CEO CFO

Protein Sciences CORPORATION

Issue:
December 24, 2012

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

Modern Vaccine Development Company, Protein Sciences is revolutionizing the Industry using their Proprietary BEVS Protein Expression Technology to produce High Quality Recombinant DNA Based Proteins quickly and at Low Cost

Healthcare
Vaccine Development

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Manon Cox
CEO

BIO:
Dr. Cox joined Protein Sciences in 1998 as Director of Business Development, became Chief Operating Officer in 2000 and became CEO in 2010. Previously, she was with Gistbrocades, a Dutch company specializing in fermentation. She held various management positions at Gistbrocades, including in Research and Development, Manufacturing and Business Development. She serves on the Scientific Advisory Boards of Pall BioPharmaceuticals and iCubed. Dr. Cox holds a Doctorate from the University of Wageningen, received her MBA with distinction from the University of Nijenrode and the University of Rochester, NY and holds a Doctorandus degree in Molecular Biology, Genetics and Biochemistry from the University of Nijmegen, The Netherlands.

About Protein Sciences:
Protein Sciences was founded in 1983 and has more than 25 years of experience in developing vaccines and biopharmaceuticals for the prevention and treatment of a variety of diseases. We use our proprietary BEVS protein expression technology to produce high quality recombinant proteins quickly, reliably and at low cost. We have developed three main business lines that employ this technology.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Ms. Cox, what is the vision at Protein Sciences?
Ms. Cox: Protein Sciences is a modern vaccine development company that wants to develop vaccines and change the vaccine industry. At this moment in time, the vaccine industry is characterized by a number of players that have been in it for a long time. The majority of vaccines are being made with technology that is about fifty years old, so it is by growing the pathogens themselves in various substrates and then using that as vaccine, whereas in the last thirty years, new technology has been developed that would enable you to develop new vaccines based on Recombinant DNA technology. We feel that the healthcare industry is changing, and with the enormously rising healthcare costs, we think there will be a change from disease treatment to disease prevention and vaccines play a crucial role in that. We want to save lives with modern vaccines.

CEOCFO: Would you tell how the technology works and what is specific to Protein Sciences Corporation as opposed to just known or available in general?
Ms. Cox: The technology that we use derives from the Baculovirus Expression Technology, which is genetic engineering technique that uses one single cell substrate and a vehicle in which you can copy and paste your protein and then make a protein of interest. Thirty years ago we were isolating insulin from calves and then purifying it and giving it to humans. When genetic engineering came around, we discovered that we could also do it using cell culture systems. The difference in the Baculovirus Expression System versus the more primitive systems is that you can make complex proteins. Many viruses that cause infectious diseases are more associated with all kinds of other disorders like cancer. For example, human papilloma virus has been associated with cervical cancer and hepatitis B virus has been associated with liver cancer. We now know that influenza infections go hand-in-glove with more heart attacks during the influenza season. These viruses interplay with your immune systems and can cause harm for your body. Viruses are complex or at least consist of very complex proteins and you

could not make those in those primitive organisms that were being used to produce something such as insulin. We use a cell line that derives from a caterpillar and make the proteins of interest in that cell line. How are we different from other companies? What I always say is somebody has to be a pioneer to get a production platform accepted because it is hard to get regulatory agencies to step onto and to embark on new technologies. With this particular technology that we are using, we are just basically spearheading with an influenza vaccine and thereafter I believe many more products and vaccines and proteins will follow. GlaxoSmithKline uses a comparable technology but they use a different cell line that derives from a different organism.

CEOCFO: Where are you with Flublok®?

Ms. Cox: Our Flublok product has been under review with the FDA for quite a few years. We now have an office action date of January 16th and the FDA has indicated to us that they are prepared to approve the product for eighteen to 49 initially. We will perform an additional clinical trial to generate more safety data in fifty and above. We expect to do a limited market launch in January 2013 and I know that is relatively late for influenza, but if you imagine that, only five to ten percent of something such as student population actually receives vaccination, there is still quite an interesting opportunity. By the time September comes, we believe we should be able to provide the FDA with additional data, which would enable us to do get approval for everyone eighteen years and above.

CEOCFO: Is the vaccine better than standard vaccines, cheaper to make?

Ms. Cox: The mechanism of action is similar. It is based on hemagglutinin, which is one of the proteins of the virus. If your immune system sees that protein, it makes antibodies, and then when the virus comes around, your antibodies can neutralize the virus. Our vaccine is different from the licensed influenza vaccines in that it contains more of that fancy antigen, so in other words, you stimulate more antibodies and that protects you. We have seen that in our clinical studies so there are more antigens. It is highly purified, so 95% of what you get is actually the active ingredient, whereas if you look at the other influenza vaccines, there are other proteins including egg-derived proteins. Flublok is not made from a live influenza virus and that sounds trivial but 30% of people believe you can get the flu from an influenza vaccine and that might be because they know influenza viruses are used in the manufacturing process. We do not use influenza viruses in the manufacturing process. It is absolutely impossible to get the flu from this vaccine. There is also no thimerosal, no adjuvants and no antibiotics, so it is basically a pure product.

CEOCFO: When doctors are purchasing vaccine, will they be able to ask for this vaccine specifically and how does the process work?

