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CHF Solutions, Inc. is providing an Ultrafiltration Therapy for Cardiologists treating Fluid Overloaded Heart Failure Patients who have Failed Diuretic Therapy

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CEOCFO: ***Mr. Erb, what is the focus behind CHF Solutions?***
Mr. Erb: We are focused on treating heart failure patients that are fluid overloaded and have failed diuretic therapy. It is interesting that in the US there are a million hospital admissions per year -- just in the US -- for heart failure. Ninety percent of those hospital admissions are due specifically to fluid overload, which is a very large, underserved market. The standard of care today is diuretics and often patients become resistant to diuretics. What we have is a solution to fluid overload in those patients who are no longer responding to diuretics, by mechanically removing the excess fluid from these heart failure patients and keeping them out of the hospital longer.

CEOCFO: ***Before we talk about Aquadex FlexFlow® system, where is the fluid coming from? How does it create a problem?***
Mr. Erb: In a healthy person's heart, every time the heart beats seventy to ninety percent of the blood that is in the heart gets pumped out. With a person that is in heart failure, the blood that is pumped out with each heartbeat may be reduced to thirty or forty percent. Unfortunately, this is not enough blood pumping to supply the entire vascular system and our autonomic nervous system takes over to address that not enough blood is available and the need to protect the vital organs, which are the brain, the lungs and the heart. The autonomic nervous system vasoconstricts and reduces blood flow to the other organs and to the rest of the body. When a normal healthy person drinks water, has a cup of coffee, has a soda or a beer or whatever, that fluid goes in, it goes into the interstitial space, it basically nourishes the intercellular space throughout our body. The capillaries would draw that fluid, bring it through the vascular system to the kidneys and the kidneys eliminate that fluid. In a heart failure patient, when the blood vessel is constricted, blood flow is reduced and the capillaries do not absorb the fluid from the cellular space so the fluid does not get taken to the kidneys and then builds up. It builds up initially in the legs, because of gravity. You may have seen gentlemen in shorts or older ladies in a skirt with big ankles and swollen feet. That is basically the fluid accumulating there. When folks with heart failure lay down at night that fluid can come up into the chest, which again is basically because of gravity, and creates a difficulty for them to breathe. Therefore, for a period of time they may sleep propped up on pillows, or sleep in a chair to keep the fluid off their lungs. However, eventually that fluid will build up to where their lungs are congested and they have difficulty breathing, they then end up going to the hospital because of shortness of breath. Because the failing heart is not pumping adequately to all of the organs or through the peripheral vasculature the fluid builds up and ends up being overloaded into the lungs. When I mentioned that there are a million admissions per year for heart failure in US hospitals, ninety percent of them are due to fluid overload; most of whom are admitted through the emergency department, where this is an acute

emergent situation with these patients where they cannot breathe. That is where we can step in and help by mechanically removing that excess fluid.

CEOCFO: ***Where does the Aquapheresis® and the Aquadex FlexFlow system come into play? Would you explain the process and the equipment?***
Mr. Erb: Typically, the standard of care today when these patients are admitted to the hospital is to give them IV diuretics. Most of these patients have been treated with diuretics at home and these pills are titrated to increasing dosages to try to keep the fluid off. They often get twenty milligrams a day, forty milligrams a day or sixty milligrams a day and yet the fluid continues to build-up. When the patient is admitted to the hospital, they will typically receive IV diuretics, which is a stronger dose of diuretics, and this still may not work. This is where Aquapheresis and the Aquadex FlexFlow system can be introduced to effectively reduce fluid from these patients mechanically.

CEOCFO: ***How does the system work?***
Mr. Erb: Typically, a catheter is placed on the patient's arm. It is a dual lumen catheter, meaning it is one catheter, but has two lumens; one for withdrawing blood from the patient and one returning blood to the patient. Therefore, the one lumen withdraws blood and the blood goes into a filter in the Aquadex FlexFlow system. The filter separates water and salt, or sodium, from the blood and collects that in a collection bag. The patient's blood is then returned back to the patient in the second lumen. There is a very small amount of blood withdrawn from the patient at any one time; only about thirty-three cc's, which is about the amount of blood a patient gives in a vial for blood tests. The therapy is very safe and gentle for this patient. However, our system can take off up to four liters of water over the course of an eight-hour treatment, which is significant!

