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Q&A with Dan Rose, CEO of LimFlow SA bringing to market their Percutaneous System to Arterialize Deep Veins of the Foot and Lessen the Risk of Lower Limb Amputation

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CEOCFO: ***Mr. Rose, what is the focus at LimFlow SA today?***
Mr. Rose: LimFlow is a medical device startup company, focused on solving a major unmet need in the space of critical limb ischemia (CLI), which is a complication of peripheral artery disease. We are focused on stopping the epidemic of lower limb amputation that is occurring in Europe, the US and across the world.

CEOCFO: ***What is limb ischemia?***
Mr. Rose: When a part of the body does not have blood flow anymore it is called ischemia. Many people are familiar with arterial sclerosis or the clogging of arteries in the heart, which is the effect of high cholesterol and the buildup of plaque in the arteries which stops blood flow from getting to the muscle of the heart. The same disease progression can occur in arteries that supply other parts of your body with blood. We are focusing on is the supply of blood to the lower leg and the feet. Patients with critical limb ischemia often experience severe pain as well as developing chronic wounds on their feet. Without sufficient blood flow, these wounds typically do not heal and ultimately may develop severe infection, leading to sepsis and death if amputation is not performed. This occurs to a massive number of people. There are over one hundred and twenty thousand people in the United States every year that have a lower limb ischemia amputation. That is a decent-sized city full of people.

CEOCFO: ***What is the current treatment to prevent this or to handle it when it happens? What is the LimFlow idea?***
Mr. Rose: The current treatment is one two things. It is either what we call a surgical bypass procedure, which is where you put a graft in to take blood from above where the artery is blocked to below where the artery is blocked or to use balloon angioplasty, which is using percutaneous techniques to but a wire and then a small balloon down into the artery, which then can push the calcium or plaque to the side and open up blood flow to the foot. Those are the traditional techniques. However, our patients are ones how have failed or are ineligible for those therapies because of the advanced nature of their disease. We call it the “no option” population. LimFlow’s solution to that is to really look at the vasculature in a different, inventive way. The best analogy is being blocked in traffic on the highway and looking across the median and seeing that the other side is empty. Why not just drive across the median and get home the “wrong” way? Unlike on the highway, in most cases there are veins for every artery so we can utilize this alternative path without compromising the overall vascular system. We all know that arteries provide red blood to different parts of the body and that veins return blood to the heart after the oxygen has been delivered to the tissue. And just like you have a “tree” of arteries throughout

your body, big giving to smaller and smaller vessels, in parallel you have veins that do the same thing. At LimFlow, we use endovascular technology to create a arterial/venous connection just above where the leg artery is blocked, placing covered stents from the artery into one of the tibial vein to direct oxygenated red blood down through the venous tree to the foot, which can relieve pain and help the wound in the foot to heal. Complete healing of the foot closes the door to infection and allows the patient to avoid amputation of the leg.

CEOCFO: ***Have similar ideas been tried? What was the impetus? What were the challenges in creating a procedure to do so?***
Mr. Rose: The technique of what we call venous arterialization is something that has been tried surgically for decades. However, to do it surgically is long, technically challenging and surgeons did not have the full tools needed to complete the procedure, especially down at the foot. Finally, when you do surgery you create more wounds for the patient, which isn't great. Our concept was to do this procedure in a fuller percutaneous way. That means that we make a tiny puncture in the groin and a tiny puncture in the ankle, allowing the passage of wires, catheters and other minimally invasive tools. The physician used non-invasive imaging technology to complete the procedure without the complications associated with open surgery. It is a very similar procedure to what is done with placing coronary stents in the heart, for example, which is now very common and has saved many lives.

CEOCFO: ***What have you found out so far?***
Mr. Rose: We found out that the procedure works. In our experience to date, the procedure can take what we think of as a cold foot without perfusion and make it a warm foot with perfusion which then helps to heal the wounds that are on the foot. There is a Pilot study that was just published out of Singapore that demonstrated a very high degree of success in healing these wounds and keeping these patients from amputation. What is important to understand is that really every patient who is eligible for LimFlow is headed for major lower limb amputation. So anytime we can restore perfusion and heal the foot, that is a huge win for the patient and for the healthcare system.

"We are focused on stopping the epidemic of lower limb amputation that is occurring in Europe, the US and across the world."- Dan Rose

CEOCFO: ***What does someone have to lose if you are looking at amputation and trying the procedure? Are there any other reasons not to when you are in this situation?***
Mr. Rose: Well all procedures carry some risk, but the nature of the LimFlow procedure means those risks are limited. You can think of it in three ways. First of all, we use an artery that is completely blocked and there is no technique available to open it again. We use a vein that is supplementary to the body's needs. As I mentioned, typically for every artery you have two veins and it is very common to harvest veins within the body to use in other places. If the procedure fails you go on to amputation. That is exactly where you were headed before. There can be some temporary swelling in the foot as the venous vasculature adjusts to the new arterial blood flow but overall there is very little downside to the procedure and a lot to gain (or keep).

