believe this is a key turning point for the company, and if positive results are reported, we expect the share price to re-rate quickly to our price target of A\$0.07, which translates to a market capitalisation of approximately A\$116m (fully diluted).

We have reviewed Heartware (HIN) which is a similar company in the heart failure space. We noted that Heartware's (HIN) had a market capitalisation of approximately A\$110m, when it released the results of its 23 patient feasibility trial for its heart assist device in April 2008. HIN's device treated Class IV heart failure patients and achieved a 6 month survival rate of 91%.

Table 1 – Milestones to focus on

Event	Timing	Impact
FDA Feasibility Trial - Finish recruitment	Achieved	Positive
Cuff changes complete for minimally invasive surgery	Achieved	Positive
New single unit driver released	3QCY11	Positive
FDA Feasibility Trial – Six month follow up	2HCY11	Positive
FDA Pivotal Trial protocol approval	4QCY11	Positive
FDA Pivotal Trial Commence	1QCY12	Positive
NASDAQ listing	3QCY11	Positive
CE Mark Approval	4QCY11	Positive
FDA Pivotal Trial Complete	1QCY14	Very Positive
Pivotal Trial Follow Up	1QCY15	Positive
PMA application	2QCY15	Very Positive
Commercial Sales C-Pulse	1QCY16	Very Positive

Source: RBS Morgans & Company Data

Recap on Clinical Trial

SHC has completed enrolment in its 20 patient FDA approved Investigational Device Exemption (IDE) feasibility study. After a 6 month follow-up of the 20 patients, SHC will submit the feasibility data to the FDA (expected in September 2011) seeking approval for a larger pivotal study. In addition, the FDA has allowed SHC to continue to enrol patients under its feasibility trial protocol potentially implanting up to another 20 patients. SHC will also use the feasibility data to apply for CE Mark approval for the C-Pulse to be marketed in the European Union and other countries accepting CE Mark, expected by the end of CY11.

The pivotal study is estimated to involve 250 – 300 patients, as a precursor to marketing C-Pulse in the US. We expect that the study would be randomised against existing medical therapy. Once

the pivotal trial begins, SHC will no longer enrol under the feasibility trial.

We believe the key to driving the commercial application and significant take up by surgeons and patients, is the ability to regularly perform the surgery minimally invasively, combining the two external components into one unit and importantly working towards a fully implantable device. The latter is a development program which has commenced and the ultimate aim is to directly connect the C-pulse to a pacemaker or an ICD device. This potentially could offer a new therapy for heart failure patients, combining the mechanical input of the C-pulse with the electrical support of the pacemaker. Clearly this is a long term objective and should be of enormous interest to major device companies.

Recap on Sunshine Heart's (SHC) product

SHC is a medical device company working towards the commercialisation of the C-Pulse Heart Assist System: an implantable, non-blood contacting, heart assist therapy for the treatment of advanced heart failure based on proven science of intra-aortic balloon pumps from 40 years ago. Therefore, the technology risk is less as compared to other experimental devices in the field. In clinical trials the C-Pulse reduced the symptoms of heart failure through the use of counterpulsation technology which enables an increase in ejection fractions, an increase in coronary blood flow and a reduction in the heart's pumping workload.

The C-Pulse system consists of an extra-aortic cuff, ECG Sense Lead, Interface Lead, Battery Pack and Driver. The C-Pulse Cuff is positioned on the exterior of the ascending aorta above the aortic valve and therefore is outside of the blood system. As a result there is minimal risk of blood clots and stroke. Other benefits include: 1) increased coronary blood flow and ejection fractions; 2) immediate and sustained symptomatic relief; 3) electively disconnectable by patient; 4) improved quality of life and 5) reduced re-hospitalisation costs. Patients like the disconnectability feature as they do not feel 100% dependent on remaining alive by being tethered to the device. It provides convenience aspects and also a measure of independence without fearing death.

Market potential

HF is a common condition in which the heart becomes unable to pump sufficient blood to meet the body's needs. A progressive condition, it can be caused by or is the end result of a range of conditions, including coronary artery disease, prolonged high blood pressure, poor valve function, damage to the heart muscle arising from a heart attack or virus or other cardiovascular abnormalities. The New York Heart Association (NYHA) has set out classifications for patients with HF. Table 2 below sets out the classification I to IV.

