



## **EARNINGS UPDATE**

## Medical Supplies & Devices: Cardiovascular

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#### Recommendation

Rating:	Outperform
Price Target (in \$):	15.00
Expected Return:	76.3%
Dividend:	NA
Enterprise Value (MM):	\$88.0

#### Revenue (MM)

	2012A	2013E	2014E
Q1	0.0	0.0 <i>A</i>	0.5
Q2	0.0	0.0 <i>A</i>	1.1
Q3	0.0	0.0	1.3
Q4	0.0	0.1	1.6
FY	0.0	<u>0.1</u>	<u>4.3</u>
EV/S		880.0x	20.5x

## Stock Statistics as of 08/06/2013 (in \$)

Price:	\$8.51
52W Range:	\$10.25-\$4.85
Shares Out (MM):	11.9
Market Cap (MM):	\$105.4
Net Debt (MM):	(21.5)
Net Cash Per Share:	1.81

## **Fundamentals**

Earnings Per Share ('12A)	\$(1.98)
Earnings Per Share ('13E)	\$(1.71)
Earnings Per Share ('14E)	\$(1.51)
P/E ('12)	NM
P/E ('13)	NM
P/E ('14)	NM



## **SUNSHINE HEART (NYSE:SSH)**

# Four EU C-Pulse Patients Implanted; U.S. Enrollment On Tap

We reiterate our Outperform rating on Sunshine Heart primarily due to our view that the C-Pulse could prove to be a disruptive solution for NYHA Class III and IV ambulatory CHF patients.

## Center Activations and EU C-Pulse Implants Have Begun To Ramp

Center activations in both the U.S. (5) and European (3) trials and reported center commitments represent meaningful data points as patient enrollment is now expected to ramp. SSH reiterated the 2013 site activation targets of 22 in the U.S. and 8 in Europe. Four patients have now been implanted with the C-Pulse in the OPTIONS HF EU trial and the first U.S. patient is expected in 3Q'13. These initial patients have tolerated the procedure well and experienced hemodynamic improvements. One patient experience a non-device related episode of atrial fibrillation which led to an ablation procedure with subsequent deterioration which necessitated an LVAD placement.

## U.S. Trial Enrollment Set To Kick Off

A total of 4 new centers have been activated for the U.S. COUNTER HF pivotal trial bringing the total number of activated sites to 5. With 12 additional sites in the activation process and 8 more in the vetting stage, SSH should meet the 2013 22 site target. Centers are taking a longer time than anticipated to begin enrolling patients after activation (~6 months) and thus previous patient enrollment guidance of 32-44 for 2013 was not reiterated. Enrollment in the U.S. is still expected to be completed by the end of 2015 while continued positive data accrual from the OPTIONS HF EU post-market study could draw significant interest from larger cardiovascular players during that time frame. A potential takeout scenario could reel in investors' timeline for a meaningful return, in our view. Our DCF analysis suggests SSH's share price could nearly double in the setting of FDA approval and meaningfully positive results from the EU post-approval study

Please see addendum of this report for important disclosures.

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## 2Q'13 Results Highlighted by Trial Updates

C-Pulse system is a promising technology platform, which could prove to be a disruptive solution for NYHA Class III and IV ambulatory heart failure patients who are not responding to optimal medical therapy. The device achieved CE Mark in July 2012. Two trials are currently up and running: a US pivotal trial COUNTER HF and a European post-market study OPTIONS HF. 2Q'13 EPS of \$(0.35) was \$0.01 higher than our estimate. The results were accompanied by positive updates on the U.S. and European clinical trials. Five centers have now been activated for the U.S. COUNTER HF trial, with 12 additional sites in the activation process. Patient enrollment is expected to start in 3Q'13, with a target of 388 patients (144 in the C-Pulse arm). The OPTIONS HF trial had 2 new sites activated in 2Q with a total of 4 patients implanted with C-Pulse. We expect COUNTER HF to complete enrollment by the end of 2015 and OPTIONS HF to end by 2014. With 17 incremental centers in the US expected to be activated by year end and multiple clinical sites in Europe lined up for activation, SSH should experience an accelerated enrollment pace in 2H'13.

#### U.S. Pivotal Trial COUNTER HF Expected to Take Off in 2H'13

A total of 3 new centers were activated for the U.S. COUNTER HF trial during the quarter with a fourth activated after June 30th, bringing the total number of activated sites to 5. So far, 17 sites have committed to participate in the trial, including the 5 that are now activated. The company is waiting to hear from an additional 8 centers with regard to intention to participate in the trial. The pace of fully activating enrollment at a committed site is taking an average 6 months, which is a tick slower than expected. SSH is in the process of expediting the activation process by allocating additional resources to the cause in the second half of 2013. Therefore, we view SSH's guidance of 22 sites target by the end of the year as achievable. Management provided a positive update on the reimbursement front in the U.S. The first three activated centers with qualifying LVAD programs have received regional CMS reimbursement approval for the C-Pulse procedure under established LVAD codes, which is demonstrative of the SSH's path for future revenue generation during the pivotal trial.

