

## 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.**

TP A\$0.07

SHC120813

### RBS Refiner

Price (close 13 Aug)	A\$0.036
3M high/low	A\$0.02/0.058
Market cap	A\$55.9m
Av (12M) turnover	A\$0.65m
Freefloat	100%
Reuters	SHC.AX
Bloomberg	SHC AU
Net debt (cash)	(US\$21.1)
3yr EPS CAGR	
Income (2013F div yield)	0.0%

Source: Bloomberg

### RBS vs consensus

PBT (US\$M)	RBS	Cons	% diff
2012F	-0.85	-0.85	0.0
2013F	-0.75	-0.75	0.0
2014F	-0.63	-0.63	0.0

Source: RBS Morgans, Bloomberg

### Key events

Date	Event
2HCY12	IDE approval
2HCY12	Start Pivotal Trial

Source: RBS Morgans

### Analysts

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# Sunshine Heart

## Funding question off the table

SHC has successfully completed a US\$20.1m capital raising which will be used to fund a proposed 338 patient 40 site pivotal trial for the C-Pulse heart assist system. The completion of the capital raising removes the funding uncertainty, which had overhung the share price. The capital raising documentation provided to the SEC, highlights the involvement of a potential corporate investor, which we view as positive. We have updated our forecasts and valuation and maintain the Buy recommendation for investors with a higher risk profile.

### Events: Fund raising strengthens outlook

SHC has announced the pricing of its underwritten public offering of 2,875,000 shares of its common stock at a price to the public of US\$7.00 per share. In addition, SHC has granted the underwriters a 30-day option to purchase up to an additional 431,250 shares solely to cover over-allotments, potentially could raise another US\$3m. The offering is expected to close on or about August 15, 2012, subject to customary closing conditions in the US. The capital will be used to fund a proposed 338 patient pivotal trial. This fund raising removes the uncertainty over hanging the share price and view this as a positive for SHC. This follows on the back of another recent positive announcement where SHC received CE Mark approval for the C-Pulse Heart Assist System treatment of Class III and ambulatory Class IV heart failure.

### Forecasts: Converted to USD and valuation updated

Following SHC's NASDAQ listing earlier this year we have converted our forecasts to US dollars and changed the year end to December. We have updated our model for the capital raising and as a result our DCF valuation is A\$0.08 (was A\$0.09). Our price target remains unchanged at A\$0.07. The key downside risk to our price target revolves around delays in the commencement of the pivotal trial.

### Catalyst achieved and upcoming

SHC completed enrolment of its US feasibility clinical trial in the 1HCY11. In November 2011, SHC announced positive preliminary results of the six-month follow-up period for the feasibility study. In March 2012, the FDA completed its review of the C-Pulse System feasibility trial data, and SHC will move forward with an IDE application which is expected to be submitted in 2HCY12, signalling the start of the pivotal trial. WHC expects to complete enrolment of the pivotal trial by the end of CY15 and then 12 months follow up a premarket approval (PMA) application can be made in 2HCY16 and product ready for sales in CY17.

**Table 1 : Milestone Table**

Event	Timing	Impact
FDA Feasibility Trial - Finish recruitment	Achieved	Positive
FDA Feasibility Trial - 6mth Follow Up	Achieved	Positive
CE Mark approval	Achieved	Positive
IDE approval from FDA	2HCY12	Positive
Initiate pivotal trial	2HCY12	Positive
FDA Pivotal Trial Complete	2HCY15 (was 1QCY14)	Positive
Pivotal Trial Follow Up	2HCY16 (was 1QCY15)	Positive
PMA application	2HCY16 (was 2QCY15)	Positive

Source: RBS Morgans

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# RBS Morgans Equities Forecasts: Sunshine Heart