"We are the only company providing ultrafiltration therapy for the cardiologist to treat heart failure patients that are fluid overloaded who are no longer responding to diuretics. It is a very large market. It is very underserved."- John Erb

CEOCFO: ***How was the concept developed? Has something similar been tried? What do you understand that brought this breakthrough to the status it is today?***
Mr. Erb: In 2001, some seventeen years ago, Dr Howard Levin, a heart failure cardiologist at Columbia Presbyterian Hospital in New York, wanted to treat his patients better. He recognized that the IV diuretics did not work effectively and patients do not do well, ending up back in the hospital quickly. Dr. Levin, along with a very inventive engineer, developed a way to mechanically remove this water and salt from the blood through this filtration system. In 2001, the company was a venture capital finance startup and I became its first CEO. We received 510(k) market clearance in the US in 2002 and began to commercialize the product in 2003. The company built the product up to just under ten million dollars in revenue when the business was acquired in 2010. During that entire ten-year period, we were focused on treating heart failure patients with fluid overload and really focusing on the cardiologist: the primary physician that cares for these heart failure patients. That was really the start of the business. Then, in 2010, the business was acquired by a nephrology company, which, in turn, in 2012, was acquired by Baxter International, a renal focused company. Unlike our original approach, Baxter was not focused on the cardiologist. The business went into a quiet period because the primary care physician was no longer being focused on and the business declined dramatically. In 2016, I had the opportunity to negotiate with Baxter International to buy this business back. Since then, with CHF Solutions, we have refocused the business back on fluid overload in cardiology; focused on the patients that suffer from fluid overload when diuretics have failed, and on the physicians that care for these patients. We are now in the process of re-engaging accounts, re-engaging physicians and really building this business back up.

CEOCFO: ***Do doctors understand immediately or is there an "ah-ha moment" where you have to make the case?***
Mr. Erb: It is a combination of things. If I go back to my first round with CHF Solutions as a venture capital financed company, we really had to prove to physicians that ultrafiltration, or this process of filtering the blood to remove salt and water, was beneficial and an alternative way of caring for patients when IV diuretics were no longer working. We ran five clinical trials to demonstrate the benefit and the value of ultrafiltration during that period of time. During this second pass, starting in 2016, we have been going back to those physicians that were neglected since 2010, and saying, "We are back, focused on cardiology and we will service, train and help you get this back into your practice." There has been a great uptake in those physicians saying, "I am glad it is back. This is valuable to my patients and I want to continue to use it." Therefore, it has kind of been a mix. Early on, it was educating and convincing them with clinical trials of the value of it. Today, it is re-engaging and revitalizing the business and saying, "Now you have a company that is really focused on supporting you and helping you treat these patients." That is what we are doing today.

CEOCFO: ***How does the patient feel while this is going on? What may be the level of discomfort? What is their feeling about having it done? What have you found about how to help make it easy for patients?***
Mr. Erb: Again, it is easy for the patient with a catheter placed in the arm. This is not abnormal. It is not painful. It is not stressful for the patient. It is a small diameter catheter for removing the blood and returning the blood, so that is pretty straightforward. However, it is a dramatic benefit for the patient, when within an eight-hour period or a sixteen-hour period they see anywhere from four to ten liters of water removed! It is almost an immediate, two-day event where they see this dramatic drop in their weight with this excess fluid pulled off! What is more important is that the situation that was bringing them back to the hospital every three to six weeks -- the continued fluid buildup – which they would take off with the drugs, go back home, come back to the hospital and take it off again has been eliminated. They are now staying out of the hospital longer. We have patients that have been out over a year who were coming back to the hospital on a monthly basis for another IV diuretic treatment, now staying out of the hospital for months. They see the immediate weight loss, they feel the immediate relief of breathing distress because of that fluid off of their lungs and they feel better for a longer period of time, which has a huge impact on their quality of life.

