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Q&A with Alessandro Biglioli PEng, MBA, Founder and CEO of Elsius Biomedical Corporation bringing to market their Extracorporeal Membrane Oxygenation Device where the Blood Pumper and Oxygenator are in One System for emergency Circulatory and Respiratory Support

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CEOCFO: *Mr. Biglioli, what is the concept behind Elsius Biomedical Corp?*

Mr. Biglioli: I will start with the technology. ECMO stands for Extracorporeal Membrane Oxygenation. It is a technology that basically takes the blood directly from the heart of a patient, it pumps it and then oxygenates it and puts it back in, in real time. The blood pump and the oxygenator do the same function as the heart and the lungs, so it is basically an artificial heart and artificial lung, if you want. It is used to take some of the load out of the cardiovascular and respiratory system of very sick patients. This has a lot of benefits for those patients and is used in a variety of pathologies. It is a complex device. It is very invasive and it used mostly in the intensive care unit. It is also now starting to be pushed in emergency situations, because they have now found out that it is really good for resuscitating some kinds of patients.

CEOCFO: *What is the science? How is it working?*

Mr. Biglioli: The technology has been around for about thirty years and maybe more. It was developed for premature babies. Very premature babies usually have problems in the heart and especially in the development of the lungs. If they were very, very premature they would be put under the ECMO machines and that would allow their lungs to develop and then after three or four months they would go their own way. The problem with the pediatric market is that it is very limited in economic terms. Therefore, no one was really investing into ECMO technologies and development because there was no market. Then about ten years ago when they had the big flu's like SARS, swine flu and the avian flu, the doctors started to use ECMO on some of those patients that were dying like flies and they found out that it also really works well with adults. From there the market kind of exploded, if you will. It was a limited explosion, because it was still very invasive and very technical, so that is what happened. However, we felt like there was really a need for a better device that would cater to the adult population, so about ten years ago our sister company embarked upon developing this device, the better ECMO. We did not invent the technology, but we feel that ours is better than what is currently on the market.

CEOCFO: *Why is your approach better than what is on the market today?*

Mr. Biglioli: It is better because the two main parts, which are the blood pump and the oxygenator, in the current systems used in clinical practice, are separated and they are put in contact with a lot of tubing. We integrated them, which has advantages in the sense that there is less tubing going around, less blood contacting surfaces. That is beneficial for the blood, because the blood does not like external to the body surfaces. When blood is put in contact with an external surface three things happen: clotting, inflammation and hemolysis, which is a measure of the damage done to the blood cells. Therefore, the less external surface contact there is, the better. The other thing is that integration of pump and oxygenator into a compact unit makes it eminently portable. That means that now you can really use it for emergency situations. In fact, we found out that the even the Army and the Air Force have an ECMO unit, which was surprising to me,

they are tasked with emergency rescues after natural disasters or life and death situations. Doctors are starting to put ECMO on ambulances, but they are so bulky that it is an issue, so that is what is driving us here. The other difference, which is the main one I would say, is that we developed a biocompatible coating that basically makes all the blood contacting surfaces much more similar to the inside of the human blood vessels. The main issue with ECMO therapy is that it is very invasive, so doctors need to give patients massive doses of blood thinners and these blood thinners come with severe side effects. The main one is that you have hemorrhage and that can happen anywhere in your body, from the brain to the liver and also to the point of entry of the cannulae and that is a very big issue. With our coating we reduce the need for anticoagulants, because the blood coagulation mechanism is not triggered. That is because it is “tricked” in a certain way by our coating to “think” that it is still inside of the body. The same mechanism happens with inflammation and we think, also according to doctors we talk to, that is actually a big game changer.

CEOCFO: Does the medical community understand what you are doing?

Mr. Biglioli: Yes, they understand. We have an international clinical advisory board, so we have doctors from Europe, doctors from the US and Canada and doctors from Asia. The medical community has been very enthusiastic about the device. The only thing is that we are preclinical, so our device is still in development. Therefore, they have not seen it on a patient and we have not seen it on a patient. That is where we are and we are very excited and very interested in seeing if all the preclinical testing we have done on human blood and on animals is going to translate to the clinical practice, which is the normal life cycle for a medical device company.

**“We feel, for all those reasons, that Elsius is not only an exceptionally good financial investment but also gives investors the possibility on investing in a technology that is cutting edge, has the potential of becoming a worldwide standard and will have a tremendous social impact saving thousands of lives.”-
Alessandro Biglioli PEng, MBA**

CEOCFO: What surprised you as you have done your preclinical work? What did you learn along the way?

Mr. Biglioli: Those devices are very complex. It takes about ten years to develop a device like this, because essentially blood has three issues. Blood was evolved with humans and it evolved to be very efficient in basically coagulating right after it leaves the body. What we are doing, which is also done in extracorporeal circulation, is kind of unnatural, because we are taking the blood out and putting it back in and trying to keep the blood in liquid form. The main issue when dealing with extracorporeal circulation technologies is that blood coagulates, that is the main thing, but there is also an inflammatory response. There is an inflammation that is created when blood contacts surfaces outside of the body and if you put it back into the body you are bringing this inflammation back. Then finally, there is a thing called hemolysis, which is the measure of how much damage you do to the blood cell due to the fact that you are using a pump and the pump is basically a blender, and that is another issue. We need to be very careful and be very precise when you develop devices that deal with blood and put blood back in, because you try to minimize and to deal with these three issues. That is why it takes so long and you need to be very careful, because if you bring back inflammation into the body of a sick patient you bring back blood that has damaged blood cells. In particular, if you bring them back clots, since we are bringing the blood directly back into the heart, those clots will go directly to the brain right away and create a stroke. Therefore, it is a very critical device and needs to be very carefully crafted. That is what we have learned in this time of our testing.

