SUNSHINE
HEART

Sunshine Heart Fourth 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 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. 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 fourth 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.

Before I comment on our fourth quarter performance, I would like to provide some perspective on the full year of 2016. As most of you know, it was a year of many changes at Sunshine Heart. I became CEO in March. In August, we announced our intention to shift our therapeutic strategy from a counterpulsation approach to a neurostim approach. This decision was based on solid empirical data and pointed us in an exciting direction that also formed the supporting basis for our capital raising efforts. However, we were both surprised and disappointed by the challenges that we faced in trying to raise sufficient capital to truly get the neurostim program off the ground. We still believe that our neurostim approach for treating heart failure patients has significant upside potential, but the resources required to fund this project remain beyond our current capacity. However, please know that we continue to consider alternative opportunities to fund the development of this technology. In that regard, we are looking for strategically creative ways to unlock the value of this therapy – possibly through a partnership or a joint venture. We continue to have meaningful discussions with potential strategic partners. There's nothing imminent at this point, but we will update you when we identify a viable path forward for this project.

In August, we announced, what turned out to be, our most important strategic change in 2016, the acquisition of Aquadex from Baxter International. As we communicated at the time, it is a strategic acquisition that allows us to maintain a working partnership with heart failure physicians. We secured it at an attractive valuation and we now have an approved product that is generating revenue and cash flow. I believe that Aquadex represents the most financially sustainable path forward for Sunshine Heart.

In that regard, let me expand further on why we are excited about Aquadex and what we are doing to realize its full potential.

First, let me just remind you of what makes up our Aquadex FlexFlow System. It 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.

Claudia will discuss the details of our Q4 financial results in a moment, but I would acknowledge that our Q4 revenue was a little below our initially targeted run-rate, which reflects a transition period that took longer than expected. This was due to several factors, including some hurdles that we needed to overcome. Initially, there were some miscommunication issues with Baxter that created some confusion with our customers. We also had some challenges getting timely and relevant customer account detail from Baxter. Finally, many hospitals required us to go through a new vendor qualification process, which required extra time to complete. We believe we've addressed these issues and we are now well into our 2017 operating plan. We are executing in deliberate stages: first, we focused on increasing utilization in the top 55 hospital accounts that accounted for about 80 percent of the activity in 2015; additionally, we expanded our efforts to re-engage the additional 110 hospital accounts that also purchased blood sets in 2015. By the end of 2016, we had 95 hospital accounts that have re-engaged and now purchasing the disposable blood sets on a regular basis. Through the end of February 2017, we now have 115 active hospital accounts, so we are exceeding our initial account activation goals. Our momentum is increasing as we reach more hospital accounts that have been somewhat dormant over the couple of years that the business was part of Baxter. From the time we acquired the business in August of 2016 to year-end 2016, we sold just under 1,200 blood sets. In January and February of 2017 alone, we sold almost 700 blood sets.

Looking ahead, our growth strategies will be focused in 4 main areas:

The first area of focus will be providing our customers with better diagnostic tools that will enable them to improve patient selection, and optimize fluid removal levels and procedure length. We are exploring possible partnerships in this area.

The second area of focus is generating meaningful economic evidence that can help optimize reimbursement and ultimately drive increased utilization.

The third area of focus is on expanding the use of Aquadex into other clinical areas within the hospital environment.

And our fourth area of focus will be expanding the use of Aquadex

into the outpatient environment. We are excited by some early initiatives in this area that involve collecting post-market clinical data. We plan to partner with several high-profile institutions in this effort and we will update you as we make progress.
We remain confident that our strategies and tactics will help us attain a targeted fourth quarter 2017 revenue run-rate of approximately $10 million per year.

I am also pleased to report the addition of two new members to our Board of Directors. Steven F. Brandt joins our board with over 35 years of medical device experience, including executive leadership roles at Thoratec, St. Jude, and CHF Solutions. Steve is very familiar with the heart failure market and he played a key role in the successful launch of the Aquadex System during its early years. Matthew Likens joins our board, and also brings with him over 35 years of healthcare experience, including 10 years as CEO of Ulthera, Inc. Matt has as strong track record of growing healthcare companies and brings valuable CEO and financing experience to the Board. I look forward to their contributions to our Board.

Before I turn the call over to Claudia, I would also like to give you my perspective on two important issues: our capital raising efforts and the status of our NASDAQ listing.

I'll start with our NASDAQ listing. On February 9th, we announced that we received a notice from NASDAQ indicating that we are now compliant with the minimum bid price requirement, resulting from our January reverse stock-split. The company still needs to meet the stockholders' equity requirement and we remain focused on meeting all NASDAQ requirements.

In terms of capital, we raised $3.5 million in late July and another $3.6 million in early November. These funds were critical for continued operations and while more dilutive than we would have liked, we strived to negotiate the most shareholder friendly terms possible available. We intend to raise additional capital in 2017 that we will use to help accelerate our Aquadex growth strategy.

We will continue to be very disciplined in identifying the best financing options available to us

I will now turn the call over to Claudia who can walk you through our Q4 results and financial details. Following that, I'll provide some closing comments.

Claudia Drayton, CFO:

Thanks John. Good morning everyone.

Turning to the P&L, this is the first **full** quarter we generated revenue from our newly acquired Aquadex business. **Revenue** for the quarter was $746,000, and it resulted mainly from the sale of new consoles and disposable blood sets. Revenue was below our expectations, however, driven mainly by a couple of factors, First, we took over customer order taking and fulfillment from Baxter in November of 2016. While we were fully prepared for this event, there were nonetheless some communication issues with Baxter that impacted the transition. Second, we underestimated the effort needed to re-engage accounts that had not been attended to for a long time or that believed that Aquadex was no longer available and had switched technologies. We are happy to report that, while reactivating accounts took longer than planned, we expect to see Q1 more in line with our expectations.

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 standard margins to be around 60% or a bit higher. Included in cost of sales are also start up manufacturing and product costs related to the manufacturing transition from Baxter.

In terms of **other operating expenses** for the fourth quarter, they totaled $3.3 million, a decrease of about $3.0 million from the same period last year. The decrease in expenditures reflects lower clinical spending resulting from the announcement earlier in 2016 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 recognized an unrealized gain of approximately $170,000 related to the change in fair value of the warrants that were issued in connection with our July and November equity raises.

Finally, our **net loss** for the period was $2.9 million, compared to a net loss of $6.6 million for the fourth quarter of 2015.

In terms of our **cash** position, at the end of the year we had approximately $1.3 million in cash and cash equivalents and no debt. We completed an equity financing in November 2016 for total gross proceeds of $3.6 million where we issued convertible preferred stock and warrants to purchase common stock.

Subsequent to quarter end, we announced that we had entered into a warrant exchange agreement to incent our institutional investors to exercise the warrants issued as part of the July and November financings. If exercised in full, this warrant exercise will yield the company approximately $4.6 million in cash.

In terms of modeling **2017**, we expect revenue to accelerate during the year and expect that our efforts to revitalize the business will begin to pay off. Regarding our operating expenses, we expect to make some modest investments in our Aquadex business, mainly to augment our presence in the field.

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 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 will continue to provide you milestones to track our progress over the coming quarters.

Operator are there any questions?

If there are no questions I want to thank you for joining our 4th quarter conference call and wish you all a good day.