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Using its Novel Site-Specific and Sustained-Release Microparticle Technology Platform, Edge Therapeutics, Inc. is Delivering Drugs to the Brain to Prevent Complication of Subarachnoid Hemorrhage, Subdural Hematoma and Intracerebral Hemorrhage

Healthcare
Biopharmaceutical
(Private)

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Brian A. Leuthner
President & CEO

BIO:

Brian A. Leuthner, President and CEO of Edge Therapeutics, Inc. has more than 22 years of experience in the hospital acute care marketplace, with a specific expertise in neurocritical care. He has held marketing and sales positions of significant responsibility at GlaxoWellcome, Ortho Biotech, ESP Pharma and The Medicines Company. In these leadership roles, Mr. Leuthner helped create and advance hospital business units, launch innovative new products, and strengthen customer relationships. Mr. Leuthner also served as an industry advisor to the Neurocritical Care Society, Society of Critical Care Medicine and the American College of Chest Physicians. His entrepreneurial experience includes starting Fontus Pharmaceuticals as CEO and prior to that serving as Director of Market Development for start-up ESP Pharma, which sold for $500 million in less than 5 years. Mr. Leuthner received his Bachelors of Science and Masters in Business Administration degree from The University of North Carolina at Chapel Hill.

Company Profile:

Edge Therapeutics is a clinical-stage, hospital-focused biopharmaceutical company that uses its novel site-specific and sustained-release microparticle technology platform to deliver drugs to the brain to prevent complications of subarachnoid hemorrhage, subdural hematoma and intracerebral hemorrhage, all of which currently have no effective therapies. Edge works with some of the world's foremost scientists and critical care physicians from leading academic research centers to develop proprietary formulations of known active drugs for direct therapeutic delivery to the site of injury in the brain.

The Company's patent-protected bio-absorbable microparticle formulations release drugs locally and consistently at therapeutic concentrations in the brain, with the objective of maximizing therapeutic activity and avoiding treatment-limiting systemic side effects seen with current treatments. Currently, oral- or i.v.-administered therapies are employed but in suboptimal concentrations due to the generation of systemic side effects. Edge's lead products, EG-1962 (nimodipine microparticles) and EG-1964 are being developed to prevent various delayed complications after brain hemorrhage. EG-1962 is a proprietary microparticle formulation of the generic calcium channel blocker nimodipine, while EG-1964 delivers a hemostatic agent.

Interview conducted by:
Lynn Fosse, Senior Editor

CEOCFO: Mr. Leuthner, what is the concept of Edge Therapeutics?

Mr. Leuthner: Edge is a private, clinical-stage, hospital-focused biopharmaceutical company. We use novel, site-specific and sustained-release microparticle technology to develop a portfolio of life-saving acute and critical care products to prevent complications that result from ruptured brain aneurysms, subdural hematoma, subarachnoid hemorrhage, intracerebral hemorrhage, and head trauma. These conditions are not being adequately addressed with current therapies and with many of these conditions, there is either no treatment, or treatment that is clearly inadequate. The primary goal of the company is simple; save lives. That was the vision as far as why this company came about. We said we needed to do something for these patients and my partner has been studying the causes and potential cures of this field for over twenty years. The problem was not that we did not have good medicines. The problem was you could not get therapeutic concentrations of the medicine to the site of injury in the brain without causing complications outside the brain. We have taken this novel idea and turned it into a site specific and sustained release microparticle technology. It is the same material that these bioabsorbable sutures are made from, and we deliver our medicine locally to the brain so that we address complications and hopefully will prevent the complications from occurring.

CEOCFO: Is microparticle delivery the distinguishing factor?

