SUNSHINE HEART

Sunshine Heart Third Quarter 2016 Financial Results Conference Call Script

Operator:

INSERT COMMENTS FOR OPERATOR

John Erb, CEO:

Thank you Operator. Good morning and welcome to Sunshine Heart's third quarter 2016 conference call. With me today is Claudia Drayton, Sunshine Heart's Chief Financial Officer, and Molly Wade, Sunshine Heart's Sr. Vice President of Strategic Operations. Following our prepared remarks, we will be happy to answer your questions.

I'd like to start by acknowledging that Q3 was a quarter with many changes. We anticipated some of those changes, and there were other changes that we weren't expecting back when we held our

Q2 call in August. Let me start with what we did not expect. As many of you know, in late September we announced that we were implementing a strategic realignment of our near-term strategy and since that time we have been focusing our limited resources on the recently acquired Aquadex FlexFlow® business. In conjunction with that decision, we also announced that we needed to pause the clinical evaluations of our neuromodulation technology. Let me stop here and emphasize that we remain very optimistic about the long-term potential of this unique neuromodulation technology. The reason we needed to pause development activities is completely due to a lack of sufficient cash to fund the program and is not due to any negative results. In fact, just prior to our pausing the neuromodulation program, we performed a successful acute first in man test in Europe with prototype electrodes and an external pulse generator. The testing showed a clear and immediate physiologic response with drops in both heart rate and blood pressure. These results strengthen our conviction that we have identified a significant clinical opportunity to improve patient outcomes by reducing the sympathetic drive in heart failure patients. We also filed two neuromodulation patent applications in the third quarter of 2016. In the future, we will consider alternative opportunities to fund the development of this valuable technology. Again, this decision was strictly financial. Our previously announced efforts on raising additional capital have been slower and less fruitful than we originally expected. While we were able to raise $3.5 million in late July and another $3.8 million in early November, these amounts were less than we expected. Based on this, it was imperative that we make changes that will reduce our cash burn from over $2 million per month in the fourth quarter of 2015. We are targeting a cash burn of less than $800,000 per month in the fourth quarter of 2016. The only way to achieve this was to significantly reduce our neuromodulation activities and increase our focus on the Aquadex business, where our efforts can quickly produce revenue generating, cash flow positive results. Of course, we will continue to look for opportunities to re-engage in the neuromodulation strategy as appropriate, but in the near-term we will be focusing on maximizing our Aquadex opportunity.

In that regard, let me expand further on why we are excited about Aquadex and how we intend to optimize its results.

First, a bit of background on the product. The Aquadex FlexFlow System consists of three primary components: the console, which is a piece of capital equipment with a list price of $28,500 and is about the size of a coffee maker; a one-time use disposable blood circuit set with a list price of $900; and a small dual lumen peripheral catheter that simultaneously withdraws blood and returns filtered blood to the patient's arm. 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. There are over 1 million hospitalizations per year in the U.S. for acute heart failure and approximately 90% present with symptoms of fluid overload. Aquadex is primarily used to treat fluid overload in congestive heart failure patients and has been shown in randomized, controlled clinical trials to reduce both the length of stay in the hospital and repeat hospitalizations. Aquadex allows us to maintain and strengthen our presence in the heart failure market as the primary sales call-point is the heart failure cardiologist.

We intend to grow the Aquadex business by providing superior service to our customers through our direct field organization, our in-house customer service team, our technical service team, and our clinical education efforts. We are actively focused on strengthening our capabilities in all of these areas.

We will execute our growth strategy in deliberate stages: initially, we are focusing on the top 55 hospital accounts that generated eighty percent of the revenue in 2015; next, we'll expand our efforts to re-engage the additional 110 hospital accounts that also purchased blood sets in 2015. In addition, we will focus on re-educating customers to help increase the utilization of the

Aquadex consoles that we know were owned by an additional 200 hospital accounts prior to 2015. There is currently a large installed base of over 500 consoles in U.S. hospitals and the business model is similar to the simple razor and razor blade model, once a console is acquired by a hospital we work to increase utilization of the console with ongoing purchases of the disposable blood sets. We had ownership of the Aquadex business for just 8 weeks in Q3. During this time of transition while we were getting our team up to speed, we were encouraged to see that forty-six U.S. hospitals purchased 480 disposable blood sets. Over this same time period, we began re-engaging dormant accounts and sold additional blood sets to eight hospitals that had not purchased any product in over a year. Of course, we will be opportunistic about opening new accounts when possible, but our initial sales focus in 2017 will be on increasing the utilization of blood sets in the accounts that already have Aquadex consoles.