#### Patients Update for the Europe OPTIONS HF Study

The European single arm post-market study (OPTIONS HF) activated 2 additional sites during the second quarter followed by another site activation in July, bringing the total number of sites to 4. SSH is targeting to activate an additional 4 sites during 2H'13. 4 patients have now been implanted with the C-Pulse device. The pace of implantation averages 1 patient per center per month. The company provided detailed update on the 4 implant patients during the earnings call. All 4 patients are male and have class III heart failure. First patient is now 3-months post implant, has become more physically active, and reportedly has lost 20lbs since the procedure. The 2nd patient experienced good initial results responding well to the C-Pulse counter pulsation evidenced by an improvement in hemodynamics (Cardiac Index from 1.1 L/min/m² to 2.5 L/min/m²). On day 4 post procedure, he experienced non-device related rapid atrial fibrillation necessitating an ablation procedure. Post ablation, the patient deteriorated with a HR sustained over 120 bpm. The patient was being cared for by a weekend covering physician

who was not familiar with the C-Pulse technology which is deactivated at heart rates above 120bpm. The doctor independently decided to replace the C-Pulse with an LVAD implying that the patient's congestive heart failure worsened and required more hemodynamic support. Patient 3 is now 30 days post implant, extremely active and satisfied with outcome. A 79 year old was the 4th patient who was implanted last week and remains in the observation stage as an inpatient but reportedly tolerated the procedure well. None of the patients have been readmitted for recurring heart failure to date. Only one exit site infection was reported, but was quickly treated with oral antibiotics.

#### C-Pulse Continues to Demonstrate Excellent Safety Profile

SSH has previously reported that two patients had been successfully weaned from the therapy due to improved results, with two additional patients being vetted for weaning. In anticipation of future patients being targeted for weaning, the company is developing a formal weaning protocol. Successful weaning has been targeted as a secondary endpoint in the European trial. SSH will provide an update with patient weaning data post the 2013 (TCT) conference at the end of October. The potential to wean patients from the C-Pulse system could be a future driver of positive physician sentiment and stronger adoption/utilization trends.

### **Infection Control Measures in Play**

SSH has established an Infection Control Committee that includes an infectious disease specialist, a cardiac imaging physician expert, a cardiac surgeon with both C-Pulse and LVAD experience, and a former LVAD clinical coordinator experienced in managing exit site infections. The committee is intended to provide general guidelines to mitigate and minimize potential adverse events associated with exit site infections. Management has cleared this level of oversight with the FDA.

## **Pipeline Development in Progress**

SSH is actively developing a fully implantable C-Pulse system. A patent application has been submitted for the system, with a trial in acute and chronic animals planned to begin in the second half of 2013. SSH also received worldwide approval for an enhanced percutaneous interface device lead with increased external length which is expected to further decrease the incidence of exit site infections. An additional external length of approximately five-inches is targeted for regulatory submission in the 4Q'13. A new driver lead assembly designed to improve device reliability was conditionally approved by the FDA.

