

ThermopeutiX, Inc. is developing a transformational Cerebral Hypothermia Technology to treat Acute Stroke



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“Our focus, of course, really is what we can do to transform the treatment of stroke and what benefit we will provide, not only for these patients, but for society. This is why we get up in the morning and this is why we do not give up.” - Ron Solar, Ph.D., FESC

CEOCFO: *Dr. Solar, the tagline on the ThermopeutiX[®] site is, “Cool solutions for hot problems.” What are you working on now?*

Dr. Solar: Our primary focus right now is on what we believe is a transformational technology to treat acute stroke. This involves the concept of cerebral hypothermia; literally cooling the brain down to low temperatures that will stop the processes that lead to cell death when a patient is experiencing a stroke.

CEOCFO: *How quickly would you need to do this?*

Dr. Solar: What you hear a lot about in treating stroke is “Time is brain”, because of the fact that brain cells die quickly when there is no oxygen getting to these cells. However, when you cool the brain the processes leading to cell death either slow or stop, so you really extend the time window. Research over the years of using hypothermia to treat stroke in animal models has shown that you actually do have a much larger time window to treat, so that even if you treat later you can still get some benefits. However, surely the faster you can get the brain temperature down the better it is going to be for the patient. The technology we have does involve the patient getting to the hospital and to a catheter lab where our catheter is inserted. However, it only takes a few minutes to insert the catheter, and with the technique we use, we cool the brain very, very quickly. In our animal models we have been able to achieve cooling rates as fast as two degrees centigrade per minute, so we can get the temperature down quite low.

CEOCFO: *How do you get the temperature down?*

Dr. Solar: We take over the blood flow to the brain. Our device is a specialized perfusion catheter that removes the patient’s blood, directs the blood to, what we call, an extracorporeal circuit which cools the blood, and then the cold blood is pumped to the patient’s brain. The extracorporeal circuit is similar to the heart/lung machine that has been

used over the years during heart surgery when they will put the patient on bypass. We use a similar machine that literally just cools the blood and then pumps it back into another channel of the catheter, directly to the brain. Therefore, we have designed this system so that we take over the blood flow to the brain with cold blood, and the brain cools immediately because it is the temperature of the blood that actually controls the temperature of the brain tissue.

CEOCFO: *Has anything similar been tried or utilized?*

Dr. Solar: Using hypothermia in medicine, what we typically call therapeutic hypothermia, has been around for decades. It has been used routinely in heart bypass surgery to protect the patient's brain and other organs when they stop the heart to do the surgical repair. This is where they will actually do the bypass where they will take the patient's blood, they will cool it, they will mix it maybe with a solution called cardioplegia, and they will pump it back into the patient. However, this is done on a systemic level. In stroke, hypothermia has been tried many, many times in clinical studies, but has not been successful. In stroke you do not want to stop the heart! The patient already has enough problems! People have said, "Hypothermia really works well in the animal models." In fact, in the animal models it has actually been shown that hypothermia is the most potent neuro protectant known to date.

We are talking about billions of dollars, decades of research and working with different types of drugs, different types of techniques to protect and help patients protect their brain in stroke. The only thing that has been extremely beneficial in the animal models has been hypothermia; lowering the temperature. The reason is that the processes that cause the brain cells to die are all metabolically controlled. One way to control metabolism is to control the temperature. A nice analogy, if you remember taking high school chemistry, and were in the classroom where the teacher has a beaker of water and drops some powder in there and nothing happens. Then all of a sudden, you change the temperature, you increase the temperature and then you see a chemical reaction, whether something like smoke occurs or whether it changes color.

It is the temperature that actually controls these reactions. In stroke, when you have a blockage in an artery and the brain cells are not getting oxygen and nutrients, it sets off a cascade of reactions that tells the brain cells it is time to go, it is time to die. Again, they are metabolically controlled. Therefore, just by controlling the temperature we drop the metabolic rate and we can actually stop these processes from occurring. The failures in previous attempts of using hypothermia in stroke have been due to the fact that the techniques used were not able to cool the brain deep enough, but we have solved this problem.

CEOCFO: *Is anyone with a stroke a candidate for this? How would a doctor decide if it is right for any given individual?*

Dr. Solar: We believe, from a theoretical standpoint, that since we are treating the tissue itself, in theory we should be able to treat all strokes, whether it is caused by a blockage, which we call ischemic stroke or whether it is caused by an aneurism that ruptures, which is called a hemorrhagic stroke or a brain bleed. Research has shown that hypothermia is also beneficial in those types of strokes as well.

The vast majority of strokes are caused by some sort of blockage. The ischemic strokes account for about eighty percent of the strokes in the United States. In certain countries the percentage is a little bit lower. There is a higher incidence of hemorrhagic stroke in certain Asian countries. However, with hypothermia, since we are treating the underlying processes where the tissue is dying, it does not matter what the cause is. Therefore, this will give us an opportunity to allow the brain to help repair itself, help the body repair itself, as well as provide more time to do additional interventions, if necessary, to resolve the cause. For example, these interventions could be removing the blockage, either by mechanical means or by drugs, which is a common way of treating strokes patients, or by fixing the aneurism that ruptured and there are technologies that can do that.

