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Using Computer-assisted Genetic Engineering and Exosome-like Nano-Vesicles, Versatope Therapeutics, Inc. is offering hope in protecting against Multiple Seasonal and Pandemic Influenza Virus Strains with a Single Immunotherapeutic Vaccine Technology

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CEOCFO: *Dr. Locher, would you tell us the vision at Versatope Therapeutics?*

Dr. Locher: Our vision is to create a healthier world through the power of immunotherapeutics and vaccines. Versatope has a unique platform technology that could transform the way the bio-pharmaceutical industry solves problems in drug and therapeutic delivery. Our cutting edge technology uses exosome-like nano-vesicles to effectively deliver therapeutics in a cost-effective way, across a broad range of industrial applications and with the capacity for large-scale manufacturing.

CEOCFO: *What do you understand about immunotherapeutics and vaccines that will help you fulfill the vision?*

Dr. Locher: We have a unique platform technology where proteins are displayed as targets on the surface of nano-size particles. The use of these nano particles stimulates a much more robust immune response than typically seen with current recombinant vaccines. In addition, we can attach antibodies for targeting specific cells and tissues, including cancer cells. As an example, we are currently working on a universal influenza vaccine that works extremely well against the strains we have tested so far. We are able to express conserved proteins from the influenza virus on the surface of the nano-size particle, which enables strong cross reaction and the elimination of the virus in preclinical models. Based on the nano particles' biological characteristics, they become naturally engulfed by antigen presenting cells to stimulate the immune system. The unique features of the exosomes allow them to be further manipulated using genetic engineering and time release formulations for superior durability and potency. This potency and targeting can be fine tuned for achieving the results one wants; therefore, we have called the company Versatope to highlight the versatility and broad applications of our technology.

CEOCFO: *Why does it work and how?*

Dr. Locher: Our vaccine candidate produces antibodies that cross react with the influenza virus. The conserved influenza proteins are expressed in the shape that enables strong cross reaction with a specific target, thereby providing potent protection against the flu. Our vaccine candidate may increase the range of protection against seasonal and pandemic influenza strains and may reduce overall economic impact, hospitalizations and death rates.

CEOCFO: *Why is shape important?*

Dr. Locher: Our body's immune system sees protein structures in three dimensions. When it comes to creating truly effective immuno-therapies that can deliver immunity, shape and structure are vital to their overall efficacy. Versatope's technology expresses the protein in a three-dimensional shape to induce more effective antibodies that neutralize the infection more effectively than some of the other technologies currently in use. For example, many of the previous and

current approaches to recombinant influenza vaccine candidates use less effective two-dimensional linear peptides. This two-dimensional shape generally does not induce cross-reactive antibodies that binds to the three-dimensional shape on the native viral particle.

CEOFCO: *Is the medical community aware of that?*

Dr. Locher: The three-dimensional structure, or protein conformation is an old idea that has been around for many years. The immunology community is aware of it, and some have tried different technologies for protein expression, however it has proven challenging to create the right shape that mimics the architecture of viruses and other pathogens. Versatope achieves the optimal shape through our particle delivery system. The way we anchor our vaccine proteins to our particles is unique because it forms a large multimeric structure that arranges the proteins in an ordered manner and makes the particle and vaccine proteins look like a virus to the immune system.

CEOFCO: *How did you know how and where to look and when did you recognize that you actually had it right?*

Dr. Locher: The technology we have is from the work of two professors at Cornell University, David Putnam and Matthew DeLisa. Dr. Putnam first recognized that he had it right when the Center for Disease Control repeated his experiments and found that his vaccine worked extremely well in protecting against human pathogenic avian influenza.

“Versatope has a unique platform technology that could transform the way the bio-pharmaceutical industry solves problems in drug and therapeutic delivery.”- Dr. Christopher Locher

CEOFCO: *How can you cover so many strains of influenza?*

Dr. Locher: We cover more than one strain of influenza because we use conserved protein domains on the surface of the virus, which don't change as much as the protein domains that are contained in the current influenza vaccine. Most influenza vaccines typically target only one strain or a few strains that has one dominant domain that is variable, or not conserved. Versatope's technology is able to express and display multiple strains on the surface of a single particle using computer-assisted genetic engineering that target the conserved or less variable protein domains across multiple strains.

