

## Initiating Coverage

## Medical Technology

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## Coverage

Rating	BUY
Price	\$6.36
Price target	\$10.00

## Key Data

52-week range	\$23-\$3
Shares out (M)	8.8
Market cap. (M)	\$56
Enterprise value (M)	\$47.8
ADTV (3 mo avg)	225,823
Short int (% s/o)	1%
Dividend (\$ / %)	NA
Book value/sh	NA
EV/EBITDA	NM

## Fiscal Year: December

	2011	2012E	2013E
Revs (\$M)	Actual	Curr	Curr
Q1	-	0A	0
Q2	-	0A	0
Q3	0	0	0
Q4	0	0	0
FY Revs	0	0	1
P/S (x)	--	--	55.8
EPS (\$)			
Q1	-	(0.66)A	(0.58)
Q2	-	(0.42)A	(0.59)
Q3	(0.85)	(0.45)	(0.56)
Q4	(0.89)	(0.46)	(0.56)
FY EPS	(2.98)	(1.95)	(2.27)
P/E (x)	NM	NM	NM
FY EBIT	(17)	(16)	(25)

## Sunshine Heart

## SSH: Lack of anticoagulation should shine; initiating coverage with a BUY rating and \$10 price target

**We initiate coverage of Sunshine Heart with a BUY rating and \$10 price target.** The C-Pulse pump will target Class III and ambulatory Class IV heart failure (HF). We see Class III as the most compelling, ~\$150B worldwide; 1% penetration would create over \$1B in revenue. C-Pulse's biggest advantage over LVADs is likely that it does not require anticoagulation, which should reduce GI bleeds and hemorrhagic strokes. The lack of anticoagulation is very important if surgeons are going to treat less sick patients who are likely to live with the pump for a long time. We look favorably on the FDA's conditional approval of Sunshine Heart's pivotal trial and we see the feasibility data on QOL and HF improvement as positive.

- **Sunshine Heart will target a very large market with limited other options.** We see Sunshine Heart's Class III HF market at ~\$150B, meaning that 1% penetration in the U.S. and Europe would lead to over \$1B in sales. While there are commercially available device treatments for sicker Class IV heart failure patients, there are few options for Class III patients as the FDA has pushed off trials from competitors. We do not know of any therapies available and reimbursed in the U.S. for those between the drug therapy/ICD/pacer stage of treatment and LVADs. This is where we believe the C-Pulse will fit.
- **The C-Pulse does not require anticoagulation and should significantly reduce hemorrhagic strokes and GI bleeds, morbidities associated with LVADs.** The biggest potential advantage vs. existing pumps is that C-Pulse does not contact the bloodstream and should not require anticoagulation. While LVADs save lives, their contact with blood often leads to thrombosis, stroke, hemolysis, bleeding, or sepsis. C-Pulse's most important advantage should be a reduction in GI bleeds and hemorrhagic strokes. This is key in long-term support of less sick patients. Serious infections are also less likely.
- **The FDA has given Sunshine Heart conditional approval to start its pivotal trial.** While the FDA could change the trial design prior to signing off completely, it seems unlikely that major changes will be made. We believe that Sunshine Heart and the FDA have compromised on the trial design and the planned trial seems reasonable, and will probably be enrollable over ~30 months with a 12-month safety follow-up. We had been worried that the FDA might require mortality as the sole primary endpoint, which could have led to a 3-5-year follow-up period. We are pleased to see that this is likely not the case.

## SEE PAGES 19-20 FOR IMPORTANT DISCLOSURES AND ANALYST CERTIFICATION

Effective May 10, 2005, Lazard Frères & Co. LLC ("LF&Co.") transferred its capital markets business (which includes equity research, syndicate, sales and trading) to a new privately-held company, Lazard Capital Markets LLC, which is neither owned nor controlled by LF&Co. LF&Co., which is part of publicly-traded Lazard Ltd, has retained, among other things, its investment banking business (including its mergers and acquisitions and financial restructuring practices).

**Investment Thesis**

The C-Pulse pump will target Class III and ambulatory Class IV heart failure (HF), a very large market with limited other options. We see Class III as the most compelling and see this opportunity as ~\$150B worldwide; 1% penetration would create over \$1B in revenue. C-Pulse's biggest advantage over left ventricular assist devices (LVADs) is likely that it does not require anticoagulation, which should reduce GI bleeds and hemorrhagic strokes. The lack of anticoagulation is very important if surgeons are going to treat less sick patients who are likely to live with the pump for a long time. We look favorably on the FDA's conditional approval of the company's pivotal trial and we see the feasibility data on QOL and HF improvement as positive.



**Company Description**

Sunshine Heart, Inc. is an early-stage medical device company developing innovative technologies for cardiac and coronary disease. The company is focused on the commercialization of their C-Pulse Heart Assist System, an implantable, non-blood contacting, heart assist therapy for the treatment of moderate-to-severe heart failure. Sunshine Heart is headquartered in Eden Prairie, Minnesota.

## REASONS TO BUY

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### **Sunshine Heart will target a very large market with limited other options.**

We see the Class III heart failure market as ~\$150B for Sunshine Heart, meaning that even 1% penetration in the U.S. and Europe would lead to over \$1B in sales. While there are commercially available device treatments for sicker New York Heart Association Class IV heart failure patients, there are few options for Class III patients as the FDA has pushed off potential trials from competitors and CMS has chosen not to reimburse left ventricular assist devices (LVADs) in Class III patients. Thoratec's HeartMate II LVAD has FDA approval for the destination therapy patient population, which includes NYHA Class IIIB and Class IV heart failure patients, but CMS does not reimburse for Class IIIB patients. HeartWare tried to run a Class III trial called Revive-It but the FDA blocked this trial. Patients who would be appropriate for the C-Pulse System have usually been on multiple medications, including statins, ACE-inhibitors, inotropes, diuretics, beta-blockers, and antiarrhythmics. Often, they have had devices implanted to help relieve their symptoms, including an ICD and/or a pacemaker. Despite this, we do not know of any commercial therapies available and reimbursed in the U.S. for those in between the drug therapy/ICD/pacer stage and LVADs. This is where we believe the C-Pulse will fit.

### **The C-Pulse System does not require anticoagulation which, should lower risk of bleeding and make the device more appropriate in less sick patients.**

In our opinion, the biggest potential advantage of C-Pulse vs. existing pumps is that it does not contact the bloodstream and thus should not require anticoagulation. There is no chance of the pump clotting, so it is unlikely that doctors will use Coumadin with the device. Other devices for heart failure patients come into contact with the blood flow. LVADs, made by Thoratec and HeartWare, move blood through a pump from the left ventricle to the aorta. While LVAD therapy has helped many patients survive and can relieve heart failure symptoms, the invasive nature of the therapy may also lead to adverse events such as thrombosis, stroke, hemolysis, a bleeding event, or sepsis. In the REMATCH II trial for Thoratec's HeartMate II, a destination therapy patient population was implanted between March 2005 and May 2007. In that trial, bleeding events related to surgery occurred 30% of the time, ischemic stroke was seen in 8% of patients, hemorrhagic stroke in 11% of patients, sepsis in 36%, a VAD-related infection in 35%, and at two years, a 1.5% rate of thrombosis requiring pump exchange. We also know that there are a significant number of GI bleeds in LVAD patients. While data are likely improving with both HMII and HVAD, we believe that, by not needing anticoagulation, Sunshine Heart's C-Pulse should significantly reduce hemorrhagic strokes and GI bleeds. The C-Pulse also is very unlikely to require pump exchange or clotting. If pumps are going to be used in less sick patients, the patients are likely to have the pumps for a long time (3-10 years) and thus not using anticoagulation and not having clotting concerns will be key to long-term low mortality and complication rates.

