Sunshine Heart Fourth Quarter 2015 Financial Results

Conference Call Script

Operator:

Before we get started, I would like to remark briefly about forward-looking statements. Except for historical information mentioned during the conference call, statements made by the management of Sunshine Heart are forward-looking statements that are made pursuant to the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements involve known and unknown risks and uncertainties that are based on management's beliefs, assumptions, expectations, and information currently available to management. Those risks include but are not limited to risks associated with the possibility that the Company's clinical studies do not meet their enrollment goals, meet their endpoints or otherwise fail, that regulatory authorities do not accept the Company's application or approve the marketing of the C-Pulse System, the possibility that the Company may be unable to raise the funds necessary for the development and commercialization of its products, that the Company may not be able to commercialize its products successfully in the EU and the other risk factors described under the caption "Risk Factors" and elsewhere in the Company's filings with the Securities and Exchange Commission. By providing this information, the Company undertakes no obligation to update or revise any projections or forward-looking statements, whether as a result of new information, new developments or otherwise.

You should review the cautionary statements and discussion of risk factors included in the Company's press release issued

today, the Company's latest 10-K, subsequent reports, as well as its other filings with the Securities and Exchange Commission, under the titles "Risk Factors" or "Cautionary Statements Related to Forward-Looking Statements," for additional discussion of risk factors that could cause actual results to differ materially from management's current expectations, and those discussions regarding risk factors as well as the discussion of forward-looking statements in such sections are incorporated by reference in this call and are readily available on the Company's website at www.sunshineheart.com. During this call, management will also discuss non-GAAP financial measures as defined by SEC regulation G. Reconciliations of these non-GAAP financial measures to the comparable GAAP financial measures are included in the Company's earnings press release and supplemental information. In addition, a replay of the call is provided through a link on the investor relations section of the Company's website. With that said, I would now like to turn the call over to John Erb, Sunshine Heart's President and Chief Executive Officer.

John:
Thank you Operator. Good morning and welcome to Sunshine Heart's fourth quarter 2015 conference call. With me today is Claudia Drayton, Sunshine Heart's Chief Financial Officer. Following our prepared remarks, we will be happy to answer your questions.

Let me begin by stating that I am very excited to have formally assumed the full-time role of CEO here at Sunshine Heart. Over the past 90 days during my time as interim CEO, I have had the

chance to roll up my sleeves, really get to know the team, and build a broader and deeper understanding of the state of affairs here at Sunshine Heart. First, I can tell you that I am impressed by the management team and employees at Sunshine. They are talented, passionate, and driven by the opportunity to help heart failure patients. Over the last 90 days, I have been focused on learning as much as I can and accomplishing the 4 primary objectives that I had as interim-CEO. Those objectives were: 1) finding a new CEO; 2) reducing the company's cash burn; 3) reviewing the COUNTER-HF clinical trial strategy; and 4) assessing the resources being allocated to the company's next-generation product, CP-2. In terms of my first objective, I can honestly say that I did not have an initial desire to become CEO. However, what I can tell you is that the more I dug in and learned about Sunshine Heart's technology and significance of how it will benefit the heart failure market, the more excited I became about the chance to help execute a strategy that realizes the full potential of C-Pulse therapy and creates significant shareholder value. In terms of the second objective, we have made significant progress on slowing the cash burn rate. Claudia will provide a financial summary in a moment. This of course does not solve all of our challenges, but it does give us more time to address our financial situation. I'll say more on this in a moment. In terms of

the last two objectives, the company's clinical strategy and R&D pipeline are clearly the two areas where I have focused the majority of my time, reviewing our COUNTER-HF clinical strategy and assessing the progress on our next generation device.

In addition to meeting with our management team, I've spent considerable time meeting directly with our engineers, clinical specialists, physicians and our clinical investigators. I've learned a lot over the past 90 days and at this point, I would summarize my thoughts into three main observations, which are: 1) the clinical experience so far, continues to give us confidence that extra-vascular counterpulsation therapy represents a significant opportunity for treating Heart Failure patients; 2) the company's current clinical strategy is not working and will not get us where we need to be; and 3) not enough resources have been invested in our next generation fully implantable product. As I mentioned, I have not reached these conclusions in a vacuum. I believe there is general consensus amongst our clinical and regulatory experts as well as many of our physician customers and clinical investigators on all three of these points. After resuming enrollment in the COUNTER-HF clinical trial in the third quarter of last year, we stood behind our clinical investigators and their enthusiasm for enrolling patients in the trial. Our clinical

