Permanere et Renovare Salutis – Jorge Reyes Esparza, Founder and CEO – Mexico



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The founder of this spin-off of the Autonomous University of the State of Morelos focusing on biologicals for human and veterinary use offers an overview of how the company came into life, the lack of culture at Mexican universities of filing patents for academic research and the potential of the country as a cost competitive regional hub for clinical trials for the US population.

Permanere et Renovare Salutis was created in 2011 as a spin-off of the Autonomous University of the State of Morelos. What is the story behind the company?

Many companies have a personal story behind their creation – that is also our case. I am a physician, a PhD in physiology and did a post-doc research program at the Weizmann Institute of Science in Rehovot, Israel. Back in Mexico, I have worked for seven years at the National Institute for Oncology and started teaching and researching at the pharmacy faculty of the Autonomous University of the State of Morelos. I have been focusing on immunostimulation, mainly researching the thymus, a specialized organ of the immune system, and on finding therapeutic alternatives to traditional antibiotics. That’s how I started working with biologicals.

Our main idea was working on immunostimulants for cancer. Though, in lab tests on pigs we realized that the products we had developed also helped the animal growing faster. Since in Mexico there is no culture of patenting research done at universities, we talked with the President of the university, we obtained the license for the patent and the Institution agreed to support the creation of the company. We started as three researchers, now we are nine and have a staff of undergraduate, master and PhD students. In 2013 we also started focusing on probiotics for human use, meaning we currently have a branch focusing on veterinary products and the other on nutraceuticals.

You mention that universities in Mexico do not have the culture of filing patents. Why is this the case?

First, research in Mexico is mainly done at public universities. Given that education is free, there has always been the idea that results of R&D should be available to everyone and not protected for commercial use. Under this premise, it is difficult for the private sector to support research, because discoveries are not protected. In addition, within the academic community patenting R&D is not seen well. Fortunately, things are changing and filing a patent is increasingly comparable to publishing in a journal. This is changing the culture at universities and, as a consequence, the government strategy and policy to provide support to R&D in the country.

What is the current status of pharmaceutical R&D in Mexico?

Most of the pharmaceutical research in Mexico focuses on development of generics. On the one hand, small and medium drug manufacturers are developing generic versions of medicines which lose their patent protection – I estimate 30-40% of all resources dedicated to innovation development in pharmaceutics are invested in this field. Only a small number of Mexican companies are actively investing in R&D, such as Laboratorios Silanes, Senosiain and NUCITEC. The big players do not have pharmaceutical R&D in Mexico, as they tend to concentrate it at their headquarters abroad, but they do conduct phase III clinical trials, often because it represents a requisite to market the drug. This has helped developing research in pharmaceutics, but the country still has a long way to go.

An interesting trend, which is taking place and is having an impact on Mexico is that the epidemiological profile of the US is increasingly moving towards the disease profile of the Hispanic community, which is estimated to soon represent 50% of the country population. This means pharmaceutical companies are increasingly interested in understanding these diseases and Mexico provides the “mother of all genetics” to conduct clinical research for the Hispanic community in the

US. As a consequence, pharma companies are increasing the number of Mexican patients enrolled in their global clinical trials – if it was 20 in the past, now it's 100 –, and they are increasingly focusing on pathologies such as diabetes, which highly affect the Latino population in the US.

Are there any other factors, which make Mexico an interesting hub for clinical trials?

The US is realizing they are losing in terms of competitiveness towards China, which sends its young people to North American universities to gather the know-how it lacks at home. For this reason, the US is increasingly looking at Latin America as a strategic ally not only from an economical point of view, but also with regard to R&D and science. In addition, Mexico provides a cost competitive model.

Unfortunately, a number of obstacles such as different regulatory framework and education system represent barriers to an increased collaboration between the two countries with regard to pharmaceutical R&D. A large number of Mexican scientists studied in the US and keep contact with their peers in the US, but we need much more than that.

An increasing trend within the healthcare and pharmaceutical industry is towards biotech and nutraceuticals. What future trends are we going to witness?

Biotech is going to increasingly move towards biologics. An example is lactase, the enzyme essential to complete the digestion of whole milk. Given the increasing penetration of lactose intolerance, drug manufacturers are looking at producing drugs, which can help patients digest milk. However, on the other hand, if we use bacteria with lactase, we can simplify the process and decrease costs. In addition, bacteria can be combined, e.g. bacteria with lactase with bacteria, which help digest gluten. This would help patients with two types of problems, and at a very competitive price.

In the past in Mexico nutraceuticals were not regulated, meaning you could register anything as nutraceutical product. Due to the boom of so-called *productos milagros* (miracle products), since 2012 COFEPRIS (the Federal Commission for the Protection against Sanitary Risk) regulated heavily this segment to make sure the manufacturers demonstrate the benefits of the product and control their advertising. As the authorities better understand the benefits nutraceuticals can provide in terms of prevention of diseases and costs, the segment will be opened. I think the product segment will grow, but it will still take a couple of years.

Which products do you have in the company's pipeline?

We currently have a mix of products for human and veterinary use. We have developed a product which features 20 lactobacillus – a comparing product in the US has only 9 – intended to help patients control their cholesterol level. We also have a product for people with celiac disease or intolerance to lactose, which is especially problematic in elder people and children. We also want to develop functional food featuring enzymes, which can help digestion and we are already carrying out lab tests in Zacatecas with bread and tortilla.

How does the company finance its activities?

The first round of investment has been own capital, now we are working to get a second injection of capital from private investors. We are currently in speeches with a company manufacturing pet food for the veterinary branch and this is helping opening additional doors.

What are the company's priorities for the next five years?

First, we want to consolidate our distribution at national level. Due to COFEPRIS' regulation marketing has been a bit of a challenge, as we can state the products help but not that it cures. We are currently looking at two distribution channels, pharmacies and distributors of natural products. Second, we want to start exporting. We are already eyeing at Asia, as we have two companies interested in importing our products. It would be funny to start operations over there and not in Mexico!

As for the veterinary branch, the potential is huge taking in consideration that the country produces 2,000 million of broilers per year. Our product promotes a growth of 5%, which taking in consideration the average chicken weights 2kgs, would represent an important increase without having to invest in additional capital. Our interest is to have an impact on the health and economic development of Mexico.

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