**C-Pulse may reduce serious infections.** While the C-Pulse had a number of driveline infections in its feasibility trial, the fact that it does not sit in the blood stream means that it is likely much less likely to cause sepsis or severe infection vs. LVADs that contact the circulation. Beyond the fact that C-Pulse should cause far fewer serious infections, over time we expect the driveline to be improved, limiting all infections, and eventually removed using transcatheter energy, which should reduce associated infections to near zero.

**The FDA has given Sunshine Heart's IDE conditional approval – this is very important.** We have followed Sunshine Heart's device for some time and while we have long liked its ability to help with heart function without contacting blood or requiring anticoagulation, we have worried that the FDA might require a larger feasibility trial (since three patients died in the previous one) or might require a hard mortality endpoint and multi-year follow-up for this or any Class III trial, based on the agency's reluctance to sign off on Revive-It. While the exact details of Sunshine Heart's trial are still pending and the agency has not given the official sign-off, the conditional approval and comments management has made are positives. We believe Sunshine Heart wanted a one-year trial that would look at heart failure hospitalizations. We believe the FDA wanted a multi-year trial focusing on mortality. It seems the trial will be a compromise in both the endpoint and length with a combo endpoint of heart failure hospitalization or heart failure-related death. Safety will likely be monitored for 12 months. The trial will be based on events and requires 265 HF-related re-hospitalization and heart failure-related mortality events. Sunshine Heart expects this to take about 2.5 years and that the events will be complete around the end of patient enrollment. We see the FDA's willingness to compromise and the fact the trial is mostly in line with what the company likely requested as positives, but we also note that this trial will likely be a bit longer than had it just been a single-year follow-up trial rather than based on event numbers.

**Early data on improvement of heart failure symptoms and quality of life with the C-Pulse System are encouraging.** In the 20-patient U.S. feasibility trial, participants improved their NYHA Class by an average of 1.1 classes at six months and showed more than a material improvement in quality of life. We give full details of this trial below in the data review section. Notably, one patient improved from Class IV to Class I and was taken off the system. With an increasing emphasis and attention being paid to the expense of heart failure, from frequent rehospitalizations to worsening symptoms and costly treatments like LVAD therapy, we think a device that can slow or possibly even reverse the progression of heart failure would be a timely and marketable innovation. While this trial was far too small to really evaluate mortality, we note that 15% of the patients died before six months, which is concerning.

**Being able to disconnect is important.** With Sunshine Heart's system, a patient can disconnect the device and still function. This allows patients freedom to do things like shower. In less sick Class III patients, we believe this flexibility is important.

**Reimbursement is very likely and will probably be favorable.** Outside of heart transplants, we believe reimbursement for LVADs carries the highest paying DRG and the payments have increased recently. We believe C-Pulse will be reimbursed under an LVAD or similar DRG code. The device has been ruled non-experimental and it is likely that CMS and many private insurers will cover the procedure during the U.S. trial. Beyond our belief that reimbursement will be routine and strong, Medicare has begun a program under which hospitals are fined 1-2% their heart failure payments if their 30-day heart failure re-admission rates are higher than Medicare feels is appropriate. If C-Pulse shows reduced hospital re-admissions, we believe it is the type of device hospitals will seek to use.

## RISKS

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**While the C-Pulse likely offers some benefits, the device's adverse event rate and mortality level in the 20-patient feasibility study are concerning.** In addition to one death (5% rate) related to the device from surgery to treat mediastinitis, there were two other deaths, bringing the total to 15% at six months. While 20 patients is far too small a sample by which to call a mortality rate, and if the rate had been 0% we would not be raving about the success, we see 15% as too high to be commercially viable given that HeartWare and Thoratec have shown 10% or lower six-month mortality in sicker Class IV patients. We believe Sunshine Heart will need to show six-month mortality below 10% in its pivotal trial to see significant success and the higher rate in the feasibility trial is a tad worrisome, though too low in patient numbers to have much value. There were 10 infections (one localized non-device, one internal pump component and eight driveline exit site infections). There was also one patient who developed acute renal dysfunction. At six months, one person had been re-hospitalized for worsening heart failure and by one year, there were three who had been admitted back to the hospital for increasing symptoms. However, management believes that these two additional patients had a low C-Pulse utilization rate, using it as little as 20% of the time, as opposed to the 80% required. Though these results are from a small sample, we believe the infection rate is too high, compared to a 35% VAD-related infection rate in the REMATCH II trial, which is now likely much lower. The majority of C-Pulse infections was related to the driveline exit site and so may be remedied with Sunshine Heart's recent securement device. We think the adverse event rate and six-month mortality rate for a larger U.S. pivotal trial will be key to determining the device's success. There were no strokes in the feasibility study. Some have wondered if the device mechanism might break off debris, but it seems that imaging studies before implant have prevented this. It will be important that the stroke rate remain low in the pivotal trial.

**As with any early-stage company, an investment in Sunshine Heart is high risk but high reward, in our view.** In addition to the potential for negative clinical data, the company faces several hurdles such as the U.S. regulatory process and timeline, European adoption and reimbursement, competition, and the need for significantly more capital. Because a U.S. commercial presence is several years away – we predict late 2016 or early 2017 – there are several catalysts in the meantime that could result in material positive or negative moves for the stock. Near term, we think the stock may be affected by whether an expected full FDA approval of the U.S. pivotal trial design and trial commencement is announced in late 2012/early 2013 and on the data from the first 50 patients implanted in Europe. Also, establishing reimbursement in key European countries at a level that allows for commercialization will be important.

**Any major change required by the FDA before signing off on the pivotal trial could be a negative if the effect is to increase the length of the trial or make the trial less likely to be successful.** While we are not expecting major changes, until the conditional approval becomes a full approval, one cannot rule out any major changes.

**The C-Pulse System and a next-generation device may come up against competitive devices as they approach the U.S. market.** There are a number of companies developing devices for Class III heart failure patients. These include: CircuLite, CardioKinetix, Abiomed, Jarvik Heart, MicroMed Technology, SynCardia Systems, Terumo Heart, HeartWare, Thoratec, and Berlin Heart.

Some of these products have similar regulatory timelines to the C-Pulse and may be approaching commercialization in 2016 or 2017. The regulatory process is unpredictable and delays or advancements could push one device ahead of another. An investment in Sunshine Heart requires staying informed of data and timeline updates from these potential competitors. In addition, Sunshine Heart is working on a next-generation C-Pulse that would get rid of the driveline and be a fully implantable system. This advancement would be powered by transcutaneous energy transfer through the patient's skin. However, HeartWare and Thoratec, the two major players in the LVAD market, are both developing TET technology to eventually commercialize fully implantable LVADs. Given these companies' marketing prowess and physician contacts, we believe Sunshine Heart will need to get the next-gen system to market at the same time or earlier in order to compete effectively. Also, the advantage of being able to temporarily disconnect from the current-generation C-Pulse could potentially be overshadowed by a TET offering from these players. Finally, TET could reduce major infections, and if HeartWare or Thoratec is able to develop it successfully it could reduce Sunshine Heart's advantage of not being in the blood stream.

