

Medical Technology — Initiation of Coverage
Sunshine Heart, Inc. (ASX: SHC)

January 18, 2012

Initiation of Coverage

Recommendation: BUY

Price Target: AU\$0.15

Mark Landy

617-532-6428

markl@ssrp.com


Source: Yahoo! Finance

Stock Data – (ASX: SHC)

Price: AU\$0.04
 52-week high: AU\$0.06
 52-week low: AU\$0.03
 Shares out: 1.2B
 Shares short: N/A
 Average volume (10-day): 135.5K

Valuation Metrics

Market cap: AU\$48.2MM
 Enterprise value: AU\$42.1MM
 Book value/share: AU\$0.01

Financial Highlights (June:2011)

Cash/equivalents: AU\$6.02MM
 Debt: \$0

	2010A	Q4:11E	2011E	2012E
Revs	\$0.4MM	\$0	\$0	\$1.0MM
Prior	--	--	--	--
EPS	(\$0.01)	(\$0.00)	(\$0.01)	(\$2.87)
Prior	--	--	--	--
P/E	NM	NM	NM	NM

Company Description

Sunshine Heart, Inc. is a development-stage company focused on developing a treatment option for late-stage heart failure patients who do not respond to traditional clinical therapies and are not yet candidates for a heart transplant or ventricular assist device (VAD). SHC is incorporated in Delaware, headquartered in Minnesota, and listed in Australia. The first C-Pulse was implanted in 2005, and commercialization OUS is planned for early 2012. The company has 20 employees and should begin the pivotal US trial for C-Pulse in 2012.

- Today we initiate coverage of Sunshine Heart, Inc. (ASX: SHC), with a BUY rating and AU\$0.15 price target.** SHC is a development-stage company focused on bringing to market a treatment option for mid- to late-stage heart failure patients who do not respond to traditional clinical therapies and are not yet candidates for a heart transplant or ventricular assist device (VAD). The company is incorporated in Delaware, headquartered in Minnesota, and listed in Sydney, Australia. Plans are underway to consolidate operations in Minnesota and move its stock listing to the US. Corporate consolidation in the US and important near-term milestone achievements present a compelling risk/reward opportunity for investors.
- C-Pulse is a unique offering in the multi-billion-dollar heart failure market.** C-Pulse, the company's lead product, is a novel and differentiated implantable cardiac assist device with little direct competition. Unlike traditional cardiac assist devices, C-Pulse is implanted via a simple minimally invasive surgical procedure, does not require a burdensome support infrastructure build out, does not touch the blood, and is a viable treatment option for many of the 1.1+ million class III/IVa HF patients not responding to typical clinical therapies.
- CE Mark approval marks transition to a commercial entity.** The upcoming year will be filled with significant transforming milestones that should drive shareholder value. Most significantly, 2012 sees the transition to a commercial entity. Key additional 2012 milestones include the NASDAQ listing and US-IDE approval. Numerous product enhancements and other regulatory milestones are catalysts scattered throughout 2012 that, combined with an EU launch, should be sufficient to maintain investor interest until the release of interim pivotal US data in 2014.
- Planned transition to US listing lays foundation for future fundraising needs.** At the end of the third quarter in 2011, SHC had \$10.3MM cash on hand, sufficient for operations through mid-2012. We forecast SHC will need to raise AU\$7-10MM shortly to solidify its employee base, complete infrastructure build out for the pivotal US trial, and prepare for the EU launch. Additional funding will likely be required to complete a US pivotal trial. The possibility to sign a corporate partner exists, which will reduce reliance on capital markets for financial needs.
- Valuation.** Heart failure companies developing support products have traditionally traded between \$200-300MM with positive feasibility data. Given the positive early data SHC has presented and the large opportunity for C-Pulse, a US\$250MM current value seems reasonable to us. With 1.7 billion fully diluted shares outstanding, we value each SHC share at AU\$0.15.

Important Disclosures and Disclaimers Can Be Viewed at <http://www.ssrp.com> and on Page 18 of This Report

REPORT SUMMARY

We are initiating coverage of Sunshine Heart, Inc. (ASX: SHC) with a BUY rating and AU\$0.15 price target. C-Pulse, the company's lead product, is a novel and differentiated implantable cardiac assist device for the treatment of late-stage congestive heart failure. Unlike traditional cardiac assist devices, C-Pulse is implanted via a simple minimally invasive surgical procedure, does not require a VAD-like support infrastructure build out, does not touch the blood, and is a viable treatment option for many of the 1.1+ million class III/IVa heart failure patients who do not respond to traditional clinical therapies. A number of significant transforming milestones will occur in 2012 that should drive further shareholder interest and a higher valuation. Most significantly, 2012 sees the transition to a commercial entity with CE Mark approval. Additionally, we expect a NASDAQ listing shortly and IDE approval for a US pivotal trial in the second quarter of 2012. In 2012 and 2013 numerous product enhancements and other regulatory milestones are catalysts that, combined with data points from the EU rollout, should be sufficient to maintain investor interest until the release of interim pivotal US data in 2013. We forecast SHC will need to raise AU\$7-10MM in early 2012 to complete its 2012 business plan. Additional funding will likely be required to complete a US pivotal trial and prepare for US commercialization. The possibility to sign a corporate partner exists, which will reduce reliance on capital markets for financial needs.

INVESTMENT SUMMARY

Heart failure is a booming epidemic for which there is no cure, and it always ends in death. It is a steadily progressive disease that causes a significant degradation in quality of life and the ability to function normally. Despite treatment, heart failure patients eventually always encounter a period during which they battle to function normally but are not yet sick enough for a heart transplant. These patients fall into NYHA class III and ambulatory class IV (IVa) and represent a tremendous cost and labor burden to the global health care system.

Cardiac resynchronization therapy (CRT-D) and ventricular assist devices (VAD) are currently the only approved/available therapies for late-stage (NYHA class III and IV) heart failure patients. While effective, these therapies are applicable to only the "less severe late-stage patients" (CRT-D) and the "very severe late-stage patients" (VAD), leaving the vast majority of these late-stage patients, or "interim patients" as we refer to them, without a plausible treatment option.

A low maintenance, implantable device that restores cardiac circulation and enables a return to normal daily living will be of great medical value to these "interim patients" and should find significant use. Such a device will likely also reduce the considerable cost burden of heart failure, as the vast majority of heart failure expenses are incurred during the latter stages of the disease.

SHC's C-Pulse is such a device and offers a unique and novel treatment option for "interim patients." C-Pulse: 1) is easily implanted through a minimally invasive approach, 2) does not come into contact with the blood stream, 3) does not require cumbersome anti-clotting drug therapy, and 4) allows patients to function normally. C-Pulse is designed around the well understood concept of counterpulsation. Counterpulsation has been used for decades, during surgery and to treat conditions such as cardiogenic shock, to increase cardiac output and reduce the heart's pumping load.

SHC and C-Pulse have flown below the radar screen for almost a decade. Raising capital and the development pathway to clinical trials has not been easy. Numerous engineering options and prototypes have been tried and tested with a solution entering the regulatory process in the middle part of the last decade. The heavy lifting is done, and SHC is on the cusp of a breakout. Bench, animal, and early human data is encouraging and has created the opportunity for CE Mark approval, EU launch, and FDA approval for a pivotal US study — the final step required for US approval and commercialization.

Assuming the addressable global market of "interim patients" approximates one million patients and the average cost of an implanted device to treat heart failure approaches \$25,000, the global market opportunity for such a device exceeds \$25B. With typical medical device penetration running around 7-10% of the total addressable market, the "real market opportunity" for C-Pulse falls in the \$1-3B range.

At an AU\$48MM market cap, it is our opinion that SHC is undervalued and investors should see meaningful appreciation over the near term as C-Pulse moves into pivotal US trials and is rolled out in CE Mark countries. We value each SHC share at AU\$0.15.

UPCOMING MILESTONES

SHC is poised to meet numerous transforming milestones in 2012. These include NASDAQ listing, EU commercialization, and US IDE approval.

Figure 1. Upcoming Milestones



NASDAQ listing: SHC is a Delaware company, but is currently listed on the Australian Securities Exchange in Australia. Moving its listing to NASDAQ significantly broadens exposure to US investors who have a history of strongly supporting young medical device companies with unique opportunities in large markets. SHC filed for NASDAQ listing at the very end of the third quarter in 2011, and expects trading to commence in the US in late January or early February. Prior to registration, SHC plans to implement a reverse stock split in the range of 250-100 to 1. SHC has requested the ticker “SSH” in the NASDAQ listing and will remain under the ticker “SHC” in the Australian Securities Exchange.

CE Mark approval and launch: SHC submitted a CE Mark application for C-Pulse in December 2011. We anticipate CE Mark approval by the end of the second quarter in 2012. We are modeling a 3Q12 launch at six centers that have prior C-Pulse experience and forecast 10 units will be implanted during 2012. SHC will initially cover six sites in Germany and Italy and estimates that the profits from selling ten devices will cover the initial commercializing costs.