## Revenue Recognition Expected in EU in 2014

SSH is working with European agencies on reimbursement. The company is expecting revenues from Germany, Italy, and U.K. in 2014. As for the U.S. market, 3 activated sites have reimbursement approval in place. Therefore, revenue will be booked as soon as patients start to enroll in the trial. However, since beginning of enrollment is a bit further out than what was initially planned, we are expecting small 2013 US revenues until C-Pulse becomes fully on

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board. SSH's cash position is expected to fund operations and the clinical development program through 2H'14.

SUNSHINE HEART INCOME STATEMENT	2011	2012	1Q13	2Q13	3Q13E	4Q13E	2013E	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E
C-Pulse Products and Service	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.5	0.9	1.3	1.6	4.3	8.6	9.5	22.8	47.0
Total Revenue	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.1	\$0.1	\$0.5	\$0.9	\$1.3	\$1.6	\$4.3	\$8.6	\$9.5	\$22.8	\$47.0
% y/y growth			NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	101.1%	10.3%	139.2%	106.3%
Cost of Goods Sold	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.1	\$0.1	\$0.4	\$0.7	\$1.0	\$1.3	\$3.5	\$7.0	\$7.6	\$16.0	\$26.9
% of sales				NM	85.0%	85.0%	85.0%	84.0%	83.0%	82.0%	81.0%	82.1%	81.0%	79.5%	70.4%	57.2%
Gross Profit	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.1	\$0.2	\$0.2	\$0.3	\$0.8	\$1.6	\$2.0	\$6.8	\$20.1
% margin	NM	NM	5.0%	5.0%	15.0%	15.0%	15.0%	16.0%	17.0%	18.0%	19.0%	17.9%	19.0%	20.5%	29.6%	42.8%
SG&A	\$5.4	\$6.9	\$2.0	\$2.2	\$2.2	\$2.3	\$8.6	\$2.4	\$2.4	\$2.4	\$2.5	\$9.6	\$10.6	\$10.5	\$11.9	\$12.4
% of sales	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	110.0%	52.2%	26.5%
R&D	\$11.2	\$8.0	\$2.4	\$3.2	\$3.2	\$3.2	\$11.9	\$2.7	\$3.5	\$3.5	\$3.5	\$13.1	\$13.9	\$8.6	\$8.9	\$8.9
% of sales	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	89.8%	38.9%	18.8%
Operating Income	(\$16.6)	(\$14.9)	(\$4.4)	(\$5.3)	(\$5.3)	(\$5.4)	(\$20.4)	(\$5.0)	(\$5.7)	(\$5.7)	(\$5.6)	(\$21.9)	(\$22.8)	(\$17.1)	(\$14.0)	(\$1.2)
% margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Adjusted EBITDA	(\$15.6)	(\$13.5)	(\$4.0)	(\$4.8)	(\$4.8)	(\$4.8)	(\$18.3)	(\$4.3)	(\$4.9)	(\$4.9)	(\$4.8)	(\$18.8)	(\$18.4)	(\$10.7)	(\$4.7)	\$12.4
% margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	26.3%
Interest/Other Expense (Income)	(\$0.3)	(\$0.0)	(\$0.0)	\$0.0	(\$0.0)	(\$0.0)	(\$0.0)	(\$0.0)	(\$0.0)	(\$0.0)	(\$0.0)	(\$0.2)	(\$0.0)	(\$0.1)	(\$0.1)	(\$0.2)
Pretax Income	(\$16.3)	(\$14.8)	(\$4.4)	(\$5.3)	(\$5.3)	(\$5.4)	(\$20.4)	(\$4.9)	(\$5.6)	(\$5.6)	(\$5.6)	(\$21.8)	(\$22.8)	(\$17.0)	(\$13.9)	(\$1.0)
% margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Income taxes (benefit)	(\$0.1)	(\$0.8)	\$0.0	(\$1.1)	\$0.0	\$0.0	(\$1.1)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	(\$2.5)	(\$0.3)
Tax Rate	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	30.0%
GAAP Net Income	(\$16.2)	(\$14.1)	(\$4.4)	(\$4.2)	(\$5.3)	(\$5.4)	(\$19.3)	(\$4.9)	(\$5.6)	(\$5.6)	(\$5.6)	(\$21.8)	(\$22.8)	(\$17.0)	(\$11.4)	(\$0.7)
One-Time Items	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Adjusted Net Income	(\$16.2)	(\$14.1)	(\$4.4)	(\$4.2)	(\$5.3)	(\$5.4)	(\$19.3)	(\$4.9)	(\$5.6)	(\$5.6)	(\$5.6)	(\$21.8)	(\$22.8)	(\$17.0)	(\$11.4)	(\$0.7)
% margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
GAAP EPS	(2.98)	(1.98)	(\$0.47)	(\$0.35)	(\$0.44)	(\$0.44)	(\$1.71)	(\$0.40)	(\$0.45)	(\$0.33)	(\$0.33)	(\$1.51)	(\$1.29)	(\$0.81)	(\$0.53)	(\$0.03)
% y/y growth		NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Adjusted EPS	(2.98)	(1.98)	(\$0.47)	(\$0.35)	(\$0.44)	<b>*</b> (\$0.44)	(\$1.71)	(\$0.40)	(\$0.45)	(\$0.33)	(\$0.33)	(\$1.51)	(\$1.29)	(\$0.81)	(\$0.53)	(\$0.03)
% y/y growth		NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Basic Shares (MM)	5.4	7.1	9.4	11.9	12.0	12.1	11.4	12.3	12.5	17.0	17.2	14.8	17.7	21.1	21.6	22.1
Diluted Shares (MM)	5.4	7.1	9.4	11.9	12.0	12.1	11.4	12.3	12.5	17.0	17.2	14.8	17.7	21.1	21.6	22.1

