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Medical Device Therapy for Mitral Regurgitation (MR) that Eliminates Placement and Fixation Problems Associated with Conventional Transcatheter Mitral Valve Replacement Technologies

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CEOCFO: ***Mr. Thatcher, what is 4C Medical?***
Mr. Thatcher: 4C Medical is an early stage medical device company focused on therapies for structural heart disease and, specifically, the treatment of mitral regurgitation today and tricuspid regurgitation in the future.

CEOCFO: ***What is problem with mitral regurgitation?***
Mr. Thatcher: In the United States alone, there are about 3.5 million people in any given year that suffer from moderate to severe mitral regurgitation (MR). MR occurs when the mitral valve, located between the left ventricle and the left atrium, does not close properly and allows blood in the left ventricle to leak back into the left atrium. Over time, MR creates clinical issues such as arrhythmias, pulmonary hypertension, and heart failure. When patients get to the severe stage of mitral regurgitation and they are over 75 years of age, about 50% of those patients die within two years.

CEOCFO: ***Is it easily identifiable by doctors?***
Mr. Thatcher: It is easily identifiable, but unfortunately, it is not easily fixed. About half of those 3.5 million patients with moderate to severe MR are not surgical candidates. Because they are so sick, they may not survive the traumatic open-heart surgery required today to replace or repair the mitral valve. They are on medical management until they pass away, so it is not a good option. If you could fix the valve in a less invasive procedure, then you could prolong the patient's life and improve their health status.

CEOCFO: ***What have you figured out at 4C Medical Technologies to make a difference?***
Mr. Thatcher: We have a really new and novel design. There are other companies at the same stage that we are in. All of those companies have devices that reside in the native mitral annulus and then protrude down into the left ventricle. When you do that, you create significant clinical and technical issues. First of all, unlike other valves, the mitral valve is very uniquely shaped with asymmetrical annulus and irregular-shaped leaflets, so trying to size the valve to fit that native annulus is problematic. Secondly, when you go down into the ventricle, you create other clinical problems like obstruction of the left ventricular outflow tract, the path where the blood goes from the ventricle into the aorta. If you close that path and prevent blood from entering the aorta, it is not a good thing. It can also damage the chordae tendineae, the little parachute string-like structures that hold the native mitral valve leaflets to the papillary muscles in the ventricle. When you destroy the chordae, the ventricle begins to negatively remodel and patients go into heart failure at a faster rate. What we do that is completely different from what anybody else is doing is we reside 100% in the left atrium above the native annulus and therefore have no interference in the ventricle. Moreover, we are not relying on a perfect fit in the mitral annulus. We literally, by design, eliminate these known issues that others are facing today.

CEOCFO: *Why did you look to put it there and why have others not done so?*
Mr. Thatcher: I always tell people it is like wheels on luggage; until someone came up with the idea it was not obvious. It was obvious in retrospect but not obvious prospectively. For hundreds of years we did not have wheels on luggage.

CEOCFO: *How does it work?*
Mr. Thatcher: It is basically a Nitinol stent-like structure shaped in the form of a ball. Nitinol is a unique shape memory alloy and it can be delivered in a very collapsed position and once it is deployed, it remembers its shape and springs back up into the ball shape. In the middle of the ball is a short little chimney where the artificial heart valve is placed. Our valve is placed above the native valve that is still working to some degree, and prevents the MR.

CEOCFO: *What have you done so far to prove it works?*
Mr. Thatcher: We are use the porcine model as our animal model. The most recent device design was tested in chronic thirty-day animals. They survived to thirty days and have really good hemodynamic functions, meaning we prevent the MR. There was not paravalvular leakage around our technology. There was not thrombus or blood clots and there was no obstruction of the pulmonary veins. We documented at sacrifice that we have endothelialization of the stent frame, meaning the native heart tissue is growing over the stent frame and incorporating it into the heart muscle. We are two quarters ahead at this time. We were not expecting to have two successful chronic animals until the end of this calendar year. We are very pleased with the results that we have had to date and are in the process of setting up our first formal meetings with the FDA to plan out our first-in-human, early feasibility study in the United States.

