



## **CHF Solutions Second Quarter Ended June 30, 2017 Financial Results Conference Call Script**

### **John Erb, CEO:**

Thank you, Scott and good morning everyone. Welcome to our second quarter 2017 earnings call and corporate update. We are very excited about our revitalized and growing Aquadex business. During the quarter, we made important progress on many fronts. Revenue grew 18% in Q2, 2017 over pro forma Q2, 2016 as we focus on increasing the penetration in our largest hospital accounts by increasing utilization of the Aquadex FlexFlow system in multiple locations within the hospitals. During the quarter, we announced that Stanford University received approval from the FDA for an IDE clinical trial using the Aquadex FlexFlow System to treat pediatric patients. In addition during the quarter, we changed our company name from Sunshine Heart, Inc. to CHF Solutions, Inc. and received positive feedback from our customers, who related very positive memories and brand recognition



from the original launch and growth of the Aquadex FlexFlow System by CHF Solutions, Inc. in 2003-2009. We also announced the hiring of Mr. Jim Breidenstein as Chief Commercial Officer to begin building a US direct sales force. We increased our direct sales team from 4 reps in Q2-17 to 10 reps today. On the manufacturing front, we recommissioned our own manufacturing cleanroom in June 2017 and transferred manufacturing equipment from Baxter at the end of July 2017, . We are currently in the process of installing and validating that equipment in our Eden Prairie facility. We expect the manufacturing transfer to ultimately have a favorable impact on our gross margins by alleviating the mark-up over standard cost charged by Baxter for manufacturing product for us. The timing and magnitude of gross margin improvements will depend on manufacturing capacity utilization.

With Mr. Breidenstein's experience and leadership we have modified our sales strategy to focus on key accounts and drive penetration to



increase utilization. This strategy is designed to achieve greater efficiency in our sales efforts by reps spending more time in the larger key accounts and less time on the road trying to touch many accounts. Many of the hospital accounts that went dormant during the year's Baxter owned the Aquadex business did so because they did not receive service and training. To revitalize the business, we are focused on bringing the accounts back to using the aquapheresis therapy by providing excellent service and training.

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 support or training. Now with our increased sales team we can expand the number of key hospital accounts and will work to increase penetration by our commitment to calling on them regularly and



providing 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 several different technologies that are FDA market cleared that can provide important hemodynamic data to our physicians and nurses. We are planning to initiate a clinical evaluation of one or more of these technologies in the near future.

Deeper account penetration is the third area of focus, by 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 who have failed diuretic therapy recovering from cardiac surgery.

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 only recently began to re-engage 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 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 who have failed diuretic therapy.

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.

I will now turn the call over to Claudia who can walk you through our Q2 2017 results and financial details. Following that, I will provide some closing comments and will open the call to questions.





**Claudia Drayton, CFO:**

Thanks John. Good morning everyone.

Turning to the P&L, **revenue** for the quarter was \$864,000, a growth of 18% over the second quarter of 2016 on a pro forma basis. The growth was driven mainly by a 22% growth in the sale of **circuit sets and consoles**, which make up 85-90% of our sales on any given period. 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, our standard margins are around the mid 60s. As John mentioned previously, during Q2, we notified Baxter that they should not initiate new production for us after June 30, 2017. We are currently in the process of transitioning the manufacturing activities in house and will continue to buy the remaining inventory held by Baxter. Included in cost of sales are startup manufacturing costs related to this manufacturing transition. We expect to start our own manufacturing during the fourth quarter of 2017, and



expect that the margin benefits from this transition will begin to materialize in 2018 as production volumes and efficiencies increase. In terms of other **operating expenses** for the second quarter, they totaled \$2.7 million, a decrease of about \$1.2 million, or 31% improvement from the same period last year. The decrease in expenditures reflects our continued efforts to consolidate and streamline activities in all areas of the company, 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, offset by increased investments in our Sales and Marketing organization.

The **net loss** for the period was \$2.5 million, compared to a net loss of \$4.2 million for the second quarter of 2016, a 40% improvement from last year.

Regarding our **cash position**, as previously announced, in April 2017, we closed an underwritten public equity offering for net proceeds of approximately \$8.0 million.



Our operating cash utilization for the first six months of the year was \$5.7 million, an improvement of 38% from the same period a year ago. We ended the quarter with approximately \$5.6 million in cash and cash equivalents and no debt.

In terms of **modeling the remainder of 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 gross margins, they will continue to reflect the inventory pricing paid to Baxter as we burn the existing inventory and prepare to begin our manufacturing in-house. Gross margins will also continue to include the startup costs associated with readying our operations to successfully transition the manufacturing in-house.

Regarding our operating expenses, we expect to make some modest investments the remainder of 2017 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 call for questions, let me reiterate that we continue to be very optimistic about our future. We know we have a lot of work ahead of us, but we 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 please open the call to questions.

I want to thank you for joining our 2<sup>nd</sup> quarter conference call and wish you all a good day.