

With A Promising DepoVax™ Vaccine Delivery Technology That Could Be A Perfect Boost For The Next Generation Of Vaccines, Including Immunovaccine's Own Therapeutic Vaccine Targeting Breast, Ovarian And Prostate Cancer, It Was The Right Time To Go Public



**Healthcare
 Biotechnology
 (IMV-TSXV)**



**Dr. Randal Chase
 President and CEO**

BIO:

Dr. Chase has a wealth of experience in vaccines and has spent his entire career, spanning more than 30 years, in the biotechnology and pharmaceutical sectors. Past positions include President of Shire Biologics, Senior Vice President Vaccines Operations of Biochem Pharma, President & CEO of North American Vaccine, President & CEO of Pasteur Merieux Connaught, and Senior Vice

President of Glaxo Canada Inc. Dr. Chase is active as a Board member with several companies and has many contacts in the biotechnology sector which will serve Immunovaccine well in the future through potential collaborations and networking opportunities.

Company Profile:

Immunovaccine Inc. is a biotechnology company developing high potential vaccines for human health. Immunovaccine's unique patented vaccine delivery and enhancement technology, the DepoVax™ platform, has achieved exciting results and positive pre-clinical safety data. The company's technology has attracted multiple partnerships and generated revenues through four licenses of its technology to Pfizer Animal Health.

Immunovaccine's most advanced product is DPX-0907, a therapeutic vaccine against ovarian, breast and prostate cancer that, in conjunction with its vaccine delivery technology, is being readied to enter Phase 1 human clinical trials. The company will pursue a fast-track regulatory strategy by taking the product through a short Phase 1 into a Phase 2 clinical trial. In addition, Immunovaccine is conducting proof of concept and pre-clinical studies for infectious disease vaccines: Pseudomonas aeruginosa, single dose pandemic influenza, and Hepatitis B.

In June, the company announced its intention to go public through an RTO transaction on the TSX-V exchange and with FDA clearance begin clinical trials in 2010. The company continues to strengthen its vaccine pipeline through licensing and strategic partnering. With

positive pre-clinical safety data and recent partnerships with LIAI, NIH, NCI, Yokohama City University, Defense Research & Development Canada, FIT Biotech, and Immunotope Inc. the value of their Depovax™ platform is significantly enhanced.

**Interview conducted by:
 Lynn Fosse, Senior Editor**

CEOCFO: Dr. Chase, you have a long history in the industry, why are you with Immunovaccine today?

Dr. Chase: I have been in the industry quite a while and have worked with a number of companies. I was in fact semi-retired; I was enjoying being on a number of boards and participating in that way. I was approached on behalf of Immunovaccine. They said, "Look, there is a little company in Halifax, they have some good ideas, will you talk to them?" I must admit that when I first met with them I was just trying to be polite and listen. They kindly presented to me their story, their work, and I have to say the data that they showed me, while pre-clinical, was probably the best data I had ever seen in my 35-year career. I have worked with a lot of companies and we grew them and did a lot of good things, but we never had a 'starting point' quite as strong as this.

CEOCFO: What is special about Immunovaccine?

Dr. Chase: The DepoVax technology Immunovaccine has developed to deliver vaccines allows immune responses that are so much stronger than you would either predict or imagine. For example, commercial Hepatitis B is normally a three-dose regimen at 0, 2 and 6 months,

so it takes over six months and you get very little, if any, protection after the first dose. They took one dose of that commercially available product, applied the DepoVax formulation and injected it in the appropriate model and got the same levels of antibodies after a single injection in just a couple of weeks compared to the full six-month regimen that the commercial product required. They took another product, acellular pertussis - whooping cough - and this is one that I know a lot about because I was president of Pasteur Merieux Connaught in Canada when we originally developed it. However, this is a multiple-dose product. They took the commercially available product, formulated with DepoVax, and injected one dose worth again into the appropriate models and they found the same levels of protection after a single injection as three doses of the commercially available product.

I guess the clincher was probably what they showed me in regard to some of the work they had done with cancer models; this would be for therapeutic cancer vaccines. They took three different models and injected the animals with cancer cells and a tumor would form. In fact, we have some extremely great pictures of MRIs of mice showing a pre-formed tumor. Then after injecting the candidate vaccine on the opposite side of the animal, and in roughly two weeks, you have a second photo showing 100% eradication of the pre-formed tumor after a single injection. These results were truly extraordinary. It is not just me saying that. When we brought the leading experts from across North America, people like Eli Gilboa from Miami and Martin Kast from Southern California and Rongfu Wang from Baylor, they said that the models used were correct. They were the valid models they used and most importantly they said nobody ever achieved that result; 100% eradication of a pre-formed tumor after a single injection.

