July 10, 2013

HEALTHCARE/MEDICAL DEVICES

Stock Rating:

OUTPERFORM

12-18 mo. Price Target	$11.00
SSH - NASDAQ	$5.63
3-5 Yr. EPS Gr. Rate	NM
52-Wk Range	$17.25-$4.85
Shares Outstanding	9.5M
Float	7.3M
Market Capitalization	$69.7M
Avg. Daily Trading Volume	88,558
Dividend/Div Yield	NA/NM
Book Value	$1.00
Fiscal Year Ends	Dec
2013E ROE	NM
LT Debt	$0.0M
Preferred	$0.0M
Common Equity	$10M
Convertible Available	No

EPS Diluted	Q1	Q2	Q3	Q4	Year	Mult.
2012A	(0.66)	(0.42)	(0.42)	(0.44)	(1.98)	NM
2013E	(0.47)A	(0.50)	(0.51)	(0.54)	(2.02)	NM
2014E	--	--	--	--	(1.92)	NM
2015E	--	--	--	--	(1.78)	NM

Revenue ($/mil)	Q1	Q2	Q3	Q4	Year	Mult.
2012A	0.0	0.0	0.0	0.0	0.0	NM
2013E	0.0A	0.1	0.2	0.5	0.8	73.5x
2014E	--	--	--	--	8.6	6.8x
2015E	--	--	--	--	20.1	2.9x

Sunshine Heart Inc.

Initiating Outperform: Right Device for a Big Market

SUMMARY

We are initiating coverage of SSH with an Outperform rating and $11 price target. SSH develops the C-Pulse Heart Assist System, a less invasive, less burdensome heart assist device for the treatment of moderate (NYHA Class III and ambulatory Class IV) heart failure (HF). Although the story is still early with US commercialization years away, feasibility trial data are encouraging, European approval is secured and the market opportunity is significant. The next major catalysts will be reimbursement notifications in Europe early in '14. In the interim, we expect patient performance and US trial milestone updates from SSH.

KEY POINTS

- **Meaningful market opportunity.** We estimate SSH's target market potential in the more severe Class III/ambulatory Class IV heart failure patient population at ~$7.5B in the US alone. The Affordable Care Act incentivizes hospitals to reduce HF re-hospitalizations, and C-Pulse plays right into this important standard.
- **Differentiated platform.** The C-Pulse holds three pivotal advantages over other device-based HF therapies: 1) no contact with blood stream, reducing the risk of stroke; 2) minimally invasive implantation approach; and 3) freedom to detach at will. These advantages convey key safety/quality-of-life benefits that we believe set C-Pulse apart.
- **Data very promising so far.** In the 20-patient feasibility study, C-Pulse was able to drive on average one full heart failure class improvement at one year. There were two "super responders" who moved to Class I heart failure and were able to disconnect from the device. Major safety endpoints were solid.
- **Clinical experience accelerating.** The next 12-24 months represent a critical period as clinical experience ramps both in the US (pivotal trial at leading HF centers) and Europe (post-approval study in key markets of Germany/Italy for reimbursement). The company is also moving forward on a fully implantable system, that while early, could be powerful.
- **Risks.** As with any early-stage medtech story, there are regulatory risks. The long path to US commercialization (we estimate '17E) and lack of European reimbursement (we expect this takes hold next year) require patience for revenue visibility. SSH may require additional cash as it ramps toward US approval.

Stock Price Performance

Company Description

SSH is an early-stage global medical device company committed to the commercialization of the C-Pulse System, an implantable, non-blood contacting, heart assist therapy for the treatment of moderate to severe heart failure. The company was founded in 1999 and is headquartered in Eden Prairie, MN.

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Investment Overview

We are initiating coverage of Sunshine Heart Inc. with an Outperform rating and 12- to 18-month $11 price target. Sunshine Heart is an early-stage medical device company focused on the treatment of moderate (NYHA Class III and ambulatory Class IV) heart failure. The company's C-Pulse Heart Assist System is a unique, less invasive product backed by encouraging US feasibility trial data and CE Mark approval and with the potential to transform the treatment paradigm for Class III heart failure, in our view. Risks are certainly present given the early stage of the U.S. regulatory pathway. US approval is still several years away, reimbursement needs to be established in Europe, and the pipeline (though exciting) is still very early. However, given SSH's lead in developing a system appropriate for the large Class III population and with CE Mark already in hand, we believe this is a name investors should be looking at now. Our $11 price target is driven by DCF analysis and conservatively assumes ~1% market penetration in 2021, driving revenues from $0 in 2012 to $135M in eight years on a risk-adjusted basis ($220M not risk-adjusted).

Investment Positives

Meaningful, Untapped Market Potential

We estimate there are roughly 1.5M NYHA Class III and ambulatory Class IV heart failure patients in the US, or roughly 25-30% of the overall US heart failure population. A key inclusion criterion of SSH's US pivotal trial is heart failure (HF) patients with left ventricular ejection fraction (LVEF) of ≤ 35%. Our analysis of the Digitalis Investigation Group trial (a large scale HF trial conducted to examine the effect of a mainstream heart failure drug on mortality and hospitalization in stable patients with HF) found that of the 7,788 stable but clinically confirmed HF patients screened for the trial, 66% had LVEF of ≤35%. Applying this 66% assumption to the broader population of 1.5M moderate heart failure patients, results in our estimate of ~1M patients in the US likely to be eligible for the trial under the LVEF inclusion criterion.

We believe that within this market, SSH's realistic target population is those patients on the more severe end of this spectrum – patients who are on the slippery slope of progressing towards advanced Class IV heart failure. We note that the treatment arm of the Digitalis Investigation Group trial (all patients had LVEF ≤ 45%) saw a 12.6% mortality rate due to worsening heart failure amongst Class III HF patients during the course of the study. While recognizing that this is a ballpark figure, if we apply this conservative cut of 13% (HF patients on pharmacologic therapy who could have most drastically benefitted from the C-Pulse since they actually died due to HF), we estimate that roughly 130,000 patients in the US are experiencing "severe" heart failure and represent the optimal target group for SSH. Our market model thus uses this 130,000 patient population as a conservative estimate of the C-Pulse target population. If fully penetrated, at an ASP of $59K per device, we estimate a total market opportunity of $7.5B in the US.

Likewise, applying similar estimates of 66% and 13% to Europe's ~3.7M patients in Class III/ambulatory Class IV heart failure implies ~320,000 patients in Europe we would mark as ideal candidates for the C-Pulse system.

Exhibit 1: OPCO Market Model: "Severe" Class III/Ambulatory Class IV Patients

	2012	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
UNITED STATES MODEL									
Class III/Ambulatory Class IV HF	1,500,000	1,511,433	1,522,952	1,534,560	1,546,256	1,558,041	1,569,916	1,581,881	1,593,938
Growth %		0.76%	0.76%	0.76%	0.76%	0.76%	0.76%	0.76%	0.76%
Stable outpatients w/ EF ≤ 35% (~66%)	990,000	997,545	1,005,148	1,012,809	1,020,529	1,028,307	1,036,144	1,044,041	1,051,999
Severe (13% died due to worsening HF)	128,700	129,681	130,669	131,665	132,669	133,680	134,699	135,725	136,760
EUROPE MODEL									
Class III/Ambulatory Class IV HF	3,700,000	3,728,200	3,756,615	3,785,247	3,814,097	3,843,167	3,872,458	3,901,973	3,931,713
Growth %		0.76%	0.76%	0.76%	0.76%	0.76%	0.76%	0.76%	0.76%
Stable outpatients w/ EF ≤ 35% (~66%)	2,442,000	2,460,612	2,479,366	2,498,263	2,517,304	2,536,490	2,555,823	2,575,302	2,594,930
Severe (13% died due to worsening HF)	317,460	319,880	322,318	324,774	327,250	329,744	332,257	334,789	337,341

Source: Oppenheimer & Co. Inc. estimates, Ahmed et al: Higher New York Heart Association Classes and Increased Mortality and Hospitalization in Heart Failure Patients with Preserved Left Ventricular Function. Am Heart J 2006; 151(2):444-450.

Unique System Offers Distinct Advantages

In our view, the C-Pulse Heart Assist System stands apart from any other device-based therapy of Class III heart failure due to three unique advantages: 1) the system is implanted outside of the patient's bloodstream, thus reducing the risk of stroke or thrombosis events as well as the need for anticoagulation; 2) the system can be implanted in a minimally-invasive approach, with meaningfully faster recovery times than other mechanical circulatory support (MCS) devices; 3) the system can be detached for short periods of time with no risk of harm to the patient.

No contact with blood stream. The C-Pulse Heart Assist System is unique as the only mechanical circulatory support device that (at the time of this report, of which we and management are aware of) is implanted outside of the patient's blood stream. The cuff sits on the ascending aorta, outside of the patient's vascular system. By avoiding direct contact with blood, the C-Pulse does not require any blood thinning agents (patients are only on anticoagulation if it is needed for another pre-existing condition). Not only does C-Pulse's unique placement offer patients quality-of-life improvements from reduced side-effects associated with anticoagulation medication, it also potentially leads to a lower risk of stroke and thrombosis complications. Thus far, the early clinical trial data has been supportive of this benefit, with no strokes/thrombotic events at 12 months in the feasibility trial or in the 25+ patients treated to date (cumulative 25 years of active C-Pulse HF treatment). In light of the recent focus on stroke risk with HTWR's HVAD pump (including hemorrhagic stroke incidence of >10% as seen in the latest bridge-to-transplant follow-up data), we believe the C-Pulse's advantage in stroke risk is an important differentiator in the eyes of physicians and investors alike.

