CEOCFO

CIVITAS THERAPEUTICS

Issue:
November 5, 2012

CEOCFO Magazine - The Most Powerful Name In Corporate News and Information

Now in Phase II Clinical Trails with their Lead Program CVT-301, an Inhalable Version of L-Dopa for the Symptomatic Treatment of Parkinson's Disease, Civitas Therapeutics is Transcending the Historic Limits of Pulmonary Delivery Technologies using their ARCUS™ Therapeutic Platform

Healthcare
Inhaled Therapeutics
Neurology/CNS disease

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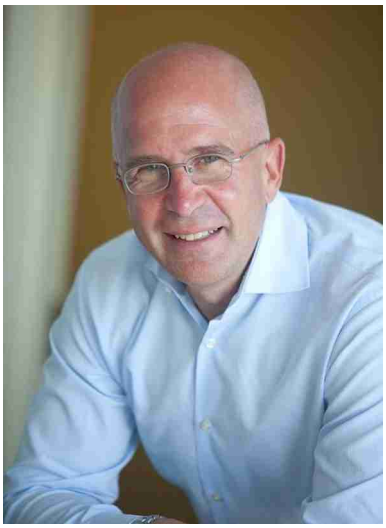

Glenn Batchelder
CEO

BIO:
Mr. Batchelder has more than 25 years of experience in senior business and technical leadership roles, including as CEO of two successful biotech companies prior to Civitas. Prior to co-founding Civitas, he was CEO and the first employee of BIND Biosciences, a leading nanotherapeutic company. Before BIND, Mr. Batchelder was CEO of Acceleron Pharma, building the company from a research start-up to a clinical stage company with a robust preclinical pipeline. Prior to Acceleron, Mr. Batchelder was Senior Vice President of Operations at Millennium Pharmaceuticals where he played an integral leadership role in the launch of VELCADE® and was responsible for the commercial supply chain and technical operations for INTEGRILIN®. Mr. Batchelder received a BS in Chemical Engineering from Lehigh University and serves on the Board of Directors of the Massachusetts Biotechnology Council.

About Civitas Therapeutics
CIVITAS THERAPEUTICS is developing breakthrough therapies that transcend the historic limits of respiratory drug delivery with the ARCUS therapeutic platform. The clinically validated ARCUS™ technology uniquely enables respiratory delivery of a large, precise dose with a simple, convenient, breath activated device. Civitas' lead program, CVT-301, is an inhaled L-dopa formulation for treating the debilitating intermittent "off" episodes associated with Parkinson's disease.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Mr. Batchelder, what is the vision of Civitas and how has it developed so far?
Mr. Batchelder: Our vision is to take our ARCUS pulmonary delivery platform and develop therapies to place dramatically improved outcomes in the hands of patients. Our pulmonary delivery technology either delivers drugs to the lungs to treat respiratory disease or delivers drugs through the lungs to provide a systemic benefit. Because of the unique features of this technology, we can provide patients a convenient device at their disposal for immediate and consistent relief at doses other technologies could not deliver. It allows us to tackle challenges facing patients that no other technology can address.

CEOCFO: Would you explain what you have figured out that others have not?
Mr. Batchelder: The foundation of the ARCUS technology is engineering of a novel type of aerosol particle that overcame the historic challenges faced by inhaled therapies. For example, whether the active agent was intended to treat a respiratory disease like asthma or an agent to be delivered to the circulatory system through the lungs, traditionally people created aerosols as small dense particles. The reason particles were small and dense was it allowed them to fly into the lungs and deposit where you needed them, but they required significant energy to disperse into aerosols. At the core of the ARCUS technology is the idea that by re-engineering particles to retain the aerodynamic characteristics of a small particles so as to be carried by the airflow stream, but by making them porous and larger in physical diameter, the powders can deliver a larger dose and a more precisely with a simpler device. This allows us to transcend the historic limits of pulmonary delivery technologies, in terms of the types of drugs and size of doses delivered. In this way we are able to deliver more precise doses that are independent of how hard a patient

breathes. They get the same dose each time with a very simple breath actuated device that requires minimal breathing coordination. You may be familiar with many asthma inhalers where you need to squirt something into your mouth and inhale simultaneously; then sometimes you get the dose intended if you do it the right way, but other times you do not. In contrast, the ARCUS technology allows for very simple and reliable delivery. The concept can be visualized in terms of popcorn. Historically aerosols were more like un-popped kernels. The ARCUS particles are more like a popped kernel with a larger diameter dispersing more easily, but retaining the aerodynamic properties of the un-popped kernel. Powders made of particle resembling popped kernels confer properties that enable us to deliver larger doses more precisely with a simpler device. This is the same principle that make a hot air popcorn popper work.

CEOCFO: Is this method unique?

Mr. Batchelder: There was a great deal of technology development that was involved in translating the simple idea into a robust technology, something that could ultimately become a commercial product. This technology was invented in the late nineties at MIT and licensed by a small company founded by Dr. Robert Langer. That company was Advanced Inhalation Research, or AIR, that took the technology from an academic laboratory setting and began to translate it into a viable therapeutic concept. Soon after AIR was operational, another company named Alkermes acquired AIR. Alkermes worked on perfecting the ARCUS technology for about a decade. Through a series of events, Alkermes reached a critical strategic inflection point where they needed to sharply focus their efforts outside of pulmonary delivery. They approached a group of us to explore creative options for accelerating product development and value creation with the ARCUS technology. We were able to spin out the ARCUS technology forming Civitas with an initial focus on developing a Parkinson's therapy.