CEOFCFO: What is the basis of the technology; what are you doing that is different?

Dr. Chase: The difference is in the delivery system. If you have a vaccination today the body immediately starts to re-

move the foreign injection and this removal process takes perhaps a couple of days, perhaps even hours. What that means is the body's immune system doesn't get a chance to see it properly, to form the strength of the response required and that is why you have to go back for booster shots, to remind the body of what it saw. What we do is use our DepoVax technology to take the vaccine into an oil, which is injected into the arm. DepoVax forms a depot that holds the vaccine there not just for days or hours, but for weeks, possibly even months. Over time, the oil is removed by the body, but not nearly as quickly. What that means is now the body gets to look at the vaccine for a longer period of time and give a much stronger, much longer immune response as a result.

CEOFCFO: Is your method patent protected?

Dr. Chase: It is patented, and the patents are issued not just applied for. They are

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issued in the United States, Europe, Japan, and Australia and these patents are very broad patents. The patented platform technology is that you take an antigen, deliver it in a cholesterol sphere called a liposome and then formulate into the oil. In fact, the patent covers any antigen that you would use, any adjuvant you would use, any liposome you would use, and any oil you would use. So it is a very, very broad patent.

CEOFCFO: What is happening today at Immunovaccine?

Mr. Chase: Well there is a lot happening along the lines of three strategies. The company had its origin in the animal business. In fact our products have been in eight different mammals for ten years, so it has been used in animals successfully. However, we don't want to be a vet company, in the animal business. What we want to do is license out that aspect. There is a value there and we want to use that money to invest in our human health business. We have done four deals so far with Pfizer Animal Health. Pfizer has

licensed the worldwide rights to certain indications developing their vaccines to be delivered using our technology. We also are looking at two strategies for humans. One is we have shown we can deliver a wide range of vaccines, a surprisingly broad range. What we say to other companies and institutions is that we think we can deliver your vaccine better than you can. We give them what we call the DepoVax™ challenge, where we take their vaccine products, formulate it in our delivery system and give it back to them to challenge within their own system, head-to-head with their best formula. Then they can see how our product works and delivers compared to theirs. Now, as a result of that, we have started to do a number of deals, with the delivery of other peoples' products better than they can. We have scientific deals in place with the NIH for the delivery of malaria and HIV peptides. We have a scientific deal in place with the National Cancer Institute and they are looking at using our technology to deliver their cancer vaccines; and we have done a deal with the Canadian Department of Defence to look at reducing the number of anthrax doses from six to something more like one or two.

This would be a product for soldiers and maybe someday for care providers in the field. Both of those strategies rely on delivering other peoples' products and ultimately getting a revenue stream from that.

Now that is great and we are delighted, but we obviously want some products of our own; new products that are completely under our control. The problem when you out-license your delivery technology, in some senses, you are not in control of your own destiny. Other companies change their minds sometimes. Strategies change. That is normal. Therefore, you want some products that are directly under your control. Plus, it ultimately has the ability to drive much larger numbers (valuation and royalties). If a product is yours or at least yours until a later stage, your share of the ultimate revenue is higher. So we are looking at two different types of products right now, one is certainly early preclinical stage, but it would be a vaccine for Pseudomo-

nas aeruginosa, which is an infection that you can get in a hospital, a nosocomial infection. Pseudomonas aeruginosa is also something that people with cystic fibrosis, burn victims and people with compromised immune systems are all vulnerable to contracting. Currently, there is no vaccine to date, so we are certainly working on one.