Source: Cowen and Company.

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Sunshine Heart C-Pulse System Revenue Build																
US Indications for C-Pulse		20125	40140	20142	001105	401405	20125	401445	201445	001445	401445	00445	20155	20125	00/85	20105
Class III or Ambulatory Class IV(a) CHF	2011	2012E	1Q'13	2Q'13	3Q'13E	4Q'13E	2013E	1Q'14E	2Q'14E	3Q'14E	4Q'14E	2014E	2015E	2016E	2017E	2018E
CHF Patients Class III or IV(a)	1,450,000	1,451,450	1,454,353	1,454,353	1,454,353	1,454,353	1,454,353	1,458,716	1,458,716	1,458,716	1,458,716	1,458,716	1,464,551	1,471,874	1,479,233	1,486,629
% y/y growth C-Pulse % Penetration of CHF Class III/IV(a)	0.00/	0.1% 0.0%	0.2% 0.0%	0.2% 0.0%	0.2% 0.0%	0.2% 0.0%	0.2% 0.0%	0.3%	0.3% 0.0%	0.3% 0.0%	0.3% 0.0%	0.3% 0.0%	0.4%	0.5% 0.0%	0.5% 0.0%	0.5% 0.0%
C-Pulse % Penetration of CHF class III/IV(a) C-Pulse Procedues	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	126	357
C-Pulse ASP	\$50,000	\$50.000	\$50,000	\$50,000	\$50,000	\$50,000	\$50,000	\$49,500	\$49,500	\$49,500	\$49,500	\$49.500	\$49.005	\$48.515	\$48.030	\$47,550
U.S. C-Pulse Implant Sales (\$MM)	\$50,000	\$50,000	\$0,000	\$0,000	\$50,000	\$50,000	\$0.0	\$49,500	\$49,500	\$49,500	\$49,500 <b>\$0.0</b>	\$49,500	\$49,005	\$40,515	\$46,030	\$17.0
y/y growth %	NM	NM	φυ.υ	φυ.υ	<b>\$0.0</b>	φυ.υ	MM	φυ.υ	<b>\$0.0</b>	φυ.υ	φυ.υ	NM	NM	NM	NM	181%
y/y growin /8	INIVI	14171					IVIVI					14171	TWV	I VIVI	I WIVI	10176
Europe Indications for C-Pulse																
Class III or IV(a) CHF	2011	2012E	1Q'13	2Q'13	3Q'13E	4Q'13E	2013E	1Q'14E	2Q'14E	3Q'14E	4Q'14E	2014E	2015E	2016E	2017E	2018E
CHF Patients Class III or IV(a)	3,700,000	3,718,500	3,737,093	3,737,093	3,737,093	3,737,093	3,737,093	3,755,778	3,755,778	3,755,778	3,755,778	3,755,778	3,774,557	3,793,430	3,812,397	3,831,459
% y/y growth		0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%
C-Pulse % Penetration of CHF Class III/IV(a)	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
C-Pulse Procedues	0	0	0	0	0	0	0	0	0	0	4	4	64	163	290	525
C-Pulse ASP	\$59,000	\$59,000	\$59,000	\$59,000	\$59,000	\$59,000	\$59,000	\$59,000	\$59,000	\$59,000	\$59,000	\$59,000	\$59,000	\$58,410	\$57,826	\$57,248
European C-Pulse Implant Sales (\$MM)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.2	\$0.2	\$3.8	\$9.5	\$16.8	\$30.0
y/y growth %	NM	NM					NM					NM	1444%	153%	76%	79%
		40.0	***	***	***	***	***	***	***	***	***	***	40.0		***	2.77
WW C-Pulse Commercial Sales (\$MM)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.2	\$0.2	\$3.8 1444%	\$9.5	\$22.8	\$47.0
y/y growth %	NM	NM					NM					NM	1444%	153%	139%	106%
C-Pulse US Clinical Trial Revenue	•															
IDE Pivotal Trial: COUNTER HF		2012E	1Q'13	2Q'13	3Q'13E	4Q'13E	2013E	1Q'14E	2Q'14E	3Q'14E	4Q'14E	2014E	2015E	2016E		
Centers at Start		20122	0	1	4	12	0	22	27	32	38	22	40	40		
Centers at End			1	4	12	22	22	27	32	38	40	40	40	40		
Average Centers per Period			1	3	8	17	11	25	30	35	39	31	40	40		
													1			
Months in Period			3.0	3.0	3.0	3.0	12.0	3.0	3.0	3.0	3.0	12.0	12.0	12.0		
Patients Enrolled			0	0	1	4	5	26	26	44	53	148	236	0		
Enrollment per Center per Month			NM	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.0		
Total Enrollment			0	0	0	4	4	29	55	99	152	152	388	388		
C-Pulse Implant Procedures		0	0	0	0	2	2	13	13	22	26	74	118	0		
C-Pulse Reimbursed Implant Procedures		. 0	. 0	. 0	. 0	. 1	. 1	. 9	. 9	15	18	52	83	0		
C-Pulse ASP		\$59,000	\$59,000	\$59,000	\$59,000	\$59,000	\$59,000	\$59,000	\$59,000	\$59,000	\$59,000	\$59,000	\$59,000	\$59,000		
C-Pulse Implant Sales		\$0.0	\$0.0	0	15,488	69,178	84,665	526,575	526,575	913,763	1,084,125	3,051,038	4,873,400	0		
U.S. IDE Pivotal Trial Sales (\$MM)		\$0.0	\$0.0	\$0.0	\$0.0	\$0.1	\$0.1	\$0.5	\$0.5	\$0.9	\$1.1	\$3.1	\$4.9	\$0.0		
