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Issue: October 27, 2014
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Novel, Injectable Therapeutics for Neurological Diseases

Wayne Laslie - *CEO*

"With 800,000 strokes in the United States alone each year, it is the leading cause of disability and one of the leading causes of death in this country and around the world. While stroke has been a difficult area of research, new therapies are urgently needed and we feel that our approach has a great chance for success." - Wayne Laslie

About Zocere, Inc.
Zocere, Inc. is a New Mexico-based biotech company that is developing novel therapeutics for neurological diseases, including stroke, and offering services to other entities developing stroke-related diagnostics and treatments. We have licensed patent-pending technology for a derivative of the brain-specific STEP protein tyrosine phosphatase, discovered in the laboratory of Dr. Surojit Paul at the University of New Mexico. This technology is the foundation for a novel, generation next therapeutic treatment of stroke that shows promise of becoming the first injectable neuroprotectant drug in the market.

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Interview conducted by:
Lynn Fosse, Senior Editor, CEOCFO Magazine

CEOCFO: ***Mr. Laslie, what is the focus for Zocere today?***
Mr. Laslie: Our company is a biotechnology company that is engaged in the development of a novel, injectable peptide for use in stroke patients.

CEOCFO: ***How does it work?***
Mr. Laslie: It is a derivative of a brain-specific enzyme called tyrosine phosphatase, sometimes known as a STEP (striatal enriched protein), which is expressed in neurons of the striatum, neo-cortex, hippocampus and related structures. STEP is an important downstream regulator of N-methyl-D-aspartate (NMDA)-dependent neuronal injury. Natural STEP is in the brain to protect it from trauma, but unfortunately, it is targeted for degradation just as the damage from a stroke begins to occur. Our peptide is a derivative of this naturally occurring enzyme, but it has been modified to resist degradation and therefore continues to protect vulnerable neurons from cell death as so often occurs with stroke.

CEOCFO: ***How have you created something where although it is mirroring what is natural, it is working better?***
Mr. Laslie: Our academic collaborator and the discoverer of the peptide, Dr. Surojit Paul at the University of New Mexico, has been working in this area for 10 to 12 years, and he understands the mechanisms that are involved in cell death as a result of a stroke. Through his research Dr. Paul has been able to modify the active fragment of the natural enzyme in such a way that it does not degrade as quickly as the natural protein during this crucial period of ischemia and subsequent reperfusion (return of blood flow). It therefore remains active for its role in neuroprotection.

CEOCFO: ***Where are you in the process?***
Mr. Laslie: Dr. Paul has demonstrated excellent proof of principle. Using both mouse and rat models he has shown that if you induce a stroke in these animals and treat one group with the modified peptide there is a significant reduction in brain damage compared to the untreated, control group. He has confirmed the activity of the modified peptide in knockout mice experiments. These are animals in which the gene for the naturally occurring STEP has been deleted. When you induce even a mild stroke in these animals, they are essentially paralyzed. If you then take a second group of these animals; induce a mild stroke, but then treat them with the peptide, you find that these animals have normal function as if they had not had a stroke. We believe that these data represent excellent proof of principle in these models.

We have raised about a half million dollars from the New Mexico Angels. We have used this money to establish our intellectual property position. We filed global patents on the peptide, and we are now prosecuting the national stages of the PCT filing. We have also worked with a group of consultants to prepare a pre-clinical development plan for IND-enabling studies. The plan is ready for implementation. Finally, these funds have enabled us to take the drug out of the academic setting and into a commercial manufacturer that can prepare high levels of the peptide.

CEOCFO: ***Would this be replacing a current therapy?***
Mr. Laslie: Currently, the only pharmacologic agent on the market for treating stroke is Activase, sometimes known as alteplase or t-PA, marketed by Genentech. That drug is a so-called clot buster that is used to break up the clot. As you know, a stroke occurs when a blood clot is formed in a vessel supplying blood to the brain, blocking the flow of blood and depriving the brain of oxygen and glucose. This results in cell death. Obviously, this can lead to severe disability and even death. With stroke, time is of the essence, so you want to break the clot up as quickly as possible. However, in breaking up the clot, the rapid reperfusion of blood into the brain can also result in neuronal damage. Neuronal protection strategies are badly needed to protect the brain both at the time of stroke and at reperfusion. That is the role we envision for our drug candidate. We see our drug candidate as adjunctive therapy to any clot busting strategy the physician prefers to use.

Current therapy with t-PA is associated with several problems: You have to have a diagnosis of the type of stoke. It can only be used in patients with ischemic strokes. Getting this diagnosis takes time and requires specialist oversight. It must be administered within a short period of time (up to 4.5 hours) after the onset of the stroke. As a result, many stroke victims are not candidates for t-PA. It is estimated that less than five percent of stroke patients actively receive the drug. It is possible that our peptide may open the window wider for t-PA use and may also be used in a setting without t-PA as a concomitant therapy.

CEOCFO: ***Have you found any potential side effects at this point?***
Mr. Laslie: At this point, we have only studied the drug in rodent models and we have not seen any deleterious side effects. We will have to do proper toxicology studies in a higher species of animals to fully elucidate its toxicology profile. That is part of the development process in which we are now engaged. Since our drug candidate is a derivative of a naturally occurring brain protein, we expect that the toxicity profile will not be a barrier to clinical development.

CEOCFO: ***You personally have a long history in the industry. What have you learned over time that you can draw upon as you move forward from here?***
Mr. Laslie: I have been very fortunate to have gained a great deal of skills and experiences along the entire continuum of drug commercialization, from drug development on the science side to commercial skills such as business development, marketing, sales and responsibility for the introduction of several products to the market in the United States and abroad. Lessons I have learned over time include a need for a thorough understanding of the entire commercialization process, from molecule to market and the skills required to get through the process and onto the market; the value of having the right people in the right roles, not only technically, but with the personality to function as a contributing and valuable member of the team; the value of early planning, even in the very earliest stages of development. With every new drug project, I like to begin with the end in sight. What is the vision for the product once it enters the market? Finally, I have learned the value of persistence and flexibility. Drug commercialization is a challenging and risky process, with many obstacles one has to navigate; persistence and flexibility are definitely needed to get to the end goal.

CEOCFO: ***Will you be looking for additional funding or partnerships?***
Mr. Laslie: Yes, both. Our strategy is to take the drug through the IND process and partner with a larger company to take it into the clinic. As I noted earlier, we have raised a half million dollars which is enough to get us started, but not enough to get us down the IND path. We are actively seeking additional capital that will be required to get to IND, and at the same time, identifying partners that may be interested in our technology. We are participating in a number of financial conferences for this funding.

We estimate that it will require about $5 million to get to IND. We are seeking to raise about $1.5 million that is required for the next 18 months; during that time we would apply for and, hopefully, get approval for a translational grant from the NIH for the remaining $3.5 million to get to IND.

CEOCFO: ***It often seems that investors have an interest in different medical problems at various times. Is stroke in favor with the investment community right now?***
Mr. Laslie: I can't say that stroke is in favor with the investment community right now. There have been a number of attempts over the years to find additional stroke therapies beyond t-PA. These attempts have not been successful and that has made it somewhat more difficult with the investment community. With 800,000 strokes in the United States alone each year, it is a large unmet medical need, and a devastating disease. We have to keep searching for treatment regimens for it. We believe our approach has a great potential for success.

CEOCFO: ***There are many companies to consider in healthcare. Why Zocere?***
Mr. Laslie: As I said earlier, stroke is an area of high unmet medical need. With 800,000 strokes in the United States alone each year, it is the leading cause of disability and one of the leading causes of death in this country and around the world. While stroke has been a difficult area of research, new therapies are urgently needed and we feel that our approach has a great chance for success. First, our academic collaborator who discovered the peptide has significant experience in understanding the mechanisms surrounding the brain damage occurring due to stroke. The mechanistic work he has done over the last decade and his discovery of this modified peptide gives us great hope for success. Secondly, our drug is a derivative of a naturally occurring brain enzyme which functions as a neuroprotectant, but degrades as the damage from a stroke begins to occur. Our modified protein drug candidate has been shown to get into the brain and provide protection during the period of ischemia and the subsequent reperfusion in animal models of stoke. Finally, we have a strong, experienced management team that can take the drug candidate forward.

BIO: Wayne Laslie has more than 30 years of experience in pharmaceutical commercialization in U.S. and international markets.

He has served in positions of clinical development, business development and commercial development, along with sales, marketing and operations. Prior to joining Zocere, Inc., Laslie held increasingly responsible positions at Pfizer and predecessor companies of Sanofi-Aventis (now Sanofi); was executive vice president at Otsuka America Pharmaceuticals, and most recently he was the chief operating officer at Myriad Pharmaceuticals and Myrexis. Laslie is a former board member of the National Pharmaceutical Council and a past member of the University of Maryland's Chancellor's Advisory Committee.