Sunshine Heart First Quarter 2016 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 Erb, CEO:

Thank you Operator. Good morning and welcome to Sunshine Heart's first quarter 2016 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.

Having just completed my first 60 days as CEO, I'd like to begin by stating that I continue to be excited and optimistic about the significant opportunities ahead of us here at Sunshine Heart. It has only been two months since our fourth quarter call in March and I am pleased with the progress the company is making on the

key clinical and financial objectives that I laid out for you during our March call. You will also recall that back in March we acknowledged that the company's previous clinical strategy was not working and that it was not the right strategy to get us to where we want to be; accordingly, we made the prudent decision to take a step back on the clinical front in order for us to take two steps forward with a more effective clinical and product strategy. I committed to working diligently with our team and our clinical investigators to lock down the specifics on a revised clinical and product strategy. At that time, we also told you our initial thoughts involved the pursuit of a dual-path clinical strategy, which included a near-term acute clinical study focused on gathering more clinical data while at the same time developing a longer-term path to a fully implantable product. Today's call is the first real chance we've had to provide you an update and I am pleased to say that we are making real progress on both of these fronts.

First, our pursuit of a short-term path is based on leveraging some very key learnings so far. We believe that significant benefit from C-Pulse therapy can be reached in the first 6 to 9 months of therapy. Thus, we do not need a trial which lasts beyond five years to demonstrate the benefits 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. Improvement in ejection fraction has been shown to correlate to improvement in long-term patient outcomes. A shorter duration therapy utilizing our current CP-1 device will also limit the time a patient has the drive-line, thus increasing acceptance of the therapy while minimizing the risk of infection. Based on this, we intend to submit a short-term clinical protocol to the FDA before the end of Q3. And while we can't predict the timing of FDA responses, we do believe the FDA sees the value of having counterpulsation therapy as an important option for late-stage heart failure patients. Based on that, we also believe that it is not unreasonable to

estimate that we could have FDA approval for this study by the end of Q4 and that we will be in a position to begin enrollment during Q1, 2017. We also intend to optimize enrollment by concentrating our efforts on the top centers who are strong supporters of C-Pulse therapy.

We have received several requests from physicians for the compassionate use of our CP-1 device, which has instigated our exploring a Humanitarian Device Exemption (HDE) designation with the FDA for our CP-1 counterpulsation system.

We are also making progress on the second clinical path, which involves accelerating the development of a fully implantable system. We continue to see our fully implantable system as a longer term therapy option, providing chronic and sustained benefits to the large class 3 heart failure market, which is in excess of 1.5M patients in the US alone. On last quarter's call, we mentioned that we are in the early research stage with evaluating the recovery capabilities from counterpulsation therapy and its neuromodulatory effects. In conjunction with those efforts we began a study in collaboration with Dr. William Cornwell and Dr. Ben Levine of University of Texas Southwestern and Dr. Phi Wiegn of Dallas VA Medical Center that is attempting to directly measure the relationship between C-Pulse and sympathetic nerve activity. As part of that study we conducted an acute assessment of a patient who had been on counterpulsation therapy for 8 months, which demonstrated a direct correlation in changes in nerve activity with the device turned on versus the device turned off. In that regard, we believe the ability to separately measure the hemodynamic effect along with any neuromodulatory effect can play a key role in helping us meaningfully reduce the size of our fully implantable system while optimizing the treatment effect at the same time. As part of this effort, we anticipate the use of a proprietary nerve cuff design to be used in an acute first-in-man study later this year.

We are also actively investigating several opportunities that will complement our counterpulsation therapy and increase our opportunities to develop a meaningful franchise in heart failure. Before I turn the call over to Claudia, let me say a few words about some upcoming clinical data and our current financial situation. First, I am pleased to announce that data from our OPTIONS-HF post-market study will be presented later this month at the European Society of Cardiology Heart Failure conference in Florence, Italy. While we can't discuss the results yet, we do expect the data to show improvements in cardiac remodeling, functional capacity, and quality of life. We will issue a press release with the results when the data is presented on May 21st. Finally, on the financial front, I am pleased with the progress we have made in reducing our cash burn rate. Operating expenses are down 35% from Q1 last year, and more importantly, we have put in place a 2016 budget that not only reduces our overall cash burn, but it does so while driving increased productivity throughout the organization.

In terms of the balance sheet, we continue to expect to raise additional capital in 2016. In that regard, we are actively exploring our financing options. Ahead of that, we remain focused on optimizing our clinical and product strategy in a way that creates a business plan and financial opportunity that is both compelling and achievable. We will continue to update you on meaningful progress and will continue to establish 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 Q1 financial results. Following that, I'll provide some closing comments before taking your questions.

Claudia Drayton, CFO:

Thanks John. Good morning everyone.
Turning to the P&L, we did not record any revenue during the first quarter of 2016, as the patients that were implanted prior to the announcement that we ceased enrollment in the COUNTER-HF study, were not eligible for reimbursement.

Operating expenses in the first quarter of 2016 totaled $4.6 million, compared to $7.1 million in the first quarter of 2015, a decrease of about 35%. Operating expenses for the quarter reflect lower spending resulting from the announcement in Q1 that we were no longer enrolling patients in the COUNTER and OPTIONS HF studies, from the consolidation and streamlining of activities in all areas of the company in an effort to increase efficiencies and reduce our cash burn, and from reduced stock compensation expense.

Net loss from operations for the period was $4.8 million, compared to a loss of $7.1 million for the first quarter of 2015. As of January 1, we began to repay principal amounts on our debt outstanding with Silicon Valley bank, as the interest only period ended at the end of 2015. At the end of the first quarter we had $16.5 million in cash and cash equivalents and $7.1 million in short and long term borrowings.

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 than in Q1 as the severance payments we've paid out are behind us. In terms of financing, we continue to continue to evaluate our options and we

are carefully analyzing our capital needs based on our revised clinical strategy. As John discussed, we intend to raise capital in 2016. I will now turn the call back over to John.

John Erb, CEO:

Thanks Claudia.
Before opening the phone line up for questions, let me reiterate that I am excited and optimistic about the future.
We know we have a lot to do, but I believe we are moving in the right direction. The entire management team is rising to the challenges in front of us and focused on delivering results. I know that we remain a “show-me” story. We will continue to endeavor to be as transparent as possible about our progress and giving you the milestones that you can use to track our progress over the coming quarters, which I believe will build our credibility over time.