RBS Morgans

Equity | Australia | Pharma & Biotech

23 September 2011

Sunshine Heart Inc

Brave Heart

Ohio State's Medical Centre has released the early results of a six month feasibility study utilising SHC's C-Pulse system for Class III/IV heart failure. Our initial impression is that the results are very positive, and should pave the way for a pivotal trial which is expected to start next year. Buy maintained.

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

SHC110923

Priced at close of business 23 September 2011.
Source: IRESS

Sunshine Heart Inc - Milestone Table

Event	Timing	Impact
FDA Feasibility Trial - Finish recruitment	Achieved	Positive
Cuff changes complete for minimally invasive surgery	Achieved	Positive
FDA Feasibility Trial – Six month follow up	Achieved	Positive
New single unit driver released	3QCY11	Positive
FDA Pivotal Trial protocol approval	1QCY12 (was 4QCY11)	Positive
CE Mark Approval	1QCY12 (was 4QCY11)	Positive
FDA Pivotal Trial Commence	2QCY12 (was 1QCY12)	Positive
NASDAQ listing	3QCY11	Positive

Source: RBS Morgans & Company Data

Early results are promising – All but one patient stabilised or improved

SHC announced Ohio State's release of early results of a six month feasibility study utilizing the company's minimally invasive C-Pulse system for Class III and ambulatory Class IV heart failure. All but one patient either improved or maintained NYHA heart failure classification. Two patients were disconnected permanently, one after eleven months on therapy due to the absence of heart failure symptoms. Overall, other improvements were realized as measured by quality of life scores, six-minute walk times, ejection fractions, or the heart's pumping ability, and reductions in medications. One patient death from an aortic disruption was reported as a result of a re-sternotomy surgery to treat a procedure related infection.

Result warrant a pivotal trial

Full results from the trial will be presented in detail during the Transcatheter Cardiovascular Therapeutics Meeting on November 8, so it is difficult to provide an in-depth analysis of the trial's success until then. However, the underlying result is stunning – all patients (with exception to the one individual who died in surgery) who were implanted with the C-Pulse device, stabilised or improved. Notably, two patients improved to a point where they were able to be disconnected from the device permanently. These results are very impressive, and we believe they should provide sufficient grounds for a pivotal trial, which SHC hopes to commence 2QCY12.

Investment View: Buy maintained – Price Target A$0.07

We have made no adjustments to our forecasts. Therefore, our DCF valuation and price target remain at A$0.07. The key risk lies in securing adequate funding to maintain momentum for the pivotal trial. Buy maintained.

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Early feasibility results are positive

The multi-center trial was led in part by Ohio State's Medical Center, where a West Virginia man and a central Ohio man became the first in the United States to receive the device in 2009.

Twenty patients, eight women and 12 men with an average age of 56, were enrolled in the North American trial. Eighteen patients were classified with New York Heart Association (NYHA) Class III heart failure and two were Class IV, the most severe forms of heart failure. For these patients, daily activities such as walking across the room, moderate exercise or climbing stairs can be a challenge. All patients had cardiac resynchronization therapy, implantable cardiac defibrillators or combination devices implanted. Three patients were successfully bridged to transplant with one patient being supported for 22 months, the longest of any patient participating in the trial.

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Key Milestones

As always the share price performance is usually directly correlated with achievement of key milestones. We have taken a slightly more conservative outlook on the immanency of the pivotal trials and have adjusted our outlook accordingly (refer to Table 1).

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
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FDA Pivotal Trial Commence	2QCY12 (was 1QCY12)	Positive
NASDAQ listing	3QCY11	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

The next step – pivotal trial

SHC will submit the feasibility data to the FDA 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 early next year.

