CEO CFO

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Focused on a Plant-Based Manufacturing Platform for Low-Cost Monoclonal Antibodies, Protein Drugs and Vaccines for Cancer, PlantForm Corp is positioned for growth having completed Animal Proof-of-Concept Studies for their Biosimilar Version of the Breast Cancer Drug Herceptin®

Healthcare
Biosimiliars

Don Stewart
CEO

BIO:
Dr. Don Stewart is an entrepreneur and scientist with more than 20 years of management experience in the biotechnology industry. He is also the founder and President of Alba Biologics Group.

Dr. Stewart served as Director Research of Cangene Corporation from 1997 to 2007. At Cangene, he led programs to develop monoclonal antibodies and recombinant protein drugs; supervised animal efficacy and toxicology studies as well as clinical trial programs; and obtained more than $15 million in external grant and contract funding over a five-year period.

Dr. Stewart has a PhD in biochemistry from the University of London in the U.K. He has given numerous lectures at international symposia on research management, manufacturing strategies and biosimilar pharmaceuticals.
Industry Associations: Member, Life Sciences Ontario; Member, Ontario Bioscience Industry Organization (OBIO)

About PlantForm Corp:
PlantForm Corporation is a Canadian company formed in 2008 to commercialize a plant-based manufacturing platform for low-cost monoclonal antibodies, protein drugs and vaccines for cancer and other critical illnesses.

PlantForm's technology platform provides several advantages over other standard systems used to produce most biologic drugs on the market today: it's fast, efficient, highly versatile (for new product development) and easily scalable. Best of all, it's capable of reducing manufacturing costs for life-saving drugs by up to 90 per cent.

PlantForm licenses its technology from the University of Guelph, where it was developed by Dr. J. Christopher Hall, the Canada Research Chair in Recombinant Antibody Technology. Dr. Hall is a PlantForm founder and the company's Chief Scientific Officer. All relevant intellectual property is protected by patent filings.

PlantForm's pipeline features both innovator and biosimilar products, including: biosimilar trastuzumab, a plant-produced version of the $6-billion breast cancer; drug Herceptin® (animal studies successfully completed, human clinical trials scheduled for 2014, market entry anticipated 2016); biosimilar versions of two additional oncology drugs with combined annual global sales of $11.4 billion (2010); innovator antibodies for HIV/AIDS, funded by the Government of Canada and the Bill & Melinda Gates Foundation; recombinant butyrylcholinesterase (rBuChE), an enzyme used as preventative medicine for people vulnerable to attack by nerve agents, organophosphates or other stimulants ($1.8-million contract with the U.S. Defense Advanced Research Projects Agency)

PlantForm is interested in establishing partnerships with other companies to develop additional targeted biosimilar and innovator drugs.

PlantForm's projected revenue is more than $50 million by 2016. The company has offices in Guelph (headquarters), Toronto and Sarnia.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Dr. Stewart, what is the grand vision at PlantForm?
Dr. Stewart: PlantForm is focused on providing affordable healthcare solutions specifically generating high-value, high-cost biological drugs at lower cost to the consumer. We will make these drugs more widely available to patients while reducing their cost of healthcare systems.

CEOCFO: Would you tell us about biological drugs in general?
Dr. Stewart: Biological drugs fall into two categories. There are protein drugs and antibody drugs. Protein drugs are quite well known and include such things as enzymes and growth hormones. On the antibody side, which is our area, there many antibody drugs that are made using recombinant technology (using microbiology techniques) and there are at least thirty of these antibody drugs approved by FDA. They tend to fall into three main categories, which are oncology, arthritis or inflammatory disease and infectious disease.

CEOCFO: What specifically are you working on and why have you chosen those particular areas?
Dr. Stewart: We are working in the area of oncology. Specifically what we are doing is we are making the biosimilar version of the breast cancer drug Herceptin®. Biosimilar drugs are the generic versions of biological drugs. Generics are small molecule drugs and a biosimilar would be a large molecule protein or antibody drug. We have three candidates in the oncology area. First of all the biosimilar Herceptin, which is a breast cancer drug, and then we have two other cancer drugs. That is our main area of focus, but we also use the same manufacturing platform to produce potential HIV-AIDS drugs in a project funded by the Bill & Melinda Gates Foundation. We have a contract from the US government from DARPA (Defense Advanced Research Projects Agency) for a project in the field of countermeasures to bioterrorism.

CEOCFO: How did you make the choice of projects?
Dr. Stewart: We looked at the potential biosimilar drug candidates, which ones the patents would expire for, because the patent must be expired to let you enter the market. We looked at the times of patent expiring and it had to match our development timeline. We looked at the current markets, which have to be more than $2 billion, our minimum criteria and we are looking for drugs that are increasing in terms of anticipated sales and expanded indications, which again results in increased sales. We did a hardcore analysis, took the thirty drugs, brought them down to a list of six and then chose three from them using those criteria.