Minimally-invasive approach. The implant portion of the procedure typically takes one hour to perform. The surgeon does not make an incision on the heart itself or any major vessels; therefore, a heart-lung bypass machine is not necessary for the procedure. The C-Pulse system may be implanted via two primary methods: through a traditional full sternotomy (as performed during the US feasibility trial), or via a small pacemaker-like incision through the ribs (mini-thoracotomy) and sternum (mini-sternotomy).

The latter, more minimally-invasive approach has been utilized successfully by surgeons since 2010, and has resulted in lower procedure-related complication risks as well as shorter hospital stays (on average, 4-7 days versus an average of 14 days using the full sternotomy approach). C-Pulse patients are expected to stay 2-3 days in the ICU. By way of comparison, looking at the less invasive of the two left ventricular assist device options, patients in HTWR's ADVANCE trial—the latest left ventricular assist device trial—spent on average 6 days in the ICU post-implant with total average hospitalization time of 20 days.

Temporary disconnection option provides patient flexibility. Unlike competitor MCS devices, the C-Pulse system can be turned on and off at any time and can be safely disconnected from the patient. Naturally, to see the full benefits of the system, patients should have the system operating as much as possible (sustained periods of inactivity could result in the return of the patient's heart failure symptoms, including shortness of breath). SSH recommends that patients remain connected to the system for at least 20 hours a day, and that disconnection periods should be kept as short as possible (preferably no longer than 15 minutes at a time). That said, the freedom to disconnect for certain activities (e.g., showering) and the peace of mind that there is no life-threatening danger in the event that the batteries run out, for example, are important benefits that improve the patient's quality of life.

European Commercialization Secured

The C-Pulse system received CE Mark approval for European commercialization in July 2012, an event we view as the clearance of an early though important hurdle. We expect commercial revenues from Europe to be minimal early on due to the lack of European reimbursement. Thus, the focus for the company near term is securing reimbursement ahead of European commercial launch. A post-approval study is currently underway at heart failure centers in Germany and Italy.

Although European commercialization is not a meaningful catalyst for SSH from a revenue perspective near term, we still believe the milestone is important for garnering clinical support and experience. As the currently approved C-Pulse in Europe is SSH's newest generation system (and the generation that is being used in the pivotal trial for future US commercialization), building enthusiasm and support around this latest system is critical.

The push for reimbursement currently ongoing is primarily focused on Germany and Italy, not only because the two countries have the largest HF populations in Europe (management estimates that Germany and Italy lead with the highest number of bed days/year for HF hospitalization in Europe, at 400K and 200K, respectively), but also as the two countries have historically provided positive reimbursement decisions for other heart failure devices.

A post-market study modeled after the US pivotal trial (will have an economic endpoint in order to establish reimbursement) is currently underway in Europe. The trial is expected to yield publications, a data update for investors and a reimbursement submission. The study focuses on introducing C-Pulse at five important centers in Germany and Italy via two (already trained) distributors. SSH has indicated that one of the sites is Berlin Heart Center, one of the leading heart failure centers in the world. The 50-patient trial is currently commencing at select sites and is expected to run through 1H14 (as of mid-June 2013, one site is currently activated with two patients already implanted and three additional sites are now capable of enrolling). By the end of 2013, SSH expects to have centers in Germany, Italy and the United Kingdown enrolling patients in the post-approval trial.

Previously, the main hurdle to European reimbursement was that each market in Europe requires for implants to be completed locally in order to consider applications. With these implants now getting underway with the post-market study, management intends to apply for reimbursement approval in the three major markets starting late this year. The once-yearly deadline for Germany's reimbursement application is in October with a decision date in early February. Management feels comfortable in securing reimbursement in Germany and Italy in 1H14, and the UK in the second half of the year.

Once the post-approval study is complete, SSH will leverage its experience and trained on-site clinical personnel at the German and Italian centers for its initial commercial launch. Following this focused launch, other countries that will be targeted in the

European commercial roll-out include Austria, Switzerland, and the UK. While the European sales effort will be primarily through distributors near term, longer term SSH does look to move to a blended direct/distributor model. Our sense from management is that a distribution agreement with a large corporate partner will likely be part of the picture longer term. Overall, we estimate European revenues of $3.6M in 2014, ramping to nearly $60M in 2018.

Aligns with Affordable Care Act

Section 3025 of the Affordable Care Act (ACA), the Hospital Readmissions Reduction Program, has already started to roll out in hospitals across the country (began October 1, 2012). According to the HRRP, hospitals must ensure that re-hospitalization rates remain below a certain threshold at 30 days, or risk reductions in Medicare payments in proportion to the percentage exceeded in the threshold. More specifically, CMS has calculated the average risk-adjusted, 30-day hospital readmission rates for patients with myocardial infarction (heart attack), pneumonia, and heart failure using claims data. If a hospital's risk-adjusted readmissions rate for a category exceeds the average (in the case of heart failure, 24.7%), the hospital is penalized in future years by all Medicare admissions in proportion to its rate of excess re-hospitalizations. The cap on the penalty is set at 1% for 2013, though this ceiling moves to 2% in 2014 and 3% in 2015.

With this new penalty on excess re-hospitalizations, hospitals are under more pressure than ever to keep their re-hospitalization rates below the threshold, and particularly so in the case of heart failure as this category has been called out as one of the three focus areas under scrutiny. Thus far, the data on C-Pulse's ability to be a meaningful tool against HF re-admissions have been encouraging, though early (as we detail in the "Feasibility Trial Data" section below, only one of the 20 patients in the North American feasibility trial was rehospitalized for worsening heart failure at 6 months—meaningfully below the 24.7% threshold). With the paucity of effective treatment options today in heart failure, we believe the HRRP could be a meaningful catalyst for interest in the C-Pulse system if US pivotal trial data show similar encouraging benefits in HF re-admissions.

Starting to See Revenue Inflow on US Pivotal Trial

On the positive side, the US pivotal trial implants will be reimbursed. The US pivotal trial though should be an incremental revenue contributor over the near- and medium-term horizon. In our model, we assume that 70% of pivotal trial implants will be reimbursed at an average ASP of $59K/device. Under these assumptions, we model in ~$770K in US pivotal trial revenue in 2013, $5M in 2014, and $3.8M in 2015. We assume the US pivotal trial completes enrollment in 1H15, and that a Continued Access Protocol will enable continued trial implants in 2015-2016. We look for device approval in 2017E.

Investment Risks

Long Path to US Commercialization

The US commercialization process for the C-Pulse is currently in the early stages, and we do not anticipate US commercialization until the 2017 timeframe. To date, SSH has completed a US feasibility study (n=20) at seven North American sites; preliminary one-year follow-up data were presented at the Transcatheter Cardiovascular Therapeutics (TCT) conference in October, 2012. The company received unconditional FDA approval to commence the US pivotal trial in November 2012.

The US pivotal trial will enroll 388 patients, randomized 1:1 to implantation with the C-Pulse system versus optimal medical therapy (OMT). The primary efficacy endpoint is

freedom from worsening heart failure resulting in hospitalization, LVAD (left ventricular assist device) implantation, cardiac transplantation or death as compared to OMT (optimal medical therapy) at 12 months; the primary safety endpoint is all serious procedure and device-related adverse events as determined by CEC (Clinical Events Committee) adjudication at 12 months. In total, the trial will be conducted at 30-40 sites across the US.

Though the size of the pivotal trial is quite large at 388 patients, management remains optimistic about the pace of signing up trial sites as well as trial enrollment. As the FDA has granted the C-Pulse CMS Category B3 status, SSH does expect to receive revenues from trial sites, and participating trial centers are anticipated to be reimbursed by CMS and most private insurance providers. The pivotal trial will also utilize the company's newest, next-gen C-Pulse driver (battery), which provides a significant step forward for patient comfort in the day-to-day living experience with the device: the new battery pack is now one single unit (previously two), and significantly lighter, quieter, and smaller (approximately half the size) than its predecessor. Finally, the trial is being led under already experienced hands: the lead investigator of the trial is Dr. William Abraham, Director of Cardiovascular Medicine at Ohio State University, who was also the lead investigator of the feasibility study.

Although initial interest in the pivotal trial is certainly encouraging, we still anticipate the US approval process to be a lengthy pathway. SSH anticipates enrollment for the event-driven trial to take approximately 2.5 years to complete. Assuming enrollment proceeds on schedule, with safety and efficacy follow-up endpoints at 12 months, we estimate PMA (premarket approval) submission in mid-2016, which places FDA approval in 2017. Management indicates there may be potential for a faster review process if the number of events is reached shortly after enrollment completion and if FDA consents that the safety endpoint of one year does not have be reached for all patients. .

On the path to US commercialization, SSH will require additional funding along the way, which could be dilutive to current shareholders. Following the completion of a public offering of shares in April 2013, we estimate the company will have about $21M in cash as of June 30. The company has stated that it has enough cash on hand to fund operations into 2H14.

Competition

Congestive heart failure is a fluid and multi-faceted disease that can arise from various etiologies, and as a result there is a spectrum of varying therapies ranging from pharmacological to heart transplant targeting the differing levels and root causes of the disease (please see under our "Heart Failure Overview" section below). Patients diagnosed as NYHA Class III heart failure are currently predominately treated with pharmacological therapy targeting reducing blood pressure, lowering cholesterol, thinning the blood, and increasing heart contractility, etc. (beta-blockers, statins, antiplatelet therapies, and inotropes, respectively). Currently, the devices most commonly seen in Class III heart failure patients include CRT-Ds, though in our view these devices are not true competitors to the C-Pulse as they focus on treating the heart's electrical (pacing) abnormalities. Below, we focus on two device-based therapies that, like the C-Pulse, seek to alleviate the heart's workload by improving cardiac output.