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

We have made no changes to our forecasts and our valuation remains A$0.09. We have maintained our short term price target at A$0.07. The key risk is securing additional funding for the larger pivotal trial which is expected to start 2QCY12 (was 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

Income statement	AIFRS 2009A	AIFRS 2010A	AIFRS 2011A	AIFRS 2012F	AIFRS 2013F	AIFRS 2014F
Divisional sales	0.1	0.3	0.3	2.2	3.2	7.1
Total revenue	0.1	0.3	0.3	2.2	3.2	7.1
EBITDA	-8.4	-7.4	-11.7	-15.8	-15.4	-13.1
Associate income	0.0	0.0	0.0	0.0	0.0	0.0
Depreciation	0.1	0.1	0.0	0.0	0.0	0.0
EBITA	-8.4	-7.5	-11.8	-15.8	-15.5	-13.1
Amortisation/impairment	0.0	0.0	0.0	0.0	0.0	0.0
EBIT	-8.4	-7.5	-11.8	-15.8	-15.5	-13.1
EBIT(incl associate profit)	-8.4	-7.5	-11.8	-15.8	-15.5	-13.1
Net interest expense	-0.3	-0.2	-0.3	-0.4	-0.8	-0.8
Pre-tax profit	-8.1	-7.3	-11.5	-15.4	-14.7	-12.3
Income tax expense	0.0	-0.8	0.0	0.0	0.0	0.0
After-tax profit	-8.1	-6.5	-11.5	-15.4	-14.7	-12.3
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
Significant items	0.0	0.0	0.0	0.0	0.0	0.0
NPAT post abnormals	-8.1	-6.5	-11.5	-15.4	-14.7	-12.3

Cash flow statement	2009A	2010A	2011A	2012F	2013F	2014F
EBITDA	-8.4	-7.4	-11.7	-15.8	-15.4	-13.1
Change in working capital	0.3	-0.8	1.4	0.8	-0.2	-0.8
Net interest (pd)/rec	0.3	0.2	0.3	0.4	0.8	0.8
Taxes paid	0.0	0.8	0.0	0.0	0.0	0.0
Other oper cash items	0.0	0.0	0.0	0.0	0.0	0.0
Cash flow from ops (1)	-7.8	-7.3	-10.1	-14.6	-14.8	-13.1
Capex (2)	0.0	0.0	0.0	0.0	0.0	0.0
Disposals/(acquisitions)	0.0	0.0	0.0	0.0	0.0	0.0
Other investing cash flow	0.0	0.0	0.0	0.0	0.0	0.0
Cash flow from invest (3)	0.0	0.0	0.0	0.0	0.0	0.0
Incr/(decr) in equity	0.0	9.2	12.2	21.5	15.0	0.0
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
Preferred dividends (4)	0.0	0.0	0.0	0.0	0.0	0.0
Other financing cash flow	0.0	0.0	0.0	0.0	0.0	0.0
Cash flow from fin (5)	0.0	9.2	12.2	21.5	15.0	0.0
Forex and disc ops (6)	0.0	0.0	0.0	0.0	0.0	0.0
Inc/(decr) cash (1+3+5+6)	0.0	0.0	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

Balance sheet	2009A	2010A	2011A	2012F	2013F	2014F
Cash & deposits	2.0	3.9	6.0	13.4	13.5	0.4
Trade debtors	0.2	0.2	0.1	0.2	0.3	0.6
Inventory	0.0	0.0	0.0	0.3	0.5	1.1
Investments	0.0	0.0	0.0	0.0	0.0	0.0
Goodwill	0.0	0.0	0.0	0.0	0.0	0.0
Other intangible assets	0.0	0.0	0.0	0.0	0.0	0.0
Fixed assets	0.2	0.1	0.1	0.1	0.1	0.1
Other assets	0.1	0.9	0.1	0.1	0.1	0.1
Total assets	**2.5**	**5.3**	**6.4**	**14.1**	**14.5**	**2.3**
Short-term borrowings	0.0	0.0	0.0	0.0	0.0	0.0
Trade payables	0.3	0.5	0.3	1.5	1.5	1.7
Long-term borrowings	0.0	0.0	0.0	0.0	0.0	0.0
Provisions	0.0	0.0	0.0	0.0	0.0	0.0
Other liabilities	0.1	0.1	0.2	0.2	0.2	0.2
Total liabilities	**0.4**	**0.5**	**0.5**	**1.7**	**1.8**	**1.9**
Share capital	48.3	57.5	69.8	75.9	76.2	63.9
Other reserves	1.8	1.8	2.1	2.1	2.1	2.1
Retained earnings	-48.0	-54.6	-66.0	-66.0	-66.0	-66.0
Other equity	0.0	0.0	0.0	0.0	0.0	0.0
Total equity	**2.0**	**4.7**	**5.9**	**12.0**	**12.3**	**0.0**
Minority interest	0.0	0.0	0.0	0.0	0.0	0.0
Total shareholders' equity	2.0	4.7	5.9	12.0	12.3	0.0
Total liabilities & SE	2.5	5.3	6.4	13.7	14.1	1.9