Table 2 : New York Heart Association Heart Failure Classification

Class	Description
I	No symptoms and no limitation in ordinary physical activity, e.g. shortness of breath when walking, climbing stairs etc.
II	Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
III	Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g. walking short distances (20-100 m). Comfortable only at rest.
IV	Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients.

Source: NYHA

There are 25m people with HF world wide. In the US there are 5.3m people with HF, with approximately 550,000 new cases diagnosed and over 200,000 deaths per annum. Approximately 50% of patients die within five years of diagnosis, and 40% to 50% of patients die from sudden cardiac death. The American Heart Association estimates the direct and indirect cost of HF in the United States for CY09 at US\$37.2bn.

While heart failure is a chronic disease, with treatment, a failing heart can become stronger and signs and symptoms of heart failure can improve. In some instances HF can be rectified by treating the underlying cause; for example, repairing a heart valve or controlling a fast heart rhythm may assist in reversing heart failure. But in the majority of cases, treatment involves a

balance of medications, and in some cases, devices that help the heart to beat properly.

Market potential - Where is the C-Pulse positioned in the competitive landscape?

SHC has positioned its device to target advanced heart failure (Class III- Class IVa), where the heart has lost some 30% to 40% of its capacity to pump blood around the body. Class III patients are typically on some form of drug therapy and over time the therapy becomes less effective.

Of the 5.3m patients with HF in the US, it is estimated that there are 1.4m patients (Dr Aggarwal estimated 1.5m) in the Class III or moderate heart failure category. The following patients may not be suited to the C-Pulse device: patients who are aortic contra-indicated (~10 -15% of patients); and patients who have had Coronary Artery Bypass Grafting (CABG) (~10-20% of patients) - physicians may be able to treat these patients if the grafts are no longer viable. They will simply remove the graft and place on the SHC cuff.

SHC's aim is to provide a minimally invasive therapy for Class III ambulatory heart failure that provides symptomatic relief and halts the disease progression. Therefore, the C-Pulse device is estimated to be appropriate for approximately 910,000 Class III heart failure patients.

Investment View: Buy for near term milestone

Following the changes to our forecasts and dilution for the current capital raising our valuation has decreased slightly to A\$0.09 (was A\$0.10). We have maintained our short term price target at A\$0.07. The key risk is securing additional funding for Tranche 2 in this volatile market. Then additional funding will be required for the larger pivotal trial which is expected to start 1QCY12. It is estimated that US\$35m to US\$40m will be required for this trial. We have maintained our Buy recommendation for investors with a higher risk profile.

