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Novel Nebulized Therapy to Combat Both Inflammation and Infection in Lung Transplant and Chronic Inflammatory Airway Diseases (e.g., Cystic Fibrosis and Others)

Dan Copeland, MBA
CEO
Renovion, Inc.

CEOCFO: ***Mr. Copeland, what is the vision behind Renovion?***
Mr. Copeland: Our vision is to be the first drug ever FDA-approved for lung transplant patients.

CEOCFO: ***What is the treatment today and what is Renovion going to do that is better?***
Mr. Copeland: Today, lung transplant patients are treated with medications approved for indications that have modest and variable efficacy. Our goal is to address both the inflammation and infection aspects of lung transplant with a single drug. In the transplanted lung, there is a cycle of inflammation and infection that often drives the current sub-optimal outcomes, and we address that cycle with our therapy.

CEOCFO: ***What is different about the lungs that we need something more specialized?***
Mr. Copeland: The lungs face oxidative stress every minute of every day. Every time we inhale, we challenge the lungs with environmental insults and pathogens. Thus, there is a high likelihood of starting the inflammation and infection process in transplanted lungs that have been immunosuppressed and damaged through the transplant process. Lung transplant patients do not have the success seen in other solid organ (e.g., kidney) transplant recipients. Unlike kidney transplant patients with a 5-year mortality rate of 10% and 10-year mortality rate of 20%, lung transplant patients have a 5-year mortality rate of approximately 50% and a 10-year mortality rate of 80%.

CEOCFO: ***How many lung transplants are done per year across the country?***
Mr. Copeland: In the US, there is a total of about 10,000 lung transplant patients, and there are slightly fewer than 2,000 lung transplants performed every year in the US. Another 5,000 patients live outside of the US.

CEOCFO: ***Would you tell us about the patent allowance?***
Mr. Copland: We received a patent allowance in December of 2015 for a combination product that has been approved for inhalation into the airways. We project that the US patent will be issued in the next few weeks.

CEOCFO: ***What is the science?***
Mr. Copeland: Our combination has potent antimicrobial activity that inhibits some of the most common bacteria, such as *Pseudomonas aeruginosa*, in lung transplant patients. The compound also has anti-inflammatory capabilities. The therapy works in the nitrate-nitric oxide pathway to restore lung homeostasis. This creates a lung environment similar to that in healthy lungs which is able to fight infection and prevent pathological inflammation more effectively than it otherwise would.

CEOCFO: ***Is it the combination or is it trying the factors you mentioned together that is new?***
Mr. Copeland: Our combination is three components. Individually, yes, there is some previous experience with one or two of these combinations, but it really is what they do together – the synergy that they have with each other – that makes the combination unique. Some of these components are actually endogenous. However, the concentrations of these components are significantly reduced in lung transplant patients, as well as patients with other chronic inflammatory airways diseases (e.g., cystic fibrosis (CF), COPD and asthma). The compound allows us to restore these components,

thus enabling the lung environment to handle oxidative stress from environmental insults and pathogens (e.g., bacteria, fungi, viruses) more effectively.

CEOCFO: ***How is ARINA-1 used?***
Mr. Copeland: It is nebulized twice a day. About 15 minutes in the morning using a specific nebulizer, and then another 15 minutes in the evening.

CEOCFO: ***Is it one dosage or might the dosage or components vary according to the patient?***
Mr. Copeland: We have seen success in patients with the formulation we have developed. These patients were able to use ARINA-1 via FDA approval of three Single-patient Investigator New Drug Applications. As we conduct further research, there is the potential to either tweak the combination or tweak the dosing schedule. We plan to conduct research to evaluate the benefit of more frequent dosing in patients with higher levels of inflammation or evidence of persistent infection in their lungs,

CEOCFO: ***What are the potential side effects?***
Mr. Copland: We have not seen any toxicity in the three patients on therapy. The patients have a combined 15 years therapy with no reported adverse events.

"Both lung transplant and CF patients, who are our first two primary therapeutic targets, are both orphan diseases, meaning that they have small populations, with critical, unmet needs in terms of therapies. As I mentioned, there are no FDA-approved treatments for lung transplant patients. We are laser-focused on providing an effective and safe medication to these underserved patient populations." - Dan Copeland, MBA

CEOCFO: ***Are you able to know it is working other than there is no infection?***
Mr. Copeland: The most common way that pulmonary medications are evaluated today is by measuring FEV1, which is a common measure of lung function. What we have seen in our current patients is evidence that each patient's FEV1 increased substantially immediately after starting ARINA-1. This lung function marker is a measure of general lung health. In our next set of studies, we will also analyze the bacterial composition and quantity in lung fluid collected during a bronchoscopy, which is much more invasive than measuring FEV1. We will evaluate this data to better understand the improved FEV1 from a microbial perspective.