"Protein Sciences is a modern vaccine development company that wants to develop vaccines and change the vaccine industry." - Manon Cox

Ms. Cox: It is interesting that many people really believe and feel that you need to get vaccines for free, so that is an interesting observation when you do market studies. What we will try to do is change the perception and we are going to position this product as a product that is truly different and that will in part be done by initially having a somewhat higher price point than the licensed vaccines that are on the market because that is one way to differentiate your product. We do not want it to become a "me-too" product where a doctor really grabs a product out of the refrigerator and the recipient is not going to ask what is this about, so we really want to change the perception and we want to have the people ask for FluBlok instead of the doctor giving them an uninfluenza vaccine. How are we going to do that? We are going to do test marketing this January working with universities, working with places here in Connecticut to see how we can best position it. I personally think there is a very big social awareness amongst younger people. They really go for things and products when they have the feeling that they can trust the supplier. I think the pharma industry is doing many good things and giving away a great deal of medicines for free to developing countries, but it is not a transparent process. I would like to make such an effort far more transparent and to come up with some objectives and goals that will give the recipients and the buyers the feeling that they are doing good beyond getting vaccinated themselves.

CEOCFO: I know you have a background in business development; how important is that when you are going from development to commercialization?

Ms. Cox: What I feel and believe is that in every part of what you do, you do have to experiment. I was originally trained as a scientist and a molecular biologist, my background is in virology but my business development approach is 1027 always centered around you try things and if it works it is great but if it does not, you move on. In a way, you just have to be innovative in what you approach. With this market introduction, we are going to do ten or fifteen large-scale experiments and each experiment has a goal to deliver ten thousand doses. Then we are going to follow up with what is going to be the most successful way to do this and that is what we will pursue. When you have been in business development, you have to come up with new things because people are not waiting for you, you have to be persistent and have a number of characteristics that might help you bring things across the finish line. You learn in business development to reach out to people and you can never do things from behind your desk, so you need to work with others and that is crucial. For example, I recently joined the board of a United Way local organization and I was at a fair where we were exhibiting what our company was doing for this community and we were talking about FluBlok there. The chairman of the United Way came to our booth and he started talking to people about our

product. You just see that it is far more powerful when other people speak about a product than when you do. When people who have heard or learned from you the benefits of this product, they are going to really talk about it and that is what you want. I learned some of that in business development is you cannot be shy, you have to pick up the phone and continue to pick up the phone if people do not return your phone calls and that is what you need here as well, keep on knocking at the door.

CEOCFO: Would you tell us about the vaccines you have coming?
Ms. Cox: FluBlok is going to be the poster child. It is going to be our first product. Beyond that we are working on as well as another influenza vaccine, which is based on neuraminidase and you have probably heard about neuraminidase inhibitors. If you get the flu, neuraminidase inhibitors can help you prevent that disease so it prevents the severity of the disease. There is also an antigen that you could use that would have the same effect, except it would be prophylactic (act in a vaccine-mode) and you would not have to take it immediately after the onset of the disease, your body would take care of it. We are working on a rabies product and we are working on various vaccine candidates with a partner. One of our partners is developing a diabetes vaccine and unfortunately they had some hiccups in clinical studies, but the product concept is very interesting and they just need to fine tune it and come up with a good way of delivering it. We are interested in alternative deliveries as people are still afraid of getting a shot so for the influenza portfolio alternative deliveries are going to be our next thing. I am interested in diseases like rabies and malaria. We have a corona virus vaccine in development and we need to make a choice of which one we are going to push hardest after this product is approved because now we all have them at a low pace moving along because I always say concentrate and focus otherwise you get nothing done.

CEOCFO: You have two other parts of the company; would you tell us what else you are doing at the moment?
Mr. Cox: We work with select partners and co-develop products with them where we provide Baculovirus production support services. For example, we help partner in the development of this diabetes vaccine and the role that we have in this program is a process development and manufacturing. These partnerships are not just fee for service; they go beyond that. Either we get a small royalty, or there are milestone payments as certain things are accomplished. We look at products and then find out how we can jointly benefit from this down the road. We are working with a company called BioArctic and they are developing a growth hormone for spinal cord injury. That product is currently in clinical studies in Europe and it is an amazing product that can actually restore people that have spinal cord injuries. There is one case of a young child that was entirely paralyzed and totally recovered after treatment with this growth hormone. The company has evolved into implanting this growth hormone into certain devices that can be inserted into the injury and that will make the nerves grow and make the nerves come together. Our idea around these co-developments is the partner pays for the development cost so we take relatively little development risk but we have the possibility to step in if the product does well or if we get royalties or milestone payments. That is one arm of our business and the other arm of the business is research antigens.

CEOCFO: Why should the business and investment community pay attention to Protein Sciences Corporation?
Ms. Cox: Protein Sciences is different in the sense that we have been profitable since 2009, which is almost an oxymoron in this biotech industry and that is how we want to continue to run this business. You see many biotech companies expanding dramatically and going through this enormous bit of consuming funds and trying to chase a dream. I think that we are realistic, so I could have when we got the BARDA contract immediately hired 200 people and speed things along but I like to go for a more cautious approach because the hire and fire mentality that you see in many biotech companies is capital destructing in my mind. In principle, we are very cash conservative. We are also different in that we have developed our own technology over the past 25 years, so we do not need to pay royalties to third parties. That might change when we take home new products down the road. We are adding substantially to cash every month and do not need investors. You cannot believe what a good feeling it is when an investor calls me who I used to call a number of years ago and ask whether they were interested in investing. Now I can say sorry, I do not have time for you because I do not need your money. If we are going to need money at this time it is going to be through a public offering or what have you where we would raise an enormous amount of money.

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