CEO CFO

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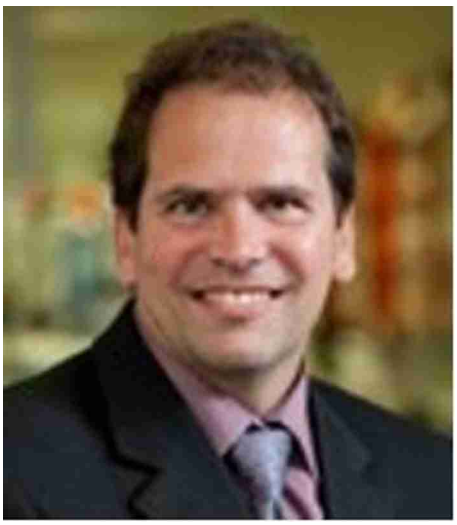
Currently in Clinical Trials with their Revolutionary ExpressDetect® Diagnostics Technology for Professional and Consumer Use, ECI Biotech has developed a very Novel Platform that can Detect Toxins Secreted by Bacteria that is Targeted at Prognosing Active Infections

Biotechnology
Diagnostics



Mitchell Sanders
CEO

BIO:
Dr. Sanders founded ECI in 1998. Dr. Sanders is a leader in the field of protein engineering, purification and diagnostic sensor development. Dr. Sanders worked as a Senior Scientist II at Genome Therapeutics in the Pathogen Genetics Program. He holds a Ph.D. in Biomedical Sciences from Worcester Polytechnic Institute (WPI) and completed postdoctoral training at the Whitehead Institute at the Massachusetts Institute of Technology (MIT). Dr. Sanders has dual assistant research professor appointments in the Bioengineering Institute and the Biology and Biotechnology Departments at WPI. He serves on numerous scientific and entrepreneurial boards at local universities. For ECI, Dr. Sanders secured an aggregate $25M in equity, corporate development funding, and SBIR grants.

About ECI Biotech:
Founded in 1998, ECI Biotech is a developer of affordable diagnostic sensors trademarked as ExpressDetect®. ECI has developed technology targeted at prognosing chronic and acute wound infections, which includes a dressing sensor and a rapid point of care diagnostic. ECI has established partnerships with leading medical device and consumer product companies to bring innovative discoveries to market on a global scale. ECI has a dominant patent portfolio that includes diagnostics, therapeutics, and advanced molecular technologies.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Dr. Sanders, what is ECI Biotech?
Dr. Sanders: ECI Biotech is a privately held developer of what we call ExpressDetect® diagnostics for professional and consumer use. Literally, we make diagnostics that are simple enough for a consumer to read and safe enough to go on your skin, rapid enough to work in 20 minutes and inexpensive enough to cost a dollar. We have made diagnostic sensors that can go on a variety of medical devices, everything from a wound dressing to a catheter to a toothbrush. The technology was developed to measure bacterial activity in a biofilm, which is very difficult to detect because it is entrenched in the tissue and it is often polymicrobial. In the case of an orthopedic infection, when a clinician taps fluid from your knee when you have pain and swelling, often it comes back culture negative because the bacteria is in a biofilm. We have been able to detect the toxins that are secreted by the bacteria, and develop a very novel diagnostic platform.

CEOCFO: What is the actual process that is happening scientifically?
Dr. Sanders: Scientifically we are detecting the toxins secreted by the bacteria, namely proteases that are often used by the bacteria to cause tissue destruction as an indicator of biofilm formation and infection. We are measuring the active molecules that cause virulence (infection markers) and we have both specific and broad spectrum diagnostics for infection. We developed this technology in a partnership very early in the genesis of the company with Johnson & Johnson.

CEOCFO: What is it that you have figured out that others have not?

