Interview: Andrew Simpson – Scientific Director, Orygen, Brazil

"Orygen is an exciting hybrid between a commercial venture and an entrepreneurial, biotech start-up."

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Andrew Simpson, Scientific Director of Orygen, elaborates on the innovative collaboration model his company is taking part in to develop biotechnologies in Brazil, the importance of developing affordable treatments for Brazilians, and the company's current research on immunostimulants.

Before presenting the company, could you tell our readers what motivated you to shift from academic research towards a commercial venture?

As I have progressed through my academic career, I increasingly felt the need to see scientific discoveries being applied to human benefit. My career has progressed from basic research to more translational activities at the Ludwig Cancer Research Institute (LCRI), which is not just an academic research institute but also has a vocation for developing and licensing products. When given a chance to lead the Orygen project, it seemed a rewarding opportunity to see the effect of science on the lives of people combined with the possibility of returning to Brazil.

Orygen is a joint venture founded in 2012 in response to the Productive Development Partnerships (PDPs) [private public partnerships set up by the government to stimulate the Brazilian biotechnology sector. PDPs generally involve a multinational company for technological transfer purposes and require the participation of a publicly-held laboratory, which will be in charge of producing the drug once the supply agreement with the government comes to an end, ed.], specifically in the area of monoclonal antibodies.

I was appointed at the very beginning of the project to really create Orygen. In the initial plan, four companies were involved, but by 2013, two companies decided to establish independent initiatives.

Eurofarma and Biolab therefore embarked on a new plan. In 2015, we signed a landmark agreement with Pfizer to manufacture and jointly commercialize some of their biosimilars monoclonal antibodies, currently in global clinical development, in Brazil. We expect the first product to be commercialized in Brazil by end of 2018. We expect to have four PDP contracts with the government to supply these antibodies.

What main challenges has Orygen faced since 2012?

The government's philosophy and strategy has evolved since the PDP program was launched, altering the associated priorities and rules. For this reason, Orygen's investments have been relatively cautious. For instance, the decision was made not to immediately construct a dedicated multi-product production facility in 2014, but to wait for formalization of the Orygen PDPs.

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Now that the PDP program has really taken off, the decision has been taken to establish our production facility on one to two floors of a new biotechnology plant currently under construction within Eurofarma's manufacturing campus.

We are still waiting for the legal formalization on the government supply side. Our public laboratory partner for all four products is Tecpar in Curitiba. This is our so-called core business.

The company has chosen not to limit itself to monoclonal antibodies; could you describe Orygen's other activities?

Around two to three years ago, we decided to diversify our activities beyond PDPs and monoclonal antibodies. Due to my personal expertise, we decided to incorporate an innovative arm, through vaccines.

Unlike the highly competitive children's vaccines, these are two areas where Orygen has the means to compete globally. As a result of their high prevalence in poorer regions, vaccines on the parasitical side have received relatively less attention than their counterparts for other infectious diseases. There are no commercial anti-parasite vaccines for human use on the market yet.

It is also an area where Brazil is relatively strong in the basic scientific community. As a result of the support and funding it has received from the government over the last two decades, Brazilian

basic science is very robust. We have some very eminent scientists, especially in the area of immunology, and even more particularly, parasite immunology. In the style of a classic biotech start-up company, Orygen is looking forward to support the development of such innovations in the field, and licensing their commercialisation.

A main project going on is with the Fundação Oswaldo Cruz, which has been developing a schistosomiasis vaccine for many years. They have a recombinant product with a very modern adjuvant, coming from the Infectious Disease Research Institute in Seattle which is at the forefront of developing parasitic vaccines. It had been taken through phase I in Brazil by Fiocruz and we licensed this product in 2015. We are now undertaking a phase II trial in Senegal in adults, and are planning to do a follow-up phase II trial in children next year.

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It is a great example of how a traditional Brazilian pharma company has invested in innovation – true innovation. It is not only a new medicine, but the first in a new class of medicines! That is highly innovative and speaks highly of their open-mindedness and sense of entrepreneurship of the Orygen owners to invest in this.

It is also a partnership with a public entity, which is a great model for future drug development in Brazil.

Our innovation side is focused in immuno-stimulation in general not just prophylactic vaccines. In the cancer area this will be more in terms of a therapeutic vaccine, i.e. a treatment, instead of prophylaxis. Interestingly, parasite and cancer immunology has more in common with each other than with viral or bacterial infections. With parasites, you are talking about diseases the people living in endemic areas have their entire lives, so the question is not about prevention. You have to deal with people who have already been exposed to the disease. Cancer has a similar principle: the patient is already living with a tumor, and the existing immune response needs to be altered to eradicate it. There is a lot in common in terms of the approaches and the underlying science, as both are grounded in T-cell immunity.

Within the antibodies space, there already exist some very good products for ‘unlocking’ the immunological response, so to speak, especially in the cancer area, but we still lack good products to stimulate the immun response – and these would be used in combination with the former. This is very exciting and I think we can compete effectively here. Despite several new entrants in the immunology market, it appears our pipeline of products is sufficiently efficient at stimulating the immune response to cancers to be competitive.

How do the capabilities of Eurofarma and Biolab help support Orygen's activities?

Orygen currently has eight employees, so conducting our operations would be impossible without the support of our partners. We rely on both of our parent companies' experience in dealing with the government's healthcare regulatory bodies and complex legal framework, for instance. As a result, we have navigated the PDP opportunity in a smooth manner and expect fast registration of our products. Once we have products on the market, we expect to rely heavily on their commercialization expertise as well.

Additionally, Eurofarma has provided tremendous resources to facilitate the industrial design of our production plant. One could say we run as a project management operation, and we leverage heavily on the capabilities of our parent companies.

How advanced is the Brazilian biopharmaceutical sector?

Brazilian biotechnology manufacturing resources are at a very early stage of development. Most of the existing resources are focused on manufacturing basic vaccines in the public sector. This is unfortunate considering many Brazilian graduates are well-versed in the biotechnology field. If these people do not find working opportunities in their field of expertise, the development of a strong biotechnological sector in Brazil may be compromised.

Brazil is a fairly complex market. Other factors are hindering the development of a biotechnological sector in the country. For instance, high customs taxes affect local production's competitiveness. Our pharmaceutical regulatory authorities are very competent but overwhelmed with their application backlog thus slowing down the possibility for biosimilar products to access the market, despite fast-tracking possibilities of drugs produced under PDPs.

How does Orygen's advancement compare to other companies involved in PDPs and what are your ambitions in the next three to five years?

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To sum up Orygen, we are innovative, cosmopolitan and visionary.

Looking forward, I would first love to see Orygen have a successful PDP project with Pfizer. The PDP is an unprecedented model, which involves innovative collaboration structures with the government. We and others in the industry are actively engaging the government to have clarity in the PDP regulations so as to maximize the chances of bringing these innovative products to the

Brazilian population.

I would like to see Orygen bring to market one – or more – of our immuno-therapies, whether for parasites or cancer.

Most ambitiously, I would like Orygen to be the first emerging market-based laboratory to develop a cost-effective treatment for cancer. Those developed in Europe, USA or Japan do not always match the needs of the patients outside of these developed countries. Indeed, most of the products developed in the aforementioned countries are developed without consideration for affordability. As a result, only very few individuals or institutions can afford to purchase these therapies.

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