

Antonio Portela - CEO, Bial



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06.06.2018

Tags: [Portugal](#), [Bial](#), [Strategy](#), [Internationalization](#)

Antonio Portela, seven years into leading the Bial operation in Portugal, shares his views on internationalization and how to maintain a stable company culture when approaching new and diverse markets. He discusses Portuguese market trends, future patent challenges and provides an intriguing insight into running a leading family-owned pharmaceutical company.

When we last spoke in 2013, US expansion was the key strategy. Can you please update our readers on your current internationalization plan?

We have strengthened our presence in Europe, given the approval from the European Commission in June 2016 for Ongentys (opicapone) for Parkinson's Disease. We have also opened new affiliates in key European markets in the past three to four years. Regarding the rest of the world, since February 2017, we have a new partnership with Neurocrine Biosciences Inc, who will be taking charge of submission and commercialization of Ongentys in the US. And at the tail end of 2017, we partnered with a subsidiary of Fosun Pharmaceuticals in China, who will commercialize our product in China. Finally, our partnership with SK Chemicals in South Korea indicates our intention to approach this market. In Japan, our collaboration with ONO exists since 2013. In this country, clinical trials are underway, and we have potential filings for new medicines scheduled for 2018.

Our first product for epilepsy (Eslicarbazepine Acetate - Zebinix in Europe, Aptiom in the US) entered the US market in 2015 through our partner Sunovion and has had strong uptake since

then.

I would like to point out that we cannot go alone in these vast markets. We have been expanding with our affiliates in Europe; indeed, this year is our 20th anniversary in Spain. In Italy, Germany and the UK, we have been present for over three years, where we commercialize our current drugs, with a view to expanding in the future within the neuroscience field. When we consider frontiers outside of Europe, we seek partners. For example, in Japan, we have in and out-licensing partnerships. South Korea and China are new markets for us and are a natural progression on a global scale.

What does Bial look for in an international partner?

We look for shared attributes or common ground between Bial and the partnership company. Regarding clinical development, for example, we target ten-year partnerships. Consequently, it is critical to understand one another's cultures in the long run. Naturally, the financial and commercialization element is crucial to the success of any partnership. However, business practice is important—in a ten-year period there will be highs and lows, and we need to be able to ride out the lows and understand each point of view. For example, regarding the last agreement we settled in the US, the Neuroscience expertise was key, combined with a strong, aggressive presence on the domestic market.

How do you maintain a healthy corporate and family image when approaching such vast and diverse cultures, notably Asia?

We have always been a family company and intend to maintain the structure long-term. The family culture enables us to manage a clear and long-term vision for the company: we do not have to be concerned with presenting quarterly figures to the shareholders, for instance. Although we know that for a company of our size going public would grant more financing for our projects, our current growth rate is sustainable, and we do not like to grow too fast. Indeed, steady growth and overcoming challenges are vital ingredients of our culture. Critically, however, our partners appreciate that when Bial enters a project or in a new market, they know that we will see the project through, as our reputation is well-known to be reliable and long-term.

The cost of making a drug nowadays is roughly one billion dollars. To what extent is the family-owned structure sustainable in such an environment?

I agree that it is immensely challenging to develop new drugs nowadays given the massive costs. In the past 25 years in R&D, we have synthesized roughly more than 12,000 molecules, of which two have made it to the market. The success ratio is very small. Nonetheless, we are aware of the costs of developing products, and if the risk were lower, we would see far more competition in the market. People outside the industry sometimes do not realize the number of molecules that are dumped before reaching the first pill. The resilience, tenacity, and perseverance required in our teams, that I see on a daily basis at Bial, is another key attribute of Bial's culture. Without this ability to not give up, and reinvent ourselves when necessary, we would not be able to bring value to patients. Our project financing is slower given our status as a family run company, but with a long-term vision, we have a comparative advantage and are competitive.

Is there a risk that as a family-based company, collaboration with big pharma is more challenging?

We have a long history of collaboration with pharmaceutical companies. In fact, one of our most significant strengths is our ability to strike up and nurture partnerships with pharma companies. We collaborate with roughly 30 companies across the pharmaceutical spectrum, from across the globe in varying sizes. The relationship with each business we manage is essential, but above all, if we deliver results, then things inevitably go well.

Opicapone has had international market access approval in four European countries, but not in Portugal. Why?

Germany, the UK, Italy, and Spain (the key European markets), have all approved the medicine. Sadly, in Portugal, one of the consequences of the crisis is that processes are slow, in some cases approvals and pricing can take around 300 days. We as a country are improving, and I hope that this can allow patients to access medicines earlier on.

As the leading pharmaceutical company in Portugal, do you feel there is a responsibility to deliver to Portuguese patients first?

Naturally, as a Portuguese man heading a Portuguese company, I want the best access for Portuguese people. Nevertheless, our responsibility is to all patients and to ensure they have access to our medicines as timely as possible. We currently have an excellent drug in our hands, and we want patients in Portugal and in other countries to access that drug urgently.

What more can be done to improve the current pharmaceutical standing of Portugal as a country?

