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RBS Morgans

1 December 2011

Sunshine Heart Inc

Easing the squeeze

Last month Dr William T. Abraham presented details of a 20-patient feasibility trial for SHC's C-Pulse device at the Transcatheter Cadiovacular Therapeutics Conference in San Francisco. All but one patient remained unchanged or demonstrated improvement in key evaluative endpoints. 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$0.037

Market capitalisation
A$44.5m

SHC111201

Priced at close of business 30 November 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	Achieved	Positive
FDA Pivotal Trial protocol approval	1QCY12	Positive
CE Mark Approval	1QCY12	Positive
FDA Pivotal Trial Commence	2QCY12	Positive
NASDAQ listing	4QCY11 (was 3QCY11)	Positive

Source: RBS Morgans & Company Data

Feasibility trial results are promising

In a presentation to analysts and health professionals at the Transcatheter Cardiovascular Therapeutics Conference held in San Fransisco, Dr William T Abraham provided details of SHC's FDA-approved feasibility trial for the C-Pulse Heart Assist System. After six months follow-up, C–Pulse therapy produced statistically significant improvements in NYHA Class reduction (3.1±0.3 to 2.2±0.8, P=0.0001), Quality of Life (64±17 to 49±26, P=0.001), and Left Ventricular Ejection Fraction (28±5 to 31±7, P=0.04). All but one patient remained unchanged or demonstrated improvement in NYHA, Minnesota Living With Heart Failure (MLWHF) quality of life and Six Minute Hall Walk (6MHW). In addition, four patients improved to NYHA Class I and two patients were permanently removed from therapy due to improvements. These preliminary results are encouraging, and should be sufficient to warrant a subsequent pivotal trial.

Pivotal trial, CE Mark plans on track

SHC will submit the feasibility data to the FDA seeking approval for a larger pivotal study, flagged to commence in 2QCY12. 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. 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. Management have said that they are on track on file for the CE Mark this month, and expect approval could be achieved as early as 1HCY12.

Investment View: Buy maintained – Price Target A$0.07

We have made no adjustments to our forecasts. Therefore, our DCF valuation remains at A$0.09 and our price target remains at A$0.07. The key risk lies in securing adequate funding to maintain momentum for the pivotal trial. Buy maintained.

Analysts

Scott Power
+61 7 3334 4884
scott.power@rbsmorgans.com

SHC111201

RBS Morgans Limited
(A.B.N. 49 010 669 726) AFSL235410
A Participant of ASX Group