Dr. Sanders: Most people use antibodies to detect surface antigens on bacteria, or other microbes. We have developed a technology to measure enzymes that are secreted by pathogen microorganisms that are required for infection. The benefit is that we are measuring the active infection, but we are not measuring commensal bacteria. The problem with an antibody is that after you treat a wound with antibiotics or a topical antimicrobial like silver and you kill the bacteria, the antibody would still detect the dead bacteria. However, because we are detecting the enzymatic activity of secretions from the bacteria, we can make a much more sensitive and rapid diagnostic that only detects the presence of an infection. When the infection is cleared, these enzymes are no longer present. We do not have many false positives. We have a very high analytical sensitivity, typically one to two orders of magnitude more sensitive than an antibody based approach. The chemistry can be so simple that it can be incorporated into a little sensor that can go on any medical device. Imagine a catheter that turns blue to let you know you are going to have a urinary tract infection or a wound dressing that changes color or turns blue if you are going to have a chronic wound infection. The technology innovation is in detecting these virulent factors, specifically proteases secreted by these microbes that cause infection. Our second major innovation was to develop simple sensors that can be incorporated into any medical device or textile.

CEOCFO: How are you reaching the various segments of the medical community that should pay attention?

Dr. Sanders: We learned early on that although we are good scientists, we do not know enough about the market opportunities. The first market opportunity that we went after was in the food quality and safety field and I actually wanted to make a frowning face on your hotdog package if your food was spoiled with Listeria monocytogenes. I sat down with several of the meat processors in the country and they said that there was no market for this product. We developed a cool technology but had the wrong market and I wondered what to do next. I realized that we could make a bandage turn blue if you are going to have an infection. We went to Johnson & Johnson and they gave us $4.5 million to develop the technology for wound care. We have learned over the years that our partners, who have the marketing muscle to understand these big opportunities, will help guide us through the opportunity both to understand the market potential and get us on the path to commercialization. We have been a B2B player where we focus on developing the technology but then we get a partner in tow to help us commercialize and better understand the market. The first products will be in wound care but we have tremendous opportunities in orthopedics, other medical devices, and consumer use as well.

"Scientifically we are detecting the toxins secreted by the bacteria, namely proteases that are often used by the bacteria to cause tissue destruction that leads to both biofilm formation and infection. We are measuring the active molecules that cause virulence (infection markers) and we have both specific and broad spectrum diagnostics for infection. We developed this technology in a partnership very early in the genesis of the company with Johnson & Johnson."- Mitchell Sanders

CEOCFO: Where are you in the process?

Dr. Sanders: We spent a great deal of time developing this technology and we filed over 22 patents. We have clinical studies ongoing for our three lead products and our first product should be out by next year. Due to confidentiality agreements with our partners, we cannot actually say which products are coming out first. What I can mention is one of our clinical studies is on an infection diagnostic in the field of orthopedics. After you have an orthopedic implant, the revision rate is very high (15%), primarily due to infections. We have developed a diagnostic for measuring those orthopedic replacement infections (called periprosthetic joint infections). We are doing a clinical study at the Mayo Clinic this QTR that I think is going to demonstrate that we have a very strong data package to then go to the FDA to design the pivotal clinical trials. Other clinical studies that we have ongoing are very confidential and sensitive and I cannot talk about those now.

CEOCFO: You mentioned a bandage turning blue; how do you get that to happen, and are you pursing that now or is that in the future?

Dr. Sanders: We are very much pursuing that now and for chronic wounds such as bedsores, diabetic foot ulcers, and venous leg ulcers. The problem in a chronic wound is the underlying conditions often mask whether you have an infection or not. Doctors can get it wrong 50% of the time when they diagnose against infection by visual cues. Having an early indicator of an infection will allow doctors to provide the right treatment the first time instead of guessing. In 2008, we partnered with a spin-out of Johnson & Johnson, Systagenix and they are leading the charge towards innovative diagnostics for wound care.

CEOCFO: When you speak with potential partners, do they 'get' it right away?

Dr. Sanders: We can show them functional prototypes and good clinical data packages. A great example is we just finished up a study last year at Thomas Jefferson on our diagnostic for knee and hip infections and the clinical data speaks for itself. Another great example is that we secured a partnership with a leading textile company in Denmark, ASLI A/S. We realized that we could make sensors on sponges and wipes for your kitchen to let you know that it is either time to throw it away because it has a high bacteria count or it has just been washed too many times. We hope to guide you to having a more hygienic kitchen if you will. We have partnered with ASLI A/S to provide wipes and

sponges for Europe and then we hope to roll those out in the US as well.

