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Changing the course of treatment for Cystic Fibrosis (CF) and other rare diseases, Synspira Therapeutics is developing products with a Broad Mechanism of Action to address

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CEOCFO: ***Mr. Gallotto, the first thing I see on the Synspira Therapeutics™ website is "Fundamentally changing the way cystic fibrosis and other rare diseases are treated." How so?***
Mr. Gallotto: We are focusing on product solutions that reduce the treatment burden and improve the long-term health of people with cystic fibrosis (CF) and other rare disease indications. Our aim is to develop products with new mechanisms of action to target and change the course of disease, initially focusing on the underlying cascade of events that lead to progressive pulmonary disease or other life-threatening pulmonary conditions.

For example, frequent pulmonary infections, mucus and biofilm accumulation, airway congestion and inflammation are key drivers of pulmonary conditions in people with CF. Patients often experience infections and chronic inflammation, typically due to the accumulation of thick, sticky mucus in the lungs, which clog airways, where bacteria colonize and form biofilms that are difficult for antibiotics to penetrate. Today, there is no single product available to effectively address the accumulation of mucus and biofilms, and which can address bacteria in the lungs.

Our lead product, SNSP113, is a first-in-class product with a broad spectrum mechanism of action, designed to target the underlying cascade of events that lead to progressive pulmonary disease or other life-threatening pulmonary conditions. Specifically, SNSP113 is designed to improve the efficacy of antibiotics, by breaking down biofilms and mucus in the lungs to reduce chronic antibiotic resistance, increase airway clearance and reduce inflammation – the key drivers of pulmonary decline in people with cystic fibrosis.

CEOCFO: ***Have similar approaches been tried?***
Mr. Gallotto: There is not a single broad spectrum product available today to treat a complex disease such as CF. Patients are typically treated with multiple drugs and products to address the various components of the disease, creating a complex and significant treatment burden that can impact an individual's quality of life.

We expect that, with SNSP113, we can reduce the accumulation of thick, sticky mucus in the lungs, which clog airways and allow for the growth of bacteria and biofilms, and thereby enable antibiotics to effectively treat infections and reduce inflammation. Over time, we hope to see a reduction in pulmonary exacerbations and stabilization of pulmonary function in people with CF and other rare diseases characterized by pulmonary disease.

CEOCFO: ***What have you learned as you have done your early testing with SNSP113?***

Mr. Gallotto: We are quite optimistic that, by addressing the underlying events that lead to chronic infections and pulmonary exacerbations, we can help patients get better faster, improve their quality of life and avoid a debilitating and often life-threatening decline in pulmonary function.

CEOCFO: ***What surprised you? What have you found that you did not expect when you started working in this area?***
Mr. Gallotto: Over the past twenty years, I have worked at several companies focused on the treatment of cystic fibrosis, but never truly appreciated the significant treatment burden people with CF are facing due to pulmonary decline and a treatment regimen which can severely impact their quality of life. They can spend hours administering four, five even six different pulmonary treatments, two or three times per day, making it challenging to live a normal lifestyle. Compliance to treatment is also a challenge, and the toll this treatment burden takes on the individual and their family can be significant. I think that this burden continues to surprise – and inspire – me to make a difference.

That is why our goal is to not just find a more efficacious and safe product, but to reduce the treatment burden and improve the quality of life of our patients.

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CEOCFO: ***Where are you today at Synspira?***
Mr. Gallotto: We have spent a fair amount of time making sure that we are strategically aligned with our board, that we have a solid long term plan that drives program development. Right now we are beginning the process to initiate a Phase II study in people with cystic fibrosis, during the back half of 2019. In the past several months, we have been granted orphan designation in the U.S. and Europe, marking huge regulatory milestones for the company. Our interactions with these regulatory authorities also continues to move forward, to advance the clinical development of SNSP113 as quickly as possible and gain the regulatory approvals needed to bring this therapy to market.