	AIFRS 2010A	AIFRS 2011A	AIFRS 2012F	AIFRS 2013F	AIFRS 2014F	Closing price (A\$) 0.036	Price target (A\$) 0.07
<b>Income statement</b>						<b>Valuation metrics</b>	
Divisional sales	0.4	0.0	0.0	3.2	7.1	Preferred methodology	DCF
Total revenue	0.4	0.0	0.0	3.2	7.1	DCF valuation inputs	Va'n (A\$)
EBITDA	-8.4	-16.6	-13.3	-15.4	-13.1	Rf	5.25%
Associate income	0.0	0.0	0.0	0.0	0.0	Rm-Rf	10-year rate
Depreciation	0.0	0.0	0.1	0.1	0.1	Beta	Margin
EBITA	-8.4	-16.6	-13.4	-15.5	-13.2	CAPM (Rf+Beta(Rm-Rf))	Kd
Amortisation/impairment	0.0	0.0	0.0	0.0	0.0	E/EV*Ke+D/EV*Kd(1-t)	Ke
EBIT	-8.4	-16.6	-13.4	-15.5	-13.2	Equity (E/EV)	NPV cash flow (A\$m)
EBIT(incl associate profit)	-8.4	-16.6	-13.4	-15.5	-13.2	Debt (D/EV)	Minority interest (A\$m)
Net interest expense	-0.2	-0.3	-0.4	-0.8	0.1	Interest rate	Net debt (A\$m)
Pre-tax profit	-8.3	-16.4	-13.0	-14.7	-13.3	Tax rate (t)	Investments (A\$m)
Income tax expense	-0.7	-0.1	0.7	0.0	-0.3	WACC	Equity market value (A\$m)
After-tax profit	-7.6	-16.2	-13.7	-14.7	-13.0		Diluted no. of shares (m)
Minority interests	0.0	0.0	0.0	0.0	0.0		<b>DCF valuation</b>
NPAT	-7.6	-16.2	-13.7	-14.7	-13.0		<b>\$0.08</b>
Significant items	0.0	0.0	0.0	0.0	0.0		
NPAT post abnormals	-7.6	-16.2	-13.7	-14.7	-13.0		
<b>Cash flow statement</b>						<b>Multiples</b>	
EBITDA	-8.4	-16.6	-13.3	-15.4	-13.1	Enterprise value (A\$m)	2010A 2011A 2012F 2013F
Change in working capital	0.4	3.1	-0.8	-0.3	-0.8	EV/Sales (x)	76.0 na #DIV/0! 64.1
Net interest (pd)/rec	0.2	0.3	0.4	0.8	-0.1	EV/EBITDA (x)	-9.0 -4.0 -5.4 -4.2
Taxes paid	0.7	0.1	-0.7	0.0	0.3	EV/EBIT (x)	-9.0 -4.0 -5.3 -4.1
Other oper cash items	0.0	0.0	0.0	0.0	0.0	PE (pre-goodwill) (x)	-2.5 -2.7 -4.8 -4.5
Cash flow from ops (1)	-7.2	-13.1	-14.4	-14.9	-13.7		
Capex (2)	0.0	-0.5	0.0	-0.1	-0.1		
Disposals/(acquisitions)	0.0	0.0	0.0	0.0	0.0		
Other investing cash flow	0.0	0.0	0.0	0.0	0.0		
Cash flow from invest (3)	0.0	-0.5	0.0	-0.1	-0.1		
Incr/(decr) in equity	11.9	7.6	21.7	0.0	15.0		
Incr/(decr) in debt	0.0	0.0	0.0	0.0	0.0		
Ordinary dividend paid	0.0	0.0	0.0	0.0	0.0		
Preferred dividends (4)	0.0	0.0	0.0	0.0	0.0		
Other financing cash flow	0.6	0.1	0.0	0.0	0.0		
Cash flow from fin (5)	12.5	7.8	21.7	0.0	15.0		
Forex and disc ops (6)	0.0	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		
Equity FCF (1+2+4)	-7.2	-13.5	-14.4	-15.0	-13.8		
<b>Balance sheet</b>						<b>At target price</b>	
Cash & deposits	12.4	6.6	13.8	-1.2	0.1	EV/EBITDA (x)	2010A 2011A 2012F 2013F
Trade debtors	0.2	0.0	0.0	0.3	0.6	EV/EBITDA (x)	-18.0 -9.0 -10.2 -7.3
Inventory	0.0	0.0	0.0	0.5	1.1	PE (pre-goodwill) (x)	-4.9 -5.2 -9.3 -8.7
Investments	0.0	0.0	0.0	0.0	0.0		
Goodwill	0.0	0.0	0.0	0.0	0.0		
Other intangible assets	0.0	0.0	0.0	0.0	0.0		
Fixed assets	0.1	0.5	0.5	0.5	0.5		
Other assets	0.2	0.3	0.3	0.3	0.3		
<b>Total assets</b>	<b>12.9</b>	<b>7.4</b>	<b>14.6</b>	<b>0.4</b>	<b>2.5</b>		
Short-term borrowings	0.0	0.0	0.0	0.0	0.0		
Trade payables	0.7	1.9	1.1	1.5	1.7		
Long-term borrowings	0.0	0.0	0.0	0.0	0.0		
Provisions	0.0	0.0	0.0	0.0	0.0		
Other liabilities	0.1	1.0	1.0	1.0	1.0		
<b>Total liabilities</b>	<b>0.8</b>	<b>2.8</b>	<b>2.1</b>	<b>2.5</b>	<b>2.6</b>		