## VALUATION

Our \$10 price target is based on 4.5x 2017E revenue discounted back 20% per year four times to arrive at equivalent 2013 revenue. We choose 2017 as we believe it will be the first year of full U.S. launch. We predict \$49M in revenue in 2017 and a share count of 11M a year from now. Using these metrics, we arrive at our \$10 price target. We note that HeartWare shares trade at over 7x NTM revenue and the group of fast growing companies trades above 4.5x NTM revenue.

Exhibit 1. Comp table

Company	Tick	Rating, PT	Market Cap \$B	Price	EV / Sales				P/E ex-Amortization				CAGR	
					NTM	F12	F13	F14	NTM	F12	F13	F14	EPS	Revs
Endologix	ELGX	BUY, \$16	\$0.8	\$13.10	6.0x	7.3x	5.6x	4.3x	NM	NM	NM	163.8x	NM	31%
Abiomed	ABMD	BUY, \$28	\$0.8	\$20.09	4.3x	5.8x	4.7x	3.9x	47.8x	59.1x	32.4x	22.1x	74%	22%
Dexcom	DXCM	Not Rated	\$1.0	\$14.07	7.5x	9.7x	7.1x	5.5x	NM	NM	NM	NM	NM	32%
Insulet	PODD	Not Rated	\$1.0	\$20.83	4.0x	4.9x	3.9x	3.2x	NM	NM	NM	44.3x	NM	23%
HeartWare	HTWR	BUY, \$110	\$1.2	\$83.50	5.2x	9.6x	4.6x	3.1x	NM	NM	NM	75.9x	NM	76%
Cyberonics	CYBX	NEUTRAL	\$1.4	\$49.01	5.3x	6.0x	5.4x	4.8x	31.0x	37.1x	31.8x	27.7x	16%	12%
Intuitive Surgical	ISRG	NEUTRAL	\$21.2	\$531.45	8.4x	9.3x	8.1x	7.1x	31.9x	34.7x	30.4x	25.7x	NM	NM
<b>Average</b>					<b>5.8x</b>	<b>7.5x</b>	<b>5.6x</b>	<b>4.6x</b>	<b>36.9x</b>	<b>43.6x</b>	<b>31.5x</b>	<b>39.1x</b>	<b>16%</b>	<b>24%</b>
Sunshine Heart	SSH	BUY, \$10	\$0.04	\$6.29	NM	NM	50.6x	5.3x	NM	NM	NM	NM	NM	NM

Source: LCM research estimates

## POTENTIAL MARKET

Sunshine Heart's C-Pulse targets a portion of the heart failure population, presenting a large market opportunity. According to the American Heart Association, there are ~5.7 million adults with heart failure in the U.S. with ~670,000 new diagnoses annually. Almost 30% of heart failure patients are younger than 60.

Heart failure progresses in stages, and symptoms include becoming exhausted quickly, shortness of breath, leg swelling, and heart palpitations. These symptoms occur as the heart weakens, stiffens, or dilates and becomes increasingly inefficient at pumping blood. The various stages of heart failure

have been categorized by the New York Heart Association (NYHA) into Class I-IV:

- Class I – Patients are not limited in their physical activity and do not suffer from fatigue, shortness of breath, palpitations or chest pain during normal physical activity.
- Class II – Patients experience some small limits to physical activity but are comfortable at rest. Regular activities give patients fatigue, palpitations, shortness of breath or chest pain.
- Class III – Patients are very limited in their physical activity but remain comfortable at rest. They cannot do regular activities without fatigue, palpitation, shortness of breath or chest pain.
- Class IV – Patients cannot do any physical activity without discomfort and they may suffer symptoms even when resting. Physical activity increases discomfort.

The C-Pulse is aimed at patients who are classified as having Class III or ambulatory Class IV heart failure. We believe Class III is the most appropriate target. Class III is about 25% of heart failure, meaning about ~1.4M people in the U.S. and likely that number or more in Europe. At about \$50,000 per device, this equates to a \$70B market in the U.S. and more than double that worldwide. Even 1% penetration would lead to over \$1B in revenue.

## **C-PULSE TECHNOLOGY**

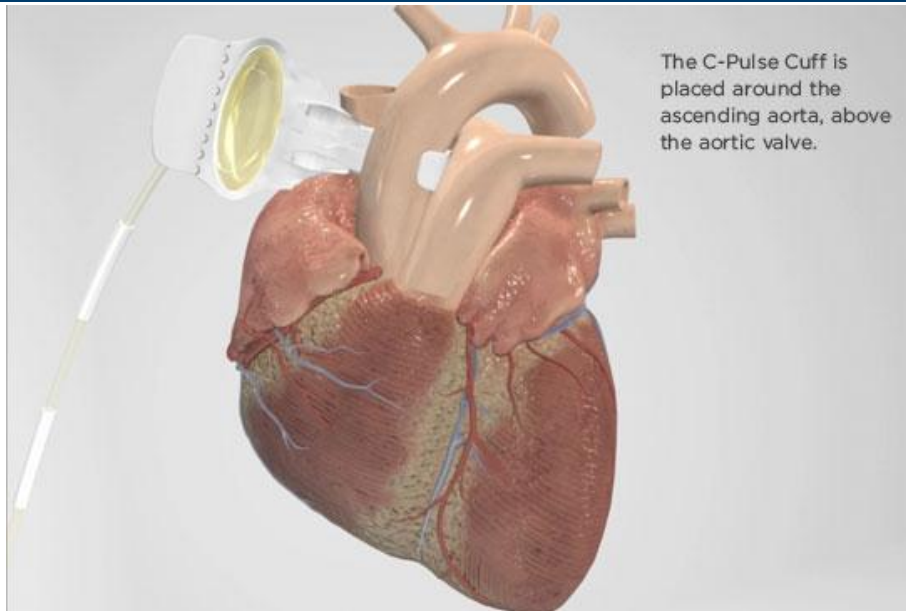
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Sunshine Heart's C-Pulse Heart Assist System is intended to treat the Class III and ambulatory Class IV heart failure population. These patients usually suffer fatigue, palpitation, shortness of breath, chest pain, dizziness, low blood pressure and fluid retention. The device helps the heart move blood through the body by squeezing the ascending aorta with appropriate timing to propel blood forward.

The C-Pulse system is implanted with a cuff that hugs the ascending aorta above the aortic valve and epicardial sensing leads are attached to the left ventricle. The system tubing enters/exits the patient through a site on the abdomen and is hooked up to the system's power driver. This set-up allows the system to sense a heartbeat and to inflate the cuff after the heart beats and the aortic valve closes. Inflation helps move blood to the body and the coronary arteries while deflation may reduce the heart workload required to pump the blood out. The increased blood flow provides blood and oxygen to the body and muscles, which makes the patient feel better and be more functional. The potentially lowered workload may allow the heart to recover or at least deter the heart failure from worsening.