HeartMate II expansion into Class III. LVAD industry leader Thoratec Corp., the company with arguably the most experience in advanced heart failure therapy to date, has recently initiated its push to extend LVAD device use to Class III heart failure patients. The company's HeartMate II left ventricular assist device is currently indicated for the treatment of advanced, NYHA Class IV patients, with the vast majority of devices implanted in INTERMACS Levels 1-4 patients (INTERMACS further classifies NYHA Class IV patients by severity, with Level 1 indicating the most severe heart failure patients and Level 7 resembling advanced NYHA Class III patients). In January 2013, THOR

announced that it had received FDA IDE approval to commence the REVIVE-IT (Randomized Evaluation of VAD Intervention before Inotropic Therapy) trial, the first study of its kind investigating left ventricular assist system use outside the current indication of Class IV heart failure patients.

REVIVE-IT will enroll up to 100 patients in NYHA Class III heart failure to the HeartMate II pump or optimal medical therapy (pharmacological therapy). The primary endpoint is a composite of survival, freedom from disabling stroke, and improvement in functional outcomes (six-minute walk test), with a total follow-up time of two years. With THOR indicating that enrollment will begin in mid-2013, we estimate the completion of two-year follow-up on the 100 patients in 2016; hence, if THOR were to receive an indication for HeartMate II in the Class III heart failure patient population, we estimate that approval timing could be shortly after C-Pulse's.

Although THOR's experience in heart failure, relationships with surgeons and cardiologists, and marketing advantage are not to be taken lightly, we do not view its potential entry to be a major negative for SSH. We believe THOR could be an important "ally" for SSH in helping to develop the device treatment for Class III heart failure market. As the current treatment paradigm for Class III heart failure is primarily based on drug therapy, THOR's experience in building the Class IV market and relationships with cardiologists represent vital tools for developing the current nascent market for heart assist devices in Class III. We believe THOR's marketing push will in particular play to the C-Pulse's benefit due to the many advantages of the C-Pulse (significantly smaller implant, much less invasive procedure, zero incidence of stroke, ability to disconnect from the battery pack, faster recovery time, etc.) over the larger, more patient-intrusive HeartMate II.

We note that THOR's entry into the Class III market will be far from easy. Recent discussions on the role of LVADs in advanced heart failure have centered on the lack of clinical evidence for LVADs in Class III and early-stage Class IV heart failure. As a reminder, in November 2012 CMS hosted a Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting to "review the available evidence on the use of ventricular assist devices, a clinical strategy for the management of heart failure." Among other things, the meeting focused on the role of VADs along the spectrum of the heart failure disease progression. The take-away consensus from expert presenters and panel members at MEDCAC was that the need for VADs in "severely sick" NYHA Class IV patients is well documented, but "evidence gaps" exist in the "less sick" spectrum of heart failure patients (which includes Class III). In light of the MEDCAC discussion, we believe CMS is more likely to be more restrictive than less toward LVAD reimbursement in the less sick patient category in the future. CMS' viewpoint, naturally, could change over the course of the next few years (especially if the data from REVIVE-IT are positive), but at present LVADs, we believe, have a high hurdle in Class III.

Circulite. Privately-held Circulite's Synergy pump is in our view the most akin to the C-Pulse: both are long-term, partial circulatory support devices that are implanted under minimally invasive procedures, both target a similar end-patient population (C-Pulse Class III and Class IV ambulatory; Synergy Class IIIB and Class IV ambulatory), and both require the patient to be hooked up to wearable, external battery packs (though, importantly, the C-Pulse patient can temporarily disconnect from his battery pack, and the Synergy patient cannot).

The Synergy itself is a "micro pump" roughly the size of an AA battery that can provide a patient with 4.25 liters of blood flow per minute. The system is comprised of the proprietary micro-pump, an inflow cannula and outflow graft, a percutaneous lead that connects to a wearable external controller, and a rechargeable dual battery pack system. The pump is implanted using a mini-thoracotomy, with the micro-pump sitting in a pacemaker-like pocket.

From a regulatory pathway perspective, the Synergy is also running roughly in tandem with the C-Pulse from a timing perspective in Europe and is slightly behind in the US. The Synergy recently received CE Mark approval in September 2012, and is currently undergoing a controlled launch in the EU. On the US pathway, the company received conditional IDE approval from FDA in March 2013 for a 20-patient feasibility trial.

Long-Term Safety Data Needed

While we are encouraged by the numerous safety advantages of the C-Pulse, at the end of the day, long-term demonstrated safety and efficacy data are needed to drive mainstream adoption of the device. Given the limited number of clinical implants to date, the risk remains that potential long-term safety issues have not yet played out. We believe the two top-most objectives for SSH to demonstrate are: 1) the device is truly at significantly lower risk for stroke given that it sits outside of the bloodstream; and 2) the device's improvements have meaningfully reduced the risk of infection. On the latter front, we believe it is key for SSH to manage down its infection rate. Our conversations with physicians pose the theoretical concern that the C-Pulse's ease-of-use (patients can easily detach and re-attach to the device) may actually lead to more frequent infections as the functionality introduces greater movement and disturbance to the exit site. Management has also indicated it is investing considerable resources to manage down the infection rate. We do note that SSH has since launched a new product for the exit site, and that this new generation product will be the one used in the US pivotal trial.

Feasibility Trial Data

The feasibility trial for the C-Pulse was a 20-patient, single-arm study headed under led by Dr. William Abraham and conducted at seven North American sites. The primary outcome of the study was a composite of device-related adverse events at six months. The study was started in December, 2008.

The twenty patients were relatively evenly split in gender (8 females, 12 males) and included 18 Class III heart failure patients and two ambulatory Class IV patients (average NYHA class of 3.1 out of 4). All twenty patients had been previously implanted with ICDs/pacemakers and were on optimal medical therapy at the time of the C-Pulse implant. Nine of the patients had already failed pacemaker therapy, sixteen were on diurectics and four were on inotropes. The mean age at the time of implant was 56 years.

Exhibit 2: Feasibility Study – Patient Baseline Characteristics

	N=20
Age, mean +/- SD years (range)	56 +/- 9 (34-71)
Gender	
Female	8
Male	12
Failed pacemaker patients	9
Patients with ICD's	20
Patients on optimal medical therapy	20
NYHA class ranking	
Class III	18
Ambulatory Class IV	2
Patients transplanted on non-urgent basis	3
Patients on diuretics	16
Patients on inotropes	4

Source: Company reports

SSH presented six-month preliminary follow-up data on 15 of the 20 patients in the feasibility trial in November 2011. At six months, the average NYHA Class for patients had improved to an NYHA class of 2.2 on average (-1.13 +/- 0.7; $p \leq 0.001$). Of the 15 patients, 12 saw a reduction in NYHA class, with seven patients seeing a one class reduction and two patients seeing a two class reduction. Additionally, there were two "super responders" who improved to NYHA Class I heart failure and were able to be permanently disconnected from the device. Quality of life outcome measures also improved: patients reported a 23.4 (+/- 19.0; $p = 0.0003$) improvement in average Minnesota Living with Heart Failure Quality of Life (MLWHF) scores, over 3x the standard reduction needed to demonstrate a meaningful improvement in QoL. On the Six Minute Hall Walk test, patients on average saw a 24.1 meter (+/- 62.6, $p = 0.1574$) improvement relative to their pre-implantation ability.

In terms of safety data, we highlight that there were no strokes, major bleeding events, or heart attacks at six months. There was one non-device related death (one of the super responders succumbed during surgery to treat an internal sternal infection that was unrelated to the device). The main adverse event reported was infection: nine patients had major infections related to the device/procedure, eight of which were at the driveline exit site.

Dr. Abraham presented one-year follow-up data at TCT in October 2012. Encouragingly, the 12 feasibility trial patients with 12 months follow-up were able to sustain their improvements in NYHA Class reduction at 12 months, with patients seeing an average NYHA class of 1.9 from 3.1 at baseline (-1.2 +/- 0.8; $p = 0.0005$). Of the 12 patients, one patient saw a NYHA reduction of three classifications within the 12 months, two patients saw a two class reduction, seven patients reported a one class decrease, and two patients remained in the same classification. Importantly, all patients (even the two patients who did not see their NYHA classifications change) reported clinically meaningful improvements in quality of life scores (>7pt improvement on the MLWHF scale, $p = 0.0003$) at 12 months, with the highest improvement being a 62-point increase (average improvement of 24.6 points). Gains in the Six Minute Hall Walk test were also statistically significant, with 10 out of the 12 patients demonstrating improvement in distances walked and with patients on average walking 46.9 meters more during the 6-minute test ($p = 0.0295$). The surviving super-responder remained permanently disconnected from the device at 12 months. Finally, we highlight that there were no additional deaths or major infections between six months and one year of follow-up. Additionally, there were zero strokes or MIs in the 12-month follow-up period.

Exhibit 3: Feasibility Study–12-Month Efficacy Data

Parameter	Change (6m from BL) Mean	Change (12m from 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 p = 0.0003	-24.6 +/- 16.5 p = 0.0003	Reduction of seven points (-7.0) demonstrates material improvement in patient QoL
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-min period 6 months after implantation vs their pre-implantation ability

Source: Company reports

Exhibit 4: Feasibility Study–12-Month Safety Data

N = 20 patients	6 months # of patients	12 months # of patients
Death / Aortic Disruption	1 (occurred during surgery to treat sternal infection)	1 (occurred during surgery to treat sternal infection)
Neurological Events (e.g., stroke)	0	0
Myocardial Infarction (MI)	0	0
Major Infection		
Localized Non-Device Infection	1	1
Driveline Exit Site Infection	8	8
Internal Pump Component	1	1
Any Other Device-Related AE Acute Renal Dysfunction	1	1
Patients Re-hospitalized Due to Worsening HF	1/20 (5%)	3/20 (15%)
30-Day Re-hospitalization rates	0	0

Source: Company reports

Looking forward, management indicates we could see further, more detailed data from the feasibility study published some time late this year. We also look for the company to provide regular updates on the European patient experiences at conferences this fall.

