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Thubrikar Aortic Valve, Inc.
Nature's Valve by Design

With their Transcatheter Aortic Valve now ready to enter Clinical Trials, Thubrikar Aortic Valve, Inc. is offering hope to Patients with Aortic Valve Disease for significantly Reduced Trauma, Complications and Recovery

Mano Thubrikar PhD FAHA
President & Founder

Thubrikar Aortic Valve, Inc.
www.tavi.us

Contact:
Dr Mano J Thubrikar
714-833-0383
mano.thubrikar@hotmail.com

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: ***Dr. Thubrikar, what is the idea behind Thubrikar Aortic Valve, Inc and TAVI?***
Dr. Thubrikar: Thubrikar Aortic Valve is primarily focused on making a transcatheter aortic valve. The main idea is that the traditional surgical replacement of the aortic valve is invasive and traumatic. The catheter technology significantly reduces trauma, complications, and recovery. Therefore, catheter technology is the future. It is anticipated that all surgical heart valve procedures will be replaced by transcatheter heart valve procedures.

CEOCFO: ***Would you explain the technology? What is the process and why you are able to do it today, when it was not thought of or was not feasible years back?***
Dr. Thubrikar: Years back the first advancements came about when heart-lung machines became available. You could use the pump and the oxygenator to take over the heart and lung function outside the body. When this machine became available, for the people dying of heart valve disease, it made it possible to treat and save them. By putting people on the heart-lung machine, you could do open-heart surgery and replace their heart valve. It became the gold standard of care, world-wide, and many people were, and continue to be, helped.

Coronary stents became available roughly 25 years ago and people started thinking stents could be used in other pathologies like aortic aneurysms. Coronary stents were tiny - four or five millimeters in diameter. However, aortic aneurysms required stents almost one-inch in diameter. Therefore, larger stents started to emerge. That is when an individual, I believe in England, thought maybe if we could put a valve inside this larger stent it could be a heart valve and it could be put in like a stent - using a catheter.

No one knew about this for years while it was in the development. Not until 2007 did people started taking this technology seriously. That is because Edwards purchased a startup company that was making a catheter heart valve. Once Edwards bought that company from Israel, other companies were watching. Then in 2007 it became clear this technology was here to stay and was going to be the biggest revolution in the treatment of the heart valve since the first revolution in 1970s, made possible by the heart-lung machine.

CEOCFO: ***Where did you come into the picture?***
Dr. Thubrikar: I was not a business person. I was a typical professor and research scientist at the university for most of my career (nearly 30 years). It so happened that I wrote a book called "The Aortic Valve," described a lot of my knowledge

and research at the University of Virginia. When the internet came into being, people with aortic valve disease would search and find my name.

One day, in 2004, I got a call from a heart valve patient. As I conversed with the patient, I was surprised that the patient's son also had a heart valve problem. She was calling because of her son, who was about 37 years of age, and had a congenital heart valve condition. For a young person, there are no good solutions; so, in 2004 she challenged me, because I had done so much research on the aortic valve, by asking, "why did you not make a valve that my son could use!?"

That really rocked my boat and I decided to leave academics and go to industry to make a heart valve. However, industry thought of me as a scientist rather than as a heart valve maker. Because of that, I left industry after a short time and went back to the university in 2007 to create a heart valve. I had realized university projects live and die in the laboratory, so, by 2010 I decided to leave the university and start a medical device company to create and take a heart valve to clinical practice.

CEOCFO: ***What are you working on today? Where are you in the development process?***
Dr. Thubrikar: The aortic valve is a type 3 medical device and has a lot of requirements the government needs satisfied before it is put in a patient. You must do a ton of testing. We spent eight years doing just that. We spent the first two or three years in developing the technology and subsequent years in testing. Just recently, we satisfied the requirements of the government regulatory process and they allowed us to implant it in a patient. Two months ago, on December 17, 2018, our first valve was implanted in a patient in Brazil.

"Right now, it is a three-billion-dollar market. However, our technology will take it to ten billion dollars because we expect it to treat surgery eligible patients. That is the best thing our valve offers to this field."- Mano Thubrikar PhD FAHA

CEOCFO: ***How did the implant go?***
Dr. Thubrikar: It went super fantastic! We had done so many experiments to mitigate the risks, to understand what could go wrong, experiment after experiment after experiment! We became quite comfortable it was going to be successful and would work very well. Low and behold, we had a first patient with a challenging anatomy - an anatomy that some companies excluded from their clinical trials! However, we said that we had done many experiments, our technology works, our surgeon is experienced, and so we should have no issues. We decided to take the challenge and went forward; it worked like a champ! It was beautiful! This was not an open-heart surgery; this is a catheter delivery. The procedure was done on Monday, December 17th and the patient was walking the next day at four o'clock. The patient was discharged on Friday. This technology provided a miraculous recovery.

CEOCFO: ***Where do you go from here? What is the plan?***
Dr. Thubrikar: The plan is traditional, like other medical device companies. We plan to do a clinical trial in Europe before doing it in the US. We have applied to the Canadian authorities and shortly plan to apply to the German authorities for a limited number of patients. We expect to get their permission in 2-3 months. As soon as we get permission, we will do the implants in Canada and Germany and then we will expand to other European countries. We will combine all these patients into a single clinical trial to get an approval in Europe.

