Sunshine Heart

SSH : NASDAQ : US$6.26

BUY

Target: US$12.50

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COMPANY STATISTICS:

52-week Range:	2.50 - 22.90
Market Cap (M):	US$57.8
Avg. Daily Vol. (000s):	196.0

EARNINGS SUMMARY:

FYE Dec		2011A	2012E	2013E
Revenue:		0.0	0.0	3.4
EPS:		(2.98)	(1.91)	(2.01)
Revenue:	Q1	0.0	0.0A	-
	Q2	0.0	0.0A	-
	Q3	0.0	0.0A	-
	Q4	0.0	0.0	-
Total		0.0	0.0	3.4
EPS:	Q1	(0.55)	(0.66)A	-
	Q2	(0.68)	(0.42)A	-
	Q3	(0.84)	(0.42)A	-
	Q4	(0.87)	(0.44)	-
Total		(2.98)	(1.91)	(2.01)

SHARE PRICE PERFORMANCE:

Source: Interactive Data Corporation

COMPANY DESCRIPTION:

Sunshine Heart develops, manufactures and markets C-Pulse, a minimally invasive assist device to treat Class III heart failure. C-Pulse, which received C.E. Mark in July 2012, is based on the proven concept of intra-aortic balloon pump (IABP) technology. Unlike IABPs, C-Pulse does not come in contact with circulating blood, which should negate thrombus formation and stroke risk. The company is listed on the Australian exchange and NASDAQ.

All amounts in US$ unless otherwise noted.

Life Sciences -- Biomedical Devices and Services

MULTIPLE MILESTONES ACHIEVED; CATALYSTS ON HORIZON; BUY

Investment recommendation

Sunshine Heart achieved several milestones in Q3, including C.E. Mark approval of C-Pulse, conditional FDA approval to begin the C-Pulse pivotal trial, and a $21M financing. Other important events include Dr. Bill Abraham signing on as the PI for the C-Pulse pivotal (which he opined at TCT was poised for success), presentation of 12-month feasibility data at TCT, and Dr. Aggarwal leading training sessions at five German centers. As for the Q3 financial results, we were glad to see OpEx lower than expected. We reiterate our BUY rating and $12.50 price target.

Investment highlights

- **LPS better than expected.** Q3 loss per share was $(0.42) vs. our $(0.46) estimate, driven by OpEx of $3.3M vs. our $3.6M estimate.
- **Progress in Europe could portend upside to our estimates.** Training at five German centers is commencing now, and one center already has at least two patients selected. Our model does not include commercial implants in 2012, reflecting conservatism.
- **Significant catalyst on the horizon:** SSH expects FDA to grant unconditional approval for C-Pulse pivotal trial in Q4; enrollment will commence immediately thereafter. Importantly, reimbursement will be available for clinical C-Pulse implants via DRG1.
- **At the recent TCT meeting, investigators opined they expect pivotal trial enrollment to be brisk** – i.e. at least 0.5 patients per site per month at 30 centers (Dr. Abraham expects 40 sites to ultimately enroll in the trial). Attendance at Dr. Abraham's presentation – and at the company's analyst meeting – was high, and interest level in C-Pulse was/is palpable among clinicians and investors alike, in our opinion.

DISCUSSION

Q3 results in brief

OpEx totaled $3.3M, which compares to our $3.6M estimate and $4.7M in the year-ago period. SGA expense of $1.5M was relatively flat Y/Y and compares to our $1.7M estimate. R&D was in-line with our estimate at $1.8M but down significantly Y/Y, as the year-ago quarter included costs associated with the C-Pulse feasibility study and other development projects. Net LPS was $(0.42) vs. our $(0.46) estimate. SSH ended Q3 with cash/equivalents of $17.4M.

Europe

According to our check, training of five German centers (led by Dr. Sanjeev Aggarwal who was involved in C-Pulse's feasibility) will begin this month. In addition, one center has two patients already slated for C-Pulse implant, which portends upside to our model (we currently assume no commercial sales in 2012). SSH shortly plans to announce which centers will participate in its EU post-approval marketing study, which could begin in Q4.

