CHF Solutions Third Quarter Ended September 30, 2017
Financial Results
Conference Call Script

Thank you for joining today's conference call to discuss CHF Solutions' corporate developments and financial results for the third quarter ended September 30, 2017. With us today are John Erb, the Company's CEO and Chairman of the Board, Claudia Drayton, the Company's CFO, and Jim Breidenstein, the Company's Chief Commercial Officer. At 8:00 AM Eastern time today, CHF Solutions released financial results for the quarter ended September 30, 2017. If you have not received CHF Solutions' earnings release, please visit the investor's page at www.chf-solutions.com.

During the course of this conference call, the Company will be making forward-looking statements. Except for historical information mentioned during the conference call, statements made by the management of CHF Solutions 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.chf-solutions.com. With that said, I would now like to turn the call over to John Erb, CHF Solutions’ Chief Executive Officer and Chairman of the Board.

John Erb, CEO:

Thank you, Scott and good morning everyone. Welcome to our third quarter 2017 earnings call and corporate update. We are very pleased with the results of our quarter, the result of our consistent execution of the strategy we implemented after closing

on the acquisition of the Aquadex Business in Q3 of 2016. During the quarter, we made important progress on many fronts.

First, we are pleased with the revenue growth of our Aquadex business. Revenue grew 21% in Q3, 2017 over pro forma Q3, 2016 and 11% over Q2, 2017. Revenue growth is the result of our focus on increasing the penetration in our largest hospital accounts by increasing utilization of the Aquadex FlexFlow system in multiple locations and clinical disciplines within each hospital, and sales to new customers. We are pleased with our revenue growth during Q3 particularly because our largest territory, Southeast, was significantly impacted by the devastation of Hurricane Irma in early September.

During the quarter, we hired and trained 6 new experienced sales representatives, increasing our direct US sales team to 10 sales territories, from just 4 territories in Q2, 2017. These six-new sales representatives became active in their new territories in the last

month of Q3. We look forward to their many contributions over the quarters to come.

In addition, during the quarter, we exhibited at two of the world's largest heart failure society meetings, with significant attention and lead generation, including the European Society of Cardiology Congress in Barcelona, Spain, and the Heart Failure Society of America meeting in Dallas, Texas. In September, we announced the initiation of our international distribution with the signing of a distribution agreement with one of the UK's premier cardiovascular distributors. Also in September, we held a successful Scientific Advisory Board (SAB) meeting in Chicago, with 6 key opinion-leading physicians participating: 4 heart failure cardiologists and 2 nephrologists. The purpose of the SAB meeting was to review and provide guidance on the protocol designs for two important clinical evaluations: a Mechanistic study and a Registry, which we anticipate initiating in early 2018.

On the manufacturing front, our manufacturing implementation is going well. During the quarter, we transitioned the manufacturing equipment from Baxter to our facility in Eden Prairie, Minnesota, successfully commissioned the cleanroom, and validation builds are underway. We are on schedule to begin building our own finished goods inventory by year-end. We expect the in-house manufacturing capability to have a favorable impact on our gross margins as it will alleviate 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 exhausting our inventory of finished goods produced by Baxter, and on our volumes and manufacturing capacity utilization beginning in 2018.

Finally, as we announced yesterday, we received notification from Nasdaq that the Company is again compliant with all listing requirements and the listing matter has been closed.

Looking ahead, we continue to fine-tune growth strategies to optimize a significant opportunity to impact both improved clinical outcomes and healthcare cost reduction by giving healthcare providers an option to diuretics.

Our mission is to improve the quality of life for people suffering from fluid overload primarily associated with heart failure and related conditions. We provide healthcare professionals with a sophisticated, yet easy to use, mechanical pump and filtration system to remove excess fluid in fluid overloaded heart failure patients and patients with related conditions. We believe that our technology will provide a competitive advantage in the fluid management market by providing an effective solution for decongestion and reducing the cost of care relative to other treatment alternatives.

We continue to develop and refine our strategic focus to demonstrate a strong business model by driving revenue. Growing revenue is the key metric employees, shareholders and potential

investors will use to judge our performance. In addition to revenues' contribution to funding operations, revenue growth is the most demonstrative metric to manifest a successful business turn-around. Management has identified five critical actions to drive revenue: (1) commercial execution; (2) enhanced product offerings; (3) demonstrate health economic advantages; (4) provide important new clinical evidence; and (5) increase partnerships with key opinion leading physicians.