Initiation of US pivotal trial: Receipt of IDE to begin a pivotal US trial is an indication that the FDA is at the very least comfortable with C-Pulse’s safety profile and has some belief in its efficacy. The FDA does not approve IDEs for therapies it believes put patients at risk and do not have a strong chance of being effective. SHC will meet with the FDA on January 23, 2012, to finalize the pivotal US trial. We anticipate the initiation of the pivotal trial by the end of the third quarter of 2012. SHC expects it will take 26 months to complete enrollment, with follow up taking an additional year. After the completion of the pivotal trial, SHC will submit a PMA to the FDA for C-Pulse approval.

Product improvements: Four product improvements will be rolled out and incorporated into the pivotal trial. These improvements are specifically aimed at enabling an easier and faster implant, improving device performance, and making daily living with the implanted device easier. These product improvements will be processed as five-day notices rather than full reviews.

Financing: SHC will need to raise \$50-60MM to get to FDA approval. Given the current market cap, fundraising will have to be done piecemeal over the next few years. This is cumbersome and expensive. The signing of a corporate partner is one possibility that could simplify and accelerate the financing process; the other is the release of strong interim data. Capital requirements will be an overhang that will plague management until sufficient cash has been raised to fund the program through US approval, and it is a risk for investors. SHC will need to raise \$7-10MM soon, and further capital toward the end of 2012 if a corporate partner is not signed in the near future.

VALUATION

Heart failure companies developing support products have traditionally traded between \$200-300MM with positive feasibility data. Given the positive early data SHC has presented and the large opportunity for C-Pulse, a US\$250MM current value seems reasonable to us. With 1.7 billion fully diluted shares outstanding, we value each SHC share at AU\$0.15.

Figure 2. SHC.AX Peer-group Comparable Valuation

Ticker	Company	Share Price	YTD	Shares (MM)	Market Cap (\$MM)	Revenue - Consensus			EPS - Consensus			Market Cap / Revenue			Enterprise Value
						2011	2012	2013	2011	2012	2013	2011	2012	2013	
MELA	MELA Sciences Inc.	\$3.90	5.96%	30.26	\$118.03	\$0.00	\$8.73	\$35.00	(\$0.85)	(\$0.87)	(\$0.45)	-	13.52	3.37	\$87.50
BMTI	BioMimetic Therapeutics Inc.	\$2.00	-31.58%	28.06	\$56.11	\$1.78	\$4.50	\$13.55	(\$1.09)	(\$1.03)	(\$0.98)	31.45	12.47	4.14	(\$20.97)
TSON	Trans1 Inc.	\$1.75	-3.23%	27.20	\$47.60	\$20.02	\$21.54	\$24.99	(\$0.75)	(\$0.59)	(\$0.48)	2.38	2.21	1.90	\$5.06
BLTI	Biolase Technology Inc.	\$2.65	5.45%	30.61	\$81.13	\$51.64	\$67.58	-	(\$0.09)	\$0.09	\$0.18	1.57	1.20	-	\$82.06
MLAB	Mesa Laboratories Inc.	\$44.03	6.06%	3.28	\$144.55	-	-	-	\$2.27	\$2.47	-	-	-	-	\$147.50
ATEC	Alphatec Holdings Inc.	\$1.85	10.47%	89.25	\$165.11	\$198.88	\$214.59	\$231.22	(\$0.02)	\$0.06	\$0.11	0.83	0.77	0.71	\$176.12
VASC	Vascular Solutions Inc.	\$10.57	-5.21%	17.03	\$179.99	\$90.02	\$95.85	\$101.80	\$0.49	\$0.55	\$0.62	2.00	1.88	1.77	\$162.63
CPTS	Conceptus Inc.	\$11.80	-6.09%	31.24	\$368.63	\$126.94	\$138.58	\$151.64	(\$0.18)	\$0.02	\$0.06	2.90	2.66	2.43	\$371.81
STAA	Staar Surgical Co.	\$11.36	1.43%	36.10	\$410.05	\$63.19	\$72.58	\$84.81	\$0.06	\$0.16	\$0.31	6.49	5.65	4.83	\$404.84
SHC-AU	Sunshine Heart Inc.	\$0.04	11.11%	1203.88	\$48.16	\$0.53	\$6.00	\$21.00	(\$0.01)	(\$0.01)	(\$0.06)	91.71	8.03	2.29	\$42.14
AVG					161.93	61.44	69.99	83.00	(0.02)	0.08	(0.08)	17.42	5.38	2.68	145.87
High					410.05	198.88	214.59	231.22	2.27	2.47	0.62	91.71	13.52	4.83	404.84
Low					47.60	0.00	4.50	13.55	(1.09)	(1.03)	(0.98)	0.83	0.77	0.71	(20.97)
SPX	S&P 500 (Operating Basis)	\$1,289.09	2.50%						\$96.78	\$103.90	\$111.67	-	-	-	-

INVESTMENT POSITIVES

- C-Pulse fills a treatment gap in a large subset of heart failure patients:** C-Pulse has the potential to overcome the industry's prior struggles in trying to develop a circulatory assist therapy for patients who are not yet transplant candidates and who no longer respond to drugs and CRT-D therapy or are not candidates for CRT-D therapy. This market represents a large unmet clinical need, which we estimate globally at \$1-3B.
- C-Pulse could compete with VADs:** We believe C-Pulse could eventually be seen not only as an instrument for interim patients, but also as a competitor to VAD therapy — especially in the bridge-to-transplant setting. Miniaturized VADs will definitely come to market and be easier to implant; however, they will still contact the blood stream and therefore require lifelong anti-clotting therapy. As a VAD competitor, the global-applicable C-Pulse market would increase significantly.
- C-Pulse does not come in contact with circulating blood:** By not coming into contact with blood, C-Pulse does not require cumbersome anti-clotting therapy. Any assist device that comes into contact with blood will always need anti-clotting therapy. While drug therapy, CRT-D, and VAD are not direct competitors for interim patients, C-Pulse is a direct competitor for early class III patients and class IVa patients. With time and clinical data, it is likely C-Pulse could move both downstream and compete with CRT-D in early stage patients and upstream to compete with VADs in late-stage patients.
- A fully implantable system is being developed.** SHC's emerging product pipeline offers upside potential. Planned upgrades include an improved single-unit driver that is smaller and quieter, an easier-to-implant cuff, an improved tunneler to enhance the current minimal approach, and most important, a fully implantable system using transdermal energy transfer that will eliminate all drawbacks of a direct drive line.
- Likely acquisition target.** We believe emerging clinical data will validate and support the C-Pulse approach, minimize technology risk, and raise the company's profile as a viable acquisition target. We see a number of companies, including Thoratec (THOR-\$29.74-NR), the current VAD market leader, HeartWare (HTWR-\$68.03-NR), and other diversified medical device companies, such as Medtronic (MDT-\$39.02-NR), St. Jude (STJ-\$37.01-NR), Boston Scientific (BSX-\$5.52-NR), Abbott (ABT-\$55.72-NR), and Johnson & Johnson (JNJ-\$65.11-NR) as possible buyers. Terumo (TRUMY-\$91.05-NR), Sorin (SORJF-\$1.70), Biotronik (Private), Philips (PHG-\$18.67-NR), and Siemens (SI-\$98.08-NR) are also possible buyers.

INVESTMENT RISKS

- 1. C-Pulse clinical risk/limited data.** There is currently little human data to analyze, and early human results sometimes do not transfer to a larger setting. Also, it is possible that the feasibility data may over time not be as robust as expected, or some untoward effects may be observed. Such an event would set the company back, delaying revenues and placing significant financial strain on the company. It could also delay FDA approval. The worst case scenario is failure of the device in upcoming trials.
- 2. Unexpected events could slow clinical trial program and EU adoption.** A small number of patients have received the C-Pulse at this time, and the device seems to be functioning well. As implant numbers increase and manufacturing ramps up, there is always the chance something could go awry. Any form of device failure or increase in adverse events from the current baseline could damage physician confidence, slow down trial enrollment, and hinder market adoption.
- 3. Limited financial resources.** SHC will need to raise \$50-60MM to get to FDA approval. Given the current market cap, fundraising will have to be done piecemeal over the next few years. This is cumbersome and expensive. The signing of a corporate partner is one possibility that could simplify and accelerate the financing process; the other is the release of strong interim data. Capital requirements will be an overhang that will plague management until sufficient cash has been raised to fund the program through US approval, and this is a risk for investors. SHC will need to raise \$7-10MM soon, and further capital toward the end of 2012 if a corporate partner is not signed in the near future.