C-Pulse System Overview

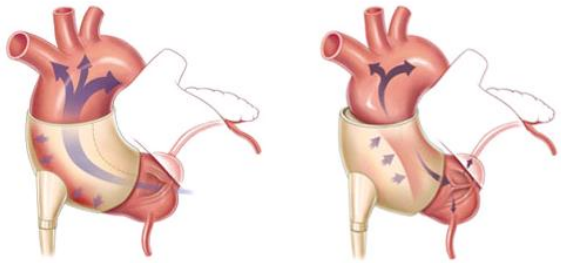
The C-Pulse Heart Assist System has several major components: an extra-aortic cuff, an electrocardiogram (ECG) sensing lead, a percutaneous interface lead (PIL), a battery pack, and a driver (pump). The extra-aortic cuff wraps around the outside of the ascending aorta, similar to a blood pressure cuff at the physician's office. The cuff contains a balloon that inflates and deflates with the pumping motion of the heart; air moves in and out of the balloon as powered by the driver, which sits outside of the patient's body along with a small rechargeable body (in the previous generation version used in the feasibility trial, the battery carrier and driver are worn seperately on the body on a belt; the newer generation model enables to patient to carry both simultaneously in a carrying bag). The driver (outside the body) is connected to the cuff (inside the body) by the percutaneous interface lead. Finally, the ECG sensing lead, which is attached to the heart, is responsible for monitoring signals from the heart to ensure the cuff inflates and deflates in step with the patient's natural heart beat.

Exhibit 5: C-PULSE System Components

Source: Company reports

The operating mechanism of the C-Pulse is based on the same proven technology as intra-aortic balloon pump counter-pulsation. The balloon inflates to help push oxygen-rich blood to the body and coronary arteries, thereby providing additional oxygen which is vital to the ailing heart. During deflation, the level of pumping required by the left ventricle is reduced, lowering the work-load of the heart. In sum, the system thus improves heart function in three primary ways: 1) increased cardiac output (more blood flow from the heart); 2) increased coronary blood flow (more oxygen to the heart muscle); and 3) decreased after-load (less work for the heart). From a patient perspective, the expected benefits of the technology include a relief in shortness of brief, increased physical activity, and improved overall cardiac function. As we note in the review of the feasibility data (above), some patients have benefitted as meaningfully as to see their heart recover to NYHA Class I or II status.

Exhibit 6: C-PULSE Mechanism of Action



Source: Company reports

As of mid-June 2013, the C-Pulse has been implanted in 25 patients in North America and Germany, for a cumulative 25 years of patient support. The 25th patient was implanted on June 14th at Berlin Heart Institute in Germany. In addition to the two patients who were weaned from the technology from the pivotal trial, an additional two patients had been targeted for weaning. There have been zero neurological events to date.

Key Device Improvements

Since completing the US feasibility trial, SSH has made several improvements to the C-Pulse system. Enhancements include: 1) a lighter, slimmer, quieter driver; 2) design modifications to the cuff to enable a faster, simpler implant process (cuff now comes with sutures already in place); 3) a more robust percutaneous interface lead to address wear concerns; 4) new C-Patch mechanism to reduce movement of the percutaneous interface lead at the exit site. Management believes that the combination of the improved PIL and

new C-Patch mechanism will meaningfully reduce the risk of driveline infections, the most prevalent adverse event seen in the feasibility trial (eight of the 20 patients experienced driveline infections at 12-month follow-up). The new enhanced model is the current system that is being used in the US pivotal trial.

In the Pipeline: Fully Implantable System

Longer term, SSH looks to move the platform to a fully implantable system, which would reside 100% in the body of the patient and remove the need for a driveline to exit the body. Not only would such a system significantly improve the patient's quality of life and device comfort, it would also solve the C-Pulse's current top patient issue in driveline infections. The fully implantable system is still in the design phase, though SSH has successfully completed an animal feasibility study with a transcutaneous energy transfer (TET) system in June of 2011 at Texas Heart Institute.

Though certainly a longer-term endeavor, management is focused on this front and in the past several months SSH has seen considerable progress in securing long-term partners for the realization of the technology. In its 4Q12 earnings release, management updated that it has completed a contract with Cirtec Medical Systems, "a firm with decades of expertise in the development of implantable mechanical circulatory support devices." SSH further expects to have a contract completed with a TET manufacturer near-term. The company has already filed for additional IP regarding the fully implantable system.

Heart Failure Overview

According to the American Heart Association (AHA), approximately 5.8 million people suffer from heart failure (HF) in the United States (1.8% of the population), with approximately 610,000 new cases diagnosed each year. The disease is chronic and progressive, one that over the course of time frequently evolves to the stages of disability and mortality. The New York Heart Association (NYHA) classifies the progression of heart failure by a 4-stage, functional assessment system, from mild heart failure (Class I) to severe, or advanced, heart failure (Class IV). We detail the stages below.

Exhibit 7: NYHA Heart Failure Classification System

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

Source: New York Heart Association

As seen above, Class III heart failure patients are the ones who see the paradigm shift when the disease progresses from mild and slightly limiting to one that begins to have a real toll on the patient's quality of life. Yet, these patients (as well as the early-stage, ambulatory Class IV patients) are still able to carry out ordinary activities (albeit with difficulty), are not at risk of imminent death, and still stand a chance of seeing their heart recover. This is the "sweet spot" patient population that SSH seeks to target. Progressing beyond the Class III and ambulatory Class IV patients, the advanced stage of the disease is associated with high economic burdens, a dismal quality of life, frequent hospitalizations, low probability of a recovery of the heart, and a high mortality rate (up to 50% at one year). Needless to say, the ability to assist a patient before crossing into the realm of advanced, Class IV heart failure would be of significant benefit not only to the patient, but also for the alleviation of healthcare costs.

We note that within this target market of Class III and early stage Class IV HF patients, few treatment options currently exist. Most patients today falling within this category of heart failure use a combination of drugs (diuretics, beta blockers, etc.) to relieve their heart failure symptoms. However, the effectiveness of drug therapy as a long-term treatment for HF is low (most drugs relieve symptoms and delay the progression of heart failure, but cannot reverse the course of the disease), and also not without side effects. Besides drugs, biventricular pacing devices (CRT-Ds) are also a treatment option for this patient category. Pacing devices, though, target a different etiology of heart failure—issues related to the electrical, rhythmic abnormalities with the heart.

In the HF patient, the heart muscle degenerates over time, reducing the pumping power of the heart and eventually leaving the heart too weak to pump blood sufficiently to meet the body's demands. HF can be caused by any condition that reduces the efficiency of the heart muscle. The two primary etiologies are due to damage or overworking (as seen, for example, with valvular or arterial diseases, or cardiomyopathy, the disease of the actual heart muscle), or due to electrical issues of the heart (problems with the control of the rate/rhythm of the heartbeat, as seen, for example, with atrial fibrillation, tachycardia or

bradycardia). Associated risk factors include hypertension, myocardial infarction, smoking, amyloidosis, diabetes mellitus, obesity, age, and gender (male).

Treatment Regimes

The treatment paradigm starts with conservative risk factor management (diet, exercise, cessation of smoking, alcohol limitation, etc.) and pharmacologic therapies in the early stages of the disease. As the disease progresses, the treatment paradigm shifts more toward surgical procedures including ICDs, pacemakers, coronary bypasses, valve replacements, ventricular assist devices, and heart transplants. We review the treatment pathways available for HF patients below.

Pharmacologic

Pharmacologic therapies for HF treatment are available in the form of angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs), anti-coagulants, diuretics, and beta blockers. Diuretics (bumetanide, furosemide) can help milder-stage HF by increasing urination to decrease fluid in the body and the lungs, thereby facilitating easier breathing. ACEs (enalapril, lisinopril, captopril), ARBs (losartan, valsartan) and anti-coagulants seek to decrease the workload on the heart by widening blood vessels and thinning the blood to lower blood pressure and improve blood flow. Beta blockers (carvedilol, metoprolol, bisoprolol) reduce HF symptoms by slowing the heart rate and reducing blood pressure.

However, drug treatments are not without side effects, including low blood pressure, dizziness, drowsiness, headaches, fatigue, coughing, elevated potassium levels, rashes, drowsiness, diarrhea, and kidney function impairment. Currently, these drug therapies represent the standard-of-care for the larger HF population, but unfortunately are not sufficient for end-stage HF patients, who require specialized interventions.

Cardiac Surgery Procedures

If a patient's HF is due to a specific aggravator, surgical options exist to alleviate the underlying source of stress on the heart. For example, coronary artery bypass surgery can facilitate blood flow if severely blocked arteries are contributing to the HF. If a patient has a defective valve and is experiencing backward blood flow, a surgeon can repair or replace the valve to eliminate the issue. On the other hand, if the source of the issue is electrical, common therapies include the use of ICDs, pacemakers, or CRT-Ds. These procedures are all associated with various risk factors, and are extremely patient-specific depending on the exact cause of each patient's HF.

Advanced Heart Failure: Transplants and VADs

When attempts to manage HF through pharmacologic therapies and surgical modifications fail, and the patient is at the end-stages of the disease paradigm, the only treatment options remaining are that of a heart transplant or left ventricular assist device (LVAD). Heart transplantation is associated with almost 90% 1-year survival, 60% 10-year survival, and 95% freedom from symptoms and activity limitations in survivors. However, due to the shortage of donors, heart transplantation is not a viable option for the great majority of advanced HF sufferers. The United Network for Organ Sharing estimated that 2,300 hearts were available for transplant in the US in the most recent 12 months reported, while approximately 2,600 patients were on the US heart transplant list during any given 12-month period (less than 1% of end-stage HF patients in America).

