Sunshine Heart Second 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 Company's products, 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, that the Company may not be able to successfully integrate acquired businesses, that the Company may not realize anticipated synergies and benefits from acquired businesses 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 Chief Executive Officer and Chairman of the Board.

John Erb, CEO:

Thank you Operator. Good morning and welcome to Sunshine

Heart's second 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 full quarter as CEO, I'd like to begin by stating that I continue to be excited and optimistic about the significant opportunities ahead of us at Sunshine Heart. We have a lot of good things happening at the company and I'd like to spend the first part of today's call updating you on two important initiatives. First, I'll discuss our revised clinical and product development strategy that we recently announced. After that, I will discuss the strategic acquisition of the Aquadex FlexFlow® product line from a subsidiary of Baxter, which we announced yesterday. Following that, I will provide my thoughts and perspective on our current financial situation and plans.

First, let me start with our revised clinical and product development strategy. For perspective, it has been about two months since we held our Annual Shareholders Meeting in May. At that time, we described some of the strategic changes we were

beginning to make. Before I go any further, I think it is very important to emphasize that the strategic changes being made are based on valuable insights learned from patients treated with C-Pulse therapy.

We have spent considerable time and effort collecting and analyzing the data and researching the most optimal strategic path forward. Based on this work, we are moving ahead with a therapeutic strategy that is focused on neuromodulation as we temporarily set-aside counterpulsation. The primary reason driving this change is based on our OPTIONS-HF European post-market trial. In that trial, the hemodynamic effects observed indicated a mechanism of action not explained solely by the principle of counterpulsation. In our COUNTER HF study, similar effects were observed during C-Pulse programming, which led physicians to initiate measurements to assess the neural effects of C-Pulse. Preliminary data demonstrated the primary mechanism of action from C-Pulse was neuromodulation. We

believe this is due to the balloon cuff being placed on the ascending aorta. During therapy, when the balloon cuff is inflated it stretches the wall of the aorta; we believe this causes mechanical activation of adjacent baroreceptors. This was an extremely important discovery that points us in a better direction compared to our previous clinical strategy. We believe our new direction provides significant benefits, including: 1) a more cost effective way to develop a fully-implantable system, 2) a faster path to commercialization, and 3) access to the broader heart failure market and potentially other indications.

For these reasons, we believe a neuromodulation-based therapy will ultimately be more impactful to both patients and physicians than our original C-Pulse System. We are confident that we are on the right track. In fact, we believe that the development and ultimate approval of a fully implantable neuromodulation device can be achieved in half the time and at half the cost of our original system. Our unique approach targets easy to find anatomical structures, which provide an immediate and measurable response

when stimulated. In addition, the mechanism of action is direct and well understood.

Moving ahead, we have identified the following clinical steps to achieve two primary objectives:

First, the company is pursuing a first-in-man acute study to demonstrate a hemodynamic response using a proprietary neuromodulation approach. The study is expected to include approximately 20 patients and will utilize an external pulse generator and prototype electrodes. Enrollment is estimated to begin and end in the fourth quarter of 2016.

Next, following the completion of the first-in-man study, we will pursue a clinical study that utilizes a proprietary fully implantable system. The purpose of this study will be to establish the effects and safety profile of our system. The study will include approximately 30 patients and the clinical endpoints will be based on a 6-month follow-up period. The results will be used to support

CE Mark approval as well as an IDE/PMA submission with the FDA. Patient enrollment is expected to begin in 2017.

I am pleased with the progress we are making on both of these clinical initiatives. For the acute study, we have already identified clinical sites in Europe and the first clinical site is fully approved to begin the study. We have also added a new clinical site at

one of Australia's premier research hospitals. We are also in active discussions with some of the leading medical device companies in the neuromodulation space and negotiations are on track to secure mutually beneficial partnerships.