US

TCT. Dr. Bill Abraham presented 12-month data from C-Pulse's feasibility study (n=20) at TCT in October. Attendance at his presentation – and at the company's analyst meeting the next day – was high, and interest level in C-Pulse was/is palpable among clinicians and investors alike, in our opinion. At 6 months, C-Pulse produced a statistically significant and clinically meaningful improvement in QoL, NYHA Class, and 6-minute walk. C-Pulse patients sustained or improved on all metrics at 12 months. One patient had an improvement of three functional NYHA classes, two patients saw an improvement of 2 classes, and seven patients reported an improvement of at least of class. At 12 months, C-Pulse patients improved 46 meters on the 6-minute walk test vs. only 20-25 meters for control patients. C-Pulse patients showed a 25-point improvement on QoL metrics (as context, most CRT patients see a QoL improvement of 8-9 points. While there were a few non-responders in the feasibility trial, according to Dr. Abraham these were patients who were not compliant with the device. On the other hand, there were also a few super-responders, in whom C-Pulse actually positively altered the substrate of the disease. Investigators told us at TCT that super-responder patients are more likely to be ischemic and male. What's more, no patients on C-Pulse experienced up-titration of drugs. As for compliance, Dr. Abraham told us investigators will take a more rigorous approach to patient compliance in the pivotal trial in order to achieve the 80% benchmark; he is hopeful they will achieve 90-95% ultimately. If successful on the compliance front, we believe it would bode well for C-Pulse to achieve its primary endpoint, given what we know about the correlation of outcomes-to-compliance in the feasibility trial (and just basic common sense).

C-Pulse pivotal trial. As a reminder, FDA granted conditional approval of Sunshine Heart's C-Pulse IDE/pivotal trial, which will enroll 388 Class III/IV HF patients randomized to either C-Pulse or OMT, in September. Renowned HF specialist, Bill Abraham/The Ohio State University, will be the P.I. for the trial. We believe patients in the control arm will be able to receive best alternative care (drug or device), which we view this positively, as it removes a potential gating factor to patient enrolment, in our view. FDA has already

cleared the use of the next-generation, C-Pulse in the pivotal. This single-unit driver is about half the size of – and lighter and quieter than -- the original driver.

Even with the ability of control patients to receive LVADs, investigators believe the trial is poised to show favorable outcomes versus control, as the primary endpoint will be the "reduction in worsening heart failure events leading to hospitalization, advanced heart failure therapies and heart failure related mortality." According to Dr. Abraham at TCT, these Class 3 HF patients typically have 2% re-hospitalizations at 1-day; 25% at 1 month and 50% at 6-months. What's more, 5-year mortality rates for Class III HF patients range from 15% to 50%. Notably, the primary endpoint reflects HF-related mortality (instead of all-cause mortality). We view endpoint positively (relevant but also easier to show statistical significance with less risk for "chance" to trip up the comparison). The trial is powered to show a 30% reduction in HF hospitalizations/mortality at 12 months in the C-Pulse arm vs. control, which we think envisions a 60% freedom rate from the primary endpoint for C-Pulse patients vs. 41% for control patients. It's possible that C-Pulse will have to show a lower relative reduction; we will wait for unconditional approval for additional details.

The company said at TCT that it is working wok with FDA on minor points, including changes to informed consent and investigator agreements, labeling updates, and a protocol for the clinical events committee. SSH expects to receive unconditional approval from FDA any day now, after which it will begin enrollment imminently. Separately, we note that Sunshine Heart added to its regulatory team during Q3, hiring a person from a large ICD manufacturer, in Q3. We view this positively, as the new hire has experience recruiting and managing large cardiac device trials. The company's regulatory team is currently in discussions with several hospitals to determine the first centers to recruit patients for the trial.

Will patients go for C-Pulse? At TCT, Dr. Abraham was asked at the analyst meeting about patients' willingness to have this type of device. He said that 8 or 9out of 10 patients who they approach about the C-Pulse device say yes. While these patients are described as ambulatory, Dr. Abraham said they cannot walk a block or climb a flight of stairs without being out of breath.