Due to the long wait periods and unavailability of heart transplants, ventricular assist devices have emerged in recent years as a promising intermediate support option or alternative to heart transplants. LVADs are heart pumps that improve cardiac outflow by assisting the pumping action of the left ventricle of the heart. Currently, the two companies operating in the left ventricular assist device market are Outperform-rated Thoratec Corp.

and Perform-rated HeartWare International. Relative to SSH's C-Pulse, the VAD implantation procedure is significantly more invasive, costly, and comes with higher risk of serious adverse events, thrombosis and stroke (keeping in mind, of course, that VADs are for the treatment of a meaningfully sicker patient population).

Financial Overview

2013 Sales and Earnings Outlook

With the commercialization of the C-Pulse System in Europe in late 2012, 2013 marks the first year of revenue generation for SSH. Without established reimbursement in Europe, however, we anticipate European revenues will be minimal this year. We estimate the bulk of the revenue contribution in 2013 to be from the ramp of the US pivotal trial.

Management expects for the US pivotal trial to enroll at a pace of ½ patients per month. The company had secured two clinical trial sites out of the gate and anticipates adding trial sites at a pace of two sites per month (with a lag time of a few months before each site begins enrolling patients). Using these targets as a guide, we assume that the clinical trial will treat 19 patients in the US in 2013. Our quarterly enrollment assumptions are as follows:

Exhibit 8: FY2013 US Pivotal Trial Enrollment Expectations

	1Q13	2Q13	3Q13	4Q13	2013
# sites	2	2	7	13	13
# sites implanting	1	2	3	8	8
patients/site	0	1.5	1.5	1.5	4.5
# patients enrolled	0	2	5	11	19
installed base enrolled	0	2	7	19	19

Source: Oppenheimer & Co. Inc. estimates

We conservatively assume that 70% of these patients will be reimbursed (some trial sites, in particular those in Canada and in some states in the US, will not be reimbursed). At an ASP of $59K per device, this translates to ~$800K in revenues generated from clinical trial participation in the US.

Below the top line, we look for $0.6M in COGS in 2013 (implies a 25% gross margin on the low top-line base). SG&A grows primarily on non-cash compensation. We look for a net loss in 2013 of $2.02.

Exhibit 9: FY2013 Earnings Snapshot

	2012	Margin	2013E	Margin	Growth
Domestic	0.0		0.8		NM
ROW	0.0		0.0		NM
Total Sales	**0.0**		**0.8**		**NM**
COGS	0.0	NM	0.6	75.0%	NM
SG&A	6.9	NM	8.7	NM	26.4%
R&D	8.0	NM	10.5	NM	31.5%
Device Fee	0.0	NM	0.0	0.0%	
Operating Income	**($14.9)**	**NM**	**($19.0)**	**NM**	**NM**
Interest Income	0.0		0.0		
Interest Expense	0.0		0.0		
Other expense (income)	0.0		0.0		
Pretax Income	**($14.8)**	**NM**	**($19.0)**	**NM**	**NM**
Taxes	-0.8		0.0		
Tax Rate	NM		NM		
Net Income	**($14.1)**	**NM**	**($19.0)**	**NM**	**NM**
Non-GAAP EPS	**($1.98)**		**($2.02)**		**NM**
Avg Diluted Shares	7.1		9.4		

Source: Company reports, Oppenheimer & Co. Inc. estimates

2014 Sales and Earnings Outlook

We look for appreciation in SSH revenues in 2014 to $8.6M as US pivotal trial enrollment is in full swing and as European commercial sales begin to ramp with the improvement of reimbursement. In the US, we model $5M in revenues during the year on an estimated 121 patients treated in the pivotal clinical trial (no changes to our assumption of $59K ASP and 70% procedural reimbursement). Our 2014E quarterly enrollment assumptions are as follows:

Exhibit 10: FY2014 US Pivotal Trial Enrollment Expectations

	1Q14	2Q14	3Q14	4Q14	2014
# sites	20	27	34	40	40
# sites implanting	12	18	23	28	28
patients/site	1.5	1.5	1.5	1.5	6
# patients enrolled	19	26	34	42	121
installed base enrolled	37	64	98	140	140

Source: Oppenheimer & Co. Inc. estimates

In Europe, we assume data from the post approval study will drive meaningful growth in reimbursed procedures starting in 2Q14. We look for $3.6M in European revenues on an estimated 147 procedures performed with an average ASP of $43K per device.

On the volume acceleration in 2014, we look for gross margin to trend higher to 35.6% for the year (exiting 4Q14 at 38%). We look for SG&A and R&D to grow on commercialization in Europe and the building US clinical trial, respectively. All-in-all, we look for 2014E adjusted loss per share of ($1.92).

Long-Term Outlook

We continue to anticipate meaningful procedural volume build in Europe on the C-Pulse's continued expansion in the core European markets (Germany, Italy) as well as introductions to other western markets. We anticipate for this European expansion to drive SSH's revenue expansion in 2015 and 2016 (+133% and +74%, respectively). We assume US FDA approval of the C-Pulse System in mid-2017. This marks a pivotal event in the top line trajectory for the company. Given the early stage of development, we apply

a 30% probability of success to US commercialization. With US commercialization ramping and the C-Pulse's reputation established in Europe, we look for the top line to accelerate to $66M in 2018.

With the acceleration in the top line beginning in 2017, we also look for gross and operating margins to steadily improve. We anticipate SSH can achieve a mid-50's gross margin long-term, and sustain SG&A margin and R&D spend in the 30%'s/20%'s long-term. Importantly, we see upside here to reach THOR levels on GM (~70%). Our model at this point has more of a international mix given our risk-adjusted revenues on the US side. As that probability rises, so will our gross margin assumption. We look for the company to be operating cash flow positive about the time it hits $100M in sales.

OPCO SSH Product Model

To recap, the key assumptions in our SSH product model are as follows:

United States:

- SSH target population of ~130,000 (1.5M Class III/ambulatory Class IV heart failure X 66% with ejection fraction ≤ 35% X 13% "severe")
- 2013-2015: 194 patients implanted with C-Pulse in pivotal clinical trial. ASP of $59K/device X 70% of implants reimbursed
- 2016: Submission of PMA data. Some C-Pulse implants as part of Continued Access Protocol
- 2017+: US commercialization. ASP of $59K/device x 100% reimbursement. All US commercialization revenues 2017 and beyond are risk-adjusted by a probability of 30% for clinical trial/FDA approval risk
- 2021: Four years post US commercialization. We conservatively assume target market penetration of 1.5%

Europe:

- SSH target population of ~318,000 (3.7M Class III/ambulatory Class IV heart failure X 66% with ejection fraction ≤ 35% X 13% "severe")
- 2013: Conservatively assume zero revenues (no reimbursement)
- 2014+: Receive reimbursement in major markets. Reimbursement builds to 90% of C-Pulse implants reimbursed. ASP of $43K/device
- 2021: Seven years post-reimbursement securement. We conservatively assume target market penetration of 0.7%

Exhibit 11: SSH Market Model

	2012	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
UNITED STATES MODEL										
Class III/Ambulatory Class IV HF	1,500,000	1,511,433	1,522,952	1,534,560	1,546,256	1,558,041	1,569,916	1,581,881	1,593,938	1,606,086
Growth %		0.76%	0.76%	0.76%	0.76%	0.76%	0.76%	0.76%	0.76%	0.76%
Stable outpatients w/ EF ≤ 35% (~66%)	990,000	997,545	1,005,148	1,012,809	1,020,529	1,028,307	1,036,144	1,044,041	1,051,999	1,060,017
Severe (13% died due to worsening HF)	128,700	129,681	130,669	131,665	132,669	133,680	134,699	135,725	136,760	137,802
		0.76%	0.76%	0.76%	0.76%	0.76%	0.76%	0.76%	0.76%	0.76%
Penetration		0.0%	0.1%	0.1%	0.1%	0.2%	0.4%	0.7%	1.1%	1.5%
Treated		19	121	93	94	201	471	950	1,504	2,067
% Reimbursed		70%	70%	70%	70%	100%	100%	100%	100%	100%
ASP		$59,000	$59,000	$59,000	$59,000	$59,000	$59,000	$59,000	$59,000	$59,000
Revenue $ (000's)		$766.6	$4,994.7	$3,840.9	$3,870.2	$11,830.7	$27,815.3	$56,054.6	$88,757.1	$121,954.9
Risk Adjusted Revenues $ (000's) 30%		$766.6	$4,994.7	$3,840.9	$3,870.2	$3,549.2	$8,344.6	$16,816.4	$26,627.1	$36,586.5
Growth			552%	-23%	1%	-8%	135%	102%	58%	37%
EUROPE MODEL										
Class III/Ambulatory Class IV HF	3,700,000	3,728,200	3,756,615	3,785,247	3,814,097	3,843,167	3,872,458	3,901,973	3,931,713	3,961,679
Growth %		0.76%	0.76%	0.76%	0.76%	0.76%	0.76%	0.76%	0.76%	0.76%
Stable outpatients w/ EF ≤ 35% (~66%)	2,442,000	2,460,612	2,479,366	2,498,263	2,517,304	2,536,490	2,555,823	2,575,302	2,594,930	2,614,708
Severe (13% died due to worsening HF)	317,460	319,880	322,318	324,774	327,250	329,744	332,257	334,789	337,341	339,912
		0.76%	0.76%	0.76%	0.76%	0.76%	0.76%	0.76%	0.76%	0.76%
Penetration		0.0%	0.0%	0.1%	0.2%	0.3%	0.4%	0.5%	0.6%	0.7%
Treated		27	147	473	804	1,140	1,481	1,827	2,178	2,534
ASP		$43,000	$43,000	$43,000	$43,000	$43,000	$43,000	$43,000	$43,000	$43,000
Reimbursed		0%	53%	80%	90%	90%	90%	90%	90%	90%
Revenue $ (000's)		$0.0	$3,637.8	$16,267.6	$31,105.1	$44,103.2	$57,297.7	$70,690.8	$84,284.6	$98,081.6
			NM	347%	91%	42%	30%	23%	19%	16%
TOTAL TREATED		46	268	566	897	1,340	1,952	2,777	3,682	4,601
TOTAL REVENUE		$767	$8,633	$20,108	$34,975	$47,652	$65,642	$87,507	$110,912	$134,668
			1026%	133%	NA	NA	38%	33%	27%	21%