Closing price (A$)	**0.040**	**Price target (A$)**	**0.07**
Valuation metrics			
Preferred methodology	DCF	Val'n (A$)	$0.09
DCF valuation inputs			
Rf	5.25%	10-year rate	5.25%
Rm-Rf	6.00%	Margin	2.0%
Beta	1.80	Kd	16.05%
CAPM (Rf+Beta(Rm-Rf))	16.1%	Ke	16.1%
E/EV*Ke+D/EV*Kd(1-t)		NPV cash flow (A$m)	158.2
Equity (E/EV)	100.0%	Minority interest (A$m)	0.0
Debt (D/EV)	0.0%	Net debt (A$m)	-2.8
Interest rate	16.05%	Investments (A$m)	0.0
Tax rate (t)	30.0%	Equity market value (A$m)	160.9
WACC	16.1%	Diluted no. of shares (m)	1780.9
		DCF valuation	**$0.09**

Multiples	2010A	2011A	2012F	2013F
Enterprise value (A$m)	69.2	67.3	65.2	57.9
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

At target price	2010A	2011A	2012F	2013F
EV/EBITDA (x)	-17.2	-10.7	-7.1	-5.8
PE (pre-goodwill) (x)	-5.9	-6.3	-6.8	-7.8

Comparable company data (x)	2010A	2011A	2012F	2013F
Acrux				
EV/EBITDA	11.3	7.3	9.9	6.3
EV/EBIT	11.4	7.3	10.1	6.5
PE	13.3	11.1	16.3	11.4
ImpediMed				
EV/EBITDA	-5.0	-4.2	-7.7	4.8
EV/EBIT	-4.7	-4.1	-7.3	4.9
PE	na	na	na	na

Per share data	2010A	2011A	2012F	2013F
No. shares	536.9	1008.9	1438.9	1588.9
EPS (cps)	-1.2	-1.1	-1.1	-0.9
EPS (normalised) (c)	-1.2	-1.1	-1.1	-0.9
Dividend per share (c)	0.0	0.0	0.0	0.0
Dividend payout ratio (%)	0.0%	0.0%	0.0%	0.0%
Dividend yield (%)	0.0%	0.0%	0.0%	0.0%

Growth ratios	2010A	2011A	2012F	2013F
Sales growth	141.8%	0.0%	587.5%	45.5%
Operating cost growth	8.6%	-55.2%	-49.3%	-3.7%
EBITDA growth	11.0%	-56.9%	-34.2%	2.2%
EBITA growth	11.0%	-56.9%	-34.2%	2.2%
EBIT growth	11.0%	-56.9%	-34.2%	2.2%
NPAT growth	19.6%	-75.9%	-33.6%	4.7%
Pre-goodwill NPAT growth	19.6%	-75.9%	-33.6%	4.7%
Pre-goodwill EPS growth	15.8%	91.0%	1126.5%	-94.4%
Normalised EPS growth	15.8%	91.0%	1126.5%	-94.4%

Operating performance	2010A	2011A	2012F	2013F
Asset turnover (%)	2.1	1.4	5.4	5.6
EBITDA margin (%)	na	-3619.5	-707.9	-476.1
EBIT margin (%)	na	-3632.2	-709.2	-477.1
Net profit margin (%)	na	-3553.8	-690.7	-452.4
Return on net assets (%)	-158.7	-200.9	-131.9	-125.5
Net debt (A$m)	-3.9	-6.0	-13.4	-13.5
Net debt/equity (%)	-83.4	-102.7	-111.6	-109.9
Net interest/EBIT cover (x)	-43.9	-46.3	-40.6	-19.3
ROIC (%)	na	-10.4	-15.0	-15.6

Internal liquidity	2010A	2011A	2012F	2013F
Current ratio (x)	7.3	11.3	7.8	7.7
Receivables turnover (x)	na	1.7	14.4	14.4
Payables turnover (x)	19.4	31.7	20.2	12.4

Source: RBS Morgans – Share Price as at 23rd September 2011

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