FINANCIAL DISCUSSION AND MODEL ASSUMPTIONS

- 1. Revenue outlook:** We forecast 2012 sales at about \$1.0MM. SHC will have a slow ramp up in the two sites in Europe. We are expecting four implants in the third quarter and six implants in the fourth quarter, which will total \$550K in revenue, based on a \$55K selling price. SHC will also gain revenue from its clinical trial enrollment. We are expecting 12 implants to be placed in the second half of 2012. Management expects 70% of patients will get reimbursed and their implants will get reimbursed at \$60K. Therefore, we expect the US pivotal trial to bring in \$480K in revenue.
- 2. Gross margins:** Currently, each C-Pulse device costs about \$13K to manufacture. SHC expects this cost to decrease to \$11K by the middle of 2012. We forecast the decrease in COGS beginning in 2013. We are forecasting the gross margin for 2012 to be 72.2%, and for 2013 to be 75.5%. It is still to be determined which financial line item the cost of the trial device will be attributed to. For the pilot study, it was in R&D; there is a chance it can be moved to COGS in the next study. For now, we put it in R&D.
- 3. Operating expense outlook:** For 2012 we expect SG&A to total \$4.7MM and R&D to total \$15.3MM. We expect both SG&A and R&D to increase in 2013 to \$6.1MM and \$19.5MM, respectively.
- 4. Tax rate:** As of September 30, 2011, SHC has \$60MM in accumulated deficit and should not have any material taxes until the NOLs are extinguished.
- 5. Share count and share price:** As of September 30, 2011, SHC had 1.2 billion shares outstanding. Before the NASDAQ listing we expect the company to do a reverse split in the range of 200:1 to 250:1. As of the end of the third quarter in 2011, this would result in a share count in the range of 4.8-6.0 million. Assuming a 225:1 split and the current market cap of \$48.2MM, the current share price would be about \$9. Two US\$7MM straight equity raises in 2012, priced at \$9 per share, will add an additional 1.6 million shares. Therefore, we forecast SHC exiting 2012 with roughly 7.2 million outstanding shares and 8.3 million fully diluted shares (given a 225:1 reverse split).
- 6. EPS outlook:** We currently forecast 2012 EPS of (\$2.82).
- 7. Balance sheet and free cash flow:** As of the end of the third quarter, SHC has \$10.3MM in cash and cash equivalents. Management has guided to SHC exiting 2011 with \$6.5MM, with a burn rate of \$3.6MM per month.
- 8. Capital structure with warrants.** Currently, there are 479.4 million warrants and options to purchase common stock at an average conversion price of AU\$0.42 and a weighted average expiration time of 5.37 years from January 1, 2012. There are 1.7 billion fully diluted shares outstanding.

COMPANY OVERVIEW

Corporate history

SHC is a development-stage company focused on developing a treatment option for late-stage heart failure patients who do not respond to traditional clinical therapies and are not yet candidates for a heart transplant or VAD. SHC was founded in 1999 by Dr. William Peters, the current CTO, and Crispin Marsh, who is currently a non-executive member of the board of directors. The first C-Pulse was implanted in 2005, and data from the first pilot trial was presented in late 2011. The company is incorporated in Delaware, headquartered in Minnesota, and listed in Australia. A US listing under the ticker symbol SSH is planned for late January or early February 2012. The company currently has 20 full-time and three part-time employees.

Capital structure

As of September 26, 2011, excluding warrants, the board of directors and executives control 52.9% of all outstanding common stock (716.3 million shares). Including warrants, Dr. Geoffrey Brooke and Dr. Mark Harvey own 23.2% and 29.0%, respectively, of all outstanding shares either directly or through their venture capitalist firms, GBS Venture Partner Plays, Ltd., and CM Capital, respectively.

As of the end of the third quarter 2011, there were 1.2 billion shares outstanding. As of December 9, there were options to purchase 418.8 million shares of common stock, and warrants to purchase 60.6 million shares of common stock. The average conversion price is at AU\$0.42. Therefore, the fully diluted share count is 1.7 billion shares. If all warrants and options were converted, the total capital raised would be AU\$20.3MM.

Figure 3. Warrants and Options Outstanding

Expiration	Placed	# of Warrants/Options	Conversion Price (AU\$)	Capital from Convert (AU\$)
31-Jan-13	31-Jan-03	1,695,947	\$ 0.070	\$ 118,716
28-Apr-13	29-Apr-03	38,800	\$ 0.120	\$ 4,656
18-May-14	19-May-04	562,600	\$ 0.080	\$ 45,008
20-Jun-14	20-Jun-04	3,200,000	\$ 0.250	\$ 800,000
23-Jun-14	23-Jun-04	3,210,000	\$ 0.280	\$ 898,800
20-Jul-14	20-Jul-04	485,000	\$ 0.500	\$ 242,500
13-Nov-14	13-Nov-10	66,710,259	\$ 0.032	\$ 2,134,728
8-Dec-14	8-Dec-10	170,147,300	\$ 0.030	\$ 5,104,419
27-Jul-15	27-Jul-11	34,333,306	\$ 0.056	\$ 1,922,665
27-Jul-15	27-Jul-11	1,818,052	\$ 0.040	\$ 72,722
9-Sep-15	9-Sep-11	9,241,800	\$ 0.056	\$ 517,541
13-Sep-15	13-Sep-11	7,500,000	\$ 0.056	\$ 420,000
16-Sep-15	16-Sep-11	4,224,819	\$ 0.056	\$ 236,590
16-Sep-15	16-Sep-11	306,250	\$ 0.040	\$ 12,250
13-Nov-15	13-Nov-10	4,699,718	\$ 0.028	\$ 131,592
21-Apr-16	21-Apr-06	300,000	\$ 0.370	\$ 111,000
2-Jun-16	2-Jun-06	58,200	\$ 0.250	\$ 14,550
31-Oct-16	1-Nov-06	698,784	\$ 0.200	\$ 139,757
30-Jan-17	13-Jan-07	269,000	\$ 0.290	\$ 78,010
13-Feb-17	14-Feb-07	170,000	\$ 0.180	\$ 30,600
17-Apr-17	18-Apr-07	706,000	\$ 0.300	\$ 211,800
23-May-17	24-May-07	50,000	\$ 0.200	\$ 10,000
17-Dec-17	18-Dec-07	291,000	\$ 0.300	\$ 87,300
9-Jul-18	10-Jul-08	2,097,500	\$ 0.110	\$ 230,725
20-Aug-18	21-Aug-08	3,493,338	\$ 0.080	\$ 279,467
31-Oct-19	29-Nov-10	10,000,000	\$ 0.050	\$ 500,000
18-Aug-21	18-Aug-11	116,118,000	\$ 0.035	\$ 4,064,130
18-Aug-21	18-Aug-11	2,337,000	\$ 0.048	\$ 112,176
18-Aug-21	18-Aug-11	3,000,000	\$ 0.052	\$ 156,000
19-Aug-21	19-Aug-11	5,842,000	\$ 0.064	\$ 373,888
2-Nov-21	2-Nov-11	18,451,000	\$ 0.041	\$ 756,491
29-Nov-21	29-Nov-11	13,274,000	\$ 0.041	\$ 544,234
Exercised:		5,954,975		
Total Outstanding:		479,374,698	\$ 0.042	\$ 20,362,315

Source: Company Reports, SSRP Estimates

MARKET OPPORTUNITY

Heart failure is a deadly disease

Heart failure is a terrible and debilitating disease for which there is no cure. It is progressive and always ends in death. As patients become sicker, they become more and more incapacitated and begin to suffer from numerous other conditions brought about by the slow failure of other organs, because the heart is unable to supply them with sufficient blood flow bringing oxygen and nutrients and taking away toxic byproducts. Treatment usually begins with drugs to increase the heart's pumping efficiency, then moves to pacemakers and CRT-D devices, progressing to VADs and transplants. The sole aim of all these therapies is to maintain an adequate blood flow through the body to ensure the body is sufficiently oxygenated and cleared of waste products. While initial treatment is relatively inexpensive, treating late-stage heart failure and patients dying from heart failure is very expensive and places a tremendous burden on healthcare resources — both financial and labor. An estimated \$39.2B was spent in the US in 2010 on direct and indirect medical costs associated with heart failure.

The primary way to classify heart failure is using the New York Heart Association functional classification system, which is detailed below.

Figure 4. NYHA Functional Classification

Class	Patient Symptoms
Class I (Mild)	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea (shortness of breath).
Class II (Mild)	Slight limitation of physical activity. Comfortable at rest, but ordinary activity causes fatigue, palpitation, or dyspnea.
Class III (Moderate)	Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or dyspnea.
Class IV (Severe)	Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.

Source: Heart Failure Society of America

The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) coordinators' council felt the NYHA class IV did not offer adequate description to allow patients to make an educated decision on which therapy would best suit them. Level 1 is the most serious form of heart failure, which requires immediate intervention. Level 7 profiles patients who are in an advanced NYHA class III and who are able to maintain some form of activity but may require monitoring. Patients in INTERMACS profile 3 tend to include stable patients who are on a temporary circulatory support device, such as VAD.