Source: Company reports, Oppenheimer & Co. Inc. estimates

Exhibit 12: Annual Sales and Earnings Model

	2012	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	'13-'17 CAGR
Domestic	0.0	0.8	5.0	3.8	3.9	3.5	8.3	16.8	26.6	
ROW	0.0	0.0	3.6	16.3	31.1	44.1	57.3	70.7	84.3	
Total Revenue	**0.0**	**0.8**	**8.6**	**20.1**	**35.0**	**47.7**	**65.6**	**87.5**	**110.9**	181%
COGS	0.0	0.6	5.6	11.3	18.5	23.8	26.3	39.4	49.9	
SG&A	6.9	8.7	11.3	16.1	20.3	23.8	27.6	30.6	33.3	
R&D	8.0	10.5	11.8	13.0	14.5	18.0	21.0	24.0	27.0	
Device Fee				0.1	0.1	0.1	0.1	0.2	0.3	
Operating Income	**(14.9)**	**(19.0)**	**(20.0)**	**(20.3)**	**(18.4)**	**(18.1)**	**(9.2)**	**(6.7)**	**0.4**	
Interest Income	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Interest Expense	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Other	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Pre-Tax Income	**(14.8)**	**(19.0)**	**(20.0)**	**(20.3)**	**(18.4)**	**(18.1)**	**(9.2)**	**(6.7)**	**0.4**	
Taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Tax Rate	NM	NM	NM	NM	NM	NM	0.0%	0.0%	0.0%	
Net Income	**(14.8)**	**(19.0)**	**(20.0)**	**(20.3)**	**(18.4)**	**(18.1)**	**(9.2)**	**(6.7)**	**0.4**	
Non-GAAP EPS	**(1.98)**	**(2.02)**	**(1.92)**	**(1.78)**	**(1.48)**	**(1.35)**	**(0.64)**	**(0.43)**	**0.03**	
Avg. Shares Out. - Fully Dil.	7.1	9.4	10.4	11.4	12.4	13.4	14.4	15.4	16.4	

Margin Analysis	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
COGS	NM	75.0%	64.4%	56.0%	53.0%	50.0%	40.0%	45.0%	45.0%
Gross Margin	NM	25.0%	35.6%	44.0%	47.0%	50.0%	60.0%	55.0%	55.0%
SG&A	NM	1131.7%	130.9%	80.0%	58.0%	50.0%	42.0%	35.0%	30.0%
R&D	NM	1373.0%	136.7%	110.0%	41.5%	37.8%	32.0%	27.4%	24.3%
Operating Margin	NM	NM	NM	NM	NM	NM	-14.1%	-7.6%	0.4%
Net Margin	NM	NM	NM	NM	NM	NM	-14.1%	-7.6%	0.4%

Growth Analysis	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
Revenue			1026.0%	132.9%	73.9%	36.2%	37.8%	33.3%	26.7%
COGS			867.4%	102.4%	64.6%	28.5%	10.2%	50.0%	26.7%
General and Administrative			30.2%	42.4%	26.1%	17.5%	15.7%	11.1%	8.6%
R&D			12.1%	10.2%	11.5%	24.1%	16.7%	14.3%	12.5%
Operating Income			5.4%	1.5%	-9.4%	-1.9%	-48.8%	-28.1%	-106.3%
EPS			-4.7%	-7.4%	-16.7%	-9.2%	-52.4%	-32.7%	-105.9%

Source: Company reports, Oppenheimer & Co. Inc. estimates

Valuation

Our $11 target price is driven by DCF using a risk-adjusted pipeline, weighted average cost of capital (WACC) of 9.5% and terminal growth rate of 4% on estimated EBITDA of $9M in 2023. Our model includes the following key assumptions:

- Reimbursement begins to ramp in Europe in 2014. We assume US approval in 2H17. Please see our Product Model assumptions as well as our margin assumptions in the Annual Sales and Earnings Model above.
- ASPs of $59,000 in the US and $43,000 outside of the US
- 30% probability of approval in the US. This low level built in at this point is simply due to the early nature of the trial and that over the next 12 months SSH will still be in enrollment mode in the US and new data will be limited. In ’14, we expect more data out of Europe and this increased visibility should increase our US probability assumptions as well

Balance Sheet, Cash Flow

SSH ended 1Q13 with $11M in cash and no debt. Recently, SSH has taken steps to strengthen its cash position by: 1) executing a $25M line of credit with Aspire Capital in January 2013; and 2) raising ~$13.1M in a public offering of 2.5M shares in early April. We anticipate operating cash burn of ~$16M in 2013, and thus estimate the new capital flexibility will be sufficient for SSH's balance sheet needs through mid-2014. Capital expenditure needs are minimal at this point.

Management

David Rosa, CEO and Member of the Board of Directors

Dave Rosa has been the Chief Executive Officer of Sunshine Heart since October 2009. Mr. Rosa has spent the past 19 years in a variety of positions in the medical device industry, including in leadership positions at large-cap giants in the cardiovascular industry.

Prior to Sunshine Heart, Mr. Rosa was President and CEO of Milksmart, Inc., a privately-held company developing a unique, stent-like agricultural technology that targeted increasing milking efficiencies, output and quality. Prior to Milksmart, from 2004-2008, Mr. Rosa was Vice President of Global Marketing for Cardiac Surgery and Cardiology at St. Jude Medical, Inc. During this period, Mr. Rosa directed the launch of 27 new products within STJ's cardiovascular division.

From 1999-2004, Mr. Rosa held executive management positions, including Vice President of Marketing and Sales, Senior Vice President of Marketing and Business Development, Chief Operating Officer and Chief Executive Officer, at privately held A-Med Systems, Inc., an emerging medical technology company that designs, develops and commercializes percutaneously placed ventricular assist devices (pVADs) for acute heart failure. From 1995- 1999, Mr. Rosa served as Product Manager for Angioplasty Balloons and Director of Intravascular Ultrasound at SCIMED Life Systems, a privately held company engaged in the development, manufacture and marketing of medical devices to treat cardiovascular disease. SCIMED was acquired by Boston Scientific Corporation and now operates as a subsidiary of Boston Scientific.

Mr. Rosa holds 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 & Chief Technical Officer

William Peters, MD, is the inventor of the proprietary C-Pulse technology and served as Sunshine Heart's initial CEO upon co-founding the company in 1999. As the company's current Medical Director and Chief Technical Officer, Dr. Peters is responsible for C-Pulse's ongoing technological development.

In addition to C-Pulse, Dr. Peters has developed a number of other successful cardiac technology innovations, including an endovascular cardiopulmonary bypass system for minimally invasive cardiac surgery. The system was commercialized by Heartport Inc., a NASDAQ-listed company that was subsequently acquired by Johnson & Johnson in 2001.

Dr. Peters has been the lead or co-author of more than 20 published articles, and has contributed chapters to four books regarding cardiac surgery and heart failure. Dr. Peter's extensive clinical experience in thoracic transplantation stems from a variety of heart failure technologies, including intra-aortic balloon pump systems and left-ventricular assist devices (LVADs) from companies such as Biomedicus, Abiomed, Thoratec and World

Heart-Novacor. He holds honorary appointments with the University of Auckland's Department of Surgery and Biomedical Engineering and is also a senior clinical research fellow in cardiothoracic surgery at Auckland City Hospital. These roles provide Sunshine Heart a direct view of the latest developments in the world of advance heart failure, particularly in the fields of congestive heart failure and with biomedical engineering advancements. Dr. Peters has served on SSH's Board of Directors from 1999 to January 2013.

Jeff Mathiesen, Chief Financial Officer

Jeff Mathiesen joined Sunshine Heart as the company's Chief Financial Officer in March of 2011. Mr. Mathiesen brings more than 20 years of experience as a finance and operations officer to Sunshine Heart, including extensive background in finance, manufacturing, administration, information technology, human resources, investor relations and risk management roles in diverse, publicly and privately held companies.

Prior to Sunshine Heart, Mr. Mathiesen served as Vice President and CFO for Zareba® Systems, Inc., a publicly held manufacturer of medical products, perimeter fencing and security systems. At Zareba, Mr. Mathiesen helped the company return to profitability, led the divestiture of two business units and helped negotiate the sale of the company to Woodstream Corp.

Prior to Zareba, Mathiesen served in numerous other finance and operations leadership roles in high growth, technology based, publicly held companies with operations around the globe. Positions held include the following: 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 for Recovery Engineering, Inc., (subsequently acquired by Proctor & Gamble); Corporate Controller at Osmonics, Inc. (subsequently acquired by General Electric Company); and as a controller at Aslesens, Inc.

Mr. Mathiesen is a Certified Public Accountant. He started his career at Deloitte & Touche, LLP, after completing a B.S in Accounting at the University of South Dakota.

