

Using Recombinant Carrier Proteins to Develop Immunostimulant Vaccines for Infectious Diseases, with One Vaccine Against Human Leptospirosis Already Generating Revenues in France and their 1st Human Clinical Trail Planned for 2013, IMAXIO is Well Positioned for Growth



**Biotechnology
 Vaccines and Genomics
 (Private)**



**Alexandre Le Vert
 CEO**

BIO:

Alexandre Le Vert holds degrees from the Ecole Polytechnique in France and the University of Harvard in the United States. He was a molecular biology researcher at Harvard and at the Institut Pasteur in Paris from 2001 to 2003. He then joined Bristol-

Meyers Squibb as Marketing Manager and Sales Director (2003-2009) after which he became a consultant in the Paris office of Boston Consulting Group (2009-2011). He has been Managing Director of Imaxio since 2011.

Company Profile:

Imaxio SA is a biopharmaceutical company specialized in the areas of vaccines and genomics.

Using its carrier protein technology (IMX313), Imaxio is developing, both individually and with its partners, recombinant vaccines based on carrier proteins for applications in both human and animal health. Carrier proteins are used to improve the effectiveness of vaccines. In France, Imaxio already markets Spirolept®, a human vaccine against leptospirosis.

Imaxio's genomics division undertakes diagnostic and therapeutic research in the field of oncology and immunology, as well as providing services in the areas of human health, the agro-food business and the environment.

Imaxio applies its knowhow and technology in the areas of vaccines and genomics.

- Vaccines: Imaxio's vaccines business is mainly based on its carrier protein technology platform (IMX313), and also on the Spirolept® vaccine marketed in France.

- IMX313 is a carrier protein that improves the immune response of B and T cells and can complement the effect of adjuvants. It is developed by Imaxio in different human health indi-

cations (tuberculosis, malaria, cancers, etc.) as well as in animal health. Imaxio expects this protein to enter phase I clinical trials in early 2013.

- Imaxio already markets Spirolept®, a vaccine against human leptospirosis, in France. Leptospirosis is an infectious disease caused by a bacterium, leptospira, which is very mobile in humid natural environments. Although it is often benign, this disease can be acute and result in renal insufficiency, and even death in 5% to 10% of untreated cases (source: Institut Pasteur).

- Genomics: Imaxio's genomics business includes a theranostic research element and a fee-for-service element. The company is developing several companion tests in the fields of oncology and immunology thanks to its state-of-the-art high-throughput genomics platform. Imaxio's genomics platform was designated a "Certified Service Provider" by Agilent Technologies in 2009. This certification has only been granted to 20 other companies and organizations in the world and is indicative of the expertise and technology developed by Imaxio.

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

CEOCFO: Mr. Le Vert, what is the basic concept for IMAXIO?

Mr. Le Vert: IMAXIO is a biotech that is present in two areas. One is vaccines and the other one is genomics where we do high-throughput sequencing. The fundraising that we just made is actually targeted to support

the development of R&D projects in the vaccine part of our business. In the vaccine area, we are doing R&D and we have a product that is already commercialized. The R&D that we are doing is basically researching and developing around a carrier protein, which is a platform that can enhance the immune response of some vaccines that may need to have a higher immune response. The way it works is this carrier protein can be fused to an antigen and this would enhance the immune response to this antigen. We want to go to the clinics in the next eighteen months with some academic partners that we already agreed with and we are raising some funds to do this. The other part of the business is that we are commercializing a product for a niche market. This product was actually acquired by IMAXIO three years ago. The strategic objective is to update the regulatory dossier for it to be presentable to regulatory agencies in Europe, so that we can commercialize it into other countries than France. That actually means updating the quality part, the production part; update it to the latest state of the art production processes. In addition, the clinical studies are pretty old, so we need to update them.

CEO CFO: Would you tell us about the commercial product?

Mr. Le Vert: The commercial product is a vaccine that protects against a disease, which is human leptospirosis. It is a niche market, and it is a professional disease. It is a disease that is a risk for the people working next to the water, where you would have some animals that may live around the water. It is a disease that can be potentially lethal, but is restricted to some very specific areas. These areas are the places where you would have mostly some rats living where they would urinate.

CEO CFO: What is the market potential for a vaccine to treat human leptospirosis and how many people might be targeted to use the vaccine?

Mr. Le Vert: It is hard to answer because we do not have the market research as of now. Today in France, there are about 70,000 people being

vaccinated every year. If you look at the publication, there could be as much as 80% of the target population that may not be vaccinated today. Therefore, probably many more people should be vaccinated.