CEOCFO: ***Are you funded for your next steps? Are you seeking partnerships or investment?***
Mr. Gallotto: We have sufficient funding to take us through a Phase II program. We have a number of internal investors that have been very supportive of the organization. We also have a very positive collaboration with the Cystic Fibrosis Foundation Therapeutics Inc., having received a development award that will fund part of our upcoming clinical study. However, there are a number of opportunities that we will look at in the back half of this year and the beginning of next, to understand if we can accelerate certain applications of the product. At that point in time, we may consider either raising capital through new investors or through partnering or other mechanisms.

CEOCFO: ***Is there any potential down side?***
Mr. Gallotto: In drug development, a product's mechanism of action is oftentimes determined in vitro, and in preclinical models. Following that, you need to study the product's safety and efficacy in humans. Our Phase I study results were encouraging and we feel pretty confident, in terms of the safety of the product. However, the clinical development process is a long and complex road, and we have much to do in terms of proving the overall safety and efficacy of our product.

CEOCFO: ***Would this tend to work the same in most patients? Would dosage depend on age or seriousness of the disease? What are some of the variables?***
Mr. Gallotto: I think the biggest variable is identifying the populations we are intending to treat – those with progressive pulmonary disease and life threatening infections. For example, in CF and bronchiectasis, those patients generally have issues with mucus accumulation which affects clogging of the airways. They have chronic infections and biofilm build-up. They have frequent pulmonary exacerbations. They have a lot of inflammation. Therefore, that population will tend to behave the same way.

In addition, when we look at delineating how patients will be treated with SNSP113, our focus is on two tiers. One is progressive pulmonary disease and one is life-threatening pulmonary infections. For pulmonary infections, we would look for pathogens, such as nontuberculous *Mycobacteria* (NTM), *Burkholderia cepacia* complex (BCC), *Pseudomonas aeruginosa* or methicillin-resistant *Staphylococcus aureus* (MRSA), which can cause an immediate life-threatening

situation. In this case, you may have one treatment regiment with one dose and one level of frequency, whereas in the more chronic case of pulmonary disease, we would look to dose less frequently, with the goal to prevent further decline in lung function while also improving quality of life.

CEOCFO: ***What percentage of the population suffers from cystic fibrosis?***
Mr. Gallotto: There are between 30,000 to 35,000 people in the US with CF. Primary ciliary dyskinesia is a disease that is characterized by similar pulmonary issues as in people with CF, affecting somewhere between 5,000 to 10,000 patients. And, there are 100,000 to 125,000 people with non-CF bronchiectasis which is a chronic, progressive respiratory disorder. These are the populations we are initially focused on – homogeneous populations, experiencing frequent pulmonary exacerbations and frequent chronic infections. They have chronic progressive decline in pulmonary function interwoven with acute exacerbations. We believe SNSP113 can have a huge impact on treatment burden and quality of life for these patients. We may also consider additional applications of SNSP113 in the future.

CEOCFO: ***What has been the response from members of the medical community that are aware of what you are doing now?***
Mr. Gallotto: Clinicians have been very enthusiastic. For example, we recently published a paper on SNSP113's impact on mucus accumulation that received a lot of positive attention. In addition, our collaboration with the CF Foundation, and the funding we have received, is a strong bellwether for how the medical community looks at our product and views its potential upside. Right now, there are many expectations in terms of our clinical development program and collecting the data to support their confidence in us. With all of this, I think the community is recognizing the opportunity with a product like SNSP113 because of its unique, broad spectrum mechanism of action.

CEOCFO: ***There are so many new ideas and new drugs to look at. Why is Synspira Therapeutics a company to watch? What sets you apart?***
Mr. Gallotto: We have a technology that is very applicable to the disease population, with a clear potential benefit. There is a huge medical need in that respect. The other novel aspect of our approach is that our team has 20-plus years of experience, mostly working in CF and rare diseases, and we understand how to get products developed in this market. Often, organizations are not built to effectively execute in this population and our experience is quite unique in that regard. Hence, our goal to not just to develop products in this space, but to have products that are fundamentally different than other treatment options – solutions that are simple to use and designed to improve the long-term health of people with CF and other rare disease indications.