SSH Quarterly Income Statement ($ in millions)												
	1Q12	**2Q12**	**3Q12**	**4Q12**	**2012**	**1Q13**	**2Q13E**	**3Q13E**	**4Q13E**	**2013E**	**2014E**	**2015E**
Domestic	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.2	0.5	0.8	5.0	3.8
International	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.6	16.3
Total Revenue	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.1**	**0.2**	**0.5**	**0.8**	**8.6**	**20.1**
COGS	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.2	0.3	0.6	5.6	11.3
SG&A	1.9	1.6	1.5	1.9	6.9	2.0	2.2	2.2	2.3	8.7	11.3	16.1
R&D	2.2	1.8	1.8	2.2	8.0	2.4	2.5	2.7	2.9	10.5	11.8	13.0
Device Fee						0.0	0.0	0.0	0.0	0.0	0.0	0.1
Operating Income	**(4.1)**	**(3.4)**	**(3.3)**	**(4.1)**	**(14.9)**	**(4.4)**	**(4.7)**	**(4.8)**	**(5.1)**	**(19.0)**	**(20.0)**	**(20.3)**
Interest Income	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Interest Expense	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
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
Pre-Tax Income	**(4.1)**	**(3.4)**	**(3.3)**	**(4.1)**	**(14.8)**	**(4.4)**	**(4.7)**	**(4.8)**	**(5.1)**	**(19.0)**	**(20.0)**	**(20.3)**
Taxes	0.0	(0.7)	0.0	(0.0)	(0.8)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Tax Rate	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Net Income	**(4.1)**	**(2.6)**	**(3.3)**	**(4.1)**	**(14.1)**	**(4.4)**	**(4.7)**	**(4.8)**	**(5.1)**	**(19.0)**	**(20.0)**	**(20.3)**
Non-GAAP EPS	**($0.66)**	**($0.42)**	**($0.42)**	**($0.44)**	**($1.98)**	**($0.47)**	**($0.50)**	**($0.51)**	**($0.54)**	**($2.02)**	**($1.92)**	**($1.78)**
Avg. Shares Out. - Fully Dil.	6.2	6.3	7.8	9.3	7.099	9.4	9.4	9.4	9.4	9.4	10.4	11.4
Margin Analysis	**1Q12**	**2Q12**	**3Q12**	**4Q12**	**2012**	**1Q13**	**2Q13E**	**3Q13E**	**4Q13E**	**2013E**	**2014E**	**2015E**
COGS	NM	NM	NM	NM	NM	NM	75.0%	75.0%	75.0%	**75.0%**	**64.4%**	**56.0%**
Gross Margin	NM	NM	NM	NM	NM	NM	25.0%	25.0%	25.0%	**25.0%**	**35.6%**	**44.0%**
SG&A	NM	NM	NM	NM	NM	NM	NM	NM	NM	**1131.7%**	**130.9%**	**80.0%**
R&D	NM	NM	NM	NM	NM	NM	NM	NM	NM	**1373.0%**	**136.7%**	**110.0%**
Operating Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	**NM**
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	**NM**
Growth Analysis	**1Q12**	**2Q12**	**3Q12**	**4Q12**	**2012**	**1Q13**	**2Q13E**	**3Q13E**	**4Q13E**	**2013E**	**2014E**	**2015E**
Revenue											**1026.0%**	**132.9%**
COGS											**867.4%**	**102.4%**
SG&A										**26.4%**	**30.2%**	**42.4%**
R&D										**31.5%**	**12.1%**	**10.2%**
Operating Income										NM	NM	NM
EPS										NM	NM	NM

Source: Oppenheimer Estimates, Company Reports

Sunshine Heart Balance Sheet

	2011	2012	2013E	2014E	2015E
Assets					
Cash and Equivalents	6.6	14.2	12.6	16.3	19.7
Restricted Cash	0.0	0.0	0.0	0.0	0.0
Accounts Receivable	0.0	0.0	0.2	1.3	2.5
Other Receivables	0.0	0.0	0.0	0.0	0.0
Inventories	0.0	0.0	0.4	2.3	3.8
Other Current Assets	0.3	0.3	0.6	0.8	1.2
Total Current Assets	**6.9**	**14.6**	**13.8**	**20.7**	**27.2**
Property, Plant, & Equipment	0.5	0.5	0.5	0.7	1.2
Other	0.0	0.0	0.0	0.0	0.0
Total Assets	**7.4**	**15.0**	**14.3**	**21.4**	**28.4**
Liabilities					
Accounts Payable and Accrued Liabilities	1.9	1.2	2.0	3.0	3.8
Accrued Salaries, Wages, etc	1.0	0.9	0.7	1.2	4.0
Current portion of Long Term Debt	0.0	0.0	0.0	0.0	0.0
Total Current Liabilities	**2.8**	**2.1**	**2.7**	**4.2**	**7.8**
Long-Term Debt	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0
Total Liabilities	**2.8**	**2.1**	**2.7**	**4.2**	**7.8**
Shareholders' Equity	**4.6**	**12.9**	**11.6**	**17.2**	**20.7**
Total Liabilities & Equity	**7.4**	**15.0**	**14.3**	**21.4**	**28.4**

Source: Oppenheimer Estimates, Company Reports

Sunshine Heart Statement of Cash Flows

	2011	2012	2013E	2014E	2015E
Cash Flow from Operating Activities					
Net Loss	(16.2)	(14.1)	(19.0)	(20.0)	(20.3)
Depreciation and Amortization	0.1	0.1	0.1	0.0	0.0
Loss on Disposal of Assets	0.0	0.1	0.0	0.0	0.0
Stock Based Comp	0.9	1.2	2.5	4.0	7.0
Expense for Warrants	0.0	0.3	0.1	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0
Total Operating Sources	**(15.2)**	**(12.3)**	**(16.3)**	**(16.0)**	**(13.3)**
Operating Uses					
Accounts Receivable	0.3	0.0	(0.2)	(1.1)	(1.7)
Other Current Assets	(0.2)	0.0	(0.2)	0.0	(2.2)
Accounts Payable and Accrued Liabilities	2.0	(0.8)	0.3	1.0	1.2
Other	0.0	0.0	0.0	0.0	0.0
Total Operating Uses	**2.1**	**(0.7)**	**(0.1)**	**(0.1)**	**(2.8)**
Operating Cash Flow	**(13.1)**	**(13.1)**	**(16.4)**	**(16.1)**	**(16.1)**
Investing					
Capital Expenditures	(0.5)	(0.2)	(0.0)	(0.2)	(0.5)
Purchase of Securities	0.0	0.0	0.0	0.0	0.0
Proceeds from Sale of Securities	0.0	0.0	0.0	0.0	0.0
Decrease in Restricted Cash	0.0	0.0	0.0	0.0	0.0
Acquisition of Businesses	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0
Net Cash Flow from Investing	**(0.5)**	**(0.2)**	**(0.0)**	**(0.2)**	**(0.5)**
Cash Flow from Financing					
Proceeds from Issuance of Common Stock	7.6	20.8	14.9	20.0	20.0
Proceeds from Employee Stock Purchase Plans	0.0	0.0	0.0	0.0	0.0
Proceeds from Stock Options	0.0	0.0	0.0	0.0	0.0
Borrowings for Capital Purchase	0.0	0.0	0.0	0.0	0.0
Repayment of Long Term Debt	0.0	0.0	0.0	0.0	0.0
Borrowings under term loan/credit facilities	0.0	0.0	0.0	0.0	0.0
Net Cash Flow from Financing	**7.6**	**20.8**	**14.9**	**20.0**	**20.0**
Effect of Exchange Rates	0.1	0.1	(0.0)	0.0	0.0
Beginning Cash	12.4	6.6	14.2	12.6	16.3
Net Increase (Decrease) in Cash	(5.8)	7.7	(1.6)	3.7	3.4
Ending Cash	**6.6**	**14.2**	**12.6**	**16.3**	**19.7**

Source: Oppenheimer Estimates, Company Reports

Investment Thesis
We rate SSH Outperform with an $11 price target. SSH's C-Pulse Heart Assist System is a unique, less invasive product backed by encouraging US feasibility trial data and CE Mark approval and with the potential to transform the treatment paradigm for Class III heart failure, in our view. Although the story is still early with US commercialization years away, given early encouraging results and the significant market opportunity in-store and uniqueness of the platform, we believe SSH is an attractive take-out opportunity and recommend investors take a look early ahead of key potential catalysts.

Price Target Calculation
Our $11 target price is driven by DCF using a risk-adjusted pipeline, weighted average cost of capital (WACC) of 9.5% and terminal growth rate of 4% on estimated EBITDA of $9M in 2023. We assume US approval in 2H17, long-term gross margin at ~55%, and risk-adjusted US commercial revenues with a 30% probability of US approval.

Key Risks to Price Target
Risks include: 1) Clinical trial and regulatory risk; 2) Competition; 3) Reimbursement risk; 4) Capital needs could be dilutive to shareholders.