The problem with these technologies today is that here is where “time is brain”. It cannot be treated fast enough because the brain tissue is dying. Once it gets signals that it is not getting blood it begins to die. Even if you try to fix the cause you have not addressed all of the processes that are causing the brain cells to die. This is where we come in. We can really treat virtually all of these strokes. We will start out initially with ischemic strokes, because these are the ones that, obviously, are more frequent and they are more treatable. Therefore, we will start there. Then we will ultimately move into the hemorrhagic strokes.

CEOCFO: *What has been the interest from the medical community who are aware of what you have created?*

Dr. Solar: This has been one of our biggest challenges. The interest is tremendous on the one hand. On the other hand, because so many people have tried and failed using hypothermia, we have a high road and huge barriers to overcome other people’s failures. Even though our approach is different — we do it selectively, we are using the patient’s own blood, we can do it rapidly — and we can go through all the various features of why our technology will work better, we still have to prove it in the clinical setting. We are currently in, what we call like, a Catch 22 situation.

We have tremendous interests from the large strategic companies involved in stroke therapy, but when we say, “Would you be interested in investing so we can get some of the clinical data,” they say, “Well, come back after you get the clinical data.” Therefore, we are now trying to find some more friendly means where we can raise some money. We are looking to various private investors, and are trying everything we can to get the clinical data that we need to really prove this.

We do have some amazing animal studies that have shown tremendous efficacy and safety in a pig model, as well as overseas, we have a small number of clinical cases that had used our technology. However, these were not in stroke, but in a situation where a patient’s heart had stopped, sudden cardiac arrest, and they could not revive the patient, so they had a very long period where there is no blood at all going to the brain. Most of the time these patients do not have a chance. These were circumstances where, as a last resort, they did our procedure with the brain cooling, and most of these patients not only survived, but they survived with no neurological deficit. These are patients that would have been dead, or had they survived, they would have survived with severe neurological problems, so they would have been institutionalized. Now, these people are living full, healthy lives! This has given us tremendous

confidence that, if we are helping that kind of patient we feel tremendously empowered that this is going to really work will in stroke.

CEOCFO: *Are there other devices you are working on or are in the pipeline?*

Dr. Solar: We have worked on a number of devices. We do have two additional product families that have regulatory clearance. We are a small company. Our focus is really more on development. When we designed these other products, it was for specific needs. We also thought that they would bring in some revenue that would really help fund our stroke clinical trials. Therefore, the products that we do have, we are selling overseas right now.

We are looking for distributors for some of these products. However, our focus is on stroke, and the stroke patients need us the most. We have been so encouraged by the animal studies that we have completed and by these initial human cases, that we really want to almost drop everything else and focus one hundred percent on attacking stroke.

CEOCFO: *How do you deal with the frustration when you are reasonably sure you have got something with so much potential and it is so hard to move forward? How do you not give up?*

Dr. Solar: We have been doing this for many years and we have not given up; we just started getting more creative in finding ways to stay alive. While we are frustrated that we are not moving the needle forward as fast as we would like to, we are still here and so many companies who have been in this space have tried and failed and are gone. How do we do it? I have an amazing cofounder and we have been working together for so many years in cardiovascular medicine and we are both so committed to this that we are just not going to give up. We just get creative in finding ways to keep moving it forward. We are very encouraged now. Obviously, one way that you do not give up is that you get encouragement.

We have been selected by MedTech Innovator as one of the top innovative companies in 2019. This was a pool of, I think, eight hundred and nineteen applicants, and we were selected, not only in the top fifty, but also in the top twenty-five to become one of their Accelerator Companies. To get this confirmation that what we are doing can be extremely valuable, has just given us even more hope. We are seeing more interest now. In fact, in two weeks we will actually be competing in the finals at AdvaMed, the MedTech Conference for the title of MedTech Innovator of the Year. While that title would be nice, what is most important is we are getting tremendous exposure.

We are now seeing more interest from the strategic companies who would be a perfect company to take this on. They have the organization that they can immediately get this into the hands of many physicians. They could help accelerate getting through the final regulatory hurdles as well as the reimbursement hurdles. However, at the same time we are also getting exposure and interest from investors. This is what has been very, very encouraging and help keeping us going.

CEOCFO: *There are so many ideas and products to look at. Why pay attention to ThermopeutiX?*

Dr. Solar: There two reasons, basically. One is that stroke is probably still the most important unmet medical need. It is not only just the

patients who are affected. It is the caregivers. It is the employers. It is society. It is friends, it is family and it is our healthcare system. In our healthcare system we are fighting to keep from going broke. Stroke is probably one of the most expensive maladies that we have, and the major cost is not treating the acute phase; it is what happens after a stroke. When a patient survives a stroke, two thirds will be disabled and the cost of care, of institutionalization, is billions and billions of dollars. This is a society problem, you might say. This is one reason why you should get involved; because we have a real, viable solution.

The other reason, if you are in business, if you are investor, is that, of course, this is a therapy that will be very successful. The number of patients who have strokes each year is phenomenal, around eight hundred thousand, just in the US each year. If you look at worldwide, we are talking of over thirteen million patients who will have a stroke each year. In fact, the statistics are that one in four people over the age of twenty-five will have a stroke in their lifetime. Therefore, there are so many people, so many procedures that can be done and of course, that would translate into tremendous revenue for someone that would be selling this type of product. I hate to think about the revenue side of it, but it is a fact of our life. Our focus, of course, really is what we can do to transform the treatment of stroke and what benefit we will provide, not only for these patients, but for society. This is why we get up in the morning and this is why we do not give up.