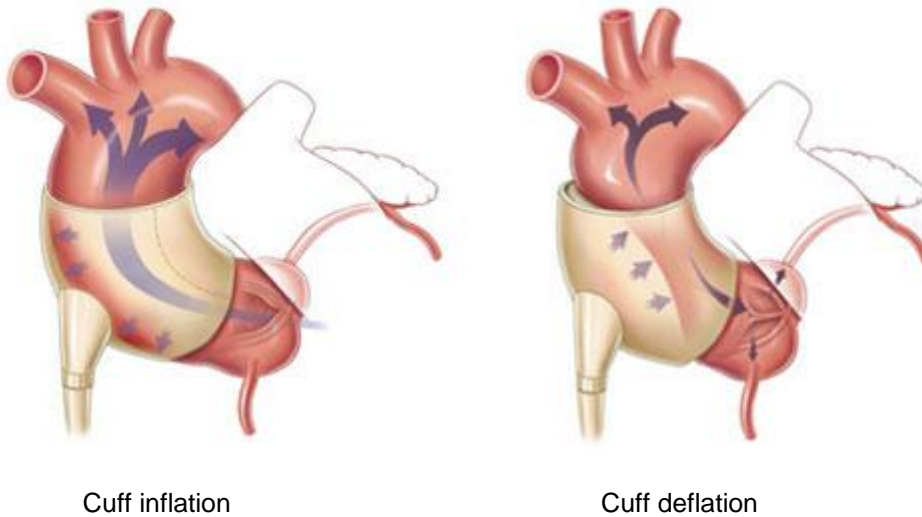
The C-Pulse System can be implanted using a mini-thoracotomy between the patient's ribs or a mini-sternotomy through the sternum. Using the minimally invasive procedure can result in a shorter hospital stay of 4-7 days. Because the system components do not have any contact with the blood stream, we think there could be a lower chance of infection, as well as blood-related complications such as stroke and thrombosis. In addition, the C-Pulse system can be turned off and detached for short times, allowing the patient to shower.

**Exhibit 2. C-Pulse**



Source: Sunshine Heart corporate website

**Exhibit 3. Cuff inflation and deflation**



Source: Sunshine Heart corporate website

**COMPETITION**

The C-Pulse System is intended for Class III heart failure patients. Though there are few currently approved devices that address this population, there are a number of companies working on pipeline products for these patients. Drug therapy and pacers/CRTDs are commonly used in heart failure patients and many of the patients in the company's U.S. feasibility trial had pacers and were



on medications before receiving the C-Pulse. Very sick patients who fit within the Class IV and Class IIIb heart failure categories can receive an LVAD in the U.S. Two companies, Thoratec and HeartWare, offer LVADs for the “bridge-to-transplant” patients, or the sickest, Class IV heart failure group. Thoratec also has an indication for use in “destination therapy” patients, which can include Class IIIb patients. These LVADs are heart pumps that move blood mechanically and can be effective and life-saving for some patients, though some complications related to the interface of the system components with the bloodstream, such as thrombosis, stroke and bleeding complications, can occur.

There are a number of companies pursuing devices for the Class III or ambulatory Class IV patient. We briefly summarize the offerings and potential regulatory timelines for these products:

- **CircuLite has created the Synergy**, a blood pump aimed at long-term partial circulatory support for NYHA Class IIIb and early Class IV patients. The 4.25 L flow capacity pump is similar in size to an AA battery and is inserted in a pacemaker pocket with the system put in place through a mini-thoracotomy procedure. The pump connects the system’s inflow cannula in the left atrium of the heart to the outflow graft on the subclavian artery. European approval was secured in September 2012. The company plans to start a U.S. pilot trial this year; to us, this indicates that U.S. approval would not be expected until ~2017/2018.
- **CardioKinetix’s Parachute device** is a small, parachute-like membrane-covered frame that is implanted into the apex of the left ventricle using a catheter. By separating the damaged heart muscle from the normal tissue, the device mimics a more natural left ventricle shape and reduces LV volume, allowing for a lower filling pressure and alleviating symptoms of heart failure. A ~500 patient U.S. pivotal trial is expected to start in 4Q12, which may indicate a U.S. approval in late 2016/2017.
- **Abiomed’s Symphony device** is an implantable, synchronized assist device intended for Class III heart failure patients who have not had improvement in symptoms on inotropes or CRT. The device is placed in a pacemaker pocket and attached with a graft to the subclavian artery. This is expected to increase coronary blood flow, cardiac output and organ perfusion before being removed. A regulatory timeline toward U.S. commercialization has not yet been announced but is probably similar to the above devices.
- **Jarvik Heart has developed the Jarvik 2000**, an LVAD that has completed a U.S. pivotal trial for the Bridge to Therapy indication and recently received the agency’s go-ahead to start a 350-patient, 50-center pivotal trial for a Destination Therapy indication. The device to be used in the DT trial does not have a driveline exit site on the abdomen, but instead uses a connector behind the patient’s ear. It’s not clear to us when a potential U.S. approval may be expected, but we would not expect a DT approval until ~2017 or later.
- **MicroMed Technology has the Heart Assist 5 LVAD**, has CE Mark approval and received approval in June to start a U.S. clinical trial on a Bridge to Transplant. The pulsatile device is billed as the smallest, lightest LVAD. We don’t know how many of 192 patients from 20 centers have been enrolled in the U.S. trial yet. Follow-up is expected to

run until patients are off the device. We don't view the BTT population as competition for Sunshine Heart and the timeline for a DT indication is not clear.

- **Terumo Heart has developed the DuraHeart LVAS**, a magnetically levitated pump that has CE Mark approval. The U.S. regulatory timeline is not clear to us.
- **Berlin Heart's EXCOR pediatric VAD** was approved by the FDA in late 2011 for babies and children with severe heart failure. EXCOR is also approved for pediatric use in Europe and Canada.
- **HeartWare and Thoratec continue innovation.** Both the HMIII and MVAD may target stage III patients. We also believe transcutaneous energy transfer could lead to LVADs being used in less sick patients.

We think that the C-Pulse's competitive benefits include the minimally invasive procedure, lack of blood contact and the possibility for patients to unplug from the device for short periods.

## CORPORATE OVERVIEW

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Sunshine Heart is a public company that has developed the C-Pulse Heart Assist System, intended for Class III and ambulatory Class IV heart failure patients. The system received CE Mark approval in July 2012 based on U.S. feasibility study data and is expected to be launched in Europe in the second half of the year. In the U.S., a feasibility study was completed on 20 patients. The company has submitted an Investigational Device Exemption (IDE) to the FDA and hopes to start a U.S. pivotal trial at about 30 centers once the submission is approved, anticipated in late 2012 or early 2013. The company has received conditional approval to begin its FDA trial. We expect U.S. device approval in 2016 or 2017.