CEOFCO: *What is the opinion from the medical community that knows what you have done so far?*

Dr. Locher: So far, we have received enthusiastic support from the National Institute of Health and in the review of our research grants. We have also received recognition in biotechnology newsletters, start-up pitch competitions and we have published our results in several scientific publications.

CEOFCO: *Where are you today in development?*

Dr. Locher: We established our operations in Lowell, Massachusetts, as a startup company. We recently licensed the technology at Cornell University. We have written several research grants, two of which are now funded. We have hired scientific staff for our laboratory who are passionately committed to Versatope's vision and mission.

CEOFCO: *When you get set up, what are some of the steps you will take perhaps throughout this year?*

Dr. Locher: We have been writing more research grants and we have been speaking to investors who are interested in our delivery platform. We hope to have a strong clinical candidate to move forward into the clinic in the next couple of years. We are also speaking to bio-pharmaceutical companies that are interested in our approach.

CEOFCO: *That is pretty quick for what you are doing!*

Dr. Locher: Yes, we have a couple of leads in mind; it is just a matter of selecting the right one. We are in the process of narrowing down that list so we choose the best candidate to advance into the clinic.

CEOFCO: *What goes into that process?*

Dr. Locher: Usually we have to do evaluations to demonstrate that what we are developing is effective in more than one preclinical model. We also work with contract research organizations to help us with the scale-up and manufacturing and to demonstrate that we can do this consistently and with little variation between different batches. We will meet with the FDA and discuss the safety and scale up work and heed their advice.

CEOFCO: *How else might your nanotechnology be effective?*

Dr. Locher: It may be effective for immunotherapy in cancer in helping to boost the immune system to tumors. There is the possibility to use these in therapeutic or drug delivery and this has been shown by other groups using similar particle-based technologies.

CEOFO: *How do you deal with the length of time it takes from an idea to something that is available, particularly when you have something that could really make a difference?*

Dr. Locher: We take a strategic approach by analyzing the pros and cons and strengths and weaknesses of a project. We talk to experts in the field, including physicians who will actually treat patients and develop their understanding and perspective to ensure that what we develop is something that doctors will use to benefit patients. We also talk about the scientific practicalities of our approach. We have project team meetings and we bring in experts who specialize in, for example, chemistry or biophysics and pharmaceutical development.

CEOFO: *What do you mean by scientific practicalities?*

Dr. Locher: For example, you need someone who understands microbiology to do the microbiology parts, you need someone who is an expert in pharmacology to do the pharmacology part, and you need an expert in structural biology if you are interested in the structural biology aspects of the project. You want to bring in people from different disciplines so that they can look at it from all angles and come up with a viable solution and plan to test an idea with limited resources.

CEOFO: *How do you find the right people - is it the novelty?*

Dr. Locher: I have gone out and actually talked to people and sought out people with specific skill sets. Also, people have found Versatope on the web and are attracted to our unique technology. They are passionate about making a difference in the field of immuno-therapeutics and want to contribute their talents to our team.

CEOFO: *Why look at Versatope Therapeutics right now?*

Dr. Locher: Versatope is an early-stage company that is poised to grow with the potential to transform the field of immunotherapies. We are seeking strategic partners who share our vision for making a positive impact in the world and improving health. Versatope offers a new solution with our platform technology. With the number of cases of influenza year after year, it is imperative that we come up with new vaccine candidates that can provide protection against multiple strains of flu.

CEOFO: *What if anything might people miss or misunderstand about Versatope Therapeutics?*

Dr. Locher: At first glance, people might not necessarily see how Versatope's exosomes can transform the biotechnology industry. The technology goes beyond vaccines into drug delivery, diagnostics and developing new biological reagents. The multiple possibilities of the different applications demonstrate the power of this transformational platform technology.

Figure of Versatope's vaccine that expresses proteins in a three-dimensional protein complex on the surface of the exosome. This 3D structure induces effective immunity to the influenza virus better than other technologies that use linear peptides targeting the same protein domain. For more information and scientific references, see www.versatope.com.