

Biosidus SA - Santiago Garcia Belmonte, President - Argentina



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Santiago Garcia Belmonte, president of Biosidus, discusses how global regulatory trends are driving change in the Argentinian biotech industry, as well the new direction his firm has taken over the last five years.

How would you describe the recent changes in the biotech market and the industries new direction?

Things have changed quite a lot in recent years. In the past, a single company could handle R&D, production, marketing, and sales by itself. Today, this is much more difficult as investment needs have increased dramatically at each of these stages, and there are now more regulatory requirements to bring a biosimilar product on the market even outside of the US and EU. For Argentinian companies with limited financing capacity, continuing to carry out all of these different activities has become less sustainable. This is why we think that partnerships are advisable, if not necessary, to materialize these ambitious projects.

Argentina has a fairly unique model for innovation, in which the majority of pre-competitive research is carried out or funded by the public sector. How well do you think this model will be able to meet the R&D needs of the Argentinian biotech sector in the future?

In Argentina, having links with academic institutions, government organizations, and commercial partners to help spread out the workload of specific projects and diversify risks is always going to be preferable to working alone. Bringing a product to market without collaborating with the public sector is extremely difficult here due to the high levels of required investment I mentioned previously. Fortunately, for the past recent years, the creation of the Ministry of Science, Technology and Innovative Production has helped foster the collaboration between public and private sectors. In the same trend, the identification of biotechnology as one of the top priority drivers of growth for the country's strategic development has contributed to the achievement of biotech projects through granting private companies special lines of credit.

In Biosidus's case, we have two long-term projects ongoing with public partners, both involving the use of transgenic animals. One of them, focused on the production of biopharmaceutical APIs in the milk of cows. We developed human growth hormone producing cows several years ago using the transgenic cattle platform, and are now working on using a similar biotechnology for the production of monoclonal antibodies. The other project involving transgenic cows is the obtention of nutraceuticals, i.e. enriched milk purported to provide extra health benefits in addition to its basic nutritional value, more specifically, containing nanoantibodies to protect infants from Rotavirus diarrhea.

We are also working on a top notch research on gene-therapy aimed at the neovascularization of ischemic tissue. We have developed a naked DNA plasmid that stimulates the growth of blood vessels, which has proven safe and efficient in preclinical testing in animals and a Phase I trial in humans. We are currently conducting collaborative research with international academic groups to conclude the development of this candidate and bring it to market at a global level.

How competitive do you feel Argentina is in the international biosimilar market, and what are some of the greatest challenges for these companies in foreign markets?

To continue to compete in emerging markets, and to have a chance at being competitive in the developed markets, much of the industry will need to make some significant upgrades and investments on some major items: cGMP production facilities to comply with local and international standards, robust documental support for the preparation of application product dossiers, and production of preclinical and clinical data. Regulatory standards are increasing world wide, so regardless of whether we choose to compete in developed markets or emerging markets, we face increasing levels of scrutiny.

Could you please introduce Biosidus, and tell us a bit about how the organizations aims have evolved over recent years, as the biotech industry itself has evolved?

Biosidus is an Argentinian biotech company that was founded in 1983, and is one of the foremost biotech manufacturers in Latin America. We launched our first recombinant protein 1990, epoetin, and now produce a total of eight proteins; epoetin, lenograstim, filgrastim, somatropin, interferon beta 1a, interferon alfa 2b, interferon alfa 2a and teriparatide. These products are manufactured at our two sites: an API plant in Almagro, and a facility in Bernal that handles lyophilisation, filling and packaging of final dosage forms.

In November 2010, the ownership of the company changed significantly because Biosidus was split from its parent company Sidus, and I became the principle shareholder of the company. At this point in time, the focus of the organization was changed to some extent; previously, we placed the most emphasis on our transgenic animal research for API production, and in 2010 we made the decision to focus more on final-dosage forms and recombinant proteins.

Consequently, our current core objective is to become the leading biosimilars company in emerging markets. We currently have a very strong market share in many of these markets, and are devoting the majority of our efforts to maintaining and increasing this position either through significant investments in research as well as through marketing initiatives. Furthermore, in pursuit of this goal we are working to build our portfolio in our main therapeutic areas of focus by in-licensing products from other companies. We seek for niche traditional pharmaceutical products to enlarge our range of recombinant biotech products.

We are also working on several possible joint ventures in countries where Biosidus would benefit from localizing some parts of the production process for our recombinant products, either the finished dosages or APIs. This is one of our key strategies for building our market share in markets like Brazil, Thailand, and Algeria to name a few.

Back in 2009, Biosidus was extremely dependent on sales of just a single product, epoetin (EPO). To what extent has Biosidus grown out of this dependency over the last five years?

In 2009, our EPO sales accounted for more than 80 percent of our sales in terms of volume and revenue. Over the last five years, we have increased our total sales by more than 100 percent in USD terms, and at this point EPO accounts for 50 to 55 percent of our sales. This is largely due to the strong growth in sales of our interferon beta 1a and filgrastim products, as well as the strong start we've seen with teriparatide.

Over the next few years, I think that the majority of our growth will come from some of the second-generation recombinant products, such as peg-interferon, peg-filgrastim and other pegylated products that we have in our pipeline, as well as some of the chemical products that we are in the process of in-licensing. Our teriparatide also holds a lot of potential as we just finished a comparative clinical trial for this product, which was our first-ever comparative clinical trial, and we are optimistic we will be launching it in eight different countries in 2015.

What biotechnology do you think holds the most potential for Biosidus and the Argentinian biotech sector in the coming years?

I would have to say gene-therapy. We have only begun to scrape the surface of what can be achieved using these methods, and there are countless applications, both biosimilar and radical, that remain for us, and our partners in the Argentinian industry, to pursue.

Where would you like to see Biosidus in five years?

First of all, I would like to be the leader in emerging markets in the biosimilars segment. We're starting construction of a big, new cGMP facility in Argentina this year and I'd like to see that up and running as soon as possible to be able to help us achieve this goal. I would also like to have set up production facilities in four different countries, sales branches in some others, and complete the development of the coming candidates in our pipeline meaning a few product launches. Finally, I would like to see us have the best team, because Biosidus is at its core just a team of talented people, and having the best team means being the best company.

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