Amega Biotech- Francisco Molinari, CEO – Argentina

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Francisco Molinari, CEO of Argentina's most sophisticated biotech group discusses Argentina's competitiveness in the global biosimilar market, the current constraints limiting innovation in Argentina, and his company's recent transition from an API producer to a fully integrated biosimilar developer and manufacturer.

How would you describe the current state of the Argentinian biotech sector, and the changes that is it undergoing?

The Argentinian biotech chamber was formed a few years ago and this year we hosted Bio Argentina for the first time. This was an effort to bring together the biotech community on a larger scale and to help groups of scientists and innovators to link with companies that could help them move their projects forward. While it is too soon to know what the results of this first conference will be, we expect this platform to be a fundamental catalyst of innovation in our country. There is a lot of innovative capacity and creativity in Argentina. Though we aren't lacking in minds or ideas, as a country we are struggling to turn these ideas into fully developed and rigorously tested products, as most of the innovation never moves past the academic research stage. Part of this is cultural, as many of our top scientists hold long term jobs at public laboratories and feel hesitant to take the risk of joining a business venture. We are working to change the mentality to promote the image of the private sector as a friend and partner, where research and innovation is encouraged and valued.

Despite these challenges, there are several great examples of isolated successful stories of innovation in Argentina. One example of a very innovative pharmaceutical company that we are working with is Eriochem, who are developing a new and improved oncology platform using nanotechnology and biotechnology. We are helping them with the recombinant engineering that is involved. They already have started testing some models in animals that have been working very well. However, despite this one example and a few others, the current structure of the industry and "rules of the game" are limiting the successes to a few players in a few very ideal situations The challenge for the industry as a whole is to work together to help change the environment and culture so that we can achieve a broader level of success across the industry.

Argentina is a strong biotech player, but the global environment is becoming increasingly competitive. What are some of the key constraints holding Argentina back from the first rank of biotech producers worldwide?

Primarily, access to capital, as there is a chronic shortage of accessible capital in Argentina and the biotech industry is a capital-intensive business. Despite the strength and potential of the life science industry in Argentina, due to the unpredictable and volatile nature of the economy here, international investors require exceedingly high rates of return on their investments to compensate for the currency and political risk, so high in fact that getting such financing is usually infeasible. As such, the capital pool is limited to investors who are familiar with the Argentinian economy, and are comfortable taking on these investment risks.

On the other hand, I do feel that Argentina is very competitive in biosimilars. We have a lot of experience and know the weak points or risks of the business. The industry, as it has developed so far, is extremely self-reliant and sustainable so we will almost surely remain in the biosimilar race for a very long time. We may not be the early leaders, but we won't stop being contenders any time soon. A lot of the current competition is starting to fall away and these are the "virtual biotech companies", shell companies with just a few employees who were just buying APIs (or making them using third party clones and processes) and producing final dosage forms using a CMO. In the past, there was a margin to be made doing this but the economics of this type of business model would only be sustainable if biosimilar prices only decrease slightly. However, we expect a substantial decrease in biosimilar prices, and as prices fall, the industry will be whittled down to the core businesses that are carrying out a majority of the technically intensive work.

What do you think of the recent regulatory changes in the US and EU regarding biosimilars?

These changes have been quite substantial, although it will take time for the affected firms to reach these markets. The US is now indicating they will allow pharmacist substitution of biosimilars which was unthinkable a few years ago, and EMA announced a few weeks ago that they are changing their biosimilar guidelines to allow clinical trials to be held outside of Europe, use non-European references, and in some limited cases to go without any clinical trials at all, like a normal generic product.

This last development is in particular very sensible because with the analytical capabilities available today it is possible to really fingerprint a molecule, see exactly what compounds are within a product and confirm product characteristics. Conducting extensive clinical trials for biosimilar products is unnecessary when the active ingredient they contain has already been tested extensively an marketed, and when you can show with an extremely high level of accuracy and precision that the product does in fact contain the molecule it claims. I'm sure that eventually regulators will fully recognize that biosimilars really are just generic products, albeit ones that are very difficult to produce ones.

I also see a bit of a contradiction in current policies and political rhetoric. Generics and biosimilars are often promoted as a solution for health systems to