Figure 5. INTERMACS Clinical Profiles

INTERMACS Profiles of Heart Failure	Time Frame For Intervention
1. Critical Cardiogenic Shock	Within Hours
2. Progressive Decline	Within a Few Days
3. Stable but Inotrope Dependent	Elective over a period of weeks to months
4. Resting Symptoms	Elective over a period of weeks to months
5. Exertion Intolerant	Variable Urgency
6. Exertion Limited	Variable Urgency
7. Advanced NYHA III	Transplantation or Circulatory Support

Source: Stevenson, et al. *Jrnl Heart Lung Transp.* 2009

Heart failure is an exploding epidemic

According to the American Heart Association, roughly 2% of the US population, or 5.7 million people, are affected by heart failure, and there are an estimated 670,000 new cases diagnosed each year. Almost 30% of all heart failure patients are below the age of 60.

Of the estimated 5.7 million heart failure patients in the US, roughly 3.8 million are classified with NYHA class I and II heart failure, and 1.5 million are classified as having NYHA class III heart failure, with 400K having NYHA class IV heart failure. Of the NYHA class III population, about 400-600K are candidates for cardiac resynchronization therapy (CRT-D), and a very small portion are candidates for VAD (100K). As there is a terrible shortage of donor hearts available, many class IV patients are left without treatment options and become candidates for VAD therapy.

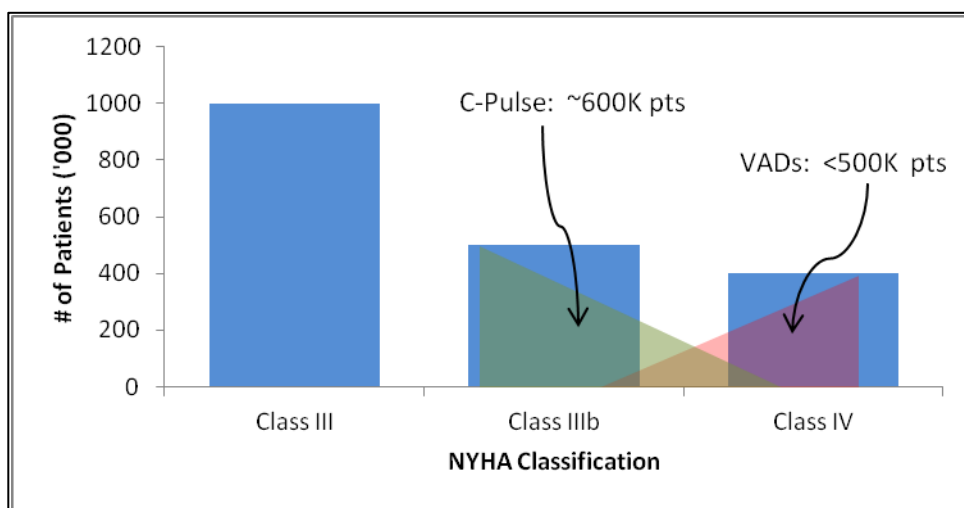
The applicable market for C-Pulse

CRT-D and VAD are currently the only approved/available non-drug therapies for late-stage (NYHA class III and IV) heart failure patients. While effective, these therapies are applicable to only the “less severe late-stage patients” (CRT-D) and the “very severe late-stage patients” (VAD), leaving the vast majority of these late-stage patients, NYHA class IIIb, or “interim patients” as we refer to them, without a plausible treatment option.

A low maintenance, implantable device that restores cardiac circulation and enables a return to normal daily living will be of great medical value to these “interim patients,” and it should find significant use. Such a device will likely also reduce the considerable cost burden of heart failure, as the vast majority of heart failure expenses are incurred during the latter stages of the disease.

SHC’s C-Pulse is such a device, and it offers a unique and novel treatment option for “interim patients.” C-Pulse: 1) is easily implanted through a minimally invasive approach, 2) does not come into contact with the blood stream, 3) does not require cumbersome anti-clotting drug therapy, and 4) allows patients to function normally. C-Pulse is designed around the well understood concept of counterpulsation. Counterpulsation has been used for decades, during surgery and to treat conditions such as cardiogenic shock, to increase cardiac output and reduce the heart's pumping load.

Figure 6. Applicable US Market



Assuming the addressable global market of “interim patients” in the NYHA class IIIb or IVa approximates one million patients and the average cost of an implanted device to treat heart failure approaches \$25,000, the global market opportunity for such a device exceeds \$25B. With typical medical device penetration running around 7-10% of the total addressable market, the “real market opportunity” for C-Pulse falls in the \$1-3B range.

With time and data, it is not unrealistic to envisage C-Pulse being a therapy for earlier-stage NYHA class III patients and less severe NYHA class IV patients. In this case, the global applicable market for C-Pulse could approximate \$5B.

COUNTERPULSATION TECHNOLOGY OVERVIEW

The basic theory upon which C-Pulse is based, counterpulsation therapy, has been safely used for decades to treat patients in cardiogenic shock and suffering from drug-resistant stable angina. Its concept and results are well understood, and some in the past have postulated and tried to use it as a chronic therapy for heart failure patients. It was not the therapy modality that resulted in failure, but rather the location of the therapeutic device that presented problems. SHC has successfully located and patented the ideal location for therapeutic delivery of such a device and has validated its research in two small but powerful clinical trials.

The history of counterpulsation technology and intra-aortic balloon pumps

Counterpulsation technology has been around since the late 1960s, when the intra-aortic balloon pump was first introduced. During intra-aortic balloon pump therapy a small balloon is guided into the descending aorta, where it resides and is rhythmically inflated and deflated by an electrocardiograph. The balloon helps support the heart by decreasing the amount of work needed to pump blood to the rest of the body and by increasing the amount of oxygen delivered to the heart muscle.

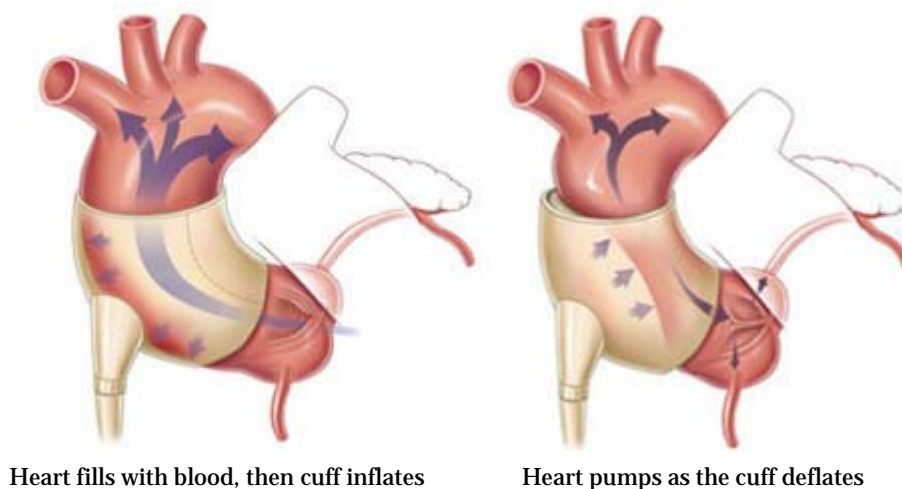
Enhanced external counterpulsation therapy (EECP)

EECP was developed as a non-invasive therapy for late NYHA class II and early class III patients with chronic stable angina not responding to medication. During EECP the patient's legs are placed in pneumatic cuffs connected to monitors that track heart rate and rhythm. The cuffs are timed to inflate and deflate according to the patient's electrocardiogram. When timed correctly, this will decrease the afterload the heart has to pump against, and increase the preload that fills the heart, increasing the cardiac output. In this way, EECP is similar to intra-aortic balloon pump therapy by increasing pressure in the aorta while the heart is relaxing and increasing blood flow into the coronary arteries reducing angina pain.

C-PULSE

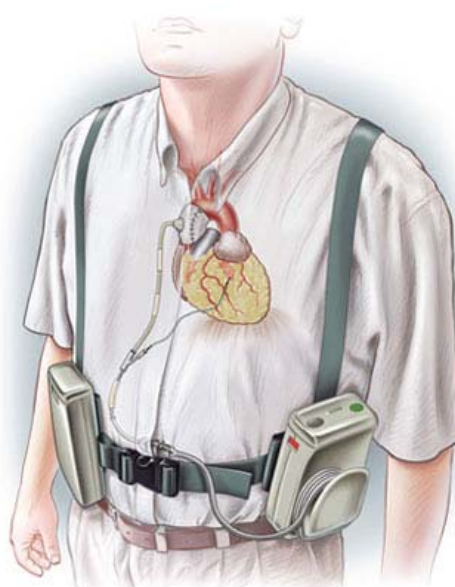
The C-Pulse system is used to assist patients with class III or ambulatory class IV heart failure. This system is based on the balloon counterpulsation technology, which reduces the amount of work the left ventricle has to do. As the balloon deflates, the workload required by the heart to pump the blood is reduced. As the balloon inflates, blood flow is increased to the coronary arteries. Similar to a pacemaker, the inflation and deflation pattern is synchronized by the patient's electrocardiogram. This device is run by a power source outside the body.

