

Interview: António Portela, CEO, Bial Portugal

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António Portela, CEO of Portugal's flagship pharmaceutical company Bial, talks about the recent approval of Aptiom by the FDA, the first Portuguese drug to ever to be approved in the US, as well as the unique long-term strategy of the company and the advantages to being a family-run business.

Last month saw the FDA approval of Aptiom/Zebinix (eslicarbazepine acetate) for epilepsy, the first approval of a Portuguese drug in the US. Could you tell us a little more about the product?

It all started in 1993, when Bial decided to be innovative in Portugal by creating an R&D department with three investigators. Over 20 years, we have developed a pipeline of molecules, of which Aptiom/Zebinix was the first success. Bial has been developing this drug for the last thirteen years, having invested more than €300 million in development. We have the first patented drug in Portugal to be approved in the European and American markets. It was a huge challenge for the team, which had no experience in developing drugs and submitting them to regulatory authorities. This project helped transform Bial from a local to an international company.

What has been the success of the product since its approval in Europe in 2009?

Epilepsy is a very complex disease. About 30 percent of patients are not controlled, and epilepsy patients cannot predict their episodes. Neurologists and epileptologists are always looking for the right combination of products to be able to provide the best solution in terms of efficacy to control patients' crises while trying to avoid complications, as these drugs are not very clean. Sometimes, the right combination of doses that can control the crisis cannot be tolerated by patients. Aptiom/Zebinix offers one of the most efficacious products with a solid tolerability and safety profile. The ease of the drug is also noteworthy. The titration of most epilepsy drugs is very complicated, whereas Aptiom/Zebinix is very easy to titrate. Unlike other drugs, it only requires one dose daily as opposed to three. The launch in Europe has been successful over the last four years. While entry is slow due to neurologists' reluctance to change controlled patients, it has been extremely rewarding to talk to neurologists around Europe; some feedback suggested that doctors were able to finally control patients after 30 years.

How do you intend to market the product in the US, and what are your expectations there?

Bial has maintained a partnership since 2007 with Sunovion Pharmaceuticals, which is part of Dainippon Sumitomo Pharma. Sunovion will market and license Aptiom in the US. We have been able to gather significant experience from four years in Europe in terms of how the drug works, who are the best patients for the drug, and Bial works with Sunovion to target the right patients in the US.

How would making a breakthrough in the US market change the face of Bial in the near future?

When Bial started this process of R&D, the company was not thinking locally. The Portuguese market is too small, so we had to think globally. Our aim is to make Bial a true international company, with presence by ourselves or with partners spread throughout Europe, US, Latin America, Japan. We hope that the revenue from the development of Aptiom will allow us to invest in continuing to develop our pipeline and our presence in international markets.

What is your internationalization strategy for targeting new markets?

At present, we sell our products in 52 countries, mainly in Europe, Africa and Latin America. Our aim is to continue to strengthen our presence in these three regions, and to expand even more in Latin America. The US and Japan are big pharmaceutical markets, where we wish to continue with our partnerships.

R&D is an important component to the Bial strategy. What therapeutic areas are you investing in the most?

Bial's strongest areas of R&D investment are central nervous system (CNS), cardiovascular and allergies—we acquired a company in Spain in 1998 focused on allergic immunotherapy. Our main successes and knowledge have been in CNS, as seen with Aptiom/Zebinix. We also have a second compound for Parkinson's (Opicapone) that is now in Phase III trials. In the spring of 2013, we licensed Opicapone out to Ono Pharmaceutical to develop the compound in Japan. Our team has delivered some truly interesting compounds over the years, and the revenue from product launches will hopefully continue to fuel Bial's pipeline.

The cost of making a drug from start to finish today is around \$1 billion. Is the family structure of Bial a sustainable one in today's market?