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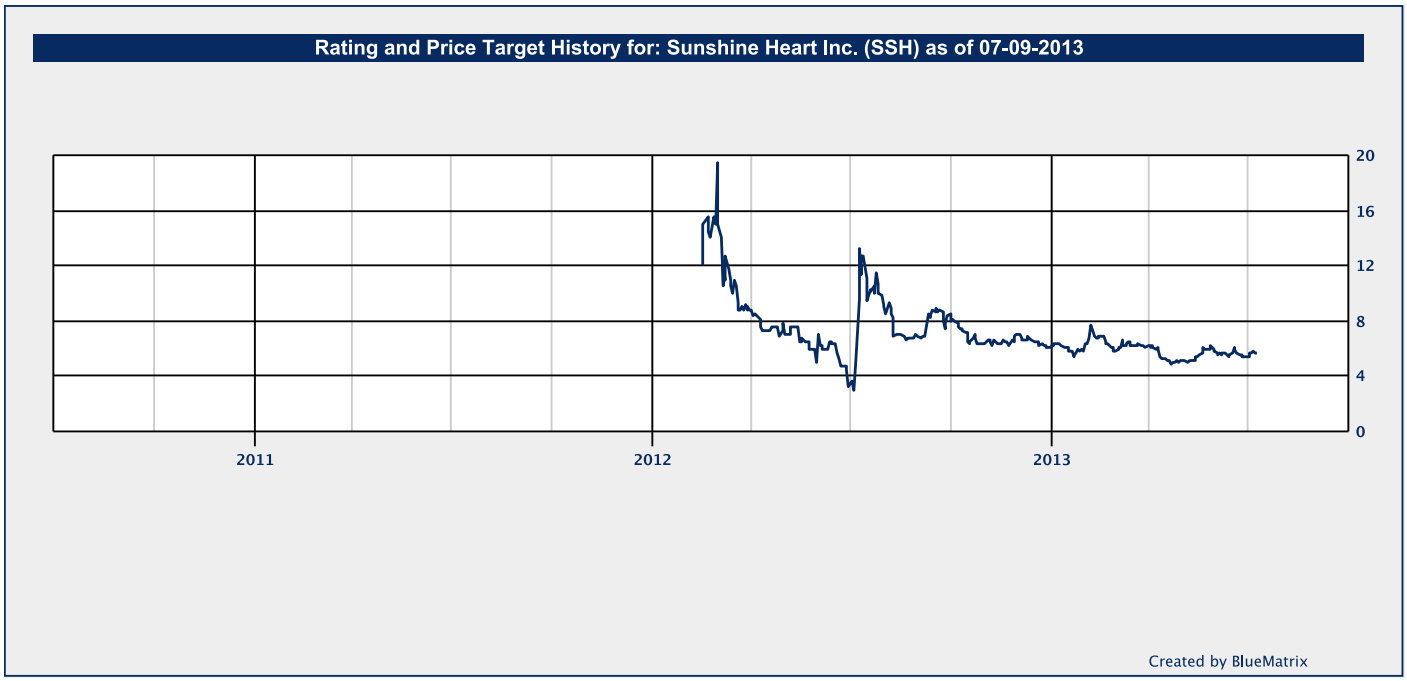
Stock Prices as of July 10, 2013
HeartWare International (HTWR - NASDAQ, $93.22, PERFORM)
Thoratec Corp. (THOR - NASDAQ, $31.32, OUTPERFORM)


Rating and Price Target History for: Sunshine Heart Inc. (SSH) as of 07-09-2013
20
16
12
8
4
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2011
2012
2013
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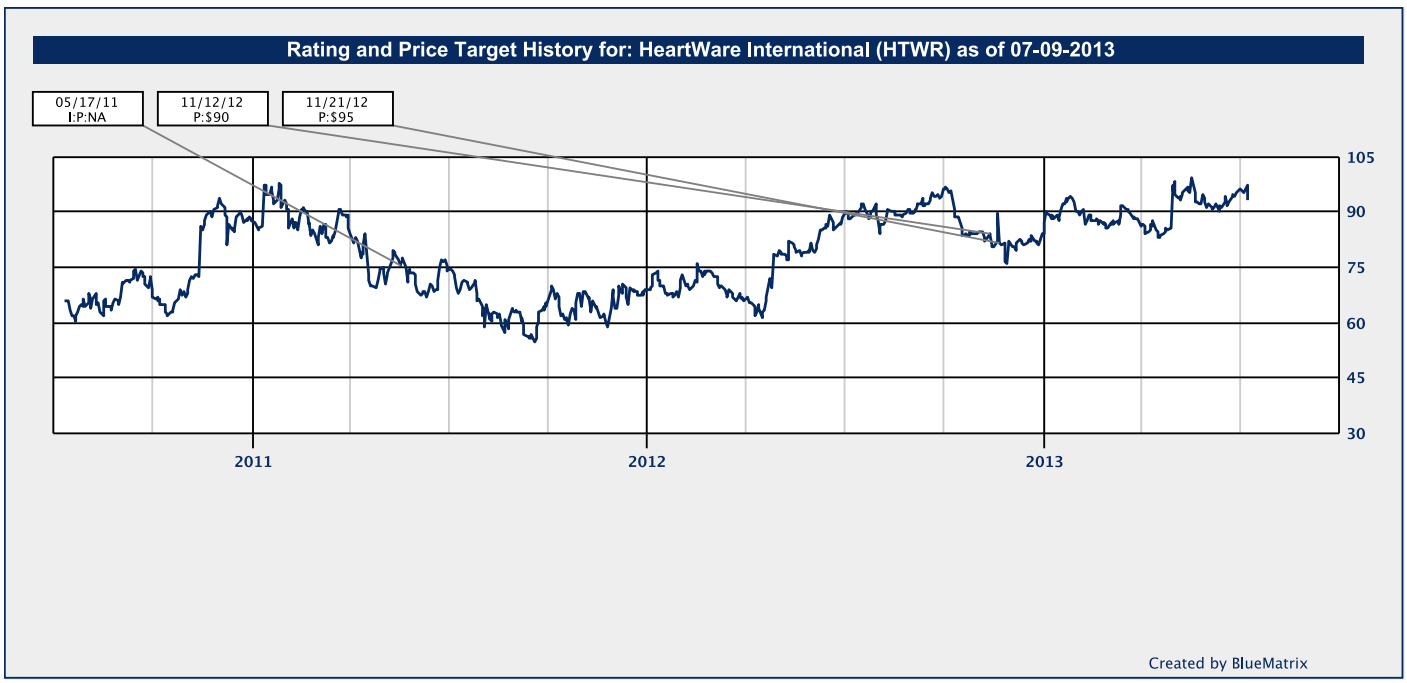
Rating and Price Target History for: HeartWare International (HTWR) as of 07-09-2013
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11/21/12
P:$95
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60
45
30
2011
2012
2013
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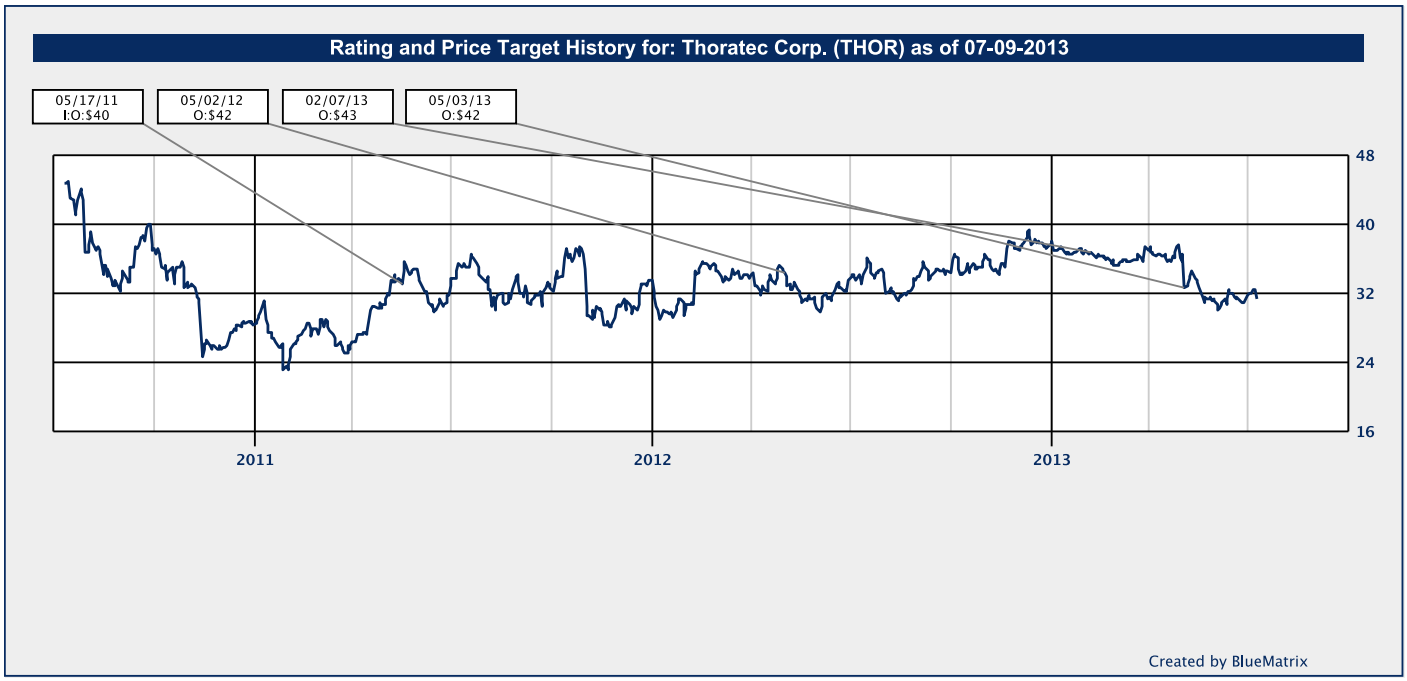

All price targets displayed in the chart above are for a 12- to- 18-month period. Prior to March 30, 2004, Oppenheimer & Co. Inc. used 6-, 12-, 12- to 18-, and 12- to 24-month price targets and ranges. For more information about target price histories, please write to Oppenheimer & Co. Inc., 85 Broad Street, New York, NY 10004, Attention: Equity Research Department, Business Manager.

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Distribution of Ratings/IB Services Firmwide

			IB Serv/Past 12 Mos.	
Rating	Count	Percent	Count	Percent
OUTPERFORM [O]	298	50.94	139	46.64
PERFORM [P]	278	47.52	96	34.53
UNDERPERFORM [U]	9	1.54	3	33.33

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