Figure 7. Diagram of C-Pulse



Source: *Sunshine Heart*

The electrocardiograph and cuff are connected to an external (outside the body) driver by a single wire or line that runs through a percutaneous interface lead. The driver is a battery pack that can be disconnected for short periods of time to allow the patient to enjoy everyday activities, such as showering. For optimal benefit, it is recommended that the C-Pulse device be kept on for at least 80% of the day.

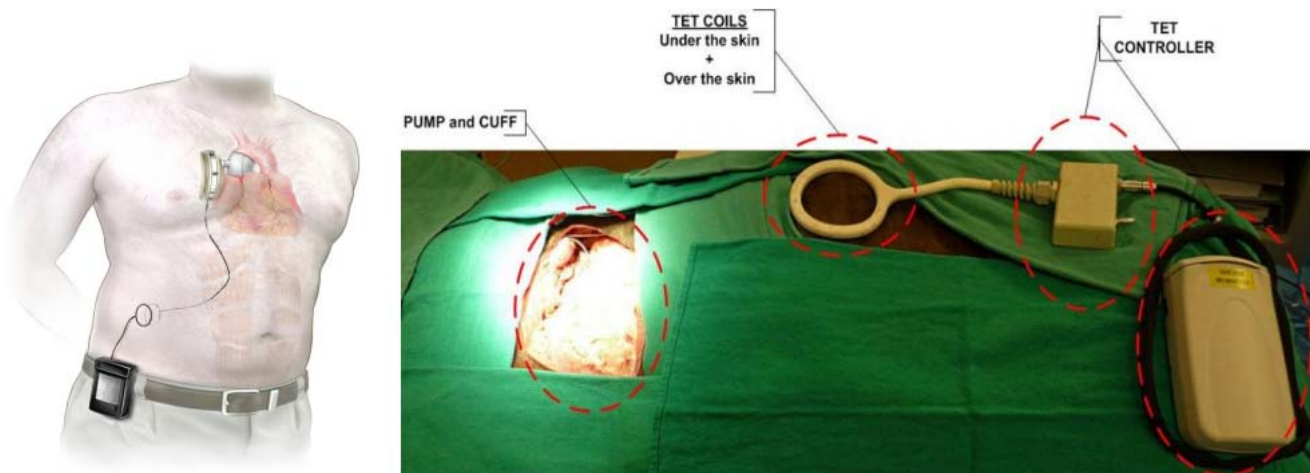
Figure 8. C-Pulse in Patient

Source: Sunshine Heart

Originally, the C-Pulse system was implanted via a full sternotomy. More recently, SHC developed a toolset to allow the C-Pulse system to be implanted in a minimally invasive fashion via a small incision made between the rib and sternum. The first implant using the minimally invasive procedure was done in 2010. In the feasibility study, six out of the 20 patients received the C-Pulse device via the new minimally invasive procedure. This minimal approach reduces hospital stay from 14 days to three or four days post surgery. It typically takes an hour for surgeons to implant the C-Pulse.

The cuff portion of the C-Pulse is placed around the ascending aorta and does not come into contact with the blood. This lack of blood contact greatly reduces the risk of stroke and blood clots and eliminates the need for cumbersome blood thinners, such as heparin or warfarin, unless the patient requires them to treat other conditions.

SHC is also developing a fully implantable C-Pulse system. This fully implantable device will eliminate the need for the percutaneous lead to breach the skin to connect to the driver. Instead, a transcutaneous energy transfer (TET) device will connect the external driver lead and the internal cuff lead. TET is an established technology that uses a high frequency electromagnetic field to transfer energy through the skin. Eliminating the internal-external communication port will improve comfort and significantly reduce the risk of infection. SHC completed the initial animal feasibility study in June 2011 at the Texas Heart Institute and will release its development plan for a fully implantable system in the first quarter of 2012.

Figure 9. Fully Implantable C-Pulse Device

Source: Sunshine Heart

COMPETITION

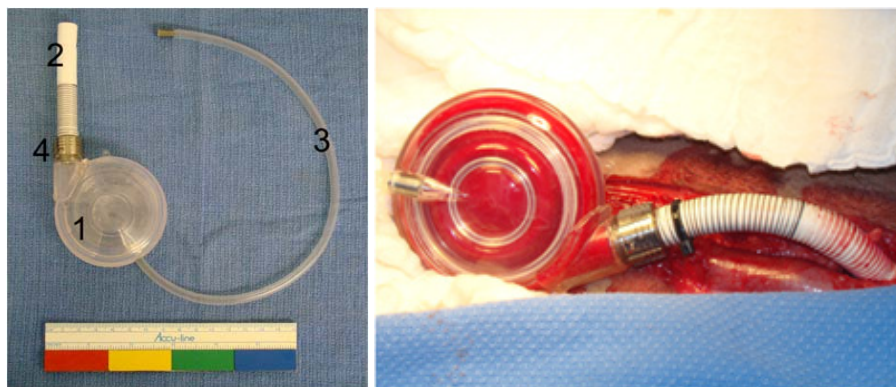
We managed to find a number of competitors to C-Pulse developing assist devices for late-stage NYHA class III and early NYHA class IV patents, but all touch the blood giving C-Pulse a strong marketing advantage.

SCR, Inc.'s counterpulsation device (CPD)

SCR, Inc.'s (Private) CPD is a valveless pneumatically driven blood sac that has a conduit connected to the subclavian artery. The device is operated by an external driver via a percutaneous air line. The device implantation is similar to a pacemaker but without the requirement of penetrating the chest wall. The pulsation is timed via electrocardiography. During the heart's natural expansion, the CPD device fills with blood, effectively lowering the ventricular workload, and blood is ejected during the heart's natural contraction, increasing the blood flow throughout the body. This device is being developed for NYHA class III and class IV ambulatory patients.

In pre-clinical studies, the CPD system was shown to be comparable to a 40 ml intra-aortic balloon pump (IABP), demonstrating feasibility in a large animal model. The clinical development phase is beginning. SCR works mostly in partnership with the Cardiovascular Innovation Institute (CII) and the University of Louisville. In 2009 and 2010 SCR received roughly \$3MM in grants from the NIH and KSTC to develop the counterpulsation device.

Figure 10. SCR's CPD



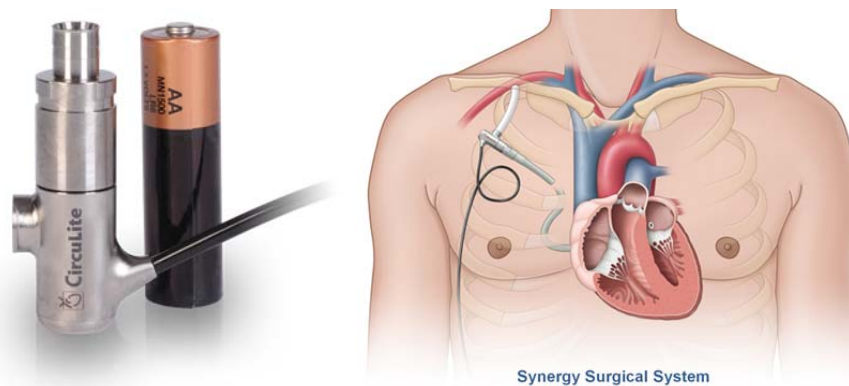
Source: University of Louisville

CircuLite's Synergy MicroPump

CircuLite (Private) was founded in 2004 to develop minimally invasive circulatory support systems for NYHA class III and IV patients. CircuLite's lead product, the Synergy MicroPump, was developed at the Helmholtz Institute in Aachen, Germany. It is a small device, about the size of a double AA battery, that works in synergy with the heart to pump 4.25 l/min of blood to the rest of the body. Synergy includes an external controller that has a percutaneous lead to the device. Synergy decreases left ventricular load by drawing blood from the left atrium and pumping it into the left subclavian artery. Synergy is designed to treat NYHA class IIIb and early NYHA class IVa patients.

A CE Mark pivotal trial began in 2007 in Europe. Data reported in a January 11, 2012 article published in the European Journal of Cardiothoracic Surgery on 27 patients with duration of support lasting from 6-281 days showed significant hemodynamic improvement in the short and intermediate term after implant, with increases in CI from 2.0+/-0.4 to 2.8+/-0.6 l min⁻¹ m⁻² (p < 0.001) and reductions in PCWP from 28+/-16 to 18+/- 7 mm Hg (p=0.002) at an average of 9.5-5.5 weeks.

