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Anti-Biofilm Platform Technology Targeting CVID Sinusitis, Middle Ear Infections and Chronic Wounds By Inhibiting and Preventing Bacterial Infection

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- Joseph D. Kittle Jr., PhD

CEOCFO: ***Dr. Kittle, would you tell us about ProclaRx, the anti-biofilm company?***
Dr. Kittle: Biofilms are an important problem in understanding persistent bacterial infections. Our technology aims at disrupting the biofilm and that allows us to create therapeutics and diagnostics.

CEOCFO: ***What is biofilm?***
Dr. Kittle: Biofilm is the jelly-like substance that bacteria extrude around themselves to protect from the environment and particularly when you have an infection in people. This biofilm will protect bacteria from the immune system.

CEOCFO: ***What have you created to prevent this?***
Dr. Kittle: The key understanding that launched our direction is that biofilms contain DNA. It turns out that DNA is also very structurally strong and these bacteria are using it in a completely different way. They are using it as structural material to hold this gelatinous biofilm together. Our technology disrupts the biofilm. It does so in an interesting way. When you have these DNA molecules holding the biofilm together, they are like big beams in a bridge. Just as with a bridge, which has small rivets holding the big beams in place, we found that the biofilm contains proteins that hold the DNA in place. Our technology attacks and pulls out those proteins that hold the DNA molecules in place and then the biofilm disintegrates. It is amazing and you can actually see it in the lab.

CEOCFO: ***What is the science behind what you are doing?***
Dr. Kittle: We have developed targeted antibodies, which are specific and very good at attacking the biofilm proteins that I described earlier. Our antibodies disrupt biofilms.

CEOCFO: ***Does the antibody dissolve or eat away the biofilm?***
Dr. Kittle: It disrupts the biofilm and makes the bacteria accessible to antibiotics and the body's own immune system to destroy the bacteria. It disrupts the biofilm; you can think of it as tearing it apart. Physically what you can do, for example, is take biofilm that has been coughed up from cystic fibrosis patients and you can put it in a test tube and add our antibodies and it will break up that biofilm material. You can actually physically watch that take place in the test tube.

CEOCFO: ***Does the medical community understand what is going on with biofilms and why your antibody can make a difference?***
Dr. Kittle: Biofilms are becoming a very hot topic. The number of publications in the area are just skyrocketing. Most bacterial diseases, about 80%, are linked to biofilms. We do not have trouble explaining to people that bacterial biofilms are important. Our task is now to explain how our particular technology addresses the need.

CEOCFO: ***Are there many competitive approaches?***
Dr. Kittle: The underlying problem that we are addressing is really the problem of persistent bacterial infections. For example, we are going after a form of sinusitis. If you have ever had sinusitis, you take antibiotics and it clears up and then a few weeks later you may get a relapse and you have to go back for different antibiotics. That is chronic sinusitis. Up to this point, prescribing different antibiotics to kill the bacteria has been historically successful but it is reaching the point of diminishing return. You have already heard in the press many discussions of a post antibiotic era, a time when antibiotics no longer work well due to bacterial resistance. Our competition is the traditional approach of making another super antibiotic to go after a super bug. That approach is becoming costly and difficult to justify on the business side because any time you come up with a super antibiotic, the new medicine is kept on the shelf as a reserve against only the most resistant bugs. Our approach is different. We are disrupting the biofilm, which is one of the reasons why these bacteria have become so resistant to begin with. In terms of competition, there are many companies trying to find some way to disrupt the biofilm. Our technology has been patented and has a strong intellectual property wall around it. We are the only ones who can develop anti-biofilm products by disrupting these DNA binding proteins.

CEOCFO: ***How have you decided on what to focus on and in what timeframe?***
Dr. Kittle: This anti-biofilm technology is a platform technology. We can go after many potential products. Currently we are pursuing three indications. One indication is CVID (Chronic Variable Immune Deficiency) sinusitis. These immune compromised patients are a small, well-defined population and this approach will qualify for an expedited FDA path called Orphan Designation. We can prevent the scarring and biofilm build-up that takes place in the sinuses of these patients. A second indication is a form of persistent middle-ear infection, called CSOM (Chronic Suppurative Otitis Media), where children are so infected that there is drainage from the ear. These two indications do not require a lot of material to treat each patient, and they can be delivered directly into the ear or sinus. Our third indication is chronic wound care. We are developing advanced wound care medical devices that have anti-biofilm properties. This medical device pathway is a much faster path to market.

CEOCFO: ***Are there potential side effects or has it been smooth sailing?***
Dr. Kittle: We have several animal models, including chinchillas, and have not yet seen any potential side effects. We find the antibodies to be well tolerated and effective. Our antibodies target bacterial proteins and there is no human equivalent for these proteins. There are many antibody therapeutics already on the market for a variety of diseases and we are using a built-in infrastructure for safety testing and manufacturing. The FDA is very familiar with therapeutic antibodies. From that point of view, the safety issues are not expected to be difficult to understand. I think our main issue is just establishing how stable our antibodies are in this environment and how effective they are and so far, that has been very positive.

CEOCFO: ***Why did they use chinchillas?***
Dr. Kittle: Chinchilla ears are a good model for ear infections, as their middle ears are about the same size as that in a child. We have shown that our technology disrupts the bacterial biofilm in an infected chinchilla ear and that the infection is cleared in a few days.

CEOCFO: ***What have you learned in your previous experiences that you are finding helpful with ProclaRx?***
Dr. Kittle: Our team has been working on diagnostic and therapeutic products together for a number of years. We have about thirty people, of which more than half are Ph.D. scientists. Having that team already in place, when we put together ProclaRx as an independent company, gave ProclaRx immediate access to world-class science facilities and a team that already knew how to work together. This is unusual for biotech startups, but I think the key ingredient is that if you have elements to your team in place prior to launching a new venture and then just pull on those, it saves you time and it avoids a lot of potential early risk.

CEOCFO: ***Why does ProclaRx standout?***
Dr. Kittle: The key to understanding why the ProclaRx technology stands out is that there is a very large unmet need out there for better ways to go after persistent bacterial infections. It is a problem that faces hospitals. There is a large market driving this but also there is a human need. Parents want to have better ways to treat middle-ear infections. People with sinus problems need something different other than taking another antibiotic. A lot of what drives us is that human need. There is a good alignment in moving this forward. We are actively looking for the types of investors who can really capitalize on this kind of activity and help us partner to move forward. Our exit is very simple; when we get to the state where this technology is in the later stage of clinical development, we see either moving it all the way through to a product or more likely we will license or sell the company to a large pharma who can more effectively market and manufacture the end product. We see a relatively early exit for this technology.