Portugal has interesting characteristics and the capacity to develop them, particularly within the pharmaceutical sector. Portugal has, over the last 20-25 years, made a significant investment in academic research, building institutions and training researchers. We now have a pool of fantastic well-trained individuals, particularly in life sciences, and we have the most Ph.D. rate in the country's history. The pharmaceutical sector is well prepared for progress. The recent tendency has been for the young and budding scientists to forge successful careers in foreign countries, as opposed to staying in Portugal. Moving forward, we must ensure that all this knowledge, training and research that we have built over the past 25 years, is translated into value for society.

We have not yet done this for two reasons: as a country, we do not have the financial resources, and the relationship between academia and industry must improve.

There is very little money to develop pharmaceuticals in Portugal, next to no venture capitalists, and scarce foreign interest to create foreign investment momentum in Portugal. We must align the supply of excellent, budding research with demand for investment. The industry plays a huge role in this relationship because a venture capitalist will only invest if they understand and trust results. We have seen a vicious cycle in recent years, that we as an industry must turn into a virtuous cycle.

Government measures taken over the past 10 to 15 years have severely hit the pharmaceutical sector. Times for approval are high, prices have been cut, and there has been little investment in Portugal, namely in industrial, (because MNCs had all but sold their manufacturing sites), and in research. We, as an industry, must attract venture capitalists to consider Portugal, but they will only do that if market conditions are attractive: if prices, timelines, and payments are competitive on the European standing.

Secondly, academia must change the way it looks to the industry and its potential for added value. Over the past 25 years, the researchers we have produced are devoted to science but have

shunned industry, therefore avoiding translation science and value generation. Academia must challenge itself regarding how they approach working with industry. Portugal does not reward scientists enough and indeed the way in which we award academia is too linear; we must focus our efforts on encouraging the generation of value for society. We must change the KPIs.

What is the plan to offset the loss of Zebinix, whose patent will expire in 2022?

The introduction of Ongentys to the market will be a crucial success factor for Bial and will offset the patent expiration for Zebinix. Further, we have a few products in the pipeline, notably a medicine for pulmonary arterial hypertension. This drug enters phase two this year, and it is a strong candidate we intend to bring to market soon. The drug does not sit in the neuroscience field; however, it adds value to our offering. To be successful, we must have the right differentiation so that the drug is made acceptable to the market. Second, we need reliable means for commercialization; or, in the case of partners, we need reliable business operators who will look after the drug. Furthermore, we seek to complement our portfolio in neuroscience, using our network and partnerships to evolve our products.

What inspired the recent change in Bial's image?

We are acutely aware that in recent years, we are a Portuguese company that is increasingly internationalized. In the past five years, our turnover has switched from 70 percent domestic, 30 percent international to 70 percent worldwide, 30 percent Portugal. Likewise, the focus of our people internally, and our customers' locations have evolved, and we, therefore, need to consider the international markets and present ourselves accordingly. We are an SME and what differentiates us is our capabilities and expertise across the entire spectrum of drug production, from very early research to commercialization and market access. Few companies have such a thorough scope of operations: from the off to market registration. Bial can drive new medicine projects forward. We must, therefore, translate this capability into our image: we are a company that invests in adding value to patients, and therefore our tagline 'Keeping life in mind,' keeps us energized and motivated on a daily basis. Indeed, the 'Keeping life,' refers to our desire to improve patients' lives, and 'in mind' is a subtle reference to our specialty in Neuroscience. We would like to transform Bial into an international company, based on its research products, and with a stronger focus on neuroscience and cardiovascular. Because of our size, a significant amount of our business derives from partnerships.

What is the mark you would like to leave on Bial, as the fourth generation of the Portela family?

To accurately respond to this question and to explain the role that I can play in this organization, we must consider the context of Bial and its family ancestry. My great-grandfather was a visionary. He created everything from scratch—with no financial backing or university degree. He was a doer. He seized the opportunity to create, build and run the company and forged a successful brand. My grandfather, a pharmacist, industrialized Bial during the 60s. Sadly, he died very young, having run the company for just ten years. His mark was to establish robust manufacturing foundations for Bial, bringing it in line with the practices of the time. My father, who was a medical doctor, unexpectedly inherited the business and inevitably his training as a doctor influenced his strategy. It is curious; he often says that he did not want to lead the company and would have preferred to conduct a career in research. His background in R&D impacted the organization in a big way. Despite that IP rights were barely respected, he sought out to revolutionize the R&D space in Portugal because he saw the future, and wanted to generate new drugs that would bring added value to patients. Over the 32 years that he led, he expanded the company, and critically, he created an R&D department from scratch.

Our challenge for the next ten to 15 years is, therefore, understanding how to bring value to society with all that my forefathers have put into place. We have been successful in developing new drugs, but we must make them a commercial success so we can feed our R&D operations. Without this commercial success, the model's sustainability weakens. In short, we must transform Bial into a truly international company that shows significant and sustainable growth to fulfill our mission: bringing new drugs and value to society, all the while, 'Keeping life in mind.'

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