CEOCFO: How do you deal with the length of time that it takes to get a device up and running?

Mr. Biglioli: I think it is a little bit typical of the life cycle of medical devices. That is because the main issue of our industry is that it is heavily regulated. However, you cannot sell a device that has not been extensively tested, first in the lab, then on animals and then on humans. That is for the simple reason that no doctor will put a patient on a device like this if the preclinical data is not extensive and positive, so that takes a lot of time. It is just the way it is. Every single aspect of how we do things, from manufacturing to how we handle documentation, to the traceability of everything, including our suppliers, needs to be according to standards. That means we and all the medical device companies needs to create systems that cater to the standards that we are under. That is because we have to consider that these are devices where if anything goes wrong they are going to basically kill a patient. Therefore, manufacturing needs to be done in a clean room, for example, according to certain standards. Everything needs to be sterilized, so everything needs to be certified for sterilization. Storage needs to be done in a certain way, so everything is according to standards. This takes time, because we need to create a structure behind it that is able to handle amount of data that comes back from handling products like this, on top of the science, of course.

CEOCFO: Are you funded for your next steps?

Mr. Biglioli: We are in the final discussions for funding for the next steps. We are raising five million US dollars. We have been funded through government money. All the research and development has been funded through government money

and through angel investors. Therefore, we have raised about one million and one half dollars in angel investor money. Now we are looking for another five million to bring the product to the market place. We are in discussion with these groups, but I am always open to angel investors because I am an angel investor myself, so I am partial to angel investors.

CEOCFO: *What do you find when you are talking with potential investors? Do they understand? Is it a difficult concept to understand?*

Mr. Biglioli: These are good questions. The answer is it depends. Investors come in all shapes and forms. There are investors in general that only invest in medical devices and some, in particular, invest specifically in cardiovascular medical devices. Those investors usually understand the business and the business cycle and they usually come with a cardiac surgeon or an ICU doctor that can also evaluate the medical side and the technical side. Sometimes that comes from an engineer that has experience in the manufacturing of medical devices to understand, again, if we are doing everything according to the standards. Therefore, our investors are a little bit particular. Angel investors are different, because sometimes there is an emotional attachment, if you will, to the fact that our device saves lives and has a social impact. That is also a driver for the people working at the company and for me, personally. I enjoy working on something that I know can change people's lives. Again, some investors are purely financial, because this, in theory, I might be biased, could be a very good investment. Most medical device companies are in general, good investments. It just takes quite a bit of time to get there. However, in our case, it is going to be around a year and a half to two years to get the product on the market, before we can even think to start to redistribute some of the money to investors. Even if I think that the most likely scenario will be that we become a target of an acquisition as soon as we have an approved product.

CEOCFO: *What have you learned from your other ventures in how to bring products to market and garner interest?*

Mr. Biglioli: That is a question I hear a lot. This is my fourteenth company. I was not involved heavily in all of them, but I would say that since the 1990s I was always involved in one or two companies at a time at the upper management level. Some of those companies did not make it. I would like to think that that is where you learn the most. Of course you learn from your successes, but also, I think you learn more from your failures. As a serial entrepreneur, because at this point I guess it became a career, I think that it is critical that you have some failures. I am a little wary as an investor from the other side, for entrepreneurs that have never experienced failures, because first I think they just do not exist and they are just not telling you. However, I think it is part of the startup environment. Most of the startup companies do not make it. In our field, when I go to startup events, people are my age, in their fifties and have a certain amount of experience under the belt, for Biomedical companies it's critical, not to pile on but I was extremely skeptical of Elizabeth Holmes and Theranos, just for her age, she simply didn't have enough experience. Negative experience is critical as it teaches you humility first, but also a lot of things that you did not learn just from successes. Also having your own money invested is critical as well, you want to see that as an investor.

CEOCFO: *There are so many concepts and companies in the health arena. Why Elsius Biomedical? Why is the company important?*

Mr. Biglioli: I would say there are three things. One is that the company has a very experienced management team that has worked together for a long time. I think "team" is critical. This is one thing. The other thing is the technology. This is a very good technology in the sense that it could really make an impact and save patients. It has the potential of becoming the standard in the field, worldwide. Also, there is a need for better technologies in the ECMO field, this is underscored by how fast the ECMO field is growing worldwide and how much money investors are putting into ECMO technologies lately. Finally, return on investment, which is what investors want to see. I think that our company could give an ROI between ten and thirty times, in between two to five years. Usually, our company, as other companies in our field, becomes a target of an acquisition as soon as we have reached the clinical stage, so that is probably what is going to happen. However, if it does not, we are focused on creating a long lasting ECMO manufacturing company and since the company will have very healthy margins on the product, we will also start giving dividends back to investors, I would say almost right away. These are the things that make Elsius Biomedical appealing for investors. Also, the competitive landscape is very favorable. We feel, for all those reasons, that Elsius is not only an exceptionally good financial investment but also gives investors the possibility on investing in a technology that is cutting edge, has the potential of becoming a worldwide standard and will have a tremendous social impact saving thousands of lives.