Now, let me shift gears. Yesterday, we announced the acquisition of the Aquadex product line from a subsidiary of Baxter International. This is a highly strategic and financially compelling transaction and we are very excited about it. First, let me describe what the Aquadex system does. Aquadex is a unique proprietary product that is used for the temporary ultrafiltration treatment of

patients with fluid overload. Ultrafiltration is a process that removes water and sodium from a patient in a manner similar to how the kidney functions. Fluid overload, a condition that is prevalent in heart-failure patients can lead to decompensation, resulting in lengthy and costly hospitalizations. Aquadex is primarily used to treat fluid overload in congestive heart failure patients and may help reduce the length of hospital stays and recurrent hospitalizations. My strong confidence in this product is based on the significant experience, knowledge, and success I have had with Aquadex earlier in my career. I have seen first-hand the value that Aquadex can deliver to patients, physicians, and the healthcare system. The Aquadex system is highly complementary to our focus on treating heart failure patients. Aquadex not only allows us to strengthen our presence in the heart failure market, it will also help us build and expand our relationships with key physician groups, which will be strategically beneficial as we pursue the development of our core neuromodulation technology. The primary sales call-point for

Aquadex is the heart failure cardiologist, who will also be the primary referring physician for our neuromodulation system. In addition to being highly strategic, the transaction is financially compelling as well. We have strategically identified and obtained a valuable and financially attractive asset. Aquadex was not part of Baxter's long-term strategic plans, but it is the perfect fit for our strategic direction. We were able to negotiate an excellent deal and the acquisition is expected be accretive in the first year with a relatively quick payback period. Exiting 2016, we estimate the quarterly revenue run-rate will be annualizing at approximately $5 million; and in 2017, we expect to exit the year with quarterly revenue annualizing around $10 million. In terms of execution, we will strategically leverage our current team of clinical specialists, which have been fully trained on this product and will allow us to start servicing customers and generating revenue immediately. I also want to emphasize that Aquadex will not in any way distract us from executing on our neuromodulation strategy.

Before I turn the call over to Claudia, let me provide some comments about our financial situation. I am pleased with the progress we have made in reducing our cash burn rate. Operating expenses are down 35% from Q2 last year, and more importantly, we are executing on 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, raising capital continues to be a top priority for us. We just recently completed an offering of convertible preferred stock and a private placement of warrants for gross proceeds of approximately $3.5 million. We expect to raise additional capital in 2016. In that regard, we remain focused and disciplined on identifying the best financing options for the company and our shareholders.

As you can see, we are not sitting still. We are excited about the direction we are going. The entire team is focused on executing

our strategy and we will continue to keep you regularly updated as we make meaningful progress.

I will now turn the call over to Claudia who can walk you through our Q2 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 second quarter of 2016, as we announced that we had ceased enrollment in our COUNTER HF study in the first quarter of this year.

Operating expenses in the second quarter of 2016 totaled $4.0 million, compared to $6.3 million in the second 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 HF 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 $4.2 million, compared to a loss of $6.4 million for the second quarter of 2015. In terms of our cash position, 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 second quarter we had $12.0 million in cash and cash equivalents and $6.1 million in short and long term borrowings. In terms of our current cash position, there have been several major cash related items that occurred subsequent to quarter end. While we don’t report intra-quarter cash balances, I can highlight the major cash related items that have occurred thus far in Q3; 1) we

paid $4.0 million for the acquisition of Aquadex; 2) we also incurred approximately $1.0 million in fees related to the closing of this transaction; 3) we repaid the $6.1 million outstanding balance with Silicon Valley Bank plus associated fees; and 4) we closed on a convertible preferred equity financing that provided gross proceeds of approximately $3.5 million. Additionally, in conjunction with the Aquadex transaction, we also announced that we signed a new agreement for a $5 million debt facility with Silicon Valley Bank; and while we do not currently meet the minimum liquidity requirements to utilize this debt facility, we expect to do so as we raise additional capital in the coming months.

In terms of modeling Q3 and Q4, we expect to begin generating revenue from Aquadex during these quarters, and we expect to exit the year with a quarterly revenue run-rate annualizing at about $5 million. Regarding our operating expenses, we expect to continue to show meaningful reductions versus last year, even

after some modest investments in our Aquadex product line. Our spending reductions should continue to reflect 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 financing, we 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 additional 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 our future.

We know we have a lot of work ahead of us, but I believe we are moving in the right strategic direction. The entire management team is rising to the challenges in front of us and we are focused on delivering results. We are striving to be as transparent as

possible and we will continue to provide you milestones to track our progress over the coming quarters. We believe this will allow us to continue to strengthen our credibility over time.