C-Pulse European Clinical Trial Revenue																
European Post-Market Clinical Trial: OPTIONS HF		2012E	1Q'13	2Q'13	3Q'13E	4Q'13E	2013E	1Q'14E	2Q'14E	3Q'14E	4Q'14E	2014E	2015E	2016E		
Centers at Start		20125	0	2Q 13 1	36 135	40 ISE	20131	8	10	10	10	8	20132	20101		
Centers at End		0	1	3	5	8	8	10	10	10	10	10	0	0		
Average Centers per Period	1	0	<u> </u>	2	4	7	4	9	10	10	10	9	0	0		
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Months in Period		12.0	3.0	3.0	3.0	3.0	12.0	3.0	3.0	3.0	3.0	12.0	12.0	12.0		
Patients Enrolled		0	0	4	5	8	17	9	9	9	7	34	0	0		
Enrollment per Center per Month		0.0	0.0	0.5	0.4	0.4	0.3	0.5	0.5	0.5	0.5	0.5	0.0	0.1		
Total Enrollment									34	43	50	50	0	0		
		0	0 '	4	9	17	17	25	34							
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C-Pulse Implant Procedures	0	0	0	4	5	8	17	9	9	9	7	34	0			
C-Pulse Reimbursed Implant Procedures	0	0	0	4 0	5	8	17 0	9	9	9	2	6	0			
C-Pulse Reimbursed Implant Procedures C-Pulse ASP	0 0 \$40,000	0 0 \$40,000	0 0 \$40,000	4 0 \$40,000	5 0 \$40,000	8 0 \$40,000	17 0 \$40,000	9 0 \$40,000	9 2 \$40,000	9 2 \$40,000	\$40,000	\$40,000	\$39,600	\$39,204		
C-Pulse Reimbursed Implant Procedures C-Pulse ASP C-Pulse Implant Sales	\$40,000 0	0 0 0 \$40,000 0.0	0 0 \$40,000 0.0	4 0 \$40,000 0.0	5 0 \$40,000 0.0	8 0 \$40,000 0.0	17 0 \$40,000 0.0	9 0 \$40,000 0.0	9 2 \$40,000 0.4	9 2 \$40,000 0.4	\$40,000 0.3	\$40,000 1.0	\$39,600 0.0	0.0		
C-Pulse Reimbursed Implant Procedures C-Pulse ASP		0 0 \$40,000	0 0 \$40,000	4 0 \$40,000	5 0 \$40,000	8 0 \$40,000	17 0 \$40,000	9 0 \$40,000	9 2 \$40,000	9 2 \$40,000	\$40,000	\$40,000	\$39,600			
C-Pulse Reimbursed Implant Procedures C-Pulse ASP C-Pulse Implant Sales European Post-Market Trial Sales (\$MM)	\$40,000 0	\$40,000 0.0 \$0.0	0 0 \$40,000 0.0 <b>\$0.0</b>	4 0 \$40,000 0.0 \$0.0	5 0 \$40,000 0.0 \$0.0	8 0 \$40,000 0.0 <b>\$0.0</b>	17 0 \$40,000 0.0 \$0.0	9 0 \$40,000 0.0 <b>\$0.0</b>	9 2 \$40,000 0.4 \$0.4	9 2 \$40,000 0.4 \$0.4	\$40,000 0.3 \$0.3	\$40,000 1.0 \$1.0	\$39,600 0.0 \$0.0	0.0 <b>\$0.0</b>		
C-Pulse Reimbursed Implant Procedures C-Pulse ASP C-Pulse Implant Sales	\$40,000 0	0 0 0 \$40,000 0.0	0 0 \$40,000 0.0	4 0 \$40,000 0.0	5 0 \$40,000 0.0	8 0 \$40,000 0.0	17 0 \$40,000 0.0	9 0 \$40,000 0.0	9 2 \$40,000 0.4	9 2 \$40,000 0.4	\$40,000 0.3	\$40,000 1.0	\$39,600 0.0	0.0		
C-Pulse Reimbursed Implant Procedures C-Pulse ASP C-Pulse Implant Sales European Post-Market Trial Sales (\$MM) Global C-Pulse Sales for Trials (\$MM)	\$40,000 0 \$0.0	\$40,000 0.0 \$0.0 \$0.0	\$40,000 0.0 \$0.0 \$0.0	\$40,000 0.0 \$0.0	5 0 \$40,000 0.0 \$0.0	\$40,000 0.0 \$0.0	\$40,000 0.0 \$0.0	9 0 \$40,000 0.0 \$0.0 \$0.5	9 2 \$40,000 0.4 \$0.4	9 2 \$40,000 0.4 \$0.4	\$40,000 0.3 \$0.3	\$40,000 1.0 \$1.0 \$4.1	\$39,600 0.0 \$0.0 \$4.9	\$0.0 \$0.0 \$0.0		
C-Pulse Reimbursed Implant Procedures C-Pulse ASP C-Pulse Implant Sales European Post-Market Trial Sales (\$MM) Global C-Pulse Sales for Trials (\$MM) C-Pulse Estimated Quarterly Revenue (\$MM)	\$40,000 0 \$0.0	\$40,000 0.0 \$0.0 \$0.0	\$40,000 \$0.0 \$0.0	\$40,000 0.0 \$0.0 \$0.0	\$40,000 0.0 \$0.0 \$0.0	\$40,000 0.0 \$0.0 \$0.1	\$40,000 0.0 \$0.0 \$0.1	9 0 \$40,000 0.0 \$0.0	9 2 \$40,000 0.4 \$0.4 \$0.9	9 2 \$40,000 0.4 \$0.4 \$1.3	\$40,000 0.3 \$0.3 \$1.4	\$40,000 1.0 \$1.0 \$4.1	\$39,600 0.0 \$0.0 \$4.9	0.0 \$0.0 \$0.0	2017E	2018E
C-Pulse Reimbursed Implant Procedures C-Pulse ASP C-Pulse Implant Sales European Post-Market Trial Sales (\$MM)  Global C-Pulse Sales for Trials (\$MM)  C-Pulse Estimated Quarterly Revenue (\$MM) US C-Pulse Commercial Sales	\$40,000 0 \$0.0 2011	\$40,000 0.0 \$40,000 0.0 \$0.0 \$0.0	\$40,000 0.0 \$0.0 \$0.0	\$40,000 0.0 \$0.0 \$0.0	\$40,000 0.0 \$0.0 \$0.0	\$0 \$40,000 0.0 \$0.0 \$0.1	\$40,000 0.0 \$0.0 \$0.1	9 0 \$40,000 0.0 \$0.0 \$0.5	9 2 \$40,000 0.4 \$0.4 \$0.9	9 2 \$40,000 0.4 \$0.4 \$1.3	\$40,000 0.3 \$0.3 \$1.4 4Q'14E 0.0	\$40,000 1.0 \$1.0 \$4.1 \$4.1	\$39,600 0.0 \$0.0 \$4.9	0.0 \$0.0 \$0.0 \$0.0	6.0	17.0
