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Using Patented Novel Techniques to Create Complex Conjugate Vaccines, Fina Biosolutions LLC has already Licensed its Technology to some of the Leading Vaccine Manufacturers in both Europe and Asia

Biotechnology Development (Private)

Dr. Andrew Lees
CEO

BIO:
Andrew Lees, Ph.D., scientific director and founder of Fina Biosolutions, is recognized for his work in the field of protein-polysaccharide conjugate vaccines. Chemistry he developed (www.ncbi.nlm.nih.gov/pubmed/8920699; www.ncbi.nlm.nih.gov/pubmed/10649629) underlie GlaxoSmithKline's new generation of pediatric conjugate vaccines, including Menhibrix, Nimenrix Menitorix, for meningococcal disease, and Synflorix, for S. pneumonia. Currently, Fina BioSolutions is co-developing conjugate vaccines with the Serum Institute of India and the Chengdu Institute of Biological Products with the goal of producing affordable vaccines for the developing world.

Dr. Lees is a frequent speaker on mixed-mode chromatography. Since 1998 he has taught protein chromatography courses from high school through the post graduate level.

Dr. Lees is an associate professor in the Department of Medicine at the Uniformed Services University of the Health Sciences and at the University of Maryland School of Medicine's Center for Vaccine Development and is an affiliate at the University of Maryland Bioprocessing Scale-Up Facility. He holds 15 patents and is the author or co-author of more than 50 peer-reviewed papers. He holds a B.S. in Chemistry from Harvey Mudd College and a Ph.D. in Biophysics from the Johns Hopkins University.

On his own time Andy indulges a passion for bicycling and entertains with magic. He has been a professional magician and now uses his tricky past to liven his seminars and lectures.

Company Profile:
Fina Biosolutions LLC is a private, research and development stage biotechnology company that discovers, develops, and collaborates to commercialize novel vaccine conjugates for prevention of life-threatening diseases. Fina has patented novel techniques to conjugate, purify, and manufacture conjugates using its proprietary chemistry to create complex conjugate vaccines. The technology is currently licensed by leading vaccine manufacturers in both Europe and Asia, including GlaxoSmithKline for marketed vaccines Synflorix™ Menitorix™, Nimenrix™, The Serum Institute of India Ltd., and others.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Dr. Lees, what was your vision when you founded Fina Biosolutions?

Dr. Lees: I have been working in the field of conjugate vaccines, which are vaccines where the protein is chemically linked to a polysaccharide to make the vaccine. These are among the most expensive and complex vaccines in the pediatric schedule. Earlier chemistry I had developed had been licensed to Glaxo and is now part of their pediatric conjugate vaccines. Because these are so expensive, my interest was in working to make this class of vaccines more affordable for the developing world. We started to work with companies in the emerging markets to help them learn to make these vaccines. Not completely coincidentally, there has been a big push on the part of the Gates Foundation, WHO, and others to bring these vaccines to the developing world and to get developing world manufacturers able to produce these so that they could be sold at low cost. Both my own urge and skill set were needed at the right time and that was the beginning.

CEOCFO: How has that worked out so far?
Dr. Lees: It has worked out great! There is tremendous need for low cost vaccines throughout the world. Because of my reputation in developing the chemistry earlier, companies in India were well aware of my work. As we started to reach out with the technology, we found that the other companies were just as eager to work with us as well. We struck our first agreement in India. As more companies started to learn of a better way to conjugate vaccines and manufacture them at low-cost, we have been fortunate to have significant interest from India, and China, two places that will

eventually supply vaccines to 2 of the worlds largest populations.

CEOCFO: What is it that you figured out that allows the vaccines to be manufactured at a lower cost than the traditional methods?

Dr. Lees: The traditional methods involve many steps, use expensive reagents, and require significant time in manufacturing plants, and are very inefficient. Fina's method basically reduces this to one step and increases manufacturing efficiencies. The traditional method might take a week to make the vaccine; Fina's method takes 1 day. That is the efficiency of the reaction; you get a much higher recovery of material than you do with the traditional method, reducing the ultimate cost of the vaccine.

CEOCFO: What do you start with and how does the process get to the finished vaccine?