CEOCFO: *When you have spoken with people in the medical community, what has been the response?*
Mr. Thatcher: The response has been delight, shock, and surprise that this design eliminates all the known clinical and technical issues that others are facing today. Most of the other companies are doing what they call a transapical delivery. This is a minor surgery, starting with a thoracotomy and sticking the device through the apex of the heart and then implanting it, which is very traumatic to these patients who are already sick. Our technology will be able to be delivered transseptally. It will be delivered through a groin stick in the low pressure venous side, up into the inferior vena cava and across the septum of the heart. It will be a simple delivery procedure, likened to the coronary stent implants that we have today.

CEOCFO: *With so many recalls of devices, how do you insure as you go forward, it is going to stand the test of time? Are there extra steps you see needing to take as you continue?*
Mr. Thatcher: The FDA has a pretty rigorous requirement in terms of testing so that you know the stent frame is not going to fracture, you know the valve is going to work, and those test conditions are conducted at the upper end of what you would see in the human model. Once you are at the point where you are doing your human clinical trials and eventually commercializing the technology, there are significant quality systems that are also part of the FDA requirements that have a lot of checks and balances in place to make sure that the product is not only performing well but it gives you the chance to improve the design at time of approval.

CEOCFO: *Are you seeking funding, investment or partnerships?*
Mr. Thatcher: Right now, we are finishing our A Round of financing, and that will be up to eight million dollars in financing. That should be closed out by July this year. As we speak, we are starting our process on the B Round of financing, which will be about fifteen million dollars and targeted to close around the first quarter of 2018. That will give us the financing that we need to initiate the early feasibility study in the U.S.

CEOCFO: W*hat do you know from past experience about the process about the industry?*
Mr. Thatcher: I have been in the medical device industry since 1981, so I know quite a bit about the history of innovation and the changes not just in technology but also in the regulatory agencies and the reimbursement agencies. I know that innovation comes through early stage companies like 4C Medical. There are very few examples of big, strategic medical device companies innovating. Most of their growth is through acquisitions, so small startup companies like 4C Medical are critical to innovation in the U.S. and the rest of the world.

CEOCFO: *What have you learned not to do when bringing a product to market or getting funding?*

Mr. Thatcher: I think the number one thing to do from a funding side is to talk to everybody. Sometimes you have people with preconceived notions that a certain group of investors may not be the right fit. You have to talk with everybody because you do not know what has changed in their models. Then in terms of bringing products to market, understand that there will be speed bumps that you hit and that you have to be flexible and able to adjust when those things happen. Knock on wood, we have had very few speed bumps so far, but the one thing that we know for sure is there will be speed bumps and then you just address those and move forward.

CEOCFO: ***You mentioned another potential product or use. Could you tell us more about where else you can go?***
Mr. Thatcher: Mitral regurgitation has a significant prevalence in the United States alone. Tricuspid regurgitation occurs at about half of the rate of MR. The tricuspid valve resides between the right ventricle and right atrium. Our technology is, with a few geometry changes, also suited for that application. Focus, focus, focus, so first thing's first which is getting our mitral valve technology into clinic trials before we start working on the tricuspid regurgitation application.

CEOCFO: ***Why pay attention to 4C Medical Technologies now?***
Mr. Thatcher: In the history of medicine, there have been very few true disruptive technologies. What we see right now in the MR space is people taking what they have learned in transcatheter aortic valve replacement and trying to transfer that to mitral regurgitation in the mitral valve. This approach is fraught with major clinical and technical issues. What we are doing is completely different and wildly disruptive. It will allow treatment of a broader patient population, leading to quicker enrollment in our early feasibility clinical study. There are a lot of patients that are very sick and dying. At the end of the day, that is what we are here to fix, the MR disease state and to give patients the highest quality of life for the remainder of their life.