C-Pulse Reimbursed Implant Procedures C-Pulse ASP C-Pulse Implant Sales European Post-Market Trial Sales (\$MM) Global C-Pulse Sales for Trials (\$MM)  C-Pulse Estimated Quarterly Revenue (\$MM) US C-Pulse Commercial Sales US C-Pulse Sales For Trials	\$40,000 0 \$0.0 \$0.0	\$40,000 0.0 \$0.0 \$0.0 \$0.0	\$0.0 \$40,000 0.0 \$0.0 \$0.0	\$40,000 0.0 \$0.0 \$0.0 \$0.0	\$0.0 \$40,000 0.0 \$0.0 \$0.0 \$0.0	\$40,000 0.0 \$0.0 \$0.1 4Q'13E 0.0 0.1	\$40,000 0.0 \$0.0 \$0.1 \$0.1	9 0 \$40,000 0.0 \$0.0 \$0.5	9 2 \$40,000 0.4 \$0.4 \$0.9	9 2 \$40,000 0.4 \$0.4 \$1.3 3Q14E 0.0 0.9	\$40,000 0.3 \$0.3 \$1.4 4Q'14E 0.0 1.1	\$40,000 1.0 \$1.0 \$4.1 2014E 0.0 3.1	\$39,600 0.0 \$0.0 \$4.9	0.0 \$0.0 \$0.0 \$0.0	6.0 0.0	17.0 0.0
C-Pulse Reimbursed Implant Procedures C-Pulse ASP C-Pulse Implant Sales European Post-Market Trial Sales (\$MM)  Global C-Pulse Sales for Trials (\$MM)  C-Pulse Estimated Quarterly Revenue (\$MM) US C-Pulse Commercial Sales US C-Pulse Sales For Trials OUS C-Pulse Commercial Sales	\$40,000 0 \$0.0 2011 0.0 0.0 0.0	\$40,000 0.0 \$0.0 \$0.0 \$0.0 \$0.0	\$40,000 0.0 \$40,000 \$0.0 \$0.0 \$0.0 0.0 0.0	\$40,000 0.0 \$0.0 \$0.0 \$0.0 \$0.0 0.0 0.0	\$0.0 \$40,000 0.0 \$0.0 \$0.0 \$0.0 0.0 0.0	\$0 \$40,000 0.0 \$0.0 \$0.1 4Q'13E 0.0 0.1 0.0	\$40,000 0.0 \$0.0 \$0.1 \$0.1 0.0 0.1 0.0	9 0 \$40,000 0.0 \$0.0 \$0.5	9 2 \$40,000 0.4 \$0.4 \$0.9 2Q'14E 0.0 0.5 0.0	9 2 \$40,000 0.4 \$0.4 \$1.3 3Q44E 0.0 0.9 0.0	2 \$40,000 0.3 \$0.3 \$1.4 4Q14E 0.0 1.1 0.2	\$40,000 1.0 \$1.0 \$1.0 \$4.1 2014E 0.0 3.1 0.2	\$39,600 0.0 \$0.0 \$4.9 2015E 0.0 4.9 3.8	0.0 \$0.0 \$0.0 \$0.0 2016E 0.0 0.0 9.5	6.0 0.0 16.8	17.0 0.0 30.0
C-Pulse Reimbursed Implant Procedures C-Pulse ASP C-Pulse Implant Sales European Post-Market Trial Sales (\$MM)  Global C-Pulse Sales for Trials (\$MM)  C-Pulse Estimated Quarterly Revenue (\$MM) US C-Pulse Commercial Sales US C-Pulse Sales For Trials OUS C-Pulse Commercial Sales OUS C-Pulse Commercial Sales OUS C-Pulse Commercial Sales	\$40,000 0 \$0.0 2011 0.0 0.0 0.0 0.0	0 0 0 \$40,000 0.0 \$0.0 \$0.0 2012E	\$40,000 0.0 \$0.0 \$0.0 \$0.0 \$0.0 0.0 0.0 0.0	\$40,000 0.0 \$0.0 \$0.0 \$0.0 \$0.0 0.0 0.0 0.0	\$40,000 0.0 \$0.0 \$0.0 \$0.0 \$0.0 0.0 0.0 0.0	\$40,000 0.0 \$0.0 \$0.1 4Q'13E 0.0 0.1 0.0 0.0	17 0 \$40,000 0.0 \$0.0 \$0.1 2013E 0.0 0.1 0.0 0.0	9 0 \$40,000 0.0 \$0.0 \$0.5	9 2 \$40,000 0.4 \$0.4 \$0.9 2Q14E 0.0 0.5 0.0 0.4	9 2 \$40,000 0.4 \$0.4 \$1.3 3QY4E 0.0 0.9 0.0	2 \$40,000 0.3 \$0.3 \$1.4 4Q14E 0.0 1.1 0.2 0.3	\$40,000 1.0 \$1.0 \$4.1 2014E 0.0 3.1 1.0.2 1.0	\$39,600 \$0.0 \$0.0 \$4.9 2015E 0.0 4.9 3.8 0.0	0.0 \$0.0 \$0.0 \$0.0 2016E 0.0 0.0 9.5 0.0	6.0 0.0 16.8 0.0	17.0 0.0 30.0 0.0
C-Pulse Reimbursed Implant Procedures C-Pulse ASP C-Pulse Implant Sales European Post-Market Trial Sales (\$MM)  Global C-Pulse Sales for Trials (\$MM)  C-Pulse Estimated Quarterly Revenue (\$MM) US C-Pulse Commercial Sales US C-Pulse Sales For Trials OUS C-Pulse Commercial Sales	\$40,000 0 \$0.0 2011 0.0 0.0 0.0	\$40,000 0.0 \$0.0 \$0.0 \$0.0 \$0.0	\$40,000 0.0 \$40,000 \$0.0 \$0.0 \$0.0 0.0 0.0	\$40,000 0.0 \$0.0 \$0.0 \$0.0 \$0.0 0.0 0.0	\$0.0 \$40,000 0.0 \$0.0 \$0.0 \$0.0 0.0 0.0	\$0 \$40,000 0.0 \$0.0 \$0.1 4Q'13E 0.0 0.1 0.0	\$40,000 0.0 \$0.0 \$0.1 \$0.1 0.0 0.1 0.0	9 0 \$40,000 0.0 \$0.0 \$0.5	9 2 \$40,000 0.4 \$0.4 \$0.9 2Q'14E 0.0 0.5 0.0	9 2 \$40,000 0.4 \$0.4 \$1.3 3Q44E 0.0 0.9 0.0	2 \$40,000 0.3 \$0.3 \$1.4 4Q14E 0.0 1.1 0.2	\$40,000 1.0 \$1.0 \$1.0 \$4.1 2014E 0.0 3.1 0.2	\$39,600 0.0 \$0.0 \$4.9 2015E 0.0 4.9 3.8	0.0 \$0.0 \$0.0 \$0.0 2016E 0.0 0.0 9.5	6.0 0.0 16.8	17.0 0.0 30.0