CE Mark is expected in 1Q12, with commercialization expected in 2Q12. A US IDE trial is planned for 2012.

Figure 11. CircuLite's Synergy MicroPump

Source: CircuLite

Figure 12. Synergy MicroPump Phase I/II Data

Comparison of hemodynamic parameters at baseline and after an average (\pm SD) of 9.5 ± 5.5 weeks of follow-up.				
Parameter	Baseline Mean \pm SD	Follow-up Mean \pm SD	p	
Mean arterial pressure (mm Hg)	74 \pm 10	81 \pm 9	0.11	
Pulmonary wedge pressure (mm Hg)	28 \pm 6	18 \pm 7	0.002	
Cardiac index ($\text{l min}^{-1} \text{m}^{-2}$)	2 \pm 0.4	2.8 \pm 0.6	<0.001	
Pulmonary systolic pressure (mm Hg)	59 \pm 12	45 \pm 9	0.01	
Pulmonary vascular resistance (Wood units)	3.1 \pm 1.4	1.9 \pm 0.9	0.01	
Systemic vascular resistance (Wood units)	20 \pm 6	16 \pm 4	0.006	

Adverse event category	Event rate per patient-year			
	CircuLite (N = 28)		HeartMate II (N = 133)	
	0–30 days	>30 days	0–30 days	>30 days
Bleeding – all reported events	6.95	0.52	12.74	0.91
Driveline or pump pocket infection	0.46	0.13	0.00	0.45
Local infection, not device related	0.46	0.52	3.63	0.64
Sepsis	0.46	0.13	1.77	0.39
Renal failure	0.46	0.00	1.47	0.08
Hemolysis	0.00	0.39	0.29	0.02
Hepatic dysfunction	0.46	0.00	0.20	0.02
Stroke	0.46	0.13	0.69	0.08
TIA	0.46	0.26	0.20	0.08
Worsening left heart failure	0.00	0.52	n/r	0.00
Hepatic dysfunction	0.46	0.00	0.20	0.02
Right-heart failure	0.00	0.13	1.57	0.12
Pleural effusion	0.46	0.13	n/r	0.00
Total	14.82	5.87	30.21	3.77

n/r, not reported.

Source: Meyns et al. *J Card Thor Surg* (2011)

CLINICAL TRIALS

First-in-man study

A FIM study was done in Australia and New Zealand starting in 2005. Initially, ten patients were to be implanted, but only five patients were implanted when the trial data was presented in August 2007.

Data on the first two implanted patients were presented on October 26, 2005, at the Australasian Society of Cardiothoracic Surgeons in Queensland, Australia. Final data was presented in April 2008 at the International Society for Heart and Lung Transplantation meeting in Boston. As this was the first experience with C-Pulse in human patients, the patients selected tended to be in critical condition, with four out of the five patients having an INTERMACS profile 4, and the other patient having INTERMACS profile 2. Patients 1 and 5 died on the device on day 81 and 207, respectively. Patient 1 died of multiple organ failure while patient 5 died after 207 days of sepsis and of multiple organ failure. Patient 4 was explanted at day 26, as he received a transplant. Patients 2 and 3 were explanted at day 34 and 58, respectively, due to mediastinitis. Patient 2 died suddenly on day 57 due to an acute myocardial infarction. Patient 3 died on day 80 due to sepsis and multiple organ failure.

Out of these five patients, three had serious infections. In this initial design there were two separate driver malfunctions in patients 4 and 5 that resulted in eight-hour interruptions of therapy. There were no side effects aside from worsening heart failure symptoms during these interruptions. All patients showed improvement at one month, as NYHA class improved from 3.6 ± 0.24 to 2.8 ± 0.2 ($p=0.02$). This data shows the surgery and device are safe, provide effective counterpulsation, and justify further studies.

Figure 13. Clinical Data from First-in-man Study

Pt	Age/ gender	BSA (m ²)	Etiology	INTERMACS level	Pulmonary hypertension	Arrhythmia	Other	Time on device (days)	Cause of death
1	56/M	2.23	Idiopathic	4	No	No	Smoker, multiple HF readmissions, LVEDD 87 mm, Grade 4 MR, not suitable for transplant, declined VAD	81 (died on device)	Multiple-organ failure Day 81
2	54/M	1.67	Ischemic	4	Yes	No	Fixed high pulmonary gradient and not suitable for transplant or VAD	34 (explanted due to mediastinitis)	Acute myocardial infarction Day 51 (no residual infection at post mortem)
3	58/M	1.99	Idiopathic	2	Yes	AFib	IV inotrope-dependent, IABP in situ, not suitable for VAD	58 (explanted due to mediastinitis)	Died day 80 of sepsis, multiple-organ failure
4	56/F	1.98	Idiopathic	4	No	VT	Syncope, listed for heart transplant	26 (device explanted at transplant)	Transplanted, remains alive
5	73/M	1.75	Ischemic	4	Yes	No	Not suitable for VAD or heart transplant	207 (died on device)	Died on Day 207 of sepsis, multiple-organ failure

AFib, atrial fibrillation; BSA, body surface area; HF, heart failure; IABP, intra-aortic balloon pump; IV, intravenous; LVEDD, left ventricular end-diastolic diameter; MR, myocardial rejection; Pt, patient; VAD, ventricular assist device; VT, ventricular tachycardia.

Source: Hayward et al. *J Heart and Lung Trans.* 2010

Feasibility trial

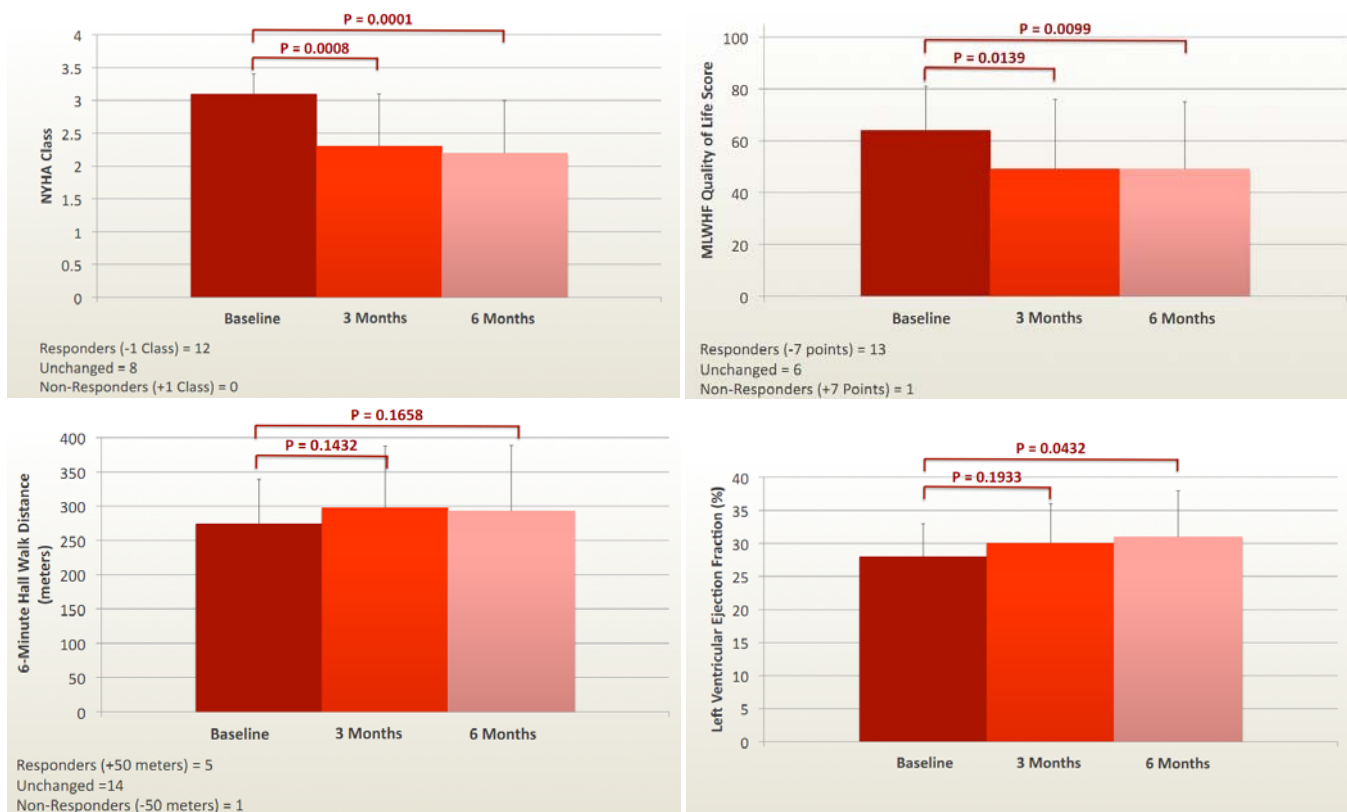
This phase I trial began in December 2008, enrolling 20 patients at eight sites. St. Luke's is the leading enroller. Enrollment was slow given the initial requirement for a full sternotomy and too restrictive inclusion/exclusion criteria. The primary endpoint of this trial was safety and efficacy at six months.