CEOCFO: ***What do you understand or what were you able to come up with that makes your implant work, while others do not?***
Dr. Thubrikar: That is an important question and is also a very important distinction for our company! Three companies in the US, Edwards Lifesciences Corporation (NYSE: EW), Medtronic, Inc. (NYSE: MDT) and St. Jude Medical (acquired by Abbott) have been the dominant suppliers of surgical heart valves to the entire world for sixty some years. These three companies are the known leaders in surgical heart valves. However, new technology appeared when a creative mind decided to implant a heart valve using a catheter, not surgery. They started a company in Israel and were bought by Edwards Lifesciences. There were also a few other startups that big companies have purchased.

The big companies knew how to design the best surgical heart valve. However, in general, they were, and are, not the ones who designed the catheter valves. Catheter valves were designed by startups. These startups did not really have a thorough knowledge of heart valves like the big companies did. As a result, the initial valve designs were, and are, not the best. One can see this fact by just looking at the valves. They have captured the market and are popular, but that is

because they offer something previously unavailable. A third of the heart valve patient population is old enough, and they have other issues like diabetes, blood pressure, etc., that make them not eligible for surgery. Such surgery ineligible patients have no treatment options, other than medicine, which is not the most effective option.

So, even though these newly designed catheter valves were not the best, they were good enough to be put into these surgery ineligible patients. You could put these valves in patients with a catheter. Even though they may not have had the best product, what they did have was better than medicine. These technologies were the first of their kind and they have offered a lot of help. When I was looking at all of this, I could see that these were not the valves that are going to last – durability would be a problem. This is a first phase of valve design and it will be replaced with better designed valves. That is where we come in.

CEOCFO: ***What makes the difference? Is it size, shape or material?***
Dr. Thubrikar: With the surgical tissue valve, tissue is sutured to a stent, or frame. The tissue makes the leaflets, like a door that opens and closes with the heartbeat. The tissue is attached to the frame using sutures. You have a surgical needle, surgical suture, and you stitch it like you would stitch a pocket on a shirt. Once you stitch, then they put a cloth around the sutures and it is stitched to the frame structure. This is very important - the cloth covers all the suture holes so you never see any suture holes in the working valve. Unfortunately, in catheter valves, no one has achieved that feat, as far as we know. All suture holes are exposed in the current catheter valves. However, in our catheter valve suture holes are not exposed. That is the biggest difference between what others have and what we have and that difference gives our valve longer durability! Furthermore, in our valve, all design parameters are optimized like in the natural aortic valve, which also adds to the efficiency and durability of our valve.

CEOCFO: ***Are you seeking funding or investment as you move forward?***
Dr. Thubrikar: Yes. Since we are planning for a European clinical trial, we would like to raise six to eight million dollars to complete the trial. We have enough funds to go forward with a limited number of patients. As we move forward, we also expect other people to come forward with investments.

CEOCFO: ***Does the investment community understand what you developed at Thubrikar?***
Dr. Thubrikar: It is kind of interesting. I have to say yes and no. We have a most unusual story in this technology. I started this, not as a company, but as a goal. I needed to make a clinical heart valve. I had no idea at the time that I would need millions of dollars – neither did I care. I decided this is what I had to do, and I would just take the first step. In taking the first step, what I found is that as soon as I established the company, people started giving me small investments. These people were my relatives, friends, and others who are friends of our board members. We started collecting money like ten thousand and twenty thousand dollars. The next thing we knew, we had one million, two million, and so on.

We have about 130 investors, but we did not approach larger investors at that time. When we did approach larger investors, two or three years later, they said, “We believe your theory, we like your valve, but we cannot invest unless you prove you can implant the valve in a patient.” The bigger boys, like Medtronic, Edwards, and Boston Scientific, have been hearing about us every year. For the last five years we have been presenting our valve in conferences and several people have said “We agree with you, but we need to see you implant it in a patient.” And that is what we just recently did!

CEOCFO: ***Then people should stay tuned!***
Dr. Thubrikar: Yes. I mentioned that the catheter valves have become popular in surgery ineligible patients. It got in, it got a boost, and it got revenue. Then everybody said, “Wait a minute; this is so good that we should replace all the surgical valves with this.” However, you are now encroaching on surgeon’s territory - now you have resistance. So, the patients want a catheter valve, but the surgeons say, “there is not a durable valve available. I am not giving you (interventional cardiologists) my patients.” Hence, the whole field is stuck at the durability issue. Unless durability is proven, younger patients, and the rest of the surgery eligible patients, will not get a catheter valve. There are methods to prove durability and we have used those methods to convince people that our valve surpasses the durability of surgical valves. That is one of the biggest distinctions; our valve will allow this catheter technology to go to surgery eligible patients. Right now, it is a three-billion-dollar market. However, our technology will take it to ten billion dollars because we expect it to treat surgery eligible patients. That is the best thing our valve offers to this field.