CEO CFO: Where is your vaccine currently available and how does it differ from what is already available to treat this disease?

Mr. Le Vert: This product is already commercialized in France but it is not commercialized outside of France, so our target is to commercialize it outside of France. There is no other vaccine that is authorized for human leptospirosis in Europe. It is a niche market, a fairly small market and there is no competition.

CEO CFO: What is your approach to further commercialize this vaccine; would it be country by country under a single brand?

What is special about IMAXIO is that it is a company that has a very exciting technology in our carrier protein, and that has the specificity of already generating some revenue. - Alexandre Le Vert

Mr. Le Vert: It would be mutual recognition procedures, and it would be country by country.

CEO CFO: Would you tell us about the carrier proteins and how it improves other vaccines?

Mr. Le Vert: First, you fuse the carrier protein to an antigen. The way it works is that it creates an oligomer, presenting seven copies of the antigen to the immune system. From having a very small antigen you suddenly, have seven copies, which make the antigen a bit larger, more recognizable and easier to see by the immune system. Then, whenever the immune system localizes such a group of antigens, it will see not only one copy of this antigen, but seven copies. We have been able to prove that in different animal models and we are looking to confirm that in a human setting in the next 18 months.

CEO CFO: What are the particular diseases and types of vaccines that you will be targeting first?

Mr. Le Vert: Today the indications that we would be targeting are basically the indications where you need a more potent immune response. We have some fairly interesting pre-clinical results in tuberculosis, malaria and weirdly enough, we have an interesting result in a veterinary setting, for immunocastration.

CEO CFO: Would you tell us the plan for the next year or so on both fronts?

Mr. Le Vert: The plan for the next 18 months, for the carrier protein platform technology is to get a proof of concept in human, which to test our IMX313 carrier protein in the human setting. It is a Phase I study and goal number one is to get started. The second objective for this carrier protein is to get some proof of principle in animal settings that it can help in other indications, not only tuberculosis and malaria, but other indications. A third objective will be to get some licensing agreements with some midsized biotech companies for them to use our technology. For the SPIROLEPT™, our vaccine against human leptospirosis, the objective for the next 18 months

is to update the dossier, so that we are in a situation where we can submit the dossier to any regulatory agency that we wish in Europe. That includes synthesizing all the clinical information on the use of the vaccine in France. This will involve modernizing the industrial process by which we produce this vaccine and that includes updating the dossier to the eCTD format, which is the new format.

CEO CFO: Will your recent raise take IMAXIO through the next 18 months?

Mr. Le Vert: For these two projects, we do not anticipate to be needing to raise additional money. If we have additional projects and that may be the case we never know, we may need to raise additional money. However, the plan for these two projects is to go forward with the money that we raised.

CEO CFO: Where does the genomics fit in for IMAXIO?

Mr. Le Vert: The genomics is another part of the story of IMAXIO. We are doing some organic growth with this part of the business. We want to make it profitable and we do not necessarily need to raise money to make it profitable, grow the revenues. The fundraising is not targeted to this part of the business, because it is already in a situation where you do not necessarily need to raise money. What we are doing there is we are basically doing high-throughput sequencing and gene expression analysis for any research laboratory that would require the platforms that they cannot necessarily afford. Therefore, it is basically outsourcing of R&D. We also capitalize on the platform to do some internal R&D, mainly on diagnostics in conjunction with industrial partners when they are in Phase I or Phase II

or even pre-clinical for the development of a product that might need some genomic analysis, to develop a companion diagnostic. We partner with them to get our part of the IP and to help them better target their patient population.

CEOCFO: Why should investors pay attention to IMAXIO today and what is special?

Mr. Le Vert: What is special about IMAXIO is that it is a company that has a very exciting technology in our carrier protein, and that has the specificity of already generating some revenue. Therefore, if we come back to the market in two or three years to finance a larger clinical trial, then it could be interesting for an investor to have a access to an extremely exciting technology and at the same time

already having some cash flow that can secure an investment. If we raise money in two to three years, I do not know whether we will separate all the business units or not. It may be easier for an investor to invest in a carrier protein and not in the other parts of the business. It is a bit tricky to answer your question now, because some investors may want to invest only in the carrier protein and not necessarily the other part of the business. However, what makes us special is that we have an extremely interesting technology that we are developing with cutting-edge academic in the UK, in France, and at the same time, that we generate revenues with other products and that is security for an investor.



IMAXIO

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