According to our checks, given the dearth of successful therapies, many Class III HF patients are essentially – and deteriorating – to the point that they are sick enough to be reconsidered for a transplant and/or LVAD. Recall that fewer than 30% of patients do not respond to cardiac resynchronization therapy (CRT). Because of this, we think it's possible trial enrollment could go faster than SSH's expectations (2 ½ years). We continue to model for trial enrollment to be completed in Q4:14. Of note, FDA granted Sunshine Heart the ability to receive revenue for C-Pulse devices used in the trial, which means the company could begin recording sales this quarter (i.e., ahead of our expectations). We're maintaining our expectation for sales to begin in early 2013, however, as it can take 3-4 months for centers to receive IRB approval prior to enrolling patients.

INVESTMENT THESIS

We reiterate our BUY rating on SSH. We believe Sunshine Heart offers investors the opportunity to participate in a nascent growth company that is commercializing potentially disruptive technology for treatment of heart failure. We view the company's C-Pulse as a novel and promising treatment option for Class III HF patients. We think there is a strong

probability C-Pulse will successfully achieve the endpoints of its pivotal trial. We also expect the trial to study C-Pulse's ability to improve patients' Quality of Life (QoL) without introducing additional adverse events (e.g. stroke, thrombosis).

We estimate Sunshine Heart's C-Pulse system could address a very large patient population approximating 500,000 in the US and 570,000 in Europe. Assuming a conservative 10% "sweet spot" penetration level, this translates into a worldwide market opportunity approaching $5 billion. Notably, the majority of Class III heart failure patients have few if any viable therapeutic options. What's more, only a relatively small portion of these patients (i.e., 20-30%) are practical candidates for bi-ventricular pacing (i.e., CRT therapy), and studies suggest approximately 30% of these patients do not respond to CRT therapy, in which case their HF progresses. We believe the majority of Class II HF patients (i.e. 70-80%) would benefit from a non-rhythm-based therapeutic approach, such as C-Pulse.

VALUATION

Our $12.50 target assumes a 20% discount rate (on 7x estimated 2015 sales).

Figure 1: Valuation analysis

Sunshine Heart Valuation - Q3:2012E

CG Revenue Est.	2012	2013E	2014E	2015E
Total	$0.0	$3.4	$6.4	$20.2

Assumptions	
Years to discount (back to 2013-end)	2
Net Cash	18.0
Shares Outstanding (mm)	9.2

Terminal value			
Disc. Rate	6.5x	7.0x	7.5x
15.0%	$117	$125	$133
20.0%	$109	$116	$123
25.0%	$102	$108	$115

Value/share			
Disc. Rate	6.5x	7.0x	7.5x
15.0%	$12.71	$13.54	$14.36
20.0%	$11.83	$12.59	$13.35
25.0%	$11.06	$11.76	$12.46

Source: Canaccord Genuity estimates

INVESTMENT THESIS POINTS

- **$5 billion potential market opportunity for C-Pulse with few potential competitors and high barriers to entry.** There are an estimated 5.8 million Americans and 6.5 million Europeans with heart failure, 25-30% of which have Class III HF. Excluding patients who 1) may receive CRT therapy, and/or 2) have A-Fib, we estimate the potential patient population for C-Pulse could be at least 1 million patients in the US and Europe combined (over 500,000 patients in each geography). Our C-Pulse market opportunity model focuses on 10% of this patient population to derive a target "sweet spot" opportunity of approximately 100,000 patients, representing a market opportunity of nearly $5 billion in the US and Europe alone.
- **Proprietary, differentiated technology.** C-Pulse, which is implanted via minimally invasive surgical techniques, is based on the proven concept of counter-pulsation that has been used in intra-aortic balloon pumps (IABP) for nearly a half century. However,

whereas IABPs are positioned within the path of the patient's circulating blood (creating the risk of thrombus formation, thus ischemic emboli), C-Pulse is implanted outside the patient's bloodstream with a proprietary cuff that is attached to the outside of the patient's aorta. Practitioners have told us that the importance of this feature cannot be overstated; since C-Pulse does not come in contact with circulating blood, it negates the risk of stroke related to device thrombus. What's more, C-Pulse is differentiated from other treatments for Class III HF by its "plumbing" approach to augment circulation as opposed to the "electrical" approach employed by CRT therapy. Based on our due diligence, we estimate such "plumbing" is applicable to the majority of Class III heart failure patients.