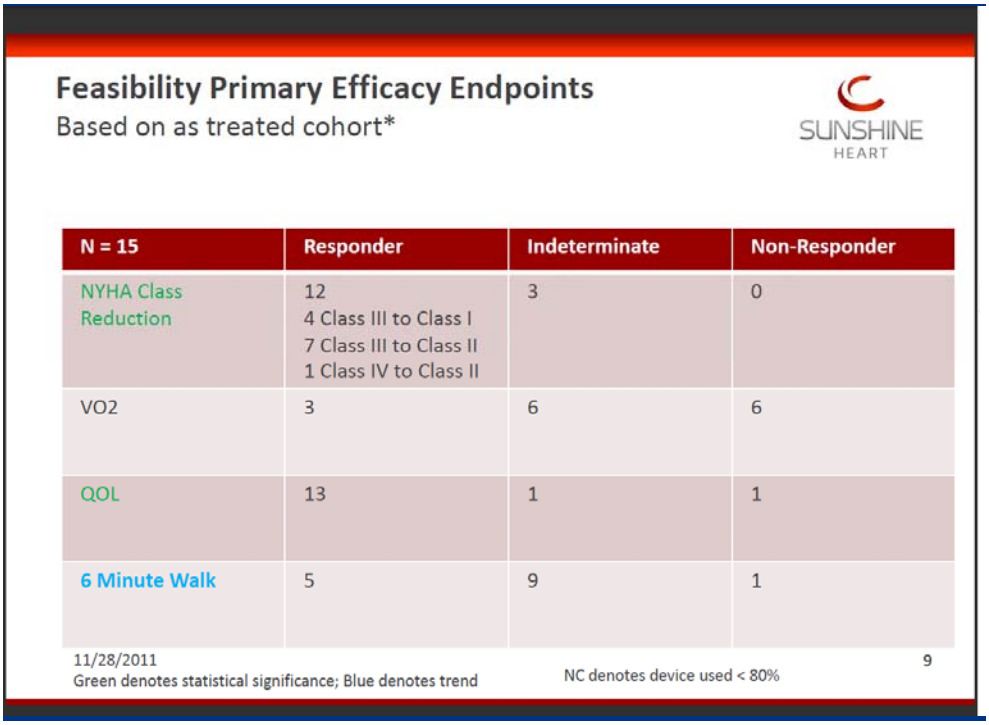
www.rbsmorgans.com

Full results announced at TCT conference

Last month Dr William Abraham, co-lead principal investigator for the C-Pulse Heart Assist System feasibility trial, presented his results to healthcare professionals and analysts at the Transcatheter Cardiovascular Therapeutics Conference held in San Francisco. The multi-center trial involved twenty patients - 8 women and 12 men with an average age of 56 (ranging 34-71). 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.

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. One of the patients that was removed permanently was a Class IV patient when the trial commenced. This result, in Dr Abraham's own words, is "remarkable". After six months follow-up, C–Pulse therapy produced statistically significant improvements in NYHA Class reduction (3.1±0.3 to 2.2±0.8, P=0.0001), Quality of Life (64±17 to 49±26, P=0.001), and Left Ventricular Ejection Fraction (28±5 to 31±7, P=0.04) which measures the heart's pumping ability. All but one patient remained unchanged or demonstrated improvement in NYHA, Minnesota Living With Heart Failure (MLWHF) quality of life and Six Minute Hall Walk (6MHW).No neurologic events or heart attacks were reported, while six superficial exit site infections were successfully treated with antibiotics. There was one instance of post operative, non-device related bleeding.

Chart 1 : Feasibility trial results



Source: Company presentation

Death clarified, steps taken to mitigate subsequent fatalities

One patient death from an aortic disruption was reported as a result of a re-sternotomy surgery to treat a procedure related infection. The death occurred in the setting of a sternal wound infection; which can arise when surgery requires the opening up of the sternum to access the chest cavity. Typically, if a sternal infection is identified the surgeon will reoperate immediately to clean out the infection and also treat the patient with antibiotics. In the case of the patient who died, the surgeon chose only to treat the patient with antibiotics. When the infection progressed four months later, the surgeon operated to treat the infection and remove the device, and tore the patient's aorta in the process. Notably, Dr Abraham emphasised that the death was due to an avoidable complication and said that steps were being taken to ensure that a similar event will not reoccur in subsequent trials.

Key Milestones

As always the share price performance is usually directly correlated with achievement of key milestones (refer to Table 1). SHC Chief Executive officer, Dave Rosa, indicated that new modified versions of the C-Pulse device, including a single unit system, would be available by the end of October.

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
FDA Feasibility Trial – Six month follow up	Achieved	Positive
New single unit driver released	Achieved	Positive
FDA Pivotal Trial protocol approval	1QCY12	Positive
CE Mark Approval	1QCY12	Positive
FDA Pivotal Trial Commence	2QCY12	Positive
NASDAQ listing	4QCY11 (was 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. SHC is planning to meet with the US Food & Drug Administration (FDA) in January 2012 to discuss the clinical data, final design and protocol for the US Pivotal trial. Patient recruitment is anticipated to begin in mid-2012.

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. 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$)	**0.037**	**Price target (A$)**	**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)	165.5
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)	168.3
WACC	16.1%	Diluted no. of shares (m)	1780.9
		DCF valuation	**$0.09**

Multiples	2010A	2011A	2012F	2013F
Enterprise value (A$m)	63.9	62.0	59.9	52.5
EV/Sales (x)	na	191.2	26.9	16.2
EV/EBITDA (x)	-8.6	-5.3	-3.8	-3.4
EV/EBIT (x)	-8.5	-5.3	-3.8	-3.4
PE (pre-goodwill) (x)	-3.0	-3.2	-3.5	-4.0

At target price	2010A	2011A	2012F	2013F
EV/EBITDA (x)	-16.7	-10.4	-6.9	-5.6
PE (pre-goodwill) (x)	-5.7	-6.1	-6.5	-7.6

Comparable company data (x)	2010A	2011A	2012F	2013F
Acrux				
EV/EBITDA	8.2	5.2	54.3	8.7
EV/EBIT	8.3	5.4	86.8	9.6
PE	10.0	8.2	86.1	16.7
ImpediMed				
EV/EBITDA	-4.8	-3.8	-5.3	14.9
EV/EBIT	-4.5	-3.7	-5.1	16.1
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 30 November 2011

RBS Morgans

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SYDNEY – HEAD OFFICE	(02) 8215 5000
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