Share capital	60.1	68.7	76.6	61.9	63.9		
Other reserves	1.0	1.1	1.1	1.1	1.1		
Retained earnings	-49.0	-65.2	-65.2	-65.2	-65.2		
Other equity	0.0	0.0	0.0	0.0	0.0		
<b>Total equity</b>	<b>12.1</b>	<b>4.6</b>	<b>12.6</b>	<b>-2.1</b>	<b>-0.1</b>		
Minority interest	0.0	0.0	0.0	0.0	0.0		
Total shareholders' equity	12.1	4.6	12.6	-2.1	-0.1		
Total liabilities & SE	12.9	7.4	14.6	0.4	2.5		
<b>Comparable company data (x)</b>						<b>Per share data</b>	
<b>AcruX</b>						No. shares	2010A 2011A 2012F 2013F
EV/EBITDA						536.9	1203.9 1823.9 1823.9
EV/EBIT						EPS (cps)	-1.4 -1.3 -0.8 -0.8
PE						EPS (normalised) (c)	-1.4 -1.3 -0.8 -0.8
ImpediMed						Dividend per share (c)	0.0 0.0 0.0 0.0
EV/EBITDA						Dividend payout ratio (%)	0.0% 0.0% 0.0% 0.0%
EV/EBIT						Dividend yield (%)	0.0% 0.0% 0.0% 0.0%
PE						na na na na	
<b>Growth ratios</b>						<b>Operating performance</b>	
Sales growth						203.7%	2010A 2011A 2012F 2013F
Operating cost growth						-3.9%	1.3 0.0 0.0 10.8
EBITDA growth						-97.2%	na na #DIV/0! -476.1
EBITA growth						0.1%	na na #DIV/0! -479.3
EBIT growth						0.1%	na na #DIV/0! -453.3
NPAT growth						6.7%	na na #DIV/0! -453.3
Pre-goodwill NPAT growth						-113.6%	-69.7 -361.2 -106.9 731.7
Pre-goodwill EPS growth						18.2%	-12.4 -6.6 -13.8 1.2
Normalised EPS growth						18.2%	-102.2 -142.8 -110.1 -55.1
<b>Operating performance</b>						<b>Internal liquidity</b>	
Asset turnover (%)						1.3	2010A 2011A 2012F 2013F
EBITDA margin (%)						na	15.2 2.3 6.7 -0.5
EBIT margin (%)						na	na 0.0 #DIV/0! 24.3
Net profit margin (%)						na	17.0 13.0 9.0 14.2
Return on net assets (%)						-69.7	
Net debt (A\$m)						-12.4	
Net debt/equity (%)						-102.2	
Net interest/EBIT cover (x)						-56.1	
ROIC (%)						na	

Source: RBS Morgans

## Recap on SHC's 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.

## Positive Feasibility Trial Results

Late last year in a presentation to analysts and health professionals at the Transcatheter Cardiovascular Therapeutics Conference held in San Francisco, 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 ( $3.1 \pm 0.3$  to  $2.2 \pm 0.8$ ,  $P=0.0001$ ), Quality of Life ( $64 \pm 17$  to  $49 \pm 26$ ,  $P=0.001$ ), and Left Ventricular Ejection Fraction ( $28 \pm 5$  to  $31 \pm 7$ ,  $P=0.04$ ). 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.

Then more recently SHC released the 12-month extended follow-up efficacy and safety data for the Feasibility Study of its C-Pulse Heart Assist System. It showed further positive trends in efficacy with continued improvements in NYHA Class reduction, MLWHF Quality of Life score and 6 Minute Hall Walk. Furthermore, at 12 months there were no additional patients with device related serious adverse events (SAEs) including exit site infections.

Also recently SHC announced that a two-year follow-up was completed for a patient implanted with the C-Pulse Heart Assist System in the feasibility trial. This was the first patient to reach two-year follow-up in the trial.

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