Source: Cowen and Company.

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SUNSHINE HEART CASH FLOW STATEMENT	2011	2,012	1Q13	2Q13	3Q13E	4Q13E	2013E	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E
							_					_		_	_	
Net Income	(\$16.2)	(\$14.1)	(\$4.4)	(\$4.2)	(\$5.3)	(\$5.4)	(\$19.3)	(\$4.9)	(\$5.6)	(\$5.6)	(\$5.6)	(\$21.8)	(\$22.8)	(\$17.0)	(\$11.4)	(\$0.7)
Depreciation & Amort.	0.1	0.1	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.2	0.2	0.2	0.2	0.2
Loss on disposal of plant and equipment	0.0	0.3	0.1	(0.1)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Stock-Based Compensation	0.9	1.2	0.4	0.5	0.5	0.6	1.9	0.6	0.7	0.8	0.8	2.9	4.3	6.2	9.1	13.4
Change in Acc. Receivable	0.3	0.0	0.0	0.0	(0.0)	(0.0)	(0.0)	(0.2)	(0.2)	(0.2)	(0.2)	(0.8)	0.2	(0.5)	(2.8)	(4.2)
Change in Inventory	0.0	0.0	0.0	0.0	(0.0)	(0.0)	(0.0)	(0.1)	(0.1)	(0.1)	(0.1)	(0.2)	(0.5)	(0.5)	(2.3)	(2.1)
Change in Other Current Assets	(0.2)	0.0	(0.2)	0.0	0.7	(0.0)	0.5	(0.2)	(0.1)	(0.2)	(0.1)	(0.6)	(0.7)	0.5	(1.8)	(2.4)
Change in Accounts Payable and Accrued Expenses	2.0	(0.8)	(0.1)	0.3	(2.2)	0.3	(1.7)	1.6	1.3	0.8	0.4	4.2	0.3	1.1	7.9	10.3
Cash flow from Operations	(\$13.1)	(\$13.1)	(\$4.1)	(\$3.5)	(\$6.3)	(\$4.5)	(\$18.4)	(\$3.1)	(\$4.0)	(\$4.4)	(\$4.6)	(\$16.1)	(\$19.0)	(\$9.9)	(\$1.1)	\$14.4
·																
Capital Expenditure	(0.5)	(0.2)	(0.0)	(0.0)	(0.1)	(0.1)	(0.2)	(0.1)	(0.1)	(0.1)	(0.1)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)
Cash flow from Investing	(\$0.5)	(\$0.2)	(\$0.0)	(\$0.0)	(\$0.1)	(\$0.1)	(\$0.2)	(\$0.1)	(\$0.1)	(\$0.1)	(\$0.1)	(\$0.4)	(\$0.4)	(\$0.4)	(\$0.4)	(\$0.4)
Issuance of Common Stock	7.6	20.8	0.9	14.0	0.0	0.0	14.9	0.0	0.0	30.0	0.0	30.0	0.0	20.0	0.0	0.0
Cash flow from Financing	\$7.6	\$20.8	\$0.9	\$14.0	\$0.0	\$0.0	\$14.9	\$0.0	\$0.0	\$30.0	\$0.0	\$30.0	\$0.0	\$20.0	\$0.0	\$0.0
Foreign Exchange Rate Adj.	0.1	0.1	(0.0)	(0.0)	0.0	0.0	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net change in cash balance	(\$5.8)	\$7.7	(\$3.3)	\$10.6	(\$6.4)	(\$4.7)	(\$3.7)	(\$3.2)	(\$4.1)	\$25.5	(\$4.8)	\$13.4	(\$19.5)	\$9.6	(\$1.5)	\$13.9
Cash balance, BoP	\$12.4	\$6.6	\$14.2	\$11.0	\$21.5	\$15.1	\$14.2	\$10.5	\$7.2	\$3.2	\$28.7	\$10.5	\$23.9	\$4.5	\$14.1	\$12.6
Cash balance, EoP	\$6.6	\$14.2	\$11.0	\$21.5	\$15.1	\$10.5	\$10.5	\$7.2	\$3.2	\$28.7	\$23.9	\$23.9	\$4.5	\$14.1	\$12.6	\$26.5
Cash flow from Operations	(\$13.1)	(\$13.1)	(\$4.1)	(\$3.5)	(\$6.3)	(\$4.5)	(\$18.4)	(\$3.1)	(\$4.0)	(\$4.4)	(\$4.6)	(\$16.1)	(\$19.0)	(\$9.9)	(\$1.1)	\$14.4
Less: Capital Expenditures	(0.5)	(0.2)	(0.0)	(0.0)	(0.1)	(0.1)	(0.2)	(0.1)	(0.1)	(0.1)	(0.1)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)
Free Cash Flow	(\$13.5)	(\$13.2)	(\$4.1)	(\$3.5)	(\$6.4)	(\$4.7)	(\$18.6)	(\$3.2)	(\$4.1)	(\$4.5)	(\$4.8)	(\$16.6)	(\$19.5)	(\$10.4)	(\$1.5)	\$13.9
Free Cash Flow Per Share	(\$2.49)	(\$1.87)	(\$0.44)	(\$0.29)	(\$0.53)	(\$0.38)	(\$1.64)	(\$0.26)	(\$0.33)	(\$0.26)	(\$0.28)	(\$1.12)	(\$1.10)	(\$0.49)	(\$0.07)	\$0.63