Sunshine Heart started in November 1999 and was incorporated in Delaware in August 2002. The company has been listed on the Australian Stock Exchange as ticker "SHC" since September 2004 and trade as CHESS Depositary Interests (CDIs). Until recently, each CDI correlated to one share of common stock, but with the January 2012 200-for-1 reverse stock split, 200 CDIs now equal one share of common stock. In February 2012, the company listed on the NASDAQ under the ticker "SSH."

At the end of 2011, there were 25 Sunshine Heart employees. The corporate headquarters is located in Eden Prairie, Minnesota, where the company has two facilities. The previous corporate headquarters was in a 10,000 square foot facility, on which the \$11,000 monthly lease runs out at the end of September 2012. In October 2011, the company signed a \$21,000/month lease for a 23,000 square foot space, and headquarters and other operations were moved into that facility. The lease on the larger facility runs through the end of March 2016.

## EUROPEAN COMMERCIAL STRATEGY

CE Mark approval was received in July 2012 and Sunshine Heart is expected to launch first in Germany in the second half of 2012 and then in Italy; Germany and Italy are two countries where the number of hospital days for heart failure is

among the highest. Three LVAD/heart transplant centers in each country have been identified for this initial launch: Herzzentrum, Leipzig; Berlin Heart; Kirkckhoff Klinik, Bad Nauheim; Niguarda; Torino; and Padova. Sunshine Heart will use distributors HSC and Aptiva to sell the C-Pulse into Germany and Italy. The company is expected to launch a 50-patient post market surveillance study in the second half of 2012. This post-market trial is expected to be completed in the third quarter of 2014.

## DATA REVIEW

For the U.S. feasibility study on the C-Pulse System, 20 patients received the device. The implants were performed at seven hospitals in North America: Ohio State University Medical Center; Penn State-Milton S. Hershey Medical Center; University of Louisville-Jewish Hospital; University of Alabama at Birmingham; United Heart and Vascular Clinic; Saint Luke's Hospital-Mid America Heart Institute; and McGill University Health Centre. Enrollment was completed in the first half of 2011. Though the FDA gave Sunshine Heart the go ahead in April 2011 to implant up to another 20 patients and expand to two more centers as part of the feasibility study, the company has not implanted more patients and plans to wait for the U.S. pivotal trial to begin.

The 20 patients in the feasibility study consisted of eight women and 12 men, mean age of 56 years (range: 34-71 y/o). All of them had ICDs and were on optimal medical therapy; 9 had failed pacemaker therapy. Using the NYHA heart failure classification, 18 of the patients had Class III heart failure and two were ambulatory Class IV patients. Sixteen patients were on diuretics and four on inotropes. Patients stayed in the hospital from four to seven days.

At six months, the mean change in NYHA classification was a reduction of 1.1 class (-1.1 +/- 0.7;  $p < 0.0001$ ), with 12 patients reduced by at least one class. Quality of life improved, reporting a reduction of 23.4 points (-23.4 +/- 19.0;  $p = 0.0003$ ), much higher than the seven-point reduction that shows a material improvement in QOL, and patients could walk an average additional 24 meters during the six-minute walk.

At one year, improvement continued, most notably with patients being able to walk 46.8 more meters than at baseline in the six-minute walk test. In addition, two patients were taken off the device after their heart failure symptoms disappeared and they improved to Class I status. Unfortunately, one of these patients died from a heart attack one year after coming off the system. Results are summarized in the company's data table in Exhibit 4.

**Exhibit 4. Six- and 12-Month Efficacy Data from U.S. Feasibility Trial**

Parameter	Change (6 mo.– BL) Mean	Change (12 mo.– BL) Mean	Significance
NYHA Class Reduction	-1.1 ± 0.7 p = <0.0001	-1.2 ± 0.8 p = 0.0005	Reduction of one class (-1.0) denotes responder to therapy.
Quality of Life (QOL)	-23.4 ± 19.0 p = 0.0003	-24.6 ± 16.5 p = 0.0003	Reduction of seven points (-7.0) demonstrates material improvement in patient QOL. Average patient results at 6 and 12 months were more than 3 times the reduction needed to show a material improvement in QOL using the MLWHF standard.
Six Minute Hall Walk (meters)	24.1 ± 62.6 p = 0.1574	46.8 ± 64.9 p = 0.0295	On average, patients were able to walk an additional 24 meters during a 6-minute period 6 months after implantation compared to their pre-implantation ability. This improvement doubled from 6-12 months.

Source: Sunshine Heart corporate presentation

One patient died during surgery to treat a sternal infection related to the C-Pulse implant procedure. Two additional patients died before the six-month time point, but those deaths were found to be unrelated to the system or procedure. There was one patient with device-related acute renal dysfunction. At six months, one patient had been re-hospitalized because of worsening heart failure. Though it is hard to compare this small sample to larger populations, one out of 20 patients is a 5% rate at six months, as compared to the 40% rate seen in similar control patients from a trial published in *Heart & Lung* in 2005 titled “Predictors of hospital readmission after discharge in patients with congestive heart failure.” In the one-year follow-up for the feasibility study, the rehospitalization rate had increased to 15%, with two more patients being rehospitalized, likely because they used the C-Pulse System only ~20% of the time, far below the required 80% use deemed necessary in the protocol.

The most common adverse event in the feasibility study was infection. At one year, there was one localized non-device infection, eight driveline exit site infections and one internal pump component infection. Management believes that the securement device that was introduced after the study to hold the drive line in place has helped reduce exit site infections.

#### U.S. PIVOTAL TRIAL

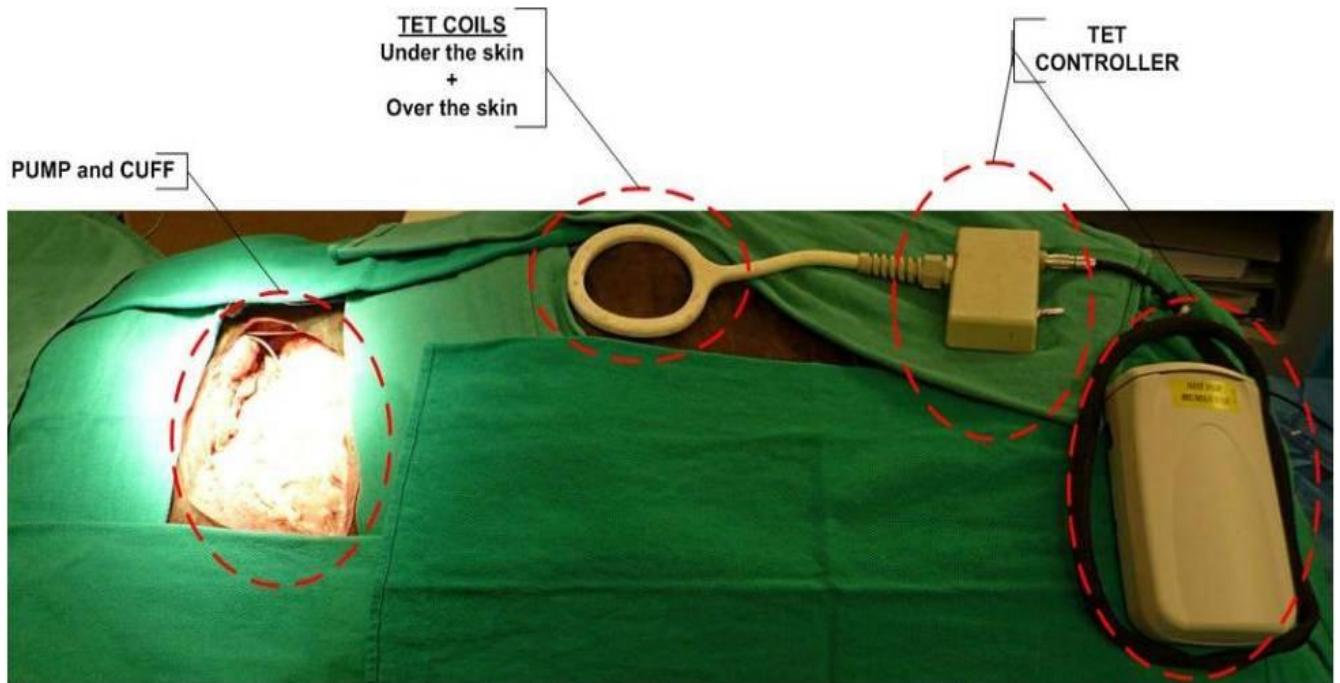
Sunshine Heart has been working the FDA this year on a potential trial design for the U.S. pivotal trial. After meeting with the agency in January, the company submitted a pre-IDE application in March and received feedback in June. Another response was received in late July and the company submitted an IDE at the end of August 2012. The FDA granted conditional approval for that IDE in early October and we expect the trial to start in late 2012 or early 2013.