The other one, and maybe it will show some of those eye-popping results we had with the therapeutic cancer prototypes, is a therapeutic cancer vaccine of our own, that we have licensed in from a company in Doylestown, near Philadelphia. The company is Immunotope Inc., which had seven peptides that we think are special. All seven are found on the surface of breast, ovarian and prostate cancer. Most importantly, we know they are seen by the immune system, and conceptually the way Immunotope identifies them is they were caught in the act of being presented. So we know the immune system sees them and we know which seven proteins they are from. In addition, we know that these are seven very critical cellular proteins so we feel the cancer can't easily get around them, certainly not all seven of them. What we intend to do is combine these special antigens with our unique delivery system and we think that this is a very promising therapeutic cancer vaccine. In addition, we have observed that the current products used are delivered by what is called GMCSF and this is quite reactogenic. It causes quite an irritation. We have been able to show that ours is less so. Therefore, our product should be safer and, of course, ours has been in eight different mammals for ten years; it has quite a track record. We also know that when the cellular response of the body is stimulated, there is simultaneously a suppressor response to make sure the immune response doesn't get out of hand. It is called T-reg suppression. The problem with GMCSF is that there is quite a significant T-reg suppression. We were able to show that our delivery system (DepoVax) causes a significantly less suppression. What that means is we think we are safer and we think we will be more effective.

CEO CFO: Is the scientific community actively looking for better delivery methods or is it just something they would be happy to have when it is presented?

Dr. Chase: The scientific community is trying to find out how to have effective vaccines and particularly now, how to have effective therapeutic cancer vaccines, because that is the next medical approach I believe that everyone thinks is necessary. Today more than a third of us will have cancer in our lifetime, and 90% of the people that die from cancer, won't even die from the primary tumor. They die from the metastasis of the secondary tumors that have spread throughout the body. When the cancer is identified, the surgeon goes in and cuts out what they can see, but obviously they can't necessarily see it all. Sometimes it might be attached to a critical organ or it may have already metastasized; so they do the surgery and their best to debulk, as it is called. Then we have something typically like chemo, which besides being brutal,

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doesn't necessarily get every cancer cell. What we all want is the ability to track down those few remaining rogue cancer cells wherever they are hiding in the body, and also be able to kill any new (cancer) cells. What if you could train the immune system, on an ongoing basis, to be capable of tracking down rogue cancer cells and killing them wherever they appear, using the body's normal natural immune system? We all want a vaccine like that and that is why it is being approached in many ways, in fact, some very complex ones. Delivery is one of those ways and there are a variety of ways that even delivery is being worked on. We are all trying to find the way to make this work.

CEO CFO: What is the financial picture like at the company today?

Dr. Chase: The company has historically been a private company and had been funded by angel investors and government grants and loans. We took the company public literally months ago, at the end of September, and we did what is called a reverse takeover to acquire a

small, clean shell that was trading on the Toronto Venture Stock Exchange. We raised \$8.5 million at that time, which is enough money to do the clinical for our therapeutic cancer vaccine. We still have over \$7 million and are about to start the Phase I clinical and when I say 'about', I literally mean within weeks. By the end of March, we will be enrolling our first patients. It will be a Phase I safety trial. It will be on a first-come, first-serve basis for the three cancers; breast, ovarian and prostate. There will be five centers. The study is led by Duke University, but there will be sites in Chicago, Dallas, New York, and Pittsburgh. The Chicago site is specifically an ovarian site and the reason that is important is because on a predominance basis breast and prostate cancer patients are in greater numbers and we want to make sure that we have patients from all three categories. We will enroll the first patients at the end of March; it is not a blinded study. We hopefully aim to issue some data from an interim analysis by Q-4 of 2010 and then have the final completion of the study by the end of Q-2 2011.

CEO CFO: There is a lot going on at Immunovaccine; how do you stay focused?

Dr. Chase: We have some wonderful bright young people that work very hard. We try to be very disciplined by listing out exactly what we have to do, making sure that we have assigned responsibility, who is going to do it and by when. We really have stuck to our three strategies. We have people in the company who are working hard to do deals, we have other people working hard to participate in the DepoVax challenge, and of course the strongest emphasis in the company is on advancing the Phase I clinical.

CEO CFO: In closing, why should potential investors pay attention to Immunovaccine Inc.?

Dr. Chase: We have a technology that appears to be able to deliver a wide range of vaccines, both animal and human. We have a strategy that we think optimizes the value of that technology by licensing out animal indications, licensing out some human indications, and using our technology not only to deliver, but to de-

velop other new products. We have two products of our own, one is an early-stage possible vaccine candidate for which

there is no vaccine today, the other is a particularly promising therapeutic cancer vaccine that we feel if successful will not

only be a medical breakthrough, but certainly will be commercially outstanding.



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