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Achieve Life Sciences – Advancing a New Therapeutic Option to Help the Millions of Smokers Who are Ready to Quit



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CEOCFO: Mr. Bencich, what is the focus behind Achieve Life Sciences, Inc?

Mr. Bencich: Achieve is focused exclusively on the development and commercialization of a prescription drug called cytisinicline for use as an aid to smoking cessation and nicotine addiction. This product is unique in that it has been on the market in Central and Eastern Europe for over twenty years, but it has never been approved in the U.S. or other major markets. Achieve's goal is to obtain regulatory approval and marketing authorization in the rest of the world to help the millions of smokers, and potentially e-cigarette users, who struggle with nicotine addiction.

CEOCFO: Would you explain how the drug works?

Mr. Bencich: The drug works in two distinct ways. First, cytisinicline blocks the nicotine receptors in the brain resulting in less satisfaction from smoking. In parallel, it also partially stimulates these receptors, so smokers continue to experience the buzz they receive from smoking, which helps to alleviate the cravings and withdrawal symptoms that make quitting so difficult. The combined effect of this dual mechanism of action is why the drug is so effective in helping smokers quit.

CEOCFO: Why has cytisinicline been off the radar screen here in the U.S.? What is the history behind it? Why did Achieve decide to take it on?

Mr. Bencich: The drug was discovered and is currently marketed in Central and Eastern Europe by the Bulgarian pharmaceutical company Sopharma. Prior to the collaboration with Achieve, which provides us with exclusive supply and rights to cytisinicline, Sopharma simply did not have the expertise or capabilities to expand beyond their core markets.

“Achieve Life Sciences is committed to advancing cytisinicline to address the global health smoking epidemic by providing a new cessation treatment option and hope to the millions of people who battle nicotine addiction. Tobacco use is currently the leading cause of preventable death that is responsible for more than eight million deaths worldwide and nearly half a million deaths in the U.S. annually. More than 87% of lung cancer deaths, 61% of all pulmonary disease deaths, and 32% of all deaths from coronary heart disease are attributable to smoking and exposure to secondhand smoke.” John Bencich

We believe cytisinicline has the ability to improve the health and well-being of millions of smokers throughout the world. We are completing the required clinical development to enable regulatory approval first in the U.S. and also evaluating opportunities to expand to other markets not currently addressed by Sopharma.

CEO CFO: *What do you understand from your own past experiences to help guide Achieve through that FDA process?*

Mr. Bencich: I have served in leadership roles at numerous biotech organizations with products in all stages of development; from pre-clinical through Phase 3 and commercialization. I, along with the team we have at Achieve, appreciate the complexity and nuances of the development process leading to successful commercialization. We engage with the FDA in a collaborative manner to ensure we are adequately designing and executing clinical trials that will meet their stringent requirements for marketing authorization. As an example, our first U.S. Phase 3 trial (ORCA-2), was recently initiated and was designed with feedback from FDA.

CEO CFO: *Why are you CEO now? Why have you taken over the realm and what might be different for the company under your leadership?*

Mr. Bencich: I have been with Achieve since we went public in 2017 and previously served as the Chief Financial and Operating Officer. During that time, I worked very closely with our former CEO and now Executive Chair, Rick Stewart, who is one of the co-founders of the company. When I joined Achieve, moving into the CEO role was one of the key considerations.

Our operations are predominantly on the West Coast, where I am located, and Rick Stewart and Tony Clarke, our co-founders are based out of the UK. It was a natural progression, and ultimately more efficient, particularly given travel restrictions in light of the pandemic, to allow the leadership to mature where most of the operations are located. I have been leading the operations of the company up until this point. Therefore, from an internal operational perspective, it is really business as usual.

CEO CFO: *What has been the interest from the medical as well as the smoking cessation community?*

Mr. Bencich: There has been a tremendous amount of interest, especially from researchers and clinicians in the field of smoking cessation. There has not been a product approved for smoking cessation in over a decade and the options that are currently available have a history of issues with side effects and black box warnings from the FDA. Even with Chantix®, the most effective smoking cessation treatment on the market, only 1 out of 5 quitters remains abstinent three months after completing treatment. Smokers need new solutions to help them quit and we believe a product like cytisinicline, that offers a shorter course of treatment and a more tolerable side effect profile, will be well received by smokers looking to quit.