investigators have been surprised at the difficulty in enrolling patients. We have been mindful and diligent in our evaluation, but it is clear to me that we need to make some changes in order to realize the significant potential C-Pulse therapy represents. Based on this, we are announcing today that the company has stopped enrollment in the COUNTER-HF IDE trial and the OPTIONS-HF post-market study in Europe. Let me be very clear, we are not stopping these clinical trials because we do not believe in the therapy. It is exactly the opposite. We very much believe in the potential of C-Pulse therapy. However, we are taking these steps in order to ensure that we focus our precious resources on pursuing a more effective and efficient clinical strategy that will help patients, physicians, and shareholders realize the full potential of this unique therapy as soon as possible.

In terms of next steps, I am working diligently with our team and our investigators to lock down the specifics on what our revised clinical and product strategy needs to be. And while we are not in a position to share specifics with you today, we do realize that we need to determine and communicate more specifics with you as soon as possible. As we work out the details, I can give you a high-level sense of the basic tenets around our thinking on how best to revise our strategy.

First, as I evaluated the enrollment progress of COUNTER-HF and heard from physicians and investigators, it quickly became apparent to me that the complexity of the current procedure was simply too invasive. The need to crack the patient's chest as well as the need for a long-term drive-line were major inhibitors for patients. On top of that, there were also strong concerns surrounding the clinical trial design. Understanding this, we had to acknowledge that we were in no position to drive adoption in Class III Heart Failure patients, which is what we believe is a key target population for C-Pulse therapy. I don't believe our efforts up until now have been wasted. The company has learned a great deal over the past two years. For instance, one of the key learnings so far from these efforts is that we believe the optimal benefit from C-Pulse can be reached in the first 6 months of therapy. Thus, we do not need a trial which lasts beyond five years to demonstrate the efficacy of C-Pulse therapy. We have also observed early signals that demonstrate the potential for clinically meaningful improvement in remodeling the heart, which translates to improvement in ejection fraction. Improvements in ejection fraction has been shown to correlate to improvement in long term patient outcomes. A shorter duration therapy will also limit the time a patient has a drive-line, thus increasing

acceptance of the therapy while minimizing risk of infection. Based on these and other assumptions, we believe the best way to revise our clinical strategy at this point is to pursue dual paths. A nearer term path and a longer term path.

The first clinical path involves optimizing and modifying our current surgical approach, making it minimally invasive in order to enroll a short term clinical study to provide further evidence of "recovery" or "restaging"; further demonstration of the benefits of CP-1 becoming a "short-term" therapy; and demonstration that we can use a minimally invasive procedure to perform the implant.

The second clinical path involves accelerating the development of a fully implantable version, which we believe will be critical to driving the adoption of C-Pulse therapy. I fully realize that revising clinical strategies and modifying products is not easy and can often be more complicated than anticipated. But, based on the in-depth look I've seen so far, I believe Sunshine Heart has the team in place and the capability to execute a strategy that creates significant shareholder value by gaining access to a larger part of the Heart Failure market. As I mentioned, in terms of general timing for the first clinical path, we are still working out the details.

But I am driving the team to have an approved clinical protocol before the end of the calendar year. I believe this is achievable as we will be reaching out to FDA shortly to begin discussions in a very transparent and efficient manner. We anticipate the revised clinical strategy will get us to regulatory approval in a shorter time frame than could have been achieved with continuing the COUNTER HF trial.

As for the timing on CP-2, we will not be in a position to begin first-in-man this year. However, I believe that our revised clinical and product development pathway will actually position us to be able to commercialize a fully implantable version sooner than what would have been possible under the previous pathway.

We are also at the early research stage with evaluating the recovery capabilities of counterpulsation and its neuromodulation effects. Many of you may be aware of the scientific investigation that our Chief Scientific Officer, Jim Georgakopoulos, is conducting. Based on some hemodynamic measurements we have collected on C-Pulse patients, the response seems to be indicative of some neuromodular effect. As you know, heart failure patients have elevated sympathetic drive, which results in fluid retention by the kidneys, increases susceptibility to

arrhythmias and enhances constriction of blood vessels, the latter of which contributes to their poor functional capacity. I'm happy to announce that we are beginning a study in collaboration with Dr. Benjamin Levine and Dr. Qi Fu of University of Texas Southwestern, Dr. William Cornwell of Texas Health Resources (Presbyterian Hospital), and Dr. Phi Wiegn of Dallas VA Medical Center where we are conducting a study that directly measures the effect of C-Pulse on sympathetic nerve activity. Dr. Levine and Dr. Fu's lab specializes in techniques that directly measure activity from a sympathetic nerve and assesses the impact of pulsatility on baroreceptor stimulation.