Until now, we have maintained the company within family control. Bial's R&D investments are huge for a company of its size. These investments were only possible because of Bial's long-term view of the pharmaceutical world and where the company needs to be. This is only possible through a family controlled business model. We feel that maintaining our current model will deliver more value in the longer term to Bial.

What do you see as the value proposition of mid-sized companies, like Bial, evolving in the worldwide marketplace today?

It is a very important value proposition. Given the substantial changes of the industry in recent years, the value that mid-sized, family-owned pharmaceutical companies in Europe have been able to bring to patients and the industry is due to their ability to think in the longer-term. They are able to bet more on independent, long-term investments, or be more cautious during crisis periods without having to cut costs abruptly.

What is the role of R&D for local companies in the future?

Portugal has a vast, unexplored knowledge base; this potential is sitting here, undelivered. Most countries and other companies have not seen Portugal as a pharmaceutical country with immense knowledge centers and talented investigators. Portugal has experienced a huge leap forward in terms of investigators doing PhDs, research coming out of universities, startups, and research centers from universities working closely with companies. There have been many changes happening in recent years, albeit on a small scale. All of these things will need money; therefore

most will not work, but there is a lot of knowledge. Bial has a small R&D team, so we concentrate the core of our development internally while trying to control the process. But we do work with research centers, universities and smaller companies in Portugal and we see there is knowledge, flexibility, and affordable costs.

Health Cluster Portugal's work has brought unknown knowledge, people and research centers together and presented them to pharmaceutical and medical technology companies to determine the best partnerships. While this takes time, Portugal has potential to manage a health cluster that truly adds value. One of the key challenges in Portugal is to find those areas that are able to bring value and be competitive internationally, and this is improving.

Do you think Portugal could become the "California of Europe"?

I do think this, and many in Portugal would agree not only because of the knowledge and people but also because of the capability to attract investigators to come to Portugal. As an example, Bial's research center represents nine nationalities. Portugal is very attractive as a safe and comfortable country. In addition to pharma/medtech, biotech is clearly within this remit. I also think that it is pointless to focus on all areas, but instead focus on niche areas where the country can have core competencies to develop and compete globally.

However, Portugal does not have the financial capabilities of California. For projects to progress, we need to attract investment by demonstrating the country's knowledge, flexibility and capability to the world.

What role will Bial play in attracting those kinds of investments to Portugal?

Bial invests hugely compared to its size, and thus cannot invest outside its own projects. We hope that our recent success with the FDA as well as our other successes might help to bring attention to Portugal's activity in the healthcare industry. We hope to attract that attention and in the future when we get revenue from our investments that we can contribute to the development of other projects.

You have been CEO for three years, in the midst of an economic crisis, yet the company continues to flourish. How did you manage to organize yourself after your father stepped down?

It is not common for a company based in a Latin country to have a clear long-term strategy. Everything we collect today is the fruit of labor from the 1990s. We have adapted to the changes over the years, but the main strategy of consistently developing new drugs and internationalizing the company has not changed. The quality and solidity of our team is also important. It is not possible to achieve projects without a strong team. The big legacy that my father left after 30 years was being able to attract people to very ambitious projects and make them grow with him.

As we approach 2014, the company's 90th anniversary, what kind of legacy would you like to leave behind?

We want to make Bial a true international company. The company does have a presence in 50 countries, but those are essentially small countries. We want a much bigger international presence, which will provide enough revenue to continue to fill our pipeline and ensure we bring innovative drugs to patients.

If we returned to Portugal in the next five years, what would you like to have achieved in that time?

We would like Aptiom/Zebinix to be a real success in the epilepsy market. If that happens, we can continue developing new projects and molecules for the benefit of patients. The current proposed reforms need to be passed and implemented successfully while maintaining the quality of the system. Portugal has a fantastic national health system with highly qualified professionals, and this system is sometimes criticized because of the current situation. If we can pass reforms without destroying the professional and industrial quality, without destroying what we have today, the country should be growing again with a strong health system.

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