CEOCFO: ***Where are you in the regulatory process?***
Mr. Rose: The system is approved in Europe as of October of last year and we are beginning commercialization in Europe in a selected number of markets; specifically, Germany, Austria, Switzerland and The Netherlands. We just started in July a small feasibility study in the United States with an IDE (Investigational Device Exemption) from the FDA. We will complete that study next month in September and we will then apply in October to start a large pivotal trial in the United States. That will be the trial we use to get FDA approval.

CEOCFO: ***What has been the reaction so far from physicians that have looked at what you are doing?***
Mr. Rose: There has been a lot of excitement, to be honest! That is because these are very challenging patients to manage and no physician likes to look at their patient and say, "Well, there is nothing I can do for you. I have no further therapies to offer." Major lower limb amputation carries with it a terrible prognosis for the patient and is the fifth most dangerous surgical procedure in the United States. It carries a five to ten percent thirty-day mortality and twenty nine percent of the patients experience a major complication following the surgery. Many patients go on to an early death following an amputation because there is considerable hospitalization involved, many patients find it difficult to get around, infection sets in and it is just a terrible outcome for a patient once they lose their lower limb. It is very different from someone who is twenty years old losing their lower limb due to a trauma or a car accident. Most of our patients are over sixty-five and rehabilitation and learning to walk again is very difficult at that age. Therefore, it is something that patients want to avoid and physicians want to avoid and in fact the healthcare system wants to avoid. In Europe and the US you

are talking about a procedure that is very expensive; fifty thousand dollars at least, in the first thirty days. Patients who get lower limb amputation cost over $800,000 to the US healthcare system. Therefore, if that procedure can be avoided it is attractive for everyone.

CEOCFO: ***You have a history in this arena. What do you understand about bringing products to market, about working with the agencies to get it done? What is the edge because of your experience?***
Mr. Rose: I am an American, but I have worked in Europe since 1999 so I know the working cultures well on both sides of the Atlantic. Early on, I started in seed stage healthcare venture capital and then have cofounded a medical device company in the diabetes space. Then I spent nine years with Medtronic here in Europe launching many products in the interventional cardiology and cardiac surgery space. That was followed by working in two major leadership positions at two different medical device startups in Europe. Therefore, to be honest, I have been through this process many, many times; both from a big company prospective and also from a startup prospective. When it comes to all of the different challenges of bringing one of these products to market; fund raising, clinical trial management, product development or regulatory affairs, I am someone who has been through the fire as a medical device leader. I find it is the history of mistakes as much as the successes that help inform your decisions and leadership as a CEO. Experience at the "coal face" is very valuable indeed.

CEOCFO: ***LimFlow opened offices in the US. Why?***
Mr. Rose: Our headquarters are in Paris, but as we began our US clinical trial work we decided to expand and open an office in Silicon Valley, because it is important for us to build up a strong US team in order to make those clinical trials successful. As you can image, running a commercial and clinical operation in Europe and a large clinical operation in the United States for a small company is taxing. Those are major projects and we wanted to make sure that we really had the best possible people on the planet working for us. Therefore, we were able to hire a tremendous clinical affairs leader in the US based in Silicon Valley and we have started to build our operation there.

CEOCFO: ***What is involved in training for the doctors or nurses?***
Mr. Rose: That is a great question! One of the advantages or our system is that it is technology that, at its base, physicians are familiar with. We utilize things like intravascular ultrasound, which many physicians have used in the endovascular space. We utilize covered stents, which are a totally familiar technology in this space. The training for the physician is about three or four hours; some hands on, some from a theoretical point of view. However, it is very straightforward, because we are not introducing an entirely new approach. What we are doing is asking them to utilize modified versions of technology they have used before in order to perfuse the foot through the veins rather than the arteries. Therefore, their training is pretty straightforward and their learning curve is just a few procedures before they are totally independent and able to do the procedure.

CEOCFO: ***Where do you stand in terms of funding?***
Mr. Rose: We have raised almost 20 million Euros to date and that is in a combined Series A and Series B. This autumn we will target to raise a significant Series C round of investment to fund us through FDA approval.

CEOCFO: ***Do you find that what you are doing is something relatively easy for investors to understand and that gives LimFlow a bit of an edge over some of the other products or ideas that are a bit more complicated?***
Mr. Rose: I think we have a number of advantages. One is that the space we are working in, peripheral arteries, is a hot space. It is a space where there are few good solutions and there are a growing number of patients and it has been a growth area for cardiovascular firms. That is one of our advantages. The technology itself is relatively straightforward and we have very much de-risked the product and procedure. We know it works and that the technology is effective in healing wounds. Most importantly, it is really at the conjunction of a major health need in a space where no one else is really focusing. Finally, it is exciting to everyone to be developing and funding a therapy for patients who have no option today.