I realize that our clinical and product challenges are not the only pressing issues we need to address. Let me now give you a sense of our current financial situation and what we're thinking in terms of where we go from here. First, we ended 2015 with $23M in cash. As I mentioned before, the team has been focused on reducing our cash burn in order to extend our cash needs into the back half of the year. However, in full transparency, we know that we will need to raise additional capital in the next 6-12 months. In that regard, we are actively exploring our financing options. One of the benefits of extending our window out into the second half of the year is that it gives us time to optimize our strategy,

communicate it with our shareholders, and establish some near term milestones that you can use to track our progress. I believe this will help us re-build credibility with investors which in turn, will help us identify better financing options.

At this point, I'll turn the call over to Claudia who can walk you through our Q4 financial results. Following that, I'll provide some closing comments before taking your questions.

Claudia:

Thanks John. Good morning everyone.

Turning to the P&L, we did not record any revenue during the fourth quarter of 2015. During the quarter, we enrolled 11 patients in COUNTER-HF, randomized 5 patients, and implanted 2 patients. However, those implants were not eligible for reimbursement because they were not covered by the patients' insurance.

Operating expenses in the fourth quarter of 2015 totaled $6.4 million, compared to $6.8 million in the fourth quarter of 2014. Operating expenses for the quarter reflect lower spending resulting from the consolidation of certain management positions

Net loss from operations for the period was $6.6 million, compared to a loss of $6.7 million for the fourth quarter of 2014. At the end of the fourth quarter we had $23.1 million in cash and cash equivalents and $8.0 million in short and long term borrowings.

As we previously announced, in December 2015 we amended our $8 million debt facility with Silicon Valley Bank. The amended agreement replaced the requirement that we raise $20 million in cash by the end of the first quarter of 2016 with a liquidity covenant that requires that we maintain cash and cash equivalents of at least eight times our monthly cash burn.

For the remainder of 2016 we do not expect to generate revenue. However, we also expect our operating expenses to meaningfully decline for the full year, reflecting the steps we've taken to reduce our cash burn going forward and the impact of the revised clinical strategy that John discussed earlier. In terms of modeling 2016, Q2, Q3, and Q4 should reflect a lower cash burn. In Q1, it will remain on the higher side, primarily due to the timing of severance payments that were accrued for in Q4. Looking ahead, as we consider our financing options, we are carefully analyzing

our capital needs based on our revised clinical strategy. I will now turn the call back over to John.

John:

Thanks Claudia.

Before opening the line up for questions, let me provide a few closing comments. First, I realize that our clinical announcements today may be frustrating to some of our shareholders who have supported and hung in with the company over the past couple of years. Making these kinds of decisions is never easy. But in assuming the role of CEO, my job is to make the tough decisions that will drive a strategy that can create shareholder value over the long term. Our former clinical pathway was not working and while it was difficult to confront that, we needed to have the strength, discipline and conviction to take one step back in order to take two steps forward. I also know that financial capital is a scarce, precious resource and while the CEO wears many different hats, I am ultimately a steward of the shareholders' capital. Knowing that, I can assure you that we are going to be very disciplined in executing our strategy as effectively and efficiently as possible.

I can’t change the past, but I took the role as CEO because I believe in the future of Sunshine Heart. In speaking with physicians, I continue to be struck by their interest in C-Pulse therapy and their belief that when we get this right, C-Pulse therapy can help address a significant unmet medical need for many heart failure patients. We know we have a lot of work ahead of us, but I believe we have the team in place to rise up to the challenges and deliver results. I also know that we are a “show-me” story. Over the coming months, we will endeavor to be as transparent as we can be about laying out a roadmap and more importantly, giving you the milestones that you can use to track our progress over the coming quarters. We know this will be critical for us to begin re-building credibility.

With that, we are now here to try and answer your questions. Operator . . .