CEOCFO: With so much opportunity, how do you stay focused?
Dr. Sanders: We brought in over $16 million in development funding from partnerships. When you have products that are reaching regulatory approval and launch, this is your focus. We focus on the low-hanging fruit first that is going to bring us real revenue next year. The opportunities that are in the pipeline that are closer, not quite approved by the FDA, but reaching FDA approval, are our secondary targets. We have tertiary things where we found an unmet need, we applied for a grant funding and have been very successful with getting small businesses innovative, research (SBIR) grant funding. Our pipeline funding is first by grants and then we go seek a partner to commercialize the product with them. We have four things in the pipeline that are gearing up to launch over the next two years and then we have some new technologies that we are developing. It is best to fund new innovations with grants first and then go seek a partner or an equity investment after you have proven the technology.

CEOCFO: Are there competing technologies that you are aware of that are new and breakthrough?
Dr. Sanders: The next innovation in healthcare is going to be coming through the integration of technologies like ECI Biotech, into digital technologies. You are going to see many of these technologies coming out actually on your cell phone. There are companies like Lifescan, Medtronic, Alere and others which are starting to go digital in a big way and I think you are going to see integration of diagnostics into your medical records, which will be instantaneous and a new revolution in providing a better quality of care. We are always constantly looking at competitors for infection diagnostics to stay ahead of the curve, but so far we have been able to beat them in terms of having rapid and sensitive broad-spectrum diagnostics for detecting active infection in biofilms. Nobody can actually do what we can do even though there are plenty of competitors out there. There is a great deal of innovation coming up in the field of diagnostics, called mobile health (mHealth) technologies related to data capture, as well as taking the cool diagnostics that we are developing specifically, remote sensors and theranostics. We are literally working on making diagnostics remotely sense an infection inside your body with an external receiver. We also have some specialty coatings that detect the presence of an infection and automatically release antimicrobials and antibiotics to stop the infection so you do not have to have that knee replacement because we have stopped the infection in its tracks. There are many great things coming down the pike, some of them may be treated like drugs and will take a much longer regulatory path to get approval on than a conventional medical device or a diagnostic.

CEOCFO: How far will your current funding take ECI Biotech?
Dr. Sanders: We have been pretty much cash flow neutral over the past several years. We brought in $7.3 million in angel investments, about $2.1 in grants, and $16M from development partnerships. The ultimate goal is to maximize product revenue and start to acquire new technologies that fit within the portfolio. All of our technology to date has been developed de-novo at ECI Biotech. I spent a great deal of time in college, both a Masters and PhD, at WPI, and seven years of postdocs at MIT/Whitehead Institute. However, there are many new technologies out there, which ECI does not have to develop that we would like expand our portfolio once we start generating significant revenue. It is a good model, partnering with industry leaders makes sense when you are at the early stages. Once we get to significant in revenue, we will be able to consider increasing our capacity to manufacture and take some of these products to market ourselves. Until we understand the whole path to commercialization, we are best to learn from our partners and work with them on the commercialization of these new products.

CEOCFO: Why should the business and investment community pay attention to ECI Biotech?
Dr. Sanders: ECI is the first developer of diagnostics for active infections in biofilms. There is substantial clinical evidence to suggest that biofilms form most infections in humans. They are very hard to detect, resistant to mechanical shear and resistant to antibiotics. We have developed a platform to make sensors to measure infection very early before they become an issue. These sensors can be incorporated into any medical device like catheters, dressings, a cannula, even sutures. We know that the technology works, and we are going to start generating significant revenue from these product offerings. When you look at our pipeline of diagnostics, you will see that we have as many product offerings in the queue as we have employees at ECI Biotech. So the opportunities are just tremendous for the future. I think that in the next couple of years, we are going to start to see that financial hockey stick and get to significant revenue. Then we will have the financial capacity to expand our product offerings beyond our current portfolio.

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