CEOCFO: ***How does a doctor know when it is the right time? It is easy to measure? Is it subjective, patient by patient?***
Mr. Erb: It is subjective, patient by patient. One of the benefits that we provide with this therapy is that the physician can be very precise on how much blood to withdraw and how much water to withdraw from the blood. When they use IV diuretics they cannot know what kind of effect they are going to get from the drug. Therefore, they start with a low dose IV. If the patient is not able to eliminate through their kidneys as normal, the physicians will titrate the IV up to the point that they say, “This is just not working.” With our therapy, they can set the rate based on how much fluid and how quickly they want to take off and tailor the therapy to each patient

CEOCFO: ***What are you physically selling to a doctor or to a clinic? What is the equipment? Are there disposables? What is the maintenance on the equipment?***
Mr. Erb: It is a razor and razor blade business model. Basically, the razor is the console. It is a peristaltic pump that is relatively small, about the size of an IV pump or about the size of a Keurig Coffee Maker, to give you a frame of reference. It has a list price of $31,000, so not a huge capital expense to buy the equipment. The disposable product, or the razor blade, is the blood set which includes the filter. The filter/blood set has a list price of $980. It is used one time per patient and the average use per patient is about 1.3 filters to satisfy the amount of fluid that they want to take off. Therefore, it is not hugely expensive per treatment, but from a business model standpoint we really make the majority of our money on selling the disposable product.

CEOCFO: ***Are there reimbursement codes?***
Mr. Erb: Our device is covered under the MS-DRG payment for heart failure when used in the hospital. We have a therapy specific ICD-10-PCS, procedure code as well. Our therapy not only provides value during initial treatment but has also been shown to reduce the risk of re-hospitalization by 53%, when compared to those patients who were only treated with diuretics. This is important because in 2012, the Affordable Care Act instituted the Hospital Readmission Reduction Program where hospitals can be penalized up to three percent of all their Medicare payments for failing to achieve a reduction in readmissions through 30-days. This may be a huge penalty to hospitals if they are not able to adequately treat these patients. We have shown in published clinical trials that we can keep these patients out of the hospital longer, obviously avoiding this penalty, but more importantly, it also a safe and effective alternative for the patient.

CEOCFO: ***What was the response at the recent Bio CEO and Investor Conference? How do you stand out with so many companies showing what they have created?***
Mr. Erb: It was a very positive meeting for us at CHF Solutions. I was very pleased! We were in a sea of biopharma CEOs for the most part. There were a few device manufacturers, device CEOs presenting. However, my presentation went very well. I had a good room of interested investors. I was pleased that after I concluded my presentation I had five or six people walk up to me with their business cards and say, “I would like to follow up with you,” or “I would like to get more information,” which I thought was very positive! I think the story was simple for them to understand. I think our market is a very large market and it is very much underserved by the current standard of care and there is a real need there for alternate therapy options. Therefore, obviously, investors are very interested in those kinds of opportunities.

CEOCFO: ***Please address our readers in the healthcare and investment communities. Why pay attention to CHF Solutions right now?***
Mr. Erb: We are the only company providing ultrafiltration therapy for the cardiologist to treat heart failure patients that are fluid overloaded who are no longer responding to diuretics. It is a very large market. It is very underserved. It is well

documented through peer reviewed publications that diuretics have their limitations, that the current standard of care is sub optimal, and that there is a need for an alternative means to take care of these patients. Right now, we are the only game in town that can do that. But again, we are early. When I say early, I mean that we are in the restart phase, early in getting back out and focusing on the right customer, the cardiologist in this case, to provide them a tool to help treat their patients and make an impact on their quality of life, while providing an economic solution to manage the rising cost of healthcare in this difficult to treat patient population.