Dr. Lees: These vaccines are based on capsular polysaccharides, which are sugar polymers from the outside of the bacteria. Antibodies against these sugar polymers, can protect against the disease caused by the bacteria. However, infants do not make an immune response to the sugar polymer by itself; you need to chemically link a protein to it. That is the basis for this class of vaccines, which includes the Haemophilus influenza type b (Hib), meningococcal, and Streptococcus pneumoniae. Those are the big three. The traditional way of chemically linking protein to polysaccharides although effective in making a good vaccine, is fairly slow and inefficient. What I developed is rapid and efficient.

CEOCFO: Why would the companies that are making it the old way not license or come to you for your newer technology?

Mr. Lees: GlaxoSmithKline has licensed the technology and uses it on 3 marketed products, Synflorix, Menhibrix, and Nimenrix. In the west and the developed markets, the actual cost of the vaccine itself is a relatively small part of the selling price. Even if you can save $0.25 on the cost of the vaccine, and the retail price is $70, you are not going to redo your clinical trials for that. They already were locked into the methods that they were already using. Each of the big vaccine companies in the west developed their own approach to making these vaccines and they stuck with it because once they have developed the expertise, they are not going to switch Emerging market companies that are just getting into this area, have a choice of methods to use. The Serum Institute and the Chengdu Institute of Biological Products Co., are basically starting from the ground up.

CEOCFO: Would you tell us more about the recent contract you did with the Chengdu Institute?

Dr. Lees: Chengdu Institute of Biological Products Co., Ltd is part of China National Biotech Group (CNBG), which is a subsidiary of China National Pharmaceutical Group Corporation (SINOPHARM). As the largest manufacturer of vaccines and blood products in China and with 6 Biological Products Institutes in house, they have been devoted to the research, development, production and supply of biological products since 1919. The institutes, including Chengdu, have supplied and manufactured billions of doses of vaccines for smallpox, polio, Japanese encephalitis, and other serious infectious diseases for the developing world. We are proud to be working with the largest vaccine manufacturer in China.

I think our model shows there is a real value place for companies without taking huge amounts risk. The agreements we have in place have long-term payoffs. We have been able to negotiate research, development, and milestones and royalties. The agreements we have provide an opportunity to grow and provide growth but they are not going to be the roll-the-dice and get a hundred times your investment kind of thing or lose everything. We don't need to put a significant amount of money into the projects but we will reap the benefits when they eventually succeed. As long as Fina gets a small royalty for any product we help commercialize, we are satisfied. - Dr. Andrew Lees

The deal we have allows Chengdu to license Fina's technology for development and manufacture pneumococcal vaccines for the China market. The structure of the license includes an upfront payment, payments based on achievement of Chinese regulatory milestones, and royalty payments that are contingent upon successful development and commercialization. The agreement includes process development, personnel training at Fina BioSolutions labs in Rockville, MD and scalable manufacturing of conjugate vaccines at CDIBP.

CEOCFO: Is your technology an area of big interest for the medical community and government health communities worldwide?

Mr. Lees: Yes! For this class of vaccines in the west, they are expensive, they are not affordable and there are not enough doses available for the rest of the world. Because it took so long for the first conjugate vaccine, Hib, to get out to the developing world, mechanisms have been put in place for trying to push the vaccines out by getting all of the pieces in place as the vaccines are developed. These efforts showed the need, convinced local governments of the medical need so they would commit resources, brought manufacturers onboard, and the funding mechanisms in place so that as these vaccines became available, there would be a market for them and the money would be there. Just to give you an idea of the scope for the strep pneumonia, it causes roughly 400 thousand vaccine preventable deaths a year in India alone. It is one of the leading killers of infants in China as well. There is a huge medical need.

CEOCFO: How do you deal with the frustration of knowing you have created something that can help so many people and yet it takes so long to get into use?

Mr. Lees: It is really just the way vaccines are. They take a long time to

come to market. The Glaxo strep pneumonia vaccine took more than thirteen years to get to market. For these vaccines there are ten to fifteen individual components, so it is like ten to fifteen individual vaccines all in one vial, it is challenging to get a good immune response against each component and animal models only go so far. At some point they need to be tested in humans to see how humans respond. In the Glaxo case there were some additional challenges as well, they changed one of the components to give broader protection and it seemed to give them some additional problems which took longer to overcome. With India and China, one of the things we can do is look at everybody else's experience and see what problems they had and try to address them. Through groups like PATH, there is a great deal of expertise that comes in, which would be in the formulation part of the actual vaccine. My role is one part of making the vaccine, nailing the protein onto the sugar polymer, to make a conjugate. There is a lot of additional work that is needed to turn each individual conjugate into a multi-component, formulated vaccine.