The proposed trial design is likely to include 30-40 centers with 388 patients 2:1 randomized to the C-Pulse system or optimal medical therapy. Sunshine Heart hopes to sell the system in the trial, as was allowed with the U.S. feasibility trial, and expects an ASP of ~\$59,000. One-year safety follow-up is expected and co-primary endpoints will likely be the reduction in hospitalization rate from worsening heart failure, advanced heart failure therapies and heart failure related mortality. The trial will be based on events and requires 265 HF-related rehospitalization and heart failure-related mortality events. The company expects this to take about 2.5 years or to be complete around the end of enrolling patients. This trial is expected to be powered for a 30% reduction in heart failure rehospitalization and heart failure-related mortality with 0.80 power and  $p < 0.05$ . Management anticipates that the trial will take ~2.5 years to enroll.

**PRODUCT PIPELINE**

Sunshine Heart’s pipeline includes a fully implantable C-Pulse System that would eliminate the external wires and power driver as well as the connected battery pack. Instead, the power driver would be implanted inside the patient and the external battery pack would be wireless. Without an entry site on the abdomen, the risk of infection around the driveline site should be reduced. In the feasibility study, there were eight patients with driveline exit site infections observed in the 20-patient study population, so we see this as a meaningful update.

**Exhibit 5. Next-generation C-Pulse System**



Source: Sunshine Heart corporate presentation

Sunshine Heart finished an animal study on this wireless C-Pulse System in June 2011 and found that the device led to an improvement in the animal’s heart function. Details of the chosen design for the fully implantable pump may be available by the end of 2012.

## **SALES AND MANUFACTURING**

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Given that the C-Pulse became available only recently for commercial sale in Europe, Sunshine Heart has not posted significant revenues. Any sales recorded historically were related to U.S. clinical trials; there were no sales in 2011. With CE Mark approval in July, a European launch is scheduled for the second half of 2012. We expect sales to ramp gradually, as securing reimbursement in each European country can be a separate, lengthy process. Sales in Europe are expected to be transacted through both a direct sales force and distributors. The initial launch in Germany and Italy is expected to be conducted by distributors HSC and Aptiva. After the initial centers have been set up, the company may contemplate a strategic distribution partnership.

In the U.S., the pivotal clinical trial has received conditional approval from the FDA and the trial is anticipated to start after the submission is fully approved. Sunshine Heart expects to be able to sell the C-Pulse to participating centers during the trial and is targeting an ASP of ~\$59,000. Management expects trial enrollment to take ~2.5 years. Assuming data from that trial are positive, we expect U.S. commercial launch in 2016 or 2017. The company's commercial timeline for other countries outside the U.S. and Europe has not yet been determined.

We expect commercial manufacturing to increase in volume as sales increase. The C-Pulse manufacturing process is currently outsourced, with many of the system parts provided by outside suppliers of various sizes. Sunshine Heart buys from its suppliers as purchase orders for the C-Pulse are placed. There are not any second-line suppliers secured for device parts, but management believes that if required, these could be found with minimal disruption.

## **REIMBURSEMENT, REGULATORY AND IP**

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In the U.S., where C-Pulse is under clinical investigation, the system has been assigned a Category B designation under IDE number G070096. This means that the device has been deemed non-experimental/investigational and hospitals can submit for coverage and reimbursement from Medicare for those patients implanted. However, an FDA approval of the company's IDE is likely needed to confirm this. We think any reimbursement may fall under an LVAD code, though of course, reimbursement payment from Medicare is not guaranteed.

Sunshine Heart recently received CE Mark approval for sale of the C-Pulse System in Europe. There are no third-party payers reimbursing for the device in Europe right now, but the company plans to work toward attaining payment. Paperwork for the German reimbursement process has been filled out but a decision on whether the C-Pulse will be paid for is not likely to be made until at least the end of February 2013 and could take another year as only about 20% of devices get paid for in Germany the first time submitted. In Italy, several procedures must be done first and then submitted to start the reimbursement process.

Sunshine Heart has 12 issued U.S. patents and eight U.S. patent applications, as well as 23 issued patents and 15 patent applications internationally. These patents cover a list that includes the aortic wrap, fluid reservoir, pump, and actuator, among other features.

## MANAGEMENT

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**David Rosa – CEO.** Before becoming Sunshine Heart's CEO in October 2009, Mr. Rosa was president and CEO of private agricultural company Milksmart, Inc. From 2004 to 2008, he was vice president of Global Marketing for Cardiac Surgery and Cardiology at St. Jude Medical and headed the launch of 27 new cardiovascular products for the company. Mr. Rosa held various roles at A-Med Systems, Inc., a private percutaneous ventricular assist device company, including vice president of Marketing and Sales, senior vice president of Marketing and Business Development, chief operating officer and CEO. He was Product Manager for Angioplasty Balloons and Director of Intravascular Ultrasound at SCIMED Life Systems from 1995 to 1999. SCIMED is now a subsidiary of Boston Scientific Corporation. Mr. Rosa has an M.B.A. in Marketing Management from Duquesne University and a B.S. in Commerce and Engineering from Drexel University.

**William Peters, MD – Medical Director and Chief Technical Officer.** Dr. Peters invented the proprietary C-Pulse technology and was Sunshine Heart's CEO when he co-founded the company in 1999. Dr. Peters has also developed other cardiac technologies, such as the endovascular cardiopulmonary bypass system for minimally invasive cardiac surgery commercialized by Heartport Inc., which was later acquired by Johnson & Johnson. Dr. Peters has authored numerous published articles and book chapters and has significant clinical experience in thoracic transplantation and technologies including intra-aortic balloon pump system and LVADs. He also holds an honorary role with the University of Auckland's Department of Surgery and Biomedical Engineering and is a senior clinical research fellow in cardiothoracic surgery based at Auckland City Hospital.