SHC: Financial summary

	AIFRS	AIFRS	AIFRS	AIFRS	AIFRS	AIFRS	Closing price (A\$)	0.040	Price target (A\$)	0.07	
Income statement	2009A	2010A	2011A	2012F	2013F	2014F	Valuation metrics				
Divisional sales	0.1	0.3	0.3	2.2	3.2	7.1	Preferred methodology	DCF	Val'n (A\$)	\$0.09	
Total revenue	0.1	0.3	0.3	2.2	3.2	7.1	DCF valuation inputs				
EBITDA	-8.4	-7.4	-11.7	-15.8	-15.4	-13.1	Rf	5.25%	10-year rate	5.25%	
Associate income	0.0	0.0	0.0	0.0	0.0	0.0	Rm-Rf	6.00%	Margin	2.0%	
Depreciation	0.1	0.1	0.0	0.0	0.0	0.0	Beta	1.80	Kd	16.05%	
EBITA	-8.4	-7.5	-11.8	-15.8	-15.5	-13.1	CAPM (Rf+Beta(Rm-Rf))	16.1%	Ke	16.1%	
Amortisation/impairment	0.0	0.0	0.0	0.0	0.0	0.0	E/EV*Ke+D/EV*Kd(1-t)		NPV cash flow (A\$m)	158.2	
EBIT	-8.4	-7.5	-11.8	-15.8	-15.5	-13.1	Equity (E/EV)	100.0%	Minority interest (A\$m)	0.0	
EBIT (incl associate profit)	-8.4	-7.5	-11.8	-15.8	-15.5	-13.1	Debt (D/EV)	0.0%	Net debt (A\$m)	-2.8	
Net interest expense	-0.3	-0.2	-0.3	-0.4	-0.8	-0.8	Interest rate	16.05%	Investments (A\$m)	0.0	
Pre-tax profit	-8.1	-7.3	-11.5	-15.4	-14.7	-12.3	Tax rate (t)	30.0%	Equity market value (A\$m)	160.9	
Income tax expense	0.0	-0.8	0.0	0.0	0.0	0.0	WACC	16.1%	Diluted no. of shares (m)	1780.9	
After-tax profit	-8.1	-6.5	-11.5	-15.4	-14.7	-12.3			DCF valuation	\$0.09	
Minority interests	0.0	0.0	0.0	0.0	0.0	0.0					
NPAT	-8.1	-6.5	-11.5	-15.4	-14.7	-12.3	Multiples	2010A	2011A	2012F	2013F
Significant items	0.0	0.0	0.0	0.0	0.0	0.0	Enterprise value (A\$m)	69.2	67.3	65.2	57.9
NPAT post abnormalities	-8.1	-6.5	-11.5	-15.4	-14.7	-12.3	EV/Sales (x)	na	207.7	29.3	17.9
							EV/EBITDA (x)	-9.3	-5.7	-4.1	-3.8
							EV/EBIT (x)	-9.2	-5.7	-4.1	-3.7
							PE (pre-goodwill) (x)	-3.3	-3.5	-3.7	-4.3
Cash flow statement	2009A	2010A	2011A	2012F	2013F	2014F	At target price	2010A	2011A	2012F	2013F
EBITDA	-8.4	-7.4	-11.7	-15.8	-15.4	-13.1	EV/EBITDA (x)	-17.2	-10.7	-7.1	-5.8
Change in working capital	0.3	-0.8	1.4	0.8	-0.2	-0.8	PE (pre-goodwill) (x)	-5.9	-6.3	-6.8	-7.8
Net interest (pd)/rec	0.3	0.2	0.3	0.4	0.8	0.8	Comparable company data (x)	2010A	2011A	2012F	2013F
Taxes paid	0.0	0.8	0.0	0.0	0.0	0.0	AcruX				
Other oper cash items	0.0	0.0	0.0	0.0	0.0	0.0	EV/EBITDA	11.3	7.3	9.9	6.3
Cash flow from ops (1)	-7.8	-7.3	-10.1	-14.6	-14.8	-13.1	EV/EBIT	11.4	7.3	10.1	6.5
Capex (2)	0.0	0.0	0.0	0.0	0.0	0.0	PE	13.3	11.1	16.3	11.4
Disposals/(acquisitions)	0.0	0.0	0.0	0.0	0.0	0.0	ImpediMed				
Other investing cash flow	0.0	0.0	0.0	0.0	0.0	0.0	EV/EBITDA	-5.0	-4.2	-7.7	4.8
Cash flow from invest (3)	0.0	0.0	0.0	0.0	0.0	0.0	EV/EBIT	-4.7	-4.1	-7.3	4.9
Incr/(decr) in equity	0.0	9.2	12.2	21.5	15.0	0.0	PE	na	na	na	na
Incr/(decr) in debt	0.0	0.0	0.0	0.0	0.0	0.0					
Ordinary dividend paid	0.0	0.0	0.0	0.0	0.0	0.0	Per share data	2010A	2011A	2012F	2013F