- **Feasibility data give us optimism about C-Pulse's ability to show superiority in a large pivotal trial.** With renowned physicians Bill Abraham/The Ohio State University and Dr. Patrick McCarthy/Northwestern acting as co-PIs, the C-Pulse feasibility study enrolled 20 patients, of whom 18 had Class III HF and two had Class IV HF. At baseline, the average NYHA classification was 3.1 out of 4, which improved to 2.2 at six months and 1.9 at 12 months. Although only a small number of patients were involved in the feasibility study, we were impressed that, on average, patients improved to the point where their HF was considered "mild." Also noteworthy, patients who had been taking inotropes prior to C-Pulse implantation were able to discontinue this therapy. Diuretic usage was also reduced or stopped completely in 11 patients. In other words, even routine HF medication could be lowered or discontinued in over half of patients receiving C-Pulse. Importantly, C-Pulse patients did not experience any stroke events or instances of major bleeding. There was one death following multiple operations for a sternal infection that was unrelated to the device. Also, there were nine major infections, eight of which were related to the driveline, to which improvements have been made by the company; the improved device will be a part of the pivotal trial, according to our research. The company expects the 12-month follow-up data from the feasibility trial to be presented at a major medical meeting in Q4/12, and we anticipate publication in a major journal within the next 12 months – both of which could be catalysts for the stock, in our estimation.
- **European commercialization about to begin.** C-Pulse received C.E. Mark approval in July 2012, and Sunshine Heart plans to execute a measured roll out of C-Pulse in up to six centers in Germany and Italy. Our sources indicate that Leipzig and Berlin Heart, both of which are highly regarded HF and structural heart centers, will be two of the first sites to use C-Pulse commercially, which we view as a positive endorsement of the C-Pulse therapy. Sunshine Heart has already trained two distributors, who are equipped with sales/training materials. Importantly, the company plans to initiate a 50-patient post-approval study that will include an economic endpoint. We conservatively assume enrollment will begin in early 2013 and be completed in mid-2014. At this time, we do not model Sunshine Heart to build a direct sales force to market C-Pulse in Europe. Rather, we anticipate the company could sign a distribution agreement with a major medical device company some time over the next 12-18 months.
- **Reimbursement environment favors treatments like C-Pulse, in our view.** According to a MedPAC report to Congress in June 2007, the cost of HF-related readmissions within 30 days of discharge amounted to over $15 billion in costs to Medicare at that time. In 2009, 25% of heart failure patients had HF-related readmissions within 30 days of

discharge, according to data from the Healthcare Cost & Utilization Project (HCUP). Starting October 2012, hospitals will see cuts to their Medicare reimbursement if their HF-related readmission rate at 30 days is higher than the rate mandated by Medicare. The penalty will be 1% of the HF-related reimbursement in federal F2013, which will increase to 2% in F2014 and 3% in F2015. Although centers have augmented efforts to coordinate care with other healthcare practitioners and facilities (e.g., nursing homes) and increased their patient education efforts at discharge, these efforts may not be sufficient to reduce 30-day readmission rates, particularly for symptomatic Class III patients, in our estimation. Consequently, we believe hospitals could become increasingly interested to treatments, such as C-Pulse, that hold the potential to improve patients' functional NYHA classification and quality of life (QoL), and thereby reduce re-hospitalization rates.

- **Seasoned management team.** We think Sunshine Heart employs an experienced management team, led by CEO David Rosa. We think the SSH team has the ability to execute successfully on its European commercialization strategy and oversee the large randomized controlled pivotal trial in the US. Mr. Rosa was previously VP of Global Marketing for St. Jude Medical's cardiac surgery and cardiology products, where he launched 27 new products during his tenure. He also held executive positions at A-Med, which was a developer of a percutaneous VAD system. The team also includes Debra Kridner, VP of Clinical Research & Regulatory Affairs, who has been involved in medical device clinical trials for over 30 years, including regulatory positions at St. Jude and Medtronic. In addition, we have received positive feedback on other members of the Sunshine Heart team, including Jim Yearick, VP of Marketing & Sales, who previously held executive sales & marketing roles at Medtronic, Boston Scientific, and Genzyme, as well as CFO Jeff Mathiesen.