Final adjudicated trial results were presented at the Transcatheter Cardiovascular Therapeutics conference on Monday, November 7, 2011, in San Francisco. Of the enrolled patients, 18 had class III heart failure and two had class IV heart failure. The six-month follow up showed a statistically significant improvement in NYHA class from 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 from 28 ± 5 to 31 ± 7 ($p=0.04$). All but one patient showed improvement in NYHA class. Four patients improved to NYHA class I, and two patients were weaned from therapy.

There were three deaths in the trial, two drop outs and two super responders who were weaned from therapy. There was one aortic disruption at 137 days post implant, which resulted in death, and two other deaths in the trial due to a drug allergic reaction and a respiratory issue, both two months post surgery. The two drop outs consisted of one patient who elected to receive a heart transplant three months post surgery, and one patient who had to receive an LVAD. Nine of the 20 patients had a major infection, with eight of these related to the exit site.

Figure 14. Feasibility Data



Source: Sunshine Heart

US pivotal phase II trial

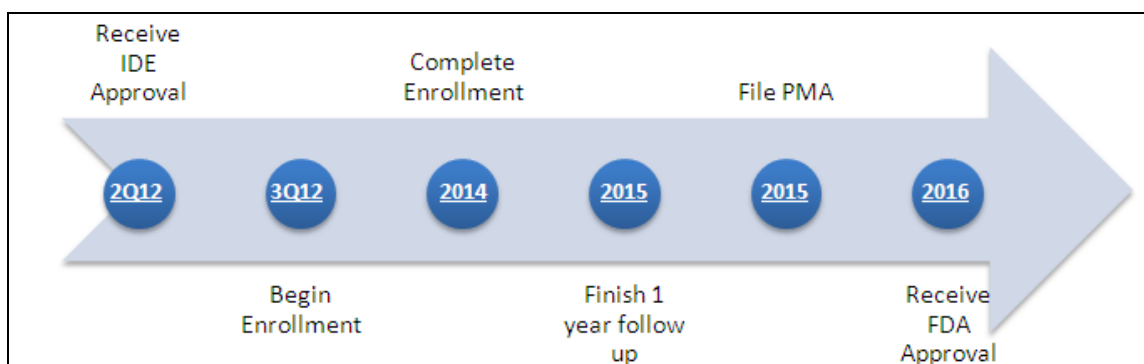
Initial plans are for this to be a 270-patient randomized trial beginning in 2Q12. InCHOIR, together with a group of five physicians, worked to develop the protocol. SHC is targeting 30 different sites. The control group is medical therapy. The primary endpoint is the number of days to first hospitalization due to worsening heart failure. Re-hospitalization is defined as signs and symptoms of heart failure, treatment with IV heart failure therapy, or minimum of 24 hours in hospital or hospitalization for VAD treatment. Other primary efficacy endpoints include quality of life based on the Minnesota Living with Heart Failure (MLWHF) score, heart failure symptoms as measured by NYHA classification, six-minute hall walk test, peak VO_2 , and left ventricular ejection fraction.

CMS and a majority of private insurers have already approved C-Pulse for use in the clinical trials. Currently, the C-Pulse is assigned to a Category B designation with an IDE code of G070096. Under a Category B designation, the C-Pulse system is determined to be non-experimental/investigational. This designation allows Medicare to pay for the device that is currently in clinical trials. The device is currently getting reimbursed at \$54,000 per device.

SHC is contemplating a number of modifications to the originally designed pivotal trial. The major changes are an increase in enrolled subjects to 300 patients and a change in the control group from medical therapy to sham therapy. Sham therapy comprises implanting the C-Pulse device and activating it but delivering a non-therapeutic dose. After control patients are re-hospitalized for worsening heart failure, these patients will become crossover patients, and a therapeutic

dose will then be delivered. This aims to prevent patient bias and eliminate any placebo effect. As patients participate in clinical trials to receive the treatment that is being studied, SHC is hoping this updated protocol, which ultimately ensures every patient who needs the studied treatment will get it, will speed patient recruitment and enrollment.

Figure 15. Pathway to Approval



PATENTS

As of the end of the third quarter, SHC has had 27 issued patents. Eleven of these patents were issued in the US, while the other 16 patents were issued in other countries, including Australia, Canada, India, Japan, and Mexico. SHC also has 30 patent applications, 10 of which are in the US. The patents in the US expire between June 9, 2020, and October 28, 2024.

MANAGEMENT

David Rosa, Chief Executive Officer

Mr. Rosa has been CEO at SHC since October 2009. Before SHC, Mr. Rosa was president and CEO of Milksmart, Inc. From 2004-2008 Mr. Rosa was vice president of global marketing for cardiac surgery and cardiology at St. Jude Medical, Inc. Mr. Rosa also served in several executive management positions, including CEO and COO, at A-Med Systems, Inc. from 1999-2004.

William Peters, M.D., Medical Director, Chief Technical Officer

Dr. Peters is the inventor of the C-Pulse technology and is one of the co-founders of SHC, serving as the initial CEO. Dr. Peters also invented an endovascular cardiopulmonary bypass system for minimally invasive cardiac surgery, which has been commercialized. Dr. Peters also has an honorary appointment with the University of Auckland's Department of Surgery and Biomedical Engineering. Dr. Peters is a senior clinical research fellow in cardiothoracic surgery based at Auckland City Hospital.

Jeff Mathiesen, Chief Financial Officer

Mr. Mathiesen joined SHC in March 2011. Prior to joining SHC Mr. Mathiesen was vice president and CFO for Zareba Systems. Mr. Mathiesen has more than 20 years of experience, including stints as CFO of various different companies, such as Delphax Technologies, Inc., Micro Component Technology, Inc., and Recovery Engineering, Inc.

Debra Kridner, Vice President, Clinical Research and Regulatory Affairs

Mrs. Kridner joined SHC in November 2009. Mrs. Kridner has more than 30 years of experience in clinical research, quality and regulatory affairs, including time spent owning her own consulting firm focusing on these issues. Prior to her time spent at her consulting firm, Mrs. Kridner was vice president, clinical research and regulatory affairs for cardiac surgery and interventional cardiology at St. Jude Medical, Inc. Mrs. Kridner also held senior management positions in clinical, regulatory, and quality at Medtronic.

Kevin Bassett, Vice President Research, Development and Quality Assurance

Mr. Bassett joined SHC in October 2010. Prior to SHC Mr. Bassett was senior vice president of operations, development, and quality assurance at Acorn Cardiovascular. Mr. Bassett was co-founder and principal at St. Paul Consulting LLC, which focused on operations, development, regulatory affairs, and quality assurance, at medical device and pharmaceutical industries.

Figure 16. SHC Quarterly Income Statement (US\$) per Assumed Stock Split of 225:1

SHC Income Statement	2010	2011E				2012E				2013E					
		Q1	Q2	Q3	Q4E	Q1E	Q2E	Q3E	Q4E	Q1E	Q2E	Q3E	Q4E		
Total revenues	407	-	-	-	-	-	-	460	570	1,030	1,086	1,448	1,590	2,020	6,144
Clinical Trial Revenue	407	-	-	-	-	-	-	240	240	480	756	1,008	1,260	1,470	4,494
Commercial Revenue	-	-	-	-	-	-	-	220	330	550	330	440	330	550	1,650
COGS	-	-	-	-	-	-	-	130	156	286	264	352	396	495	1,507
Gross profit	407	-	-	-	-	-	-	330	414	744	822	1,096	1,194	1,525	4,637
SG&A	2,598	700	1,120	1,430	1,100	4,350	1,100	1,150	1,200	1,250	4,700	1,400	1,500	1,550	6,050
R&D	6,229	2,200	2,466	3,273	3,500	11,439	3,500	3,500	4,000	4,250	15,250	4,500	4,750	5,000	19,500
Medical Device Excise Tax	-	-	-	-	-	-	-	-	-	-	17	23	29	34	103
Other operating costs, net	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total operating expenses	8,827	2,900	3,586	4,703	4,600	15,789	4,600	4,650	5,200	5,500	19,950	5,917	6,273	6,579	25,653
Operating income	(8,420)	(2,900)	(3,586)	(4,703)	(4,600)	(15,789)	(4,600)	(4,650)	(4,870)	(5,086)	(19,206)	(5,095)	(5,177)	(5,385)	(21,016)
Interest expense, net	(150)	(90)	(107)	(31)	(40)	(268)	(50)	(50)	(50)	(50)	(200)	(50)	(50)	(50)	(200)
Other non-operating Income	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Income before taxes	(8,270)	(2,810)	(3,479)	(4,672)	(4,560)	(15,521)	(4,550)	(4,600)	(4,820)	(5,036)	(19,006)	(5,045)	(5,127)	(5,335)	(20,816)
Provision for income taxes	(670)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported net income, net	(7,600)	(2,810)	(3,479)	(4,672)	(4,560)	(15,521)	(4,550)	(4,600)	(4,820)	(5,036)	(19,006)	(5,045)	(5,127)	(5,335)	(20,816)
Special charges	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
GAAP net income	(7,600)	(2,810)	(3,479)	(4,672)	(4,560)	(15,521)	(4,550)	(4,600)	(4,820)	(5,036)	(19,006)	(5,045)	(5,127)	(5,335)	(20,816)
Shares Outstanding ('000)	577,024	1,014,342	1,018,846	1,203,748	1,207,748	1,111,171	6,243	6,293	7,168	7,218	6,730	8,093	8,143	9,018	9,068
EPS Reported	(\$0.01)	(\$0.00)	(\$0.00)	(\$0.00)	(\$0.00)	(\$0.01)	(\$0.73)	(\$0.73)	(\$0.67)	(\$0.70)	(\$2.82)	(\$0.62)	(\$0.63)	(\$0.59)	(\$2.43)
EPS GAAP	(\$0.01)	(\$0.00)	(\$0.00)	(\$0.00)	(\$0.00)	(\$0.01)	(\$0.73)	(\$0.73)	(\$0.67)	(\$0.70)	(\$2.82)	(\$0.62)	(\$0.63)	(\$0.59)	(\$2.43)

