Venter Pharma â?? Jose Luis Martin, CEO â?? Spain

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The CEO of Venter Pharma explains the challenges of bringing a diagnostic drug to the market, and how they hope to leverage the science behind their product, LacTEST, in various new forms and indications.

Before you came on board at Venter Pharma, the research for your product LacTEST was being carried out at the Autonomous University of Madrid and CSIC. At what point did the researchers realize that they had a product that could be commercialized, and what were the steps taken at that point?

The moment arrived when the researchers achieved proof of concept for gaxilose, a molecule that could be used in the diagnosis of hypolactasia, the cause of lactose intolerance, as well as toxicology results for the molecule. It was at this point that the scientists behind the molecule decided to start up a company, joining CRB to do this, with the university as the third party. The assets of the company at that point were the patent for the molecule, the data from the toxicology and EUR 20,000 (USD 24,972) in cash.

This was the position of the company when I came on board. I had very little experience in biotech at this point, which was arguably a positive point, as it meant that we started out from the gate with a lot of energy, believing that everything would be done in three to four years. And our team had never taken a drug through the development stage, which meant that although we made some inevitable missteps in the regulatory process, but on the upside, we approached the development in a very open way, based on solid science, and the results were very thorough â?? this type of research would have taken an established pharma company much more resources to put together.

What was the first major challenge that you encountered?

Our product is a diagnostic drug â?? the patient must ingest the product, so that we can collect urine (and in the future, blood), and perform an assay on it. But it is a new molecule, and the patient must ingest it; therefore, the product is classified as a drug, rather than as a diagnostic. For this reason, the regulatory process has been very complex.

How did you proceed from there?

When I came on board, the system for synthesizing the molecule was in place, but only on a small scale â?? my first objective was to ensure that it could be scaled up in an affordable way, which took eight months to ascertain. At that point, we were raising money from different sources, and in 2005, we applied for the IND by contracting a CRO and performing the first Phase I clinical trial in September 2005. This was eventually followed by a Phase IB and a Phase IIB-III study that took two years â?? the results of this showed that the product was much more efficient than existing lactose intolerance diagnostic techniques. The alternatives before LacTEST were the hydrogen breath test, the most widely-used, together with the lactose tolerance test, both of which have a very limited reliability and cause gastrointestinal disorders due to the lactose overload administration to the patient together with several interactions and contraindications. The intestinal biopsy, infrequently used, which is extremely aggressive and expensive, is a test that involves consuming large amounts of lactose and assessing the response, which again can be very aggressive and uncomfortable for people that are lactose intolerant. Finally,the stool acidity test, with a reduced reliability practically reduced to the infant population.

When we finished the trial, we faced another mountain to climb: the application for authorization, which required an enormous amount of work, in part done by people without experience in collaboration with consultants. It was a complex process both for us and for the regulators â?? diagnostic drugs are very rarely evaluated.

Where did you apply for authorization and why?

We didnâ??t apply for EMEA authorization, but instead only for Spain and Germany, after a lot of thought, because we wanted to ensure that our team was fully capable of dealing with the authorization process â?? at this stage, EMEA authorization would have been too complex.

Our business model aimed to maximize efficiency with a small team â?? but this was more than sufficient for our first product. Basic research was outsourced to the university and to CSIC, and went extremely well, and allowed us to manage the process perfectly.

What about on the marketing and distribution side?

90 percent of our sales in the future will be outside of Spain â?? it therefore makes no sense to build a marketing team for each country that we want to eventually enter. So we have worked with partners for licensing the product. Our first contract was with Ferrer for Spain, Germany, and some Latin American countries. The second contract we signed was for Russia, and we began the regulatory process two weeks ago. We are also in advanced discussions for a partnership that covers some other countries, and our main target markets for the future will be France, Italy and Poland.

How does lactose intolerance vary regionally?

Ten thousand years ago, 100 percent of humans were lactose intolerant when they were adults, like every other mammal, because originally, we only could digest lactose in the first years of life: there was a genetic mechanism that silenced the gene that produced the enzyme that digests lactose. In China and Japan today, many people are still lactose intolerant, but in Europe, a genetic mutation

developed and spread that led to lactose tolerance, and diets shifted as a result. This is where the problem lies: lactose is present in so much of our diet in Europe that lactose intolerance becomes a burden.

Having successfully brought one product to market, what lessons have you learned for future ventures?

For the next product, the model we have in mind is the same: we can be even more effective at the basic research stage by concentrating on just what we need for the product. We would keep the same model for the development team: a mix of company staff and researchers from research institutions. This year we have developed a new xylose assay method to be used with LacTEST, , and it has been hyper effective: in only eight months we have developed an enzyme for its in- vitro use that will allows measuring xylose in automatized equipment. We are fitting the software equipment today, having started only in February 2014. The secret has been this mix of human resources from industry and science.

In looking for future partners for our current product LacTEST, we will focus on the gastrointestinal area, because this means that we will be able to work together on future projects.

Venter Pharmaâ??s next major project will be for pediatric indicationâ??developing LacTEST for children. The second indication we have in mind, for which we have received Horizon 2020 funding for the Phase I, is related to using lactase activity as a biological marker to monitor some gastrointestinal diseases and consequently ,tracking the effectiveness of the prescribed treatment . Next year, we will begin trials in this area.

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