Figure 2: Income Statement

($ in millions, except per share data)

	CY 2010	2011 Mar	2011 Jun	2011 Sep	2011 Dec	CY 2011	2012E Mar	2012E Jun	2012E Sep	2012E DecE	CY 2012E	CY 2013E	CY 2014E	CY 2015E
Total Revenue	**0.4**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**3.4**	**6.4**	**20.2**
Cost of sales	-	-	-	-	-	-	-	-			-	2.5	3.3	8.5
Gross Profit	0.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.9	3.1	11.7
S G & A	2.6	0.6	1.2	1.4	2.1	5.4	1.9	1.6	1.5	1.9	6.9	9.5	10.4	11.5
R&D	6.2	2.3	2.4	3.3	3.3	11.2	2.2	1.8	1.8	2.2	8.0	11.5	12.7	15.0
Total Operating Expenses	8.8	2.9	3.6	4.7	5.4	16.6	4.1	3.4	3.3	4.1	14.9	21.0	23.1	26.5
Operating Income	**(8.4)**	**(2.9)**	**(3.6)**	**(4.7)**	**(5.4)**	**(16.6)**	**(4.1)**	**(3.4)**	**(3.3)**	**(4.1)**	**(14.9)**	**(20.1)**	**(20.0)**	**(14.8)**
Net other Income/(Expense)	0.2	0.1	0.1	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pretax Income	(8.3)	(2.8)	(3.5)	(4.7)	(5.4)	(16.3)	(4.1)	(3.4)	(3.3)	(4.1)	(14.8)	(20.1)	(19.9)	(14.7)
Income Tax	(0.7)	-	-	-	(0.1)	(0.1)	-	(0.7)	-	-	(0.7)	-	-	-
Tax Rate	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Net Income (Pro Forma)	**(7.6)**	**(2.8)**	**(3.472)**	**(4.7)**	**(5.2)**	**(16.2)**	**(4.1)**	**(2.6)**	**(3.3)**	**(4.1)**	**(14.1)**	**(20.1)**	**(19.9)**	**(14.7)**
Non-recurring expenses (taxed)						-					-			
Net Income (GAAP)	(7.6)	(2.82)	(3.47)	(4.6720)	(5.235)	(16.2)	(4.1)	(2.6)	(3.3)	(4.1)	(14.1)	(20.1)	(19.9)	(14.7)
Shares Outstanding (mm)	2.9	5.1	5.1	5.6	6.0	5.4	6.2	6.3	7.8	9.2	7.4	10.0	13.5	14.4
EPS (Pro Forma)	**$ (2.63)**	**$ (0.55)**	**$ (0.68)**	**$ (0.84)**	**$ (0.87)**	**$ (2.98)**	**$ (0.66)**	**$ (0.42)**	**$ (0.42)**	**$ (0.44)**	**$ (1.91)**	**$ (2.01)**	**$ (1.48)**	**$ (1.02)**
EPS (GAAP)	(2.63)	(0.55)	(0.68)	(0.84)	(0.87)	(2.98)	(0.66)	(0.42)	(0.42)	(0.44)	(1.91)	(2.01)	(1.48)	(1.02)
Margin Analysis:														
Gross Margin	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	26.0%	48.5%	58.0%
SG&A as a % of Sales	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
R&D as a % of Sales	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Growth:														
Revenue Growth (Y/Y)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	90.8%	213.4%
Cost Growth (Y/Y)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	32.8%	155.6%
Op. Exp Growth (Y/Y)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	41.3%	10.0%	14.7%

Source: CG estimates and company reports

Figure 3: Revenue Model

($ in millions, except per share data)