We are also excited by some early initiatives that will increase the evidence basis for use of Aquadex in the outpatient setting by collecting post-market clinical data. We plan to partner with several high-profile institutions in this effort and more details will be forthcoming in future communications.

We are confident that the measures we are taking will help us attain a targeted fourth quarter 2016 revenue run-rate of approximately $5 million per year, and a fourth quarter 2017 revenue run-rate of approximately $10 million per year.

Before I turn the call over to Claudia, let me quickly update you on the status of our NASDAQ listing. Our strong desire is to continue to remain listed on NASDAQ. We have a hearing at NASDAQ in mid-November to petition for a further extension of time so that we can meet the NASDAQ listing requirements. While we can't predict the outcome of that hearing, we intend to make a strong case and we will update you when we have additional information.

I will now turn the call over to Claudia who can walk you through our Q3 results and some key financial details. 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, this is the first quarter we generated revenue from our newly acquired Aquadex business. Revenue for the post acquisition period from August 5th to September 30th was $484,000, and it resulted mainly from the sale of disposable blood sets and catheters. During the first 90 days post acquisition we worked on transitioning order-taking and fulfilment from prior management to our internal team at Sunshine Heart. We are happy to report that after the end of the quarter, all of these activities have successfully transitioned to our in-house team. Having instant visibility to our sales activity will allow us to more effectively track and monitor the performance of our customer accounts and field personnel.

During the quarter we also recorded $59,000 of clinical revenue for an implant that occurred under our COUNTER HF study prior to the announcement earlier this year that we were no longer enrolling patients in the trial.

Cost of sales reflect the prices paid for inventory under a manufacturing and services agreement we signed at the time of acquisition. Under this pricing structure, we expect our gross margins to be around 60% or a bit higher.

In terms of operating expenses for the third quarter, they totaled $4.4 million, a decrease of about $1.9 million from the same period last year. In addition, during the quarter, we expensed approximately $900,000 of transaction related costs for the acquisition of the Aquadex product line. Exclusive of these costs, our operating expenses would have decreased by $2.8 million versus last year. The decrease in expenditures reflects lower clinical spending resulting from the announcement earlier in the year that we were no longer enrolling patients in our clinical studies, from the consolidation and streamlining of activities in all areas of the company, and from reduced stock compensation expense.

In terms on non-operating expenses, during the quarter we incurred approximately $500,000 in expenses related to the early payoff of our term loan with Silicon Valley Bank. These expenses related mainly to the accelerated write off of unamortized warrants, final interest payment, and debt issuance costs. Additionally, during the quarter we recognized an unrealized gain of approximately $600,000 related to the change in fair value of the warrants that were issued in connection with our July equity raise.

Finally, our net loss for the period was $3.9 million, compared to a net loss of $6.6 million for the third quarter of 2015.

In terms of our cash position, at the end of the third quarter we had approximately $800,000 in cash and cash equivalents and no debt. During the quarter, we completed an equity financing for gross proceeds of $3.5 million by issuing convertible preferred stock and warrants to purchase common stock. In August, we repaid the entire $6.0 million loan that was outstanding with

Silicon Valley Bank and paid $4.0 million in cash for the acquisition of Aquadex plus approximately $900,000 in fees and expenses related to the closing of this transaction. Subsequent to quarter end, we signed on a new round of financing for gross proceeds of approximately $3.8 million in exchange for convertible preferred shares and warrants to purchase our common stock.

In terms of modeling Q4 revenue, we expect to exit the year with an annualized quarterly run-rate of 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 business. 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 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 strategy. We are working diligently to grow the business and invest judiciously to bring it to a breakeven point as soon as possible. In the meantime, we will look for additional financings to provide us with the necessary capital to get to a point where the business is self-sustaining.

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 remain very optimistic.

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

Operator are there any questions?

If there are no questions I want to thank you for joining our 3rd quarter conference call and wish you all a good day.