CEOCFO: Where are you in the development/commercialization process?

Mr. Batchelder: We are now in Phase II trials of lead program, CVT-301, which is an inhalable version of L-Dopa. For the past 30 years L-Dopa has remained the most widely used and effective therapy for symptomatic treatment of Parkinson's disease. Unfortunately, the efficacy of L-Dopa is compromised by the inherent variability when delivered orally. When patients take an L-dopa pill they are not sure whether enough will get into the blood to abate their symptoms and keep their symptoms controlled. Also, they do not know when it will take effect, maybe 30 minutes, maybe 120 minutes. While L-dopa is a very good drug, this unreliability ends up changing patients' lives because they know the symptoms can suddenly and unpredictably return. With CVT-301, delivering L-dopa through the inhaled route allows the drug to take effect almost immediately and ensure consistency in the amount that the patient receives. If a patient's are oral medication is suddenly wearing off, then they could inhale our therapy and confidently bring themselves back to a state where their symptoms are abated.

Above and beyond everything else I have described, our most important success factor is the people. This is a complicated business that requires the integration of diverse talents and experience in order to effectively execute. We have been able assemble a group of industry veterans, people who have in many cases, pioneered this technology and others that have developed many drugs over the course of their careers. - Glenn Batchelder

CEOCFO: Did you choose this because the technology is particularly applicable or because there is a need?

Mr. Batchelder: In today's environment, new innovative technologies are important but that innovation also needs to translate into a significant clinical benefit. Also, we need to be confident payers, like insurance companies, will be convinced there is enough benefit that they would be willing to pay for it. In selecting our lead program we focused on identifying a therapy that would make a very significant difference in patients' lives and a therapy the ARCUS technology could uniquely enable. With CVT-301, both of these criteria were clearly met. In fact, the significance of the unmet need, the technology's ability uniquely address that need and the anticipated clinical benefit to both patients and payers were all critical criteria in our backers decision to invest $25 million.

CEOCFO: What attracted you to this particular opportunity? What have you learned from previous experience which would be helpful in commercialization?

Mr. Batchelder: This my third biotech company as the founding CEO. Each one had a different area of focus. Each one has been very successful. And each one has reinforced the importance of having a very clear vision for the company and an understanding of how that vision will improve patients' lives. There was a time when exciting science or novel inventions on their own could be the basis for a company and then over time you could expect good things would happen to you. In today's world, it is important that right from the beginning to focus on the potential therapeutic benefit and commercial dimensions of the product. Over my career, it has become clear to me and my colleagues in biotech that focusing on the patient and how ideas become viable and important products is the key to success.

CEOCFO: How far will the current funding take Civitas Therapeutics?

Mr. Batchelder: We have funding that takes us through the middle of next year.

CEOCFO: Has the industry been looking for a better way and are there competing technologies?

Mr. Batchelder: The ARCUS technology has unique capabilities that set it apart from any other technology.

We are constantly looking for the areas of unmet need where our unique capabilities can translate into a significant improvement in the standard of care. An additional advantage we have is the energy and resources invested in this technology and the progress made by Alkermes and their partners over time. As a result we are headquartered in a state-of-the-art 90,000 square foot commercial manufacturing facility they built that has produced over 25 million doses of product. Also we have over 130 issued patents around the technology. While people may develop interesting new ideas for pulmonary delivery, we have a very strong intellectual property position and have a running head-start in rapidly and capital efficiently in developing and commercializing products. Relative to Parkinson's disease specifically, it is well recognized that the variability of oral L-Dopa is the is a real challenge. We have a grant from the Michael J. Fox Foundation based on their recognition of this unmet need and that the ARCUS technology is uniquely positioned to address that need. In fact, we will be presenting our Phase 1 clinical data at the Michael J. Fox annual Parkinson's disease therapeutics conference that is in New York.

CEOCFO: What sets Civitas apart?
Mr. Batchelder: Our investors remain excited about the company because it is very unique to have a cutting edge technology and, at the same time, have the technology be so clinically validated. Secondly, with our lead program there is a very clear unmet need and we are leveraging thirty plus years of clinical pharmacology and safety learnings for L-dopa. We are able to couple a highly de-risked technology with a very well characterized, safe and effective agent, and then formulate that agent so that patients can manage their symptoms much more effectively. The technology, the capital efficiency and the therapeutic application each on their own set Civitas apart, together they make Civitas a truly unique company.

CEOCFO: What should people remember most about Civitas Therapeutics?
Mr. Batchelder: Above and beyond everything else I have described, our most important success factor is the people. This is a complicated business that requires the integration of diverse talents and experience in order to effectively execute. We have been able assemble a group of industry veterans, people who have in many cases, pioneered this technology and others that have developed many drugs over the course of their careers. Bringing an experienced group together with complementary skills who function a high-performing team is essential to any biotech success story and that is absolutely true for us as well.

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