CEOCFO: Where are you in the process with the various drugs?
Dr. Stewart: We have completed animal proof-of-concept studies, so the next step with our lead candidate is going to be to move towards Phase 1 Clinical Trials. We have to do safety and toxicology studies and some other work to reach that point but we are about eighteen months away from starting the trials. We are currently raising financing to advance the company to completion of Phase 1 clinical trials for the first product.

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- Dr. Don Stewart

CEOCFO: Financing is difficult everywhere; is your area in favor these days?
Dr. Stewart: There are pros and cons in our area. The advantage is that it is a relatively new area. Biosimilar drugs are new in the pharmaceutical area, so there is an interest in that but it is also a disadvantage. By doing something new, sometimes investors are concerned about the regulatory pathways. We actually enjoyed considerable amounts of interest from offshore investors and we are focusing our attention on the Middle East for financing.

CEOCFO: Will you be starting in the US as far as regulatory approval?
Mr. Stewart: With our lead candidate, biosimilar Herceptin, the patents on Herceptin first expired in Europe, so our first major market is actually going to be Europe and then that will be followed two or three years later by the US. We will engage the US regulatory authorities, the FDA at the same time we engage the European authority (EMEA) and also Health Canada so that we are sure that when we present a package it will be acceptable in all the major markets in the world.

CEOCFO: Would you tell us about your background, what you bring to the table that will help PlantForm advance?
Dr. Stewart: I am an entrepreneur and a scientist; sometimes they are a bit of a dichotomy! I worked for Cangene Corporation, which is Canada's largest biotechnology company for more than twenty years. I joined the company running the research group and left the company when it had grown from eleven people at the start to eight hundred people. When I left the company I was the director of research and development, so I had gained a great deal of experience in understanding how to generate a drug as a pharmaceutical and how to advance it through early development and later stages of manufacturing, as well as advancing drugs through clinical trials and other regulatory requirements. On the business side, I have a couple of other companies. I started a real estate home-flipping company in Toronto and the other is a consulting company in the pharmaceutical arena. I bring a blend of early-stage business experience and a lot of knowhow in drug development.

CEOCFO: What are the one or two most important things you have learned in your various ventures that are going to help PlantForm succeed?

Dr. Stewart: In our area, you have to make thoughtful decisions early on. You have to think through how your product is going to get into someone who is being treated for a disease. It is very important to think through all the steps because there are many hazards in drug development; technical issues, issues from the patent point of view, financing and also in the regulatory approval process. Once you have made that decision, I think it is very important to stick to it and to press down because there are many distractions and many interesting things you can do in science and drug development but it is important to have the goal in mind that what you are trying to do is generate return for your investors.

CEOCFO: Would you tell us about the medical counter-terrorism area?
Dr. Stewart: This is a very neat project actually. We are funded by DARPA, which is a US funding agency, and it is part of the government that funds development related to biodefense. We are working on generating an antidote to nerve gas exposure. Nerve gas was released on the Tokyo subway several years ago. The drug we are developing is in collaboration with a couple of US companies and a Canadian Department of Defense Research Institute. It is an exciting project because it brings together a group and it is quite exciting to work with a team. We are working with a contract manufacturer in Kentucky and an analytical company in California. The first project is for one year and if it is successful, we are hoping that there will be considerable interest from the Canadian and US governments in advancing the project into clinical trials.

CEOCFO: How did you come about the project?
Dr. Stewart: Our technology at the company is based on using plants, so it is very low-cost manufacturing system. We were invited with the other North American companies who have this type of technology, to a workshop by DARPA and they presented the proposal and invited applications. It was an outreach by DARPA to people known to have capabilities in this area.

CEOCFO: What is ahead one or two years down the road?
Dr. Stewart: We are excited about the progress. With financing, we are going to be moving our first drug through clinical trials. We are going to be expanding the number of drugs on which we are working. We are excited about the possibility of partnering with a major pharmaceutical company to bring our drugs to the market. We see a great opportunity in the area of biosimilar drugs, and with our low-cost plant based production system, we feel we are going to establish a position as a leading technology provider to Pharmaceutical partners who will bring significant expertise required to market a product.

CEOCFO: Why should the business and investment community pay attention to PlantForm?
Dr. Stewart: We stand out because we have a unique technology to produce drugs at low-cost. We have a unique capability to advance drugs quickly. Our production system can produce drugs at ten percent of the cost of standard pharmaceutical production methods and we are focusing on biosimilar drugs. Our path to market is in the order of five to six years as opposed to twelve to eighteen for an innovative drug, so for the investor, there is a product that has a much reduced risk profile getting to the market. In summary, there is growth potential in the market and a shorter timeline through to a return on investment.

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