		2013E Q1	2013E Q2	2013E Q3	2013E Q4	2013E	2014E Q1	2014E Q2	2014E Q3	2014E Q4	2014E	2015E Q1	2015E Q2	2015E Q3	2015E Q4	2015E
United States																
US	centers	6	12	22	29	**29**	30	30	30	30	**30**	30	30	30	30	**30**
	util/center/mo	0.2	0.4	0.5	0.5	**n/a**	0.4	0.4	0.4	0.1	**n/a**	0.6	0.6	0.6	0.6	**n/a**
Total Units		4	13	31	34	**81**	32	36	38	7	**112**	51	52	54	56	**213**
ASP		$55,000	$55,000	$55,000	$55,000	**$55,000**	$55,000	$55,000	$55,000	$55,000	**$55,000**	$55,000	$55,000	$55,000	$55,000	**$55,000**
% units reimbursed		65%	68%	70%	71%	**69%**	71%	71%	72%	73%	**72%**	74%	75%	75%	75%	**75%**
US Revenue ($M)		**0.13**	**0.50**	**1.19**	**1.32**	**3.14**	**1.25**	**1.40**	**1.50**	**0.26**	**4.42**	**2.09**	**2.15**	**2.23**	**2.30**	**8.77**
OUS																
Germany	centers	2	2	2	4	**4**	5	6	8	9	**9**	10	12	12	13	**13**
	util/center/mo	0.3	0.3	0.3	0.3	**n/a**	0.3	0.3	0.3	0.4	**n/a**	0.7	0.8	0.9	0.9	**n/a**
	units	2	2	2	4	**10**	4	6	9	15	**34**	20	27	32	37	**116**
Italy	centers	1	1	2	3	**3**	5	5	5	5	**5**	5	6	6	6	**6**
	util/center/mo	0.1	0.2	0.2	0.3	**n/a**	0.2	0.2	0.3	0.3	**n/a**	0.4	0.5	0.5	0.7	**n/a**
	units	0	1	2	3	**5**	3	3	3	6	**16**	6	9	9	12	**36**
Other Euro	centers	-	-	-	-	**0**	-	-	2	6	**6**	7	8	10	12	**12**
	util/center/mo					**n/a**					**n/a**	0.4	0.4	0.5	0.6	**n/a**
	units	-	-	-	-	**0**	-	-	1	9	**9**	8	11	16	23	**58**
Canada	centers	1	1	1	2	**2**	2	2	2	2	**2**	3	3	3	3	**3**
	util/center/mo	0.3	0.3	0.3	0.3	**n/a**	0.3	0.3	0.3	0.3	**n/a**	0.4	0.4	0.4	0.4	**n/a**
	units	1	1	1	2	**4**	2	2	2	2	**7**	3	4	4	4	**14**
Total # OUS centers		**4**	**4**	**6**	**9**	**9**	**12**	**13**	**17**	**24**	**24**	**25**	**29**	**31**	**34**	**34**
Avg. Util/center/mo		0.2	0.3	0.3	0.3		0.3	0.3	0.3	0.4		0.5	0.6	0.7	0.7	
Total units		**3**	**4**	**5**	**8**	**19**	**10**	**11**	**14**	**23**	**57**	**38**	**51**	**61**	**75**	**224**
ASP		$49,000	$49,000	$49,000	$49,000	**$49,000**	$49,000	$49,000	$50,000	$50,000	**$49,500**	$51,000	$51,000	$51,000	$51,000	**$51,000**
% units reimbursed		25%	25%	25%	25%	**25%**	50%	60%	70%	85%	**66%**	100%	100%	100%	100%	**100%**
OUS Revenue ($M)		**0.03**	**0.04**	**0.06**	**0.10**	**0.24**	**0.23**	**0.33**	**0.48**	**0.99**	**2.03**	**1.92**	**2.58**	**3.10**	**3.83**	**11.42**
Worldwide																
Total units		**7**	**17**	**36**	**42**	**101**	**42**	**47**	**51**	**30**	**170**	**89**	**103**	**115**	**131**	**330**
ASP		$52,000	$52,000	$52,000	$52,000	**$52,000**	$52,000	$52,000	$52,500	$52,500	**$52,250**	$52,313	$52,328	$52,332	$52,333	**$52,396**
Total Revenue		**0.17**	**0.55**	**1.25**	**1.41**	**3.38**	**1.49**	**1.73**	**1.97**	**1.25**	**6.44**	**4.01**	**4.73**	**5.33**	**6.13**	**20.19**

