Interview with Marcelo Argüelles, President of Bio Sidus and the Sidus Group, Bio Sidus

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Tags: Bio Sidus

Sidus was originally established in 1938. Today, the Sidus Pharmaceutical Group is one of the most respected in Argentina and Latin America. To what extent is the company today still the same company that was founded in 1938, and how has it developed to the position that it is in today?

The original vision for the company was to develop a successful pharmaceutical company, and it gradually became clear that an innovative and prudent way to do this would be through vertical integration. In the 1970s, the two possible routes that a pharmaceutical company could take to achieve this level of integration were entering into either pharmachemicals, or biologics. At this time, Sidus decided to take the biological route. To even consider biotechnology was very innovative at that time, and Sidus' work in this field began at the start of the 1980s. Sidus started to develop its first product, interferon, which at the time was a wonder product, filled with possibilities.

The reason that Sidus decided to enter the biological rather than the pharmachemical market was the company felt that Argentina had a chance to be more competitive in this field: the country has a history of biological innovation, and has had three Nobel Prize winners, all of whom were involved in the life sciences.

Originally, the biological work was done as part of Sidus, but the company quickly realised that the two operations needed to be separated, because the vision of an R&D company is very different to

that of a business focused on production. So, in 1983, Bio Sidus was formed as an independent company. The first focus of this newly formed business was to continue development of its first product, interferon, followed by the company flagship product EPO, and we were fortunate to successfully develop it in a relatively short space of time. We launched our first Erythropoietin (EPO) product in 1990. This was one of the first biotechnological developments in the Latin American region, and was Bio Sidus' principal product for many years. Today, sales of EPO contribute to 60% of Bio Sidus' sales.

On its side, Sidus continued developing alongside Bio Sidus during this period. One of the major milestones for the company during that time was a partnering agreement with Merck. This was a major development in the worldwide pharmaceutical industry, as it was the first agreement between a multinational company and a regional one: all of Merck's production and therapeutic lines were entrusted to Sidus. This was very important for Sidus, and Merck's philosophies helped to shape the business into the successful company that it is today. Although this agreement ended ten years ago, we still have a very good relationship with MSD in the country.

Back to Bio Sidus, today, work continues in the two areas that produce biotechnological products: cell cultures and bacterial fermentation, and the company has expanded to market its products in thirty countries worldwide. At present the company is focused on providing products to non-regulated markets in Eastern Europe, Asia, parts of Africa, and the whole of Latin America. A challenge for Bio Sidus in the years to come will be to take our biogenerics to first world markets such as the US and Europe, and we are currently very focused on this goal.

In terms of developing new products, the future of Bio Sidus is very clear, and we believe transgenic animals to produce therapeutic proteins in their milk will be the company's key to future success. The company currently produces three target therapeutic molecules in the milk of Holstein and Jersey cows: one line which produces human growth hormone, one for bovine growth hormone, and one which produces human insulin. This has taken a very high level of investment over the last ten years, and we hope to receive approval for the use of the human growth hormone in both Argentina in Brazil in the very near future. Bio Sidus have twenty cows at the moment that produce human growth hormone, and these are enough to produce all the human growth hormone currently being used in the world. While we don't yet have the market, Bio Sidus has the capacity. We hope this will change in the near future.

Monoclonal antibodies are a revolution in biotechnological therapeutics, and the key feature of these products is that compared to other raw materials, the production volume needed is incredibly high– since a therapeutic dose of monoclonal antibody represents, for instance, as much as 1,000

times the erythropoietin is needed to achieve biological effect. For this reason, the transgenic animal approach will be a very useful technological tool to produce this kind of therapeuticals.

With transgenic animals, there are two main issues to be tackled before the products can be released on the market. The first is developing the animal, which in itself is a huge challenge. The second is the regulatory pathway. In the US and Europe at the moment, products that come from transgenic goats have recently obtained sales authorization, and so we hope that in a short period of time, opinions will begin to change on this matter.

The other strong project in development is gene therapy. It’s a new development, and Bio Sidus is looking into cardiological gene therapy, which involves using one specific gene as a treatment, which in our case is VEGF. At this moment, the company has concluded successful Phase I clinical trials, and are working towards Phase II. Gene therapy will give Bio Sidus the chance to become one of the few players to enter in a completely new type of pharmaceutical business, that is, the administration of human genes in human tissues as a therapeutical agent.

Last but not least, we are working on what we call White Genome Project. The major goal of this project is the isolation, identification and characterization of Antarctic bacterial strains for further sequencing of the complete genome. To date, a new bacterial species has been isolated in the Antarctic Territory, named Bizionia Argentinensis, which is the first microorganism whose complete genome has been fully sequenced in the framework of a national collaboration. The industrial objective of this project consists in the identification of genes coding for enzymes of industrial interest, and further cloning and expression for large-scale production of said cold enzymes.

A lot of the plans you have mentioned for future growth are related to Bio Sidus, but how have you found the growth of the whole group has progressed, and how do the synergies work between the different parts of the Sidus group?