**Jeff Mathiesen – CFO.** Mr. Mathiesen has been CFO since March 2011. Before coming to Sunshine Heart, he was vice president and CFO for Zareba Systems, Inc., a publicly held manufacturer and marketer of medical products, perimeter fencing and security systems. Mr. Mathiesen's experience includes previous roles such as vice president and CFO for Delphax Technologies, Inc.; vice president of Business Development, vice president, and CFO for Micro Component Technology, Inc.; vice president and CFO Recovery Engineering, Inc.; corporate controller at Osmonics, Inc.; and controller at Aslesens, Inc. After earning his B.S. in Accounting at the University of South Dakota, Mr. Mathiesen began his career at Deloitte & Touche, LLP and is a certified public accountant.

## FINANCIAL FORECAST

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**Revenue:** We do not model revenue until 2013. For 2013, we forecast \$0.77M in revenue, increasing to \$7.33M in 2014 and \$20.62M in 2015. Our 2013-2016 sales are purely OUS sales and clinical trial implants, as we don't model the company entering the U.S. commercially until the first quarter of 2017. However, we have U.S. commercial sales ramping more quickly than OUS sales, as we believe reimbursement will be established and longer-term data should be known by then. We model an OUS ASP of \$40,000 until 2015 and then \$50,000 after 2015. We model consistent OUS reimbursement by 2014/2015. We model a U.S. ASP of \$55,000 during the trial, with approximately 90% of pumps being reimbursed. We expect a commercial U.S. ASP of \$66,000.

**Gross margin:** For 2013, we model a negative gross margin, -179.2%, with GM turning positive to 22.5% in 2014 and 38.7% in 2015. We see the high 60s or

low 70s as an appropriate gross margin range as the company's operations mature.

**SG&A:** Our SG&A estimate is 1,298.7% of revenue in 2013, 166.5% in 2014, and 73.2% in 2015. As sales grow in the outer years, our SG&A forecast moves toward 45-50% of revenue.

**R&D:** We estimate R&D expense at 1,779.2% of revenue in 2013, 240.2% in 2014, and 101.8% in 2015. This decreases to 132% of revenue in 2016, 62% of revenue in 2017, and below 50% in 2018.

**EPS:** We have forecasted a loss per share of \$1.95 in 2012, \$2.27 in 2013, and \$2.16 in 2014. We continue to estimate LPS through 2018.

**Shares outstanding:** As of July 20, 2012, there were 6,277,538 shares outstanding. Sunshine Heart completed a public offering of 2,875,000 shares of common stock on August 15, 2012. We estimate that there are ~9,152,538 shares outstanding after the offering.

**Cash and debt:** As of June 30, 2012, Sunshine Heart had \$1.8M in cash and equivalents. The company raised ~\$18.7M during the August 2012 offering. We model the company raising additional funds in 2013, 2015 and 2016.



LAZARD CAPITAL MARKETS  
**Exhibit 6. Sunshine Heart Income Model (\$M)**

	2010	2011	Fiscal Year End, December 2012				2012	Fiscal Year End, December 2013				2013	Fiscal Year End, December 2014				2014	2015	2016	2017	2018
	FYA	FYA	1QA	2QA	3QE	4QE	FYA	1QE	2QE	3QE	4QE	FYE	1QE	2QE	3QE	4QE	FYE	FYE	FYE	FYE	FYE
Revenue	0.41	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.31	0.46	0.77	1.19	1.48	1.76	2.90	7.33	20.62	19.48	49.20	76.76
YY Growth	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	472.7%	526.6%	851.5%	181.4%	-5.6%	152.6%	56.0%
Cost of Goods Sold	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.40	0.40	0.65	0.70	2.15	0.95	1.15	1.38	2.20	5.68	12.63	9.17	18.66	26.83
Gross Profit	0.41	0.00	0.00	0.00	0.00	0.00	0.00	-0.40	-0.40	-0.34	-0.24	-1.38	0.24	0.33	0.39	0.69	1.65	7.99	10.30	30.54	49.93
Research and Development	6.23	11.20	2.17	1.57	2.30	2.50	8.54	3.00	3.20	3.50	4.00	13.70	4.00	4.20	4.40	5.00	17.60	21.00	25.70	30.50	37.90
Sales, General, & Administrative	2.60	5.36	1.94	1.79	1.80	1.80	7.33	2.30	2.50	2.50	2.70	10.00	3.00	3.00	3.10	3.10	12.20	15.10	16.70	29.10	39.70
Other expenses	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Total Operating Expenses	8.83	16.56	4.11	3.36	4.10	4.30	15.86	5.30	5.70	6.00	6.70	23.70	7.00	7.20	7.50	8.10	29.80	36.10	42.40	59.60	77.60
EBIT	(8.42)	(16.56)	(4.11)	(3.36)	(4.10)	(4.30)	(15.86)	(5.70)	(6.10)	(6.34)	(6.94)	(25.08)	(6.76)	(6.87)	(7.11)	(7.41)	(28.15)	(28.11)	(32.10)	(29.06)	(27.67)
Other income (expense)	0.15	0.25	0.03	0.00	0.00	0.00	0.03	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.64
Pre-tax Income	(8.27)	(16.31)	(4.08)	(3.35)	(4.10)	(4.30)	(15.83)	(5.70)	(6.10)	(6.34)	(6.94)	(25.08)	(6.76)	(6.87)	(7.11)	(7.41)	(28.15)	(28.11)	(32.10)	(29.06)	(27.03)
Income Tax Expense	-0.67	-0.12	0.00	-0.73	0.00	0.00	-0.73	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Net Income	(7.60)	(16.20)	(4.08)	(2.62)	(4.10)	(4.30)	(15.10)	(5.70)	(6.10)	(6.34)	(6.94)	(25.08)	(6.76)	(6.87)	(7.11)	(7.41)	(28.15)	(28.11)	(32.10)	(29.06)	(27.03)
<b>EPS</b>	<b>(2.63)</b>	<b>(2.98)</b>	<b>(0.66)</b>	<b>(0.42)</b>	<b>(0.45)</b>	<b>(0.46)</b>	<b>(1.95)</b>	<b>(0.58)</b>	<b>(0.59)</b>	<b>(0.56)</b>	<b>(0.56)</b>	<b>(2.27)</b>	<b>(0.53)</b>	<b>(0.53)</b>	<b>(0.54)</b>	<b>(0.55)</b>	<b>(2.16)</b>	<b>(1.50)</b>	<b>(1.48)</b>	<b>(1.18)</b>	<b>(1.01)</b>
Diluted shares outstanding	2.89	5.44	6.17	6.28	9.15	9.40	7.75	9.90	10.40	11.40	12.40	11.03	12.65	12.90	13.15	13.40	13.03	18.78	21.65	24.71	26.65
EBIT	(8.42)	(16.56)	(4.11)	(3.36)	(4.10)	(4.30)	(15.86)	(5.70)	(6.10)	(6.34)	(6.94)	(25.08)	(6.76)	(6.87)	(7.11)	(7.41)	(28.15)	(28.11)	(32.10)	(29.06)	(27.67)
Depreciation and amortization	0.03	0.05	0.03	0.03	0.00	0.00	0.06	0.00	0.00	0.00	0.00	0.10	0.00	0.00	0.00	0.00	0.10	0.10	0.10	0.10	0.00
EBITDA	(8.39)	(16.51)	(4.08)	(3.32)	(4.10)	(4.30)	(15.80)	(5.70)	(6.10)	(6.34)	(6.94)	(24.98)	(6.76)	(6.87)	(7.11)	(7.41)	(28.05)	(28.01)	(32.00)	(28.96)	(27.67)
<b>MARGINS</b>																					
Gross margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-179.2%	20.0%	22.0%	22.0%	24.0%	22.5%	38.7%	52.9%	62.1%	65.0%
EBIT	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Pre-tax Income	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
NI	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
<b>EXPENSES</b>																					
R & D as a % of Revenue	NM	NM	NM	NM	NM	NM	NM	NM	NM	1136.4%	865.8%	1779.2%	336.1%	284.3%	249.4%	172.7%	240.2%	101.8%	132.0%	62.0%	49.4%
S, G, & A as a % of Revenue	NM	NM	NM	NM	NM	NM	NM	NM	NM	811.7%	584.4%	1298.7%	252.1%	203.0%	175.7%	107.1%	166.5%	73.2%	85.8%	59.1%	51.7%
Total Operating Expenses	NM	NM	NM	NM	NM	NM	NM	NM	NM	1948.1%	1450.2%	3077.9%	588.2%	487.3%	425.2%	279.8%	406.7%	175.1%	217.7%	121.1%	101.1%
Tax Expense	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
NOLs	(49.00)	(65.20)	(71.90)	(76.00)	(80.30)	(80.30)	(80.30)	(86.00)	(92.10)	(98.44)	(105.38)	(105.38)	(112.14)	(119.02)	(126.13)	(133.53)	(133.53)	(161.65)	(193.74)	(222.81)	(249.84)