1. *Commercial Execution Strategy* – We have allocated, and plan to continue to allocate, resources to build sales and marketing strength and grow the worldwide market for the Aquadex FlexFlow system. In the third quarter of 2017, we increased our direct sales force by six experienced employees and plan to further expand our direct sales force in 2018. Our trained sales team is focused on sales penetration in large hospital accounts. The Aquadex FlexFlow system can be used in large hospital in multiple

areas, including: the emergency department, the heart failure telemetry floor, the intensive care unit, and the coronary care unit. In addition to expanding our direct sales force, we are implementing high quality customer service support systems and technical servicing to increase support to customers. We have also initiated international distribution and support of our products by entering into a new distribution and service provider agreement with APC Cardiovascular Ltd., a distributor based in the United Kingdom.

2. *Enhance Product Offering Strategy* – We intend to develop products and product enhancements to improve performance and customer satisfaction. We have several projects currently underway to enhance product performance. We plan to introduce a new peripheral access catheter and enhance the functionality of the hematocrit sensor that is part of the Aquadex FlexFlow

system console. We also are working to identify or develop a diagnostic tool for physicians to use during an Aquapheresis therapy to more precisely determine the amount of excess fluid to be removed, the rate of ultrafiltration, and when to stop therapy.

3. *Health Economics Strategy* – We plan to support the organization of previously published clinical trial evidence that compares the healthcare cost impact of using ultrafiltration therapy versus diuretic therapy, primarily measuring hospital costs for patients admitted to the hospital and rehospitalizations of patients with fluid overload. We plan to publish information on the budgetary impacts to hospitals that adopt the Aquadex FlexFlow system into their continuum of care when treating heart failure patients with fluid overload in whom diuretic therapy has failed.

4. *New Clinical Evidence Strategy* – We plan to expand the body of clinical evidence for Aquapheresis and the Aquadex FlexFlow system to drive adoption and support reimbursement. We plan to initiate an ultrafiltration mechanism of action clinical study to provide scientific evidence on how ultrafiltration effectively decongests patients without causing clinically significant harm to the kidneys. We also plan to initiate a registry to build individual account evidence sets, identify use patterns, and attain customer feedback to support marketing claims regarding clinical efficacy demonstrating weight reduction, reduced length of hospital stays, and reduced readmission rates.

5. *Key Opinion Leaders Strategy* – We plan to partner with key opinion leaders to advance medical understanding of ultrafiltration as a therapy for treating fluid overload. We have recruited a scientific advisory board comprised of six key opinion leading physicians to help us develop and

implement both the mechanistic clinical study and the registry. We are partnering with the Cardio Renal Society of America in a leadership role and increasing our involvement with the Heart Failure Society of America. In addition, we are working with several physicians that are implementing hospital observation unit use of the Aquadex FlexFlow system to provide outpatient care for patients that are fluid overloaded but may not require hospitalization.

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 repeat hospitalizations.

I will now turn the call over to Claudia who can walk you through our Q3 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 $957,000, a growth of 21% over the third quarter of 2016 on a pro forma basis, and 11% on a sequential basis from the second quarter of 2017. The sequential growth was driven mainly by growth in our top 20 accounts and from accounts that were reactivated in the last three quarters. The year over year growth was driven mainly by revenue from both reactivated accounts and from newly opened accounts.

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 we mentioned previously, earlier in the year, we notified Baxter that they should not initiate new production for us after June 30, 2017. We are currently in the process of starting up manufacturing activities in house and we expect to start our own manufacturing during the fourth quarter of 2017. Included in reported cost of sales are the startup manufacturing costs related to this manufacturing transition. In

addition, we are in the process of buying up the remaining raw materials and finished goods inventory from Baxter. We expect that the margin benefits from the manufacturing transition will begin to materialize in 2018 as we consume the Baxter-manufactured units, and production volumes and efficiencies increase.

In terms of other **operating expenses** for the third quarter, they totaled $3.0 million, a decrease of about $1.4 million, or 31% improvement from the same period last year. The decrease in expenditures reflects lower clinical spending resulting from the announcement in 2016 that we were no longer enrolling patients in our C-Pulse related clinical studies, lower transaction costs associated with the acquisition of the Aquadex business in 2016, and our continued efforts to consolidate and streamline activities in all areas of the company, partially offset by increased investments in our Sales and Marketing organization.

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The **net loss** for the period was $2.8 million, compared to a net loss of $3.9 million for the third quarter of 2016, a 27% improvement from last year.

Regarding our **liquidity position**, our operating cash utilization for the first nine months of the year was $8.8 million, an improvement of 35% from the same period a year ago. We ended the quarter with approximately $2.5 million in cash and cash equivalents and no debt.

In terms of **modeling Q4**, we expect revenue to continue to accelerate and expect that our newly hired sales force and 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 sell through 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 in Q4, mainly to fine tune the investments we made in Q3 in the field and in manufacturing operations.

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 3rd quarter conference call and wish you all a good day.