Mr. Leuthner: Yes, there are really two things that differentiate Edge. First, the site-specific and sustained release technology platform is a rather pragmatic approach to overcome the limitation of oral or intravenous administrations. Instead of trying to figure out how to outsmart the body's protective system, the blood-brain barrier, we have gone around it. We've figured out a way to deliver therapeutic concentrations of FDA-approved medicines to the site of injury, without causing unwanted side effects in other parts of the body, and without requiring doctors to perform another procedure to administer it. The other thing that differentiates what we are is that despite the catastrophic complications caused by ruptured brain aneurysms, subdural hematoma, subarachnoid, intracerebral hemorrhages and head trauma, there is limited research being conducted today in these areas. While most of these patients will arrive alive at the hospital, the majority will be dead or have permanent brain damage after 30 days as a result of the primary injury or the delayed complications.

The brain is the last frontier of medicine. Our products have the potential to truly revolutionize the treatment for several unmet medical conditions and ultimately save lives. - Brian A. Leuthner

CEOCFO: Why is it that people are not addressing the issue?

Mr. Leuthner: I think part of it is that these are very sick patients who have serious medical problems who are being treated by very specialized doctors. Also, these are orphan conditions, so orphan drugs were not as hot as they are now so it takes some time for people to understand these conditions. Also, while local delivery to the brain might seem intuitive, we are really the first ones to advance this whole thinking of site-specific and sustained-release microparticle technology for these conditions. Sometimes you think things are obvious but that is only in retrospect.

CEOCFO: What are you doing that is different from what is available elsewhere?

Mr. Leuthner: Our lead product is a drug called EG-1962 (nimodipine microparticles) and this is to prevent delayed complications after ruptured brain aneurysms also called aneurysmal subarachnoid hemorrhage (aSAH). What I mean by delayed complications is there is this condition called delayed cerebral ischemia (DCI) where a patient is doing relatively well after neurosurgeons have secured the bleeding aneurysm, but then all of a sudden 3-10

days later they may start becoming paralyzed, losing consciousness, or slip into a coma for no detectable reason. This is called DCI and is the leading cause of death and permanent brain damage after the hemorrhage itself. The current treatment today in universally all patients is oral nimodipine, approved by the FDA in 1988, almost 25 years ago. Unfortunately, at the approved dose of nimodipine, concentrations in the brain are sub-optimal and thus oral nimodipine is only marginally effective. For years doctors have tried to figure out how to increase brain concentrations of nimodipine, however, they have been stymied and so far found that it is not possible without causing dangerous side effects outside the brain. Edge has finally solved the problem and is taking this well known, well-understood medicine with a long track record of safety, and delivering it locally in the brain over a period of 21 days to dramatically increase its effectiveness.

CEOCFO: Where are you in the development process?

Mr. Leuthner: EG-1962 is currently being studied in patients in Germany. We have five patients so far with the goal of gathering additional safety information and determining a therapeutic dose. Because of the drug's previous approval, we will only conduct one Phase 2 and then we go all the way to Phase 3. Additionally, the studies are short with outcome measurements at 30 and 90-days. After this abbreviated development timeline, we are ready to launch. Because these drugs address unmet medical needs and the fact that these are life-saving drugs, we are eligible for fast track approval as well as priority review.

CEOCFO: Are you working in partnership with other companies or on your own?

Mr. Leuthner: Right now, we are doing this on our own although we would not count out strategic partnerships. Edge's long-term vision is to build a biopharmaceutical company, commercialize our current acute and critical care drugs and continue to develop medicines internally using our site-specific and sustained release delivery platform as well as develop other life-saving therapies. Why we can do that is because the vast majority of these patients will receive treatment at less than 500 hospitals throughout the country, so you have a very small number of customers that you have to reach. A sales force of 25 to 50 reps could commercialize it.

CEOCFO: Is the medical community aware of Edge?