CEO CFO: *What about the investment community? Sometime, certain areas are more in favor than others for investors. Is*

smoking always of interest? What do you find today, in the COVID era?

Mr. Bencich: We are seeing much more interest over the last twelve months than we have historically. In part, that has been driven by COVID-19. We know today that smokers have worse outcomes if they do get coronavirus than non-smokers, which means there has never been a better time to quit smoking.

Overall, there are still more than thirty-four million smokers in the U.S., and it continues to be the leading cause of preventable death. We believe that our product can make a significant impact, based on the data we have seen, and investors are now taking notice. Unlike many life sciences companies that are very high science and hard to understand, I think smoking cessation is an area that everyone can relate to, either being former smokers or knowing family members that have struggled to quit. Therefore, I think everyone sees the size of the opportunity and the ability to make a real impact in the world.

CEOCFO: Are you surprised so many people are still smoking or starting to smoke?

Mr. Bencich: Nicotine is the third most addictive substance in the world, behind cocaine and heroin. There are also very few treatment options to help smokers overcome their addiction. While the health warnings of smoking are apparent, the effect nicotine has on the brain is a powerful force to overcome. For those reasons, I am not surprised there remain over 1 billion smokers around the globe and nearly 34 million smokers in the U.S. alone.

We are also now facing a vaping epidemic that has led to even more people becoming addicted to nicotine. There are an estimated 14 million adults and roughly 30% of high schoolers using e-cigarettes. This is an area we also believe cytisinicline has great potential to help.

CEOCFO: Development is always expensive. Are you funded for your next steps? Are you seeking funding, partnerships, investment?

Mr. Bencich: We are a biotech company and we are not currently selling our product, so we will always be looking for more funding. However, we did just initiate our ORCA-2 Phase 3 trial. This is a 750-patient study, being conducted at fifteen clinical trial locations in the U.S. We were very excited to hit that milestone of initiating that trial last month. We are looking forward to driving this forward quickly and anticipating results as soon as the end of next year, which is relatively quick in this industry, where trials can often take several years to get results.

CEOCFO: What did you learn earlier in testing that might have surprised you?

Mr. Bencich: That is a great question! Not really surprising, but what we continue to be impressed by the incredibly tolerable safety profile demonstrated by cytisinicline in numerous clinical studies, conducted both by Achieve and external smoking cessation thought leaders. One of the leading issues for smokers agreeing to use or staying compliant with cessation treatments is the adverse events. Specifically, with Chantix we

know roughly 75% of users don't complete their prescribed course of therapy and a majority state it is due to side effects like nausea and abnormal dreams. Many smokers won't even consider Chantix given its historical issues with suicidality and the black box warning. We believe cytisinicline, when approved, will offer an efficacious and more tolerable option that will compel smokers to make a quit attempt.

CEO CFO: *How are you reaching out to both investors and the medical community?*

Mr. Bencich: We have a great group of external thought leaders that stem from key academic institutions that have been involved in historical smoking cessation product development and tobacco research for decades. We are working closely with these individuals to ensure our development program, and ultimately the drug itself, will best serve the needs of clinicians and smokers.

On the investor side, we are educating the community on the smoking cessation market and why there really is a critical need for a new treatment option. We have been successful over the last three years at attracting capital to further the development of this program and expect that to continue based on the interest we have seen.

CEO CFO: *Why is Achieve Life Sciences important?*

Mr. Bencich: Achieve Life Sciences is committed to advancing cytisinicline to address the global health smoking epidemic by providing a new cessation treatment option and hope to the millions of people who battle nicotine addiction. Tobacco use is currently the leading cause of preventable death that is responsible for more than eight million deaths worldwide and nearly half a million deaths in the U.S. annually. More than 87% of lung cancer deaths, 61% of all pulmonary disease deaths, and 32% of all deaths from coronary heart disease are attributable to smoking and exposure to secondhand smoke.