Source: Company reports and LCM Research estimates

**Exhibit 7. Sunshine Heart Revenue Model (\$M)**

SSH Revenue Model	2011	2012	Fiscal Year End, December 2013				2013	Fiscal Year End, December 2014				2014	Fiscal Year End, December 2015				2015	2016	2017	2018
	FYA	FYE	1QE	2QE	3QE	4QE	FYE	1QE	2QE	3QE	4QE	FYE	1QE	2QE	3QE	4QE	FYE	FYE	FYE	FYE
C-pulse - Europe	-	-	3	5	4	7	19	10	12	6	14	42	25	40	35	55	155	285	357	433
Y/Y Growth			NA	NA	NA	NA	NA	233%	140%	50%	100%	121%	150%	233%	483%	293%	269%	84%	25%	21%
% of total			100%	56%	33%	37%	44%	33%	32%	16%	22%	25%	29%	36%	30%	52%	37%	75%	43%	34%
C-pulse - U.S.	-	-	-	4	8	12	24	20	25	32	50	127	60	70	80	50	260	95	475	835
Y/Y Growth					NA	NA	NA	NA	NA	300%	317%	429%	200%	180%	150%	0%	105%	-63%	400%	76%
% of total					67%	63%	56%	67%	68%	84%	78%	75%	71%	64%	70%	48%	63%	25%	57%	66%
<b>Total pumps</b>	-	-	<b>3</b>	<b>9</b>	<b>12</b>	<b>19</b>	<b>43</b>	<b>30</b>	<b>37</b>	<b>38</b>	<b>64</b>	<b>169</b>	<b>85</b>	<b>110</b>	<b>115</b>	<b>105</b>	<b>415</b>	<b>380</b>	<b>832</b>	<b>1,268</b>
Y/Y Growth			NA	NA	NA	NA	NA	900%	311%	217%	237%	293%	183%	197%	203%	64%	146%	-8%	119%	52%
OUS ASP (\$000s)			\$40	\$40	\$40	\$40	\$40	\$40	\$40	\$40	\$40	\$40	\$50	\$50	\$50	\$50	\$50	\$50	\$50	\$50
% of units reimbursed			0%	0%	0%	0%	0%	50%	50%	75%	75%	63%	100%	100%	100%	100%	100%	100%	100%	100%
<b>OUS Revenue</b>	-	-	-	-	-	-	-	0.2	0.2	0.2	0.4	1.0	1.3	2.0	1.8	2.8	7.8	14.3	17.9	21.7
Y/Y Growth			NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	84%	25%	21%
U.S. ASP (\$000s)			-	-	\$55	\$55	55.0	\$55	\$55	\$55	\$55	\$55	\$55	\$55	\$55	\$55	\$55	\$55	\$66	\$66
% of units reimbursed			-	-	70%	70%	70%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	100%	100%	100%
<b>U.S. Revenue</b>	-	-	-	-	0.3	0.5	0.8	1.0	1.2	1.6	2.5	6.3	3.0	3.5	4.0	2.5	12.9	5.2	31.4	55.1
Y/Y Growth							NA	NA	414%	436%	716%	200%	180%	150%	0%	105%	-59%	500%	76%	
Blended ASP (\$000s)			-	-	25.7	24.3	17.9	39.7	39.9	46.4	45.2	43.4	49.6	49.7	49.7	49.8	49.7	51.3	59.1	60.5
<b>Total Revenue</b>	-	-	-	-	0.3	0.5	0.8	1.2	1.5	1.8	2.9	7.3	4.2	5.5	5.7	5.2	20.6	19.5	49.2	76.8
Y/Y Growth			NA	NA	NA	NA	NA	NA	NA	473%	527%	851%	255%	270%	224%	80%	181%	-6%	153%	56%
<b>Worldwide</b>																				
Total pumps, period	-	-	3	9	12	19	43	30	37	38	64	169	85	110	115	105	415	380	832	1,268
Average ASP (\$000s)			\$0.00	\$0.00	\$25.67	\$24.32	\$24.99	\$39.67	\$39.93	\$46.42	\$45.23	\$42.81	\$49.65	\$49.68	\$49.65	\$49.76	\$49.69	\$51.17	\$58.83	\$60.52
<b>Total pumps, cumulative</b>	-	-	3	12	24	43	43	73	110	148	212	212	297	407	522	627	627	1,007	1,839	3,107

Source: Company reports and LCM Research estimates

## ANALYST CERTIFICATION

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All of the recommendations and views about the securities and companies in this report accurately reflect the personal views of the research analyst named on the cover of this report. No part of this research analyst's compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst in this research report.

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OVERALL DISTRIBUTION			BANKING CLIENT DISTRIBUTION*		
BUY	NEUTRAL	SELL	BUY	NEUTRAL	SELL
55%	43%	1%	15%	5%	0%

\*Indicates the percentage of each category in the Overall Distribution that were banking clients of Lazard Frères in the previous 12 months.

RATING	GUIDELINE (return targets may be modified by risk or liquidity issues)
BUY	Expected to produce a positive total return of more than 10% in the next 12 months.
NEUTRAL	Fairly valued; expected to produce a total return +/- 10% in the next 12 months.
SELL	Expected to produce a negative total return of more than 10% in the next 12 months.

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