The relationship between Bio Sidus and Sidus is a natural one, as both companies are primarily concerned with human health. Close to 40% of the sales of Sidus come from biotechnological products. Biotechnology has three big potential applications: human health, agribusiness, and the environment. Bio Sidus decided to work primarily in human healthcare, because it is our principal subject, but we, at Sidus have also made our bet in agribusiness. Sidus’ first venture was to micrpropagate berries: blueberries, cranberries and others. In Argentina, there is no local market for fresh fruit since normally, they can only be found in jams, sweets or ice cream. This scenario brings us the opportunity to export fresh fruit in counter-season to Northern countries – the US, Europe and Japan. The whole production process is vertically integrated: we produce the first plant,

the progeny, which is micropropagated. From this progeny, we mass-produce the plant, and sell the fruit, both in Argentina and markets abroad. Sidus has many plantations, such as the one in San Luis, which is 80 hectares and roofed, which is very impressive to see. Driven by our core business, we are also developing healthcare products with our blueberries for combating urinary infections, and as anti-oxidants.

What do you envision for the future of Bio Sidus?

The company's greatest possibility is in entering regulated markets. It is very likely that biogenerics will play a big role in these markets in the near future, and this means opportunities for companies like Bio Sidus that come from non-regulated markets. We expect to enter these markets with our products through a company already established in these first world markets.

There are very few companies in the world that can produce these kinds of products. Bio Sidus has been developing EPO since 1990. At this moment the company has sold more than 60 million units of EPO, competing with the larger international companies. In Argentina for example, Sidus has close to 80% market share, and in Latin America we have nearly 50% of the market. In many ways, this makes Bio Sidus the future partner of choice.

How difficult do you find it being such an innovative company in the Argentinean market, which is very focused on the branded copy?

The problem for innovative companies in Argentina is the long term. The problem lies in the fact that Argentina doesn't have the same level of credit and financial structures that would be found in other countries. If Bio Sidus had been established in Australia, for example, the value of the company today would be very different. The big challenge is that our products are always long term, often requiring more than five years' development, and to continue along the same line in a country like Argentina for this amount of time is very difficult.

How difficult do you find it to successfully join science and business in Argentina?

I am the president of FAB, the Argentinean Biotechnology Forum, who are dedicated to foster biotechnology endeavours in Argentina, helping pharmaceutical and biotechnology companies gain access to the latest scientific innovation in the country, which is being conducted in research institutes. As a company that comes from a relatively small country, Bio Sidus' best chance of success is to have a good quality product, and a high level of innovation. Standard quality products can be made by many, but there are few companies who are really producing to high innovative standards.

The difference between the decrease in prices of biogenerics and generics when compared to their originator products show that there are fewer companies that have the technology to produce them, while there is still a high level of demand. When a pharmaceutical generic goes to market the price decreases by an average of 80%. However, in view of the above, the decrease for biogenerics is expected to be more like 30-40%.

There is a lot of competition between Latin America and Asia for biotechnological investment. Bio Sidus is present in the Asian market: do you see this competition as a challenge or an opportunity?

Asia is a very tough market for Bio Sidus, and a major factor in this is that the cultures of the two continents are so different. For Bio Sidus, Latin America is definitely more of a priority than Asia. With Brazil, Mexico, Colombia and Argentina, there is a market large enough for development. However, India and China are very big markets, and this makes them very attractive for a group like Sidus. But competition in these markets is fierce due to the presence of many local manufacturers. A very important market for the company is Thailand: it is our third largest market, but the potential for growth in Asia is a lot more complicated than it is in Latin America. Bio Sidus have set themselves a great challenge in inking license agreements to extend its territorial scope to more than 50 different countries worldwide, made even tougher by the fact that we operate from a country like Argentina, which is not as open to the world markets as others.

How is the Sidus group an example of an Argentinean company acting as a trade ambassador for the country?

We feel indeed as the ambassadors of the innovation and technological achievements that can effectively and successfully be conducted in Argentina. Sidus-Bio Sidus have excellent relations with the Argentinean Ministry of Foreign Affairs. The Ministry has always been very proactive in the promotion of our company and the scientific activities we are engaged in and is always a close collaborator in our day-to-day business. The Ministry is very keen to work with innovative companies like Bio Sidus, who can really show the potential of investing in, and doing business with, Argentina. I have been personally on several international missions in collaboration with the Ministry, with the heads of other leading Argentinean companies, in order to push this point further on the global stage.

What do you think have been the keys to your success in managing Sidus?

I have always worked in pharmaceutical industry, as my father was the founder of Sidus. The aims that I strive for are to create quality products, and to always work towards vertical integration with every product that is developed. After this has been achieved, international expansion is the next

logical step. This vision is quite unusual in the Argentinean market, but I believe that if you follow your dreams, only success can follow.

How far away do you think you are from achieving the dreams that you had for the company?

At Sidus Group, we are always thinking about that next dream, that next step towards the future. This philosophy is shared for all the people that work at the company. Sidus has a wonderful team, and it’s a team that is looking for the future of the company, trying to be successful and always looking for ways to develop the company.

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