Source: Cowen and Company estimates; Company filings and transcripts

SUNSHINE HEART BALANCE SHEET	2011	2,012	1Q13	2Q13	3Q13E	4Q13E	2013E	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E
Assets																
Cash and Equivalents	\$6.6	\$14.2	\$11.0	\$21.5	\$15.1	\$10.5	\$10.5	\$7.2	\$3.2	\$28.7	\$23.9	\$23.9	\$4.5	\$14.1	\$12.6	\$26.5
Accounts Receivable	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.4	0.6	0.8	0.8	0.6	1.0	3.8	8.0
Inventories	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.2	0.3	0.3	0.7	1.2	3.5	5.6
Other Current Assets	0.3	0.3	0.5	0.7	0.0	0.0	0.0	0.2	0.4	0.5	0.6	0.6	1.4	0.9	2.7	5.1
Total Current Assets	\$6.9	\$14.6	\$11.5	\$22.2	\$15.2	\$10.6	\$10.6	\$7.8	\$4.1	\$30.0	\$25.6	\$25.6	\$7.1	\$17.2	\$22.6	\$45.3
																1
Property, Plant and Equipment	0.5	0.5	0.4	0.4	0.5	0.5	0.5	0.6	0.7	0.7	0.8	0.8	1.1	1.3	1.6	1.8
Total Assets	\$7.4	\$15.0	\$11.9	\$22.6	\$15.7	\$11.1	\$11.1	\$8.4	\$4.8	\$30.8	\$26.4	\$26.4	\$8.2	\$18.5	\$24.2	\$47.2
Liabilities & Equity																1
Accounts Payable	1.9	1.2	1.6	1.3	0.0	0.2	0.2	1.2	2.0	2.5	2.9	2.9	2.3	4.1	8.4	14.6
Accrued Expenses and Other	1.0	0.9	0.4	0.9	0.0	0.1	0.1	0.7	1.2	1.5	1.6	1.6	2.5	1.8	5.4	9.5
Total Current Liabilities	\$2.8	\$2.1	\$2.0	\$2.3	\$0.1	\$0.3	\$0.3	\$1.9	\$3.2	\$4.1	\$4.5	\$4.5	\$4.8	\$5.9	\$13.8	\$24.1
																1
Long-Term Debt and Other	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Liabilities	\$2.8	\$2.1	\$2.0	\$2.3	\$0.1	\$0.3	\$0.3	\$1.9	\$3.2	\$4.1	\$4.5	\$4.5	\$4.8	\$5.9	\$13.8	\$24.1
Stockholder Equity	4.6	12.9	9.9	20.4	15.6	10.8	10.8	6.5	1.5	26.7	21.9	21.9	3.4	12.7	10.4	23.0
Total Liabilities & Shareholders' Equity	\$7.4	\$15.0	\$11.9	\$22.6	\$15.7	\$11.1	\$11.1	\$8.4	\$4.8	\$30.8	\$26.4	\$26.4	\$8.2	\$18.5	\$24.2	\$47.2

Source: Cowen and Company.



# Valuation Methodology & Investment Risks

## **Valuation Methodology**

## Medical Supplies & Devices:

Our valuation methodology is primarily based on current year and forward year EV/Sales and EV/EBITDA multiples, as well as current year and forward P/E multiples, total return/PE ratio, market cap/free cash flow metrics, and dividend yield comps.

## **Investment Risks**

## Cardiovascular:

(1) continued utilization pressure in the U.S. as Accountable Care Organizations play a bigger role in health care delivery; (2) competitive dynamics globally; (3) potential regulatory delays, rejections, or failures of devices in clinical trials; (4) economic sensitivity, pricing pressures and/or weakening consumer demand in developed markets; (5) economic and/or political uncertainty in emerging markets; (6) intellectual property challenges.

## **Company Specific Risks**

(1) slow enrollment in both the U.S. pivotal trial and European post marketing trial (2) future competitive dynamics globally; (3) potential regulatory delays, rejections, or failures of devices in clinical trials; (4) delay in European C-Pulse adoption trends.

# EQUITY RESEARCH

## Addendum

#### STOCKS MENTIONED IN IMPORTANT DISCLOSURES

Ticker	Company Name
SSH	Sunshine Heart

## **Analyst Certification**

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## **COWEN AND COMPANY RATING DEFINITIONS**

Cowen and Company Rating System effective May 25, 2013

Outperform (1): The stock is expected to achieve a total positive return of at least 15% over the next 12 months

Market Perform (2): The stock is expected to have a total return that falls between the parameters of an Outperform and Underperform over the next 12 months

Underperform (3): Stock is expected to achieve a total negative return of at least 10% over the next 12 months

**Assumption:** The expected total return calculation includes anticipated dividend yield

Cowen and Company Rating System until May 25, 2013

Outperform (1): Stock expected to outperform the S&P 500

**Neutral (2):** Stock expected to perform in line with the S&P 500

**Underperform (3):** Stock expected to underperform the S&P 500

Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period

Cowen Securities, formerly known as Dahlman Rose & Company, Rating System until May 25, 2013

**Buy** – The fundamentals/valuations of the subject company are improving and the investment return is expected to be 5 to 15 percentage points higher than the general market return

**Sell** – The fundamentals/valuations of the subject company are deteriorating and the investment return is expected to be 5 to 15 percentage points lower than the general market return

**Hold** – The fundamentals/valuations of the subject company are neither improving nor deteriorating and the investment return is expected to be in line with the general market return

### **COWEN AND COMPANY RATING ALLOCATION**

Distribution of Ratings/Investment Banking Services (IB) as of 06/30/13

Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	380	58.37%	48	12.63%
Hold (b)	247	37.94%	2	0.81%
Sell (c)	24	3.68%	1	4.17%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions.

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## **Legend for Price Chart:**

I = Initation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | T = Terminated Coverage | \$xx = Price Target | NA = Not Available