CEOCFO: What is happening day-to-day at Fina Biosolutions?
Dr. Lees: We have five employees and I work with each one of them on a day to day basis. Since I am also Scientific Director, I am involved with brainstorming, experimental design, and troubleshooting of experiments. I do a great deal of troubleshooting of problems and reviewing experiments. That is the nature of our business. I also spend time in discussions with our collaborators around the world. With China 12 hours ahead of Washington DC and India 9.5 hours ahead, I often have early morning or late night teleconferences.

We strive to have a fun, exciting, and rewarding workplace. We are a small biotech company that is tackling diseases that affect millions worldwide and it is rewarding to know that our work will save lives.

CEOCFO: Are you still doing magic?
Dr. Lees: I do some, most of it comes up when I teach, give seminars, and entertain my employees. Sales reps like to visit Fina because they know there will be some "tricky" business.

I have many other projects as well as our vaccine work. I will give you an overview of other things I do.

I am the scientific director for a Chinese bread ingredient company, which comes out of our contract protein purification work. I arranged for their lab space, got them set up with equipment, hired scientists for them. They do the molecular biology and fermentation and, Fina takes over the purification process.

We are developing a new business line based on the conjugation work, assembling proteins and polysaccharides, leveraging our vaccine conjugation chemistry expertise to make polymer based diagnostic reagents. This business area started from one keyword on my website which resulted in a company contacting Fina to make a polymer reagent for them. I realized that this could be another business area for Fina. We have had quite a bit of interest in our products and are in the process of negotiating several R& D agreements. I think this is going to be a very good business area for us.

I call Fina a not-for-much-profit business, because the goal there is not to get rich. Our motto is doing good while having fun and not going bankrupt. We need money to come in but the agreements that I have in place are not the kind where you make and millions of dollars or you put millions in and you get hundreds of millions out. These are agreement with the developing world companies to make affordable vaccines, so they are deliberately set to bring in some money but not the kind that would attract venture capitalists.

CEOCFO: Do you have an objection to making a great deal of money?
Ms. Lees: Fina's mission is to provide the expertise to allow for low cost manufacturing of vaccine throughout the world. When you are working with companies in the emerging market, their goal is to make affordable vaccines for their countries, so if you are trying to extract money out of them, you are not really going to get anywhere and it is going to be very difficult to make these agreements. It also does not match my mission. By taking the longer term view and not trying to be greedy, especially upfront, it was possible to make these agreements. Once the emerging market companies start selling their vaccines, the number of doses is going to be very large, so even with a low price and a low royalty rate, Fina will make money.

Another element of what I do is I work with other companies besides the ones that I have formal agreements with. I reached out to companies especially in India, so most I have a relationship with most of the major vaccine companies in India and those will eventually pay off in some way. There has been a great deal of serendipity in running the company such as the one word on my website that started the polymeric diagnostic business. By not trying to reach for the stars, I am actually likely to reach to the moon without going bankrupt, so it reduces my risk quite a bit.

CEOCFO: Why should investors pay attention to Fina Biosolutions?
Dr. Lees: We are doing well, we are successful, and we are doing it all while doing good. That is very tough to do in this business environment. This model of growing slowly in an appropriate manner can be much more successful than people who invest with the idea that they are going to make a lot of money right out of the gate. We are not doing two of the expensive things which are discovery and bringing things to clinical trial. I think our model shows there is a real value place for companies without taking huge amounts risk. The agreements we have in place have long-term payoffs. We have been able to negotiate research, development, and milestones and royalties. The agreements we have provide an opportunity to grow and provide growth but they are not going to be the roll-the-dice and get a hundred times your investment kind of thing or lose everything. We don't need to put a significant amount of money into the projects but we will reap the bene-

fits when they eventually succeed. As long as Fina gets a small royalty for any product we help commercialize, we are satisfied.

Another facet of our model is that despite being a very small biotech company, we have successfully reached out to some of the largest vaccine companies in the world to make favorable agreements. We see emerging market companies as a tremendous opportunity for us to both do business and to do good. Because our agreements provide for upfront R&D support, we have very little money at risk.

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