CEOCFO: ***Why have you taken on the CEO role at this juncture?***
Mr. Copeland: I reviewed the patient data and science associated with the components of the therapy. The combined information is what drove me to accept the role as CEO. I saw an opportunity at Renovion to execute a clinical program and get a therapy into the hands of patients that can really change their patient experience and clinical outcomes post-transplant.

CEOCFO: ***What do you understand from past experience, about how to shepherd drugs along through the scientific part, both the regulatory part and the investment part?***
Mr. Copeland: One of the first things I did when joining the company as CEO was to find the right team of expertise to build out our board of directors and advisors. This is critically important to our success. Prior to Renovion, I spent 10 years as founder and president of a consulting company that worked with emerging companies and technologies on a daily basis. Much of the work we performed was focused on respiratory therapies. There are so many important factors in achieving success. Partnering with right regulatory and scientific experts is extremely important. Thus, we are looking for partners that have experience in inhaled pulmonary medications. The route to approval for inhalational medications is very different from oral medications, and we are striving to build a team of people that have deep expertise in that area. Financially, we want to raise money for our pre-clinical and clinical programs by finding partners who are familiar with translational medicine and appreciate the efficacy that we have already been able to show in patients.

CEOCFO: ***Certain medical conditions seem to be in and out of favor with the investment community. Where do you fit in to the interest overall today?***
Mr. Copeland: Both lung transplant and CF patients, who are our first two primary therapeutic targets, are both orphan diseases, meaning that they have small populations, with critical, unmet needs in terms of therapies. As I mentioned, there are no FDA-approved treatments for lung transplant patients. We are laser-focused on providing an effective and safe medication to these underserved patient populations.

CEOCFO: ***Is it easier than a pill or just different?***
Mr. Copeland: Inhalation actually delivers the medication to the lungs in a way that taking a pill cannot achieve. Therefore, inhaling a therapy is often a better way to address chronic inflammatory airways diseases. Lung transplant, CF, COPD and asthma patients are accustomed to using inhaled medications and are generally compliant. Developing inhaled medications requires specific inhalational toxicology for FDA approval, which is more involved timewise and monetarily than the toxicology studies required for an oral medication. However, the results from using inhaled medications in these patients is worth the extra time and money. Finding the right inhalational specialists to collaborate with in the pre-clinical and clinical stages is critical to the success of inhalational drug development programs.

CEOCFO: ***How do rodents inhale something?***
Mr. Copland: Each rodent will be in a chamber with a nebulizer attached to it. The therapy, a liquid solution, is placed in a reservoir, and then air is pumped into the reservoir at a very rapid rate, which turns the liquid into droplets that are propelled into the chamber by the airflow. The rodents simply breathe in the nebulized solution in the air of the chamber. The exposure time and respiration rate of the rodent is calculated to determine the specific concentration/dose inhaled by each animal.

CEOCFO: ***Time wise, what do you envision?***
Mr. Copeland: We hope to secure funding by the end of Q3 2016. We will then proceed with our pre-clinical program, which will take about a year. Using the data from the pre-clinical program, Renovion will file an Investigational New Drug Application with the FDA for ARINA-1. After this application is approved, we will begin Phase II clinical trial in which we will enroll lung transplant patients for a three-month study. We project results from the Phase II trial and FDA feedback from the trial 2018.

CEOCFO: ***Why is transplant the first area?***
Mr. Copeland: We chose lung transplant as our first area of focus because there are currently no FDA-approved therapies. Additionally, the data from our lung transplant patient is very compelling. This patient went from moderate airway disease to essentially normal airway function. We are confident that we actually have a medication that can make a difference in the lives of patients. Additionally, there is a desire from the FDA to have a medication that can serve this underserved patient population.

CEOCFO: ***Why does Renovion standout?***
Mr. Copeland: Renovion stands out because we have the ability to impact the lives of thousands of patients similarly to the way we have impacted the individual lives of a lung transplant, CF and asthma patient. We believe we can dramatically improve the lung function and quality of life of patients without the toxicities associated with many of the medications on the market today and with better efficacy than many of the medications being used by lung transplant patients today.

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