Preferred dividends (4)	0.0	0.0	0.0	0.0	0.0	0.0	No. shares	536.9	1008.9	1438.9	1588.9
Other financing cash flow	0.0	0.0	0.0	0.0	0.0	0.0	EPS (cps)	-1.2	-1.1	-1.1	-0.9
Cash flow from fin (5)	0.0	9.2	12.2	21.5	15.0	0.0	EPS (normalised) (c)	-1.2	-1.1	-1.1	-0.9
Forex and disc ops (6)	0.0	0.0	0.0	0.0	0.0	0.0	Dividend per share (c)	0.0	0.0	0.0	0.0
Incr/(decr) cash (1+3+5+6)	0.0	0.0	0.0	0.0	0.0	0.0	Dividend payout ratio (%)	0.0%	0.0%	0.0%	0.0%
Equity FCF (1+2+4)	-7.8	-7.3	-10.1	-14.6	-14.8	-13.1	Dividend yield (%)	0.0%	0.0%	0.0%	0.0%
							Growth ratios	2010A	2011A	2012F	2013F
Balance sheet	2009A	2010A	2011A	2012F	2013F	2014F	Sales growth	141.8%	0.0%	587.5%	45.5%
Cash & deposits	2.0	3.9	6.0	13.4	13.5	0.4	Operating cost growth	8.6%	-55.2%	-49.3%	-3.7%
Trade debtors	0.2	0.2	0.1	0.2	0.3	0.6	EBITDA growth	11.0%	-56.9%	-34.2%	2.2%
Inventory	0.0	0.0	0.0	0.3	0.5	1.1	EBITA growth	11.0%	-56.9%	-34.2%	2.2%
Investments	0.0	0.0	0.0	0.0	0.0	0.0	EBIT growth	11.0%	-56.9%	-34.2%	2.2%
Goodwill	0.0	0.0	0.0	0.0	0.0	0.0	NPAT growth	19.6%	-75.9%	-33.6%	4.7%
Other intangible assets	0.0	0.0	0.0	0.0	0.0	0.0	Pre-goodwill NPAT growth	19.6%	-75.9%	-33.6%	4.7%
Fixed assets	0.2	0.1	0.1	0.1	0.1	0.1	Pre-goodwill EPS growth	15.8%	91.0%	1126.5%	-94.4%
Other assets	0.1	0.9	0.1	0.1	0.1	0.1	Normalised EPS growth	15.8%	91.0%	1126.5%	-94.4%
Total assets	2.5	5.3	6.4	14.1	14.5	2.3	Operating performance	2010A	2011A	2012F	2013F
Short-term borrowings	0.0	0.0	0.0	0.0	0.0	0.0	Asset turnover (%)	2.1	1.4	5.4	5.6
Trade payables	0.3	0.5	0.3	1.5	1.5	1.7	EBITDA margin (%)	na	-3619.5	-707.9	-476.1
Long-term borrowings	0.0	0.0	0.0	0.0	0.0	0.0	EBIT margin (%)	na	-3632.2	-709.2	-477.1
Provisions	0.0	0.0	0.0	0.0	0.0	0.0	Net profit margin (%)	na	-3553.8	-690.7	-452.4
Other liabilities	0.1	0.1	0.2	0.2	0.2	0.2	Return on net assets (%)	-158.7	-200.9	-131.9	-125.5
Total liabilities	0.4	0.5	0.5	1.7	1.8	1.9	Net debt (A\$m)	-3.9	-6.0	-13.4	-13.5
Share capital	48.3	57.5	69.8	75.9	76.2	63.9	Net debt/equity (%)	-83.4	-102.7	-111.6	-109.9
Other reserves	1.8	1.8	2.1	2.1	2.1	2.1	Net interest/EBIT cover (x)	-43.9	-46.3	-40.6	-19.3
Retained earnings	-48.0	-54.6	-66.0	-66.0	-66.0	-66.0	ROIC (%)	na	-10.4	-15.0	-15.6
Other equity	0.0	0.0	0.0	0.0	0.0	0.0	Internal liquidity	2010A	2011A	2012F	2013F
Total equity	2.0	4.7	5.9	12.0	12.3	0.0	Current ratio (x)	7.3	11.3	7.8	7.7
Minority interest	0.0	0.0	0.0	0.0	0.0	0.0	Receivables turnover (x)	na	1.7	14.4	14.4
Total shareholders' equity	2.0	4.7	5.9	12.0	12.3	0.0	Payables turnover (x)	19.4	31.7	20.2	12.4
Total liabilities & SE	2.5	5.3	6.4	13.7	14.1	1.9					

Source: RBS Morgans – Share Price as at 10th August 2011

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