Figure 17. SHC Balance Sheet

SHC Balance Sheet (AU\$)	2009	2010	3Q11
Assets			
Cash and cash equivalents	7,028	12,350	10,344
Accounts receivables, net	124	247	-
Other current assets	88	182	191
Total current assets	7,240	12,779	10,535
Property and equipment, net	145	120	121
Intangible assets, net	-	-	-
Total assets	7,385	12,899	10,656
Liabilities and Shareholders' Equity			
Accounts payable	230	696	968
Other accrued expenses incl. dividend	84	114	310
Total current liabilities	314	810	1,278
Long-Term Debt/Obligations	-	-	-
Total liabilities	314	810	1,278
Common Stock	455	924	931
Additional Paid-In Capital	47,637	59,163	67,361
Retained Earnings (Accumulated Deficit)	(41,393)	(48,993)	(59,954)
Adjustments to Shareholder's Equity	372	995	1,040
Total Shareholders' Equity	7,071	12,089	9,378
Total Liabilities and Shareholders' Equity	7,385	12,899	10,656

Figure 18. SHC Cash Flow Statement

SHC Cash Flow (AU\$)	Yr End 31-Dec-09	Yr End 31-Dec-10	9 mo. End 30-Sep-11
Net Loss	\$ (5,342)	\$ (7,600)	\$ (10,961)
Adjustments			
Depreciation and Amortization	11	32	25
Loss on disposal of equipment	-	-	6
Stock based compensation expense	128	78	555
Changes in Assets and Liabilities			
Accounts Receivable	(118)	(123)	259
Other Current Assets	(12)	(94)	(24)
Accounts Payable and accrued expenses	(477)	496	480
Net Cash Used In Operations	\$ (5,810)	\$ (7,211)	\$ (9,660)
Purchase of Property and Equipment	(3)	(7)	(34)
Net Cash Used in Investing Activities	\$ (3)	\$ (7)	\$ (34)
Net Proceeds from Sale of Common Stock	7,950	11,917	7,650
Net Cash Provided by Financing Activities	\$ 7,950	\$ 11,917	\$ 7,650
Effect of Foreign Exchange	849	623	38
Net Increase (Decrease) in Cash and Cash Equivalents	2,986	5,322	(2,006)
Cash and Cash Equivalents - Beginning of Period	\$ 4,042	\$ 7,028	\$ 12,350
Cash and Cash Equivalents - End of Period	\$ 7,028	\$ 12,350	\$ 10,344

Important Disclosures and Disclaimers – First Quarter 2012

Analyst Certification: Each research analyst who authored the attached research report certifies the following: 1) All of the views expressed in this research report reflect my personal opinions about the subject company or any company mentioned in this research report; 2) I have not and will not receive compensation in exchange for the recommendation or views in this research report; and 3) Neither I nor the firm that employs me believes or have reason to believe that I have any material conflicts of interest with regard to the subject company or any company mentioned in this research report at the time of its publication.

Analyst/Firm Financial Interest/Control: Neither the analyst nor any members of his/her household has a financial interest in the covered company, or companies mentioned in this research report, including the ownership of shares, warrants, or options on the subject company's securities. In addition, neither the analyst nor any member of his/her family is an officer, director or advisory board member of the subject company. At the end of the month immediately preceding the publication of this research report, the firm and/or its affiliates did not beneficially own 1% or more of any class of common equity securities of the subject company, nor any company mentioned in this research report. Summer Street Research Partners ("SSRP" or "the Company") does not make markets in any securities, including those of the subject companies in this research report. The research analysts' compensation is not directly related to the specific recommendations or views expressed in this research report. Research Analyst(s) compensation is however based upon various factors including SSRP's total revenues, a portion of which may in the future be generated by investment-banking related activities.

Investment Banking and Other Services: SSRP has not provided investment-banking, advisory or other similar services to the subject companies described in this research report, nor are they clients of the SSRP. Further, the firm and its affiliates have not managed or co-managed a public/private offering of securities for the subject companies in this research report, and have not received compensation for investment-banking services from the subject companies in this research report. We expect to receive or intend to seek compensation from the subject companies for investment-banking related services in three months from the date of this research report. The firm has not received investment-banking revenues or participated in a public/private offering of securities as a manager or co-manager of the subject company's securities in the past 12 month from the date of this research report. Nor has the firm or its research analysts received compensation from the subject company or any company mentioned in this research report for products and services in the past 12 months. In addition, no research analyst, employee or affiliate of SSRP with the ability to influence the substance of this research report has received any compensation for products and service in the past 12 months.

Definition of SSRP's Stock Rating System as used in this Research Report: BUY – We believe the stock's total return will significantly outperform its peer group; NEUTRAL – We believe the stock's total return will not be significantly different than its peer group; SELL – We believe the stock's total return will significantly under perform its peer group.

General Disclaimers: The information contained herein is intended for distribution to institutional investors and is for informational purposes only. SSRP's research reports should be considered as only a single factor in making an investment decision. The information herein was obtained from various sources; we do not guarantee its accuracy or completeness and it should not be relied upon as such. Additional information is available by contacting SSRP. Neither the information nor any opinion expressed constitutes an offer, or an invitation to make an offer to buy or sell any securities. The data contained herein is intended for the sole and exclusive use of clients of SSRP. No reproduction, transmission or replication of any of the information or data contained within this document may be done without the expressed written consent of SSRP. Medical Consulting Research Inc. (MCRI) is a division of SSRP.

Investment Rating Distribution for the Period 10/1/11 through 12/31/11:

Rating	Count	Percentage
BUY	29	76%
NEUTRAL	8	21%
SELL	1	3%
Companies under coverage at 12/31/11	38	100%

We have assigned an investment rating for at least one year for the following subject companies mentioned in this report:

SHC

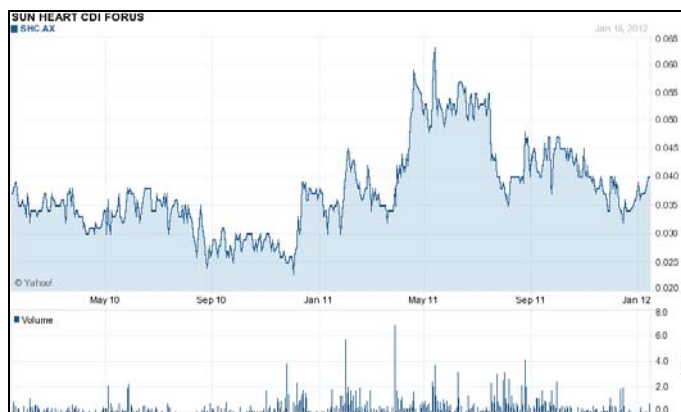
Ratings History

Date	Rating	Share Price	Price Target
1/17/12	BUY	AU\$0.04	AU\$0.15

SHC Investment Risks

- **C-Pulse clinical risk/limited data.** There is little human data to analyze, and early human results sometimes do not transfer to a larger setting.
- **Unexpected events could slow clinical trial program and EU adoption.** Any form of device failure or increase in adverse events from current baseline could damage physician confidence, slow down trial enrollment, and hinder market adoption.
- **Limited financial resources.** SHC will need to raise \$50-60MM to get to FDA approval.

Valuation Method for Price Target: Valuation of comparative companies



Source: Yahoo! Finance