Source: CG estimates and company reports

Investment risks

Large, randomized trial must be managed well. The C-Pulse pivotal is a large randomized surgical medical device trial that will require significant skill to manage and oversee, which can be challenging for a small company. Sunshine and the trial investigators will likely need to devote resources to make sure that patients randomized to the C-Pulse cohort are compliant with the trial protocol, i.e., device turned on 80% of the time.

C-Pulse may fail to gain FDA approval. Should C-Pulse fail to gain FDA approval, the company's revenue and earnings potential could be severely impacted.

CRT devices currently "own" the Class III HF market. Medtronic, St. Jude Medical, and Boston Scientific dominate medical device treatment of Class III HF. In addition, Medtronic and Boston Scientific have invested considerable sums to expand labeling for their CRT products to include Class II HF patients. All of these companies have substantial marketing muscle and vast financial resources compared to Sunshine Heart.

The company may need to return to the capital markets. Sunshine Heart may need additional capital to fund its clinical trial and regulatory activities. If the company were to return to the equity market, current shareholders would see dilution.

Limited float. The company's limited float may make it difficult for investors to trade the equity.

APPENDIX: IMPORTANT DISCLOSURES

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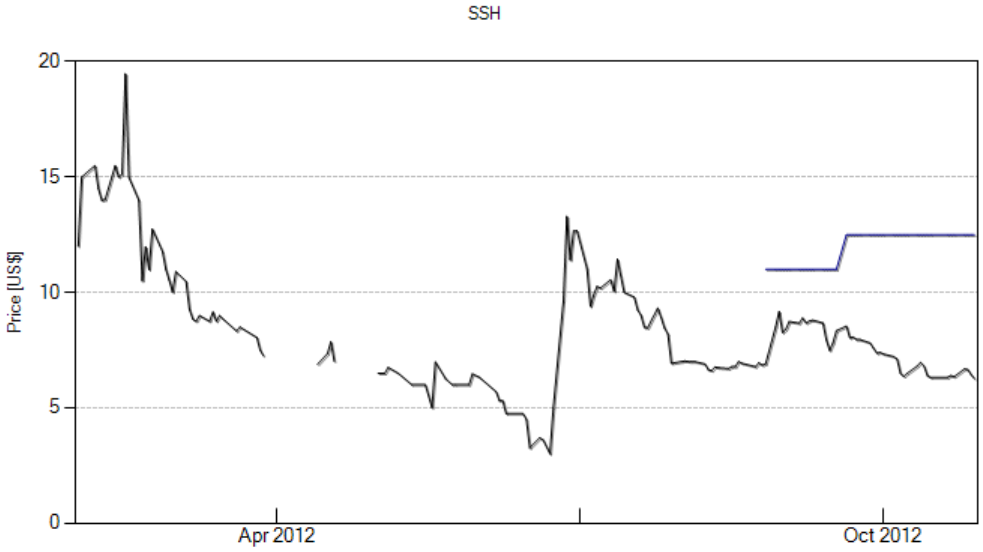
Site Visit: An analyst has not visited Sunshine Heart's material operations.

Price Chart:*



	Date	Analyst	Rating	Target Price		Date	Analyst	Rating	Target Price
1)	09/07/2012	Mills	Buy	11.00	2)	10/01/2012	Mills	Buy	12.50

*Price charts assume event 1 indicates initiation of coverage or the beginning of the measurement period.

Distribution of Ratings:
Global Stock Ratings
(as of 1 October 2012)

	Coverage Universe		IB Clients
Rating	#	%	%
Buy	575	60.7%	31.5%
Speculative Buy	63	6.7%	50.8%
Hold	267	28.2%	13.9%
Sell	34	3.6%	5.9%
	947*	100.0%	

*Total includes stocks that are Under Review

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Company	Disclosure
Sunshine Heart	1A, 2, 3, 5, 7

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