Sunshine Heart First Quarter 2017 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. We are very excited about our revitalized and growing Aquadex business. We are increasing the number of hospitals utilizing the Aquadex FlexFlow System, revenues are growing double digits with 21% revenue growth in Q1, 2017 over Q4, 2016, there is increased use of Aquadex in hospital observation units and outpatient clinics, we have successfully completed a financing to fund operations through Q1 of 2018, and we received a Nasdaq compliance determination last week.

Let me remind you that the Aquadex FlexFlow System consists of three primary components: The console pump, which has a $28,500 list price; 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 salt from a patient in a manner similar to how the kidney functions. Fluid overload is a condition that is prevalent in heart failure patients, which can lead to decompensation resulting in lengthy and costly hospitalizations. There are over 1 million patients hospitalized per year in the US for acute heart failure and approximately 90% of these patients present with symptoms of fluid overload. Aquadex has been shown in randomized, controlled clinical trials to remove more fluid than diuretics and to reduce both the length of stay in the hospital and repeat hospitalizations.

Sunshine Heart acquired the Aquadex business from Baxter International approximately 9 months ago. Although there is a large installed base of Aquadex consoles, with over 500 consoles owned by over 300 US hospitals, at the time of the acquisition there were only about 55 hospitals that were providing the therapy to their patients. By the end of Q4, 2016 we had re-engaged and increased the number of US hospitals ordering Aquadex products and services to 95 hospitals. Today, we have 135 US hospitals that have ordered Aquadex product or services. Claudia will discuss the details of our Q1 financial results in a moment, but I am pleased to let you know we saw a 21% increase in revenue for product and services in Q1, 2017 over Q4, 2016.

I am also very pleased with the April 24th addition of our new Chief Commercial Officer, Mr. Jim Breidenstein. Prior to joining Sunshine Heart, Mr. Breidenstein was President and Chief Operating Officer of Surgical Theater, a medical virtual reality software company. Prior to Surgical Theater, Mr. Breidenstein

was Senior Vice President of Sales at Cardiovascular Systems, Inc., a company focused on developing and commercializing innovative solutions for treating peripheral and coronary vascular disease, and Director of Sales at Kyphon, Inc, a startup company specializing in spine surgical instruments that was acquired by Medtronic in 2007. While at CSI and Kyphon, Mr. Breidenstein was instrumental in helping these companies achieve rapid revenue growth and increased market valuation.

Looking ahead, our growth strategies remain focused on 4 main areas:

The first area of focus is to continue to re-engage and revitalize the many hospitals that have already invested in the Aquadex therapy but have been dormant for the past few years due to the lack of any sales effort to provide service or training. We are renewing a commitment to these hospitals to call on them regularly and provide the service and training necessary to ensure quality patient care.

The second area of focus will be providing our customers with better diagnostic tools to enable them to improve patient selection and optimize fluid removal. We have identified two FDA market cleared bioimpedance spectroscopy products that can provide important hemodynamic data to our physicians and nurses. We are also exploring the potential utilization of an approved device that measures pulmonary artery pressure to help manage heart failure and fluid levels.

The third area of focus is on expanding the use of the Aquadex FlexFlow System into other clinical areas within the hospital environment. Heart failure patients with fluid overload can be treated in the Emergency department, on the hospital telemetry floor, and in the intensive care unit. Aquadex can also help manage fluid overload in patients recovering from cardiac surgery and in burn units.

The fourth area of focus is to generate economic evidence to help optimize reimbursement to drive increased utilization in hospital

observation units and outpatient clinics. We are collaborating with several hospital systems to support physician and hospital initiated clinical evaluations treating fluid overloaded heart failure patients in the outpatient setting.

We see significant opportunity for growth of the Aquadex product line in the large, underserved heart failure market identified in six key strategic areas:

1. **Existing Installed Base:** There is a large established customer base to re-engage and revitalize in over 300 US hospitals that have already implemented the aquapheresis therapy at some point in the past
2. **Under-penetrated In-patient Market:** There is a large under-penetrated in-patient market with over 1 million US hospital admissions each year for heart failure and over 5,000 US hospitals treating heart failure patients
3. **Under-served Outpatient Market:** There is a significant and growing need for outpatient treatment to prevent hospital

readmissions due to fluid overload. Hospitals are under financial pressure to reduce the length of stay of the heart failure admission but yet need to avoid the costly Medicare penalties assessed when a heart failure patient is readmitted within 30 days of the initial hospital discharge

4. **Untapped Large OUS Market:** There is a market for the Aquadex System outside the US that is significant and we have not yet re-engaged these efforts
5. **Differentiated Technology:** Aquadex FlexFlow System is a very differentiated technology with published clinical trials showing many clinical benefits over the current standard of care, IV diuretic drugs
6. **Hospital Economic Drivers:** We are well aligned with the market dynamics created by the Affordable Care Act that is forcing hospitals to reduce the heart failure hospital length of stay while reducing readmission rates

Before I turn the call over to Claudia, I would like to update you two important issues: our successful capital raise and the status of our Nasdaq listing.

I'll start with our Nasdaq listing. On May 4, 2017 we received formal notification from Nasdaq that we have regained compliance with all criteria for continued listing on The Nasdaq Capital Market, including the minimum stockholder's equity requirement and that the Nasdaq listing matter has been closed..

In terms of capital, we raised gross proceeds of approximately $9.2 million before deducting underwriter discounts and commissions and offering expenses in a successful underwritten public equity offering in April, which includes the full exercise of the underwriter's over-allotment option to purchase additional shares and warrants. With this financing, Sunshine Heart expects to have enough cash to fund our operations through Q1-2018.

I will now turn the call over to Claudia who can walk you through our Q1 results and financial details. Following that, I will provide some closing comments.

Claudia Drayton, CFO:

Thanks John. Good morning everyone.

Turning to the P&L, **revenue** from our newly acquired Aquadex business was $901,000 for the quarter, a sequential growth of 21% over the fourth quarter of 2016. The growth was driven mainly from a 23.5% sequential growth in the sale of **circuit sets**, which make up 85-90% of our sales on any given period. Also, during the period, our **tech services** revenue grew sequentially by about 71% as more and more customers send us their consoles for recalibration services.

Our **Cost of sales** reflect the prices paid for inventory under a manufacturing and services agreement we signed with Baxter 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 costs related to our planned manufacturing transition from Baxter.

In terms of other **operating expenses** for the first quarter, they totaled $2.7 million, a decrease of about $1.9 million from the same period last year. The decrease in expenditures reflects lower clinical spending resulting from the announcement in the first quarter of 2016 that we were no longer enrolling patients in our C-Pulse related clinical studies, from the consolidation and streamlining of activities in all areas of the company, and from reduced stock compensation expense.

In terms of **non-operating expenses**, they reflect an unrealized gain of approximately $1.4 million related to the change in fair value of the warrants that were issued in connection with our July and November equity raises. Those warrants were classified as a liability on our balance sheet as of December 31, 2016 and

required fair market valuation at each reporting period. Also, included in our non-operating expense is a charge to earnings for $67,000 related to the incremental fair value of the new warrants provided to investors as part of the Q1 warrant exchange. I will say more about this transaction in a moment.

Continuing down the P&L, our **net loss** for the period was $940,000, compared to a net loss of $4.8 million for the first quarter of 2016.

Now on to the **warrant exercise agreement**. As we have previously disclosed, during Q1, we entered into a warrant exercise agreement with the investor that was holding the majority of those warrants to induce the cash exercise of their warrants. The motivation for this agreement was two-fold: first, to encourage the cash exercise of the warrants as a way to secure short term financing, and second, to remove the warrant liability from our balance sheet and avoid future fair value adjustments and volatility in our P&L. As a result of this exchange agreement, we received approximately $1.8 million in net cash proceeds from

the warrant exercises and we issued approximately 868,000 replacement warrants. These warrants are considered equity instruments based on their terms, and do not contain repricing or anti-dilution clauses that trigger variable accounting.

In terms of our **cash position**, we ended the quarter with approximately $1.6 million in cash and cash equivalents and no debt. Our operating cash utilization improved by 71% from the same quarter a year ago.

During the quarter, in addition to the warrant exercises for cash, we closed on the second close of the November financing after we obtained shareholder approval for the November equity financings. Net proceeds to the company were approximately $0.2 million. Subsequent to quarter end, on April 24, 2017, we closed an underwritten public equity offering that provided us with net proceeds of approximately $8.1 million.

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.

I will now turn the call back over to John.

John Erb, CEO:

Thank you, Claudia.

Before opening the phone line for questions, let me reiterate that I continue to be very optimistic about our future. We know we have a lot of work ahead of us, but I believe we are headed in the right strategic direction. The entire management team is rising to the challenges 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 no questions, I want to thank you for joining our 1st quarter conference call and wish you all a good day.