Mr. Leuthner: Somewhat, and they are becoming more and more aware. My partner, Dr. R. Loch Macdonald, M.D., PhD. has been involved in the research and clinical trials of acute care and critical care products for over 20 years. Dr. Macdonald is a leading scientist, clinical researcher, and neurosurgeon in the fields of brain hemorrhages and their complications. In fact Dr. Macdonald is among the most cited researchers in the world in subarachnoid hemorrhage. I have been working in the acute and critical care area doing this for the last twenty years, so together we are very comfortable with the clinical development and market for our drugs. Also, based on our collective relationships and past scientific work, we continue to draw insight from leading academic researchers throughout the world. Many are extremely excited about our approach and the work that we are doing to develop life-saving medicines.

CEOCFO: Are you aware of other research in the same area or do you pretty much have the field?

Mr. Leuthner: We pretty much have the field when it comes to complications after brain aneurysms, subarachnoid hemorrhage, and subdural hematoma. In civilian head trauma and traumatic brain injuries in our soldiers, which are typically caused by the blast waves from improvised explosive devices (IEDs), the Department of Defense and National Institutes of Health are heavily supporting research in this area. Edge is working closely with the Department of Defense and the U.S. Army to potentially test our lead product - EG-1962 in traumatic brain injury. If you go on clinicaltrials.gov, there are few if any plausible treatments being studied in the areas that

we are exploring, even though treatments are badly needed.

CEOCFO: Does Edge Therapeutics have the funding to get to where you need to go?

Mr. Leuthner: We are currently working to wrap up a financing round that will take our lead product EG-1962 to Phase 3 ready And our follow-up product, EG-1964, into Phase 2 trials. Frankly, EG-1964 is an amazing product and our clinical advisors are really excited about its potential; it is to prevent recurrent bleeding after a chronic subdural hematoma. Many older people bump their heads and about thirty days later, it results in this big clot on their brain. Some family members think they have Alzheimer's or dementia until doctors diagnose this as a subdural hematoma. When neurosurgeons drill a hole in the head and drain the blood, which is the standard treatment, in a significant population, about thirty days later this clot will come back. We believe that EG-1964 will prevent or certainly reduce this recurrence from happening, which is not only a good thing for the patient, but will be very cost-effective for the hospitals.

CEOCFO: What else is on the backburner now?

Mr. Leuthner: EG-1962 is our lead product. If it works in aneurysm patients and in patients with head trauma, it has potential to address other unmet needs. There is a patient population that is growing and these subdural hematomas occur on a routine basis, about three times as many as your rupture brain aneurysm patients.

CEOCFO: Is the cost of the drug a factor?

Mr. Leuthner: For ruptured brain aneurysm and SAH patients, the average age of these patients is fifty years old, with many in their forties. And while 85-90% of people arrive alive at hospitals, 75% will be dead or permanently brain damaged within thirty days. Since there is currently no really effective treatment options, we do not see price as an issue.

CEOCFO: Why should investors pay attention to Edge?

Mr. Leuthner: There are four primary points that make us unique. First, since 2009, we have taken our lead drug from concept to use in patients. Second, we have attracted two of the most legendary and successful biopharmaceutical entrepreneurs and scientists to the company, namely Dr. Sol Barer who is a board director, and Dr. Bob Langer who chairs our scientific advisory committee. Next, we have raised over $4 million from private investors and another $1.5 million in grants, while building a clinical advisory board of worldwide leaders in the field of acute and critical care medicine. And finally, Edge has a portfolio of products that have the potential to fundamentally change the way in which a substantial segment of young critically ill patients are treated. These products could be game changers. Our approach is de-risked because we are taking FDA-approved medicines, which are well known, well understood and have a long track record of safety, and delivering them locally over a sustained period of time. We feel that this approach has the potential to dramatically increase effectiveness in our target conditions. These are unmet needs. These conditions strike people in the prime of their lives and either claim their lives or cause permanent brain damage.

CEOCFO: What should people remember most about Edge Therapeutics?

Mr. Leuthner: The brain is the last frontier of medicine. Our products have the potential to truly revolutionize the treatment for several unmet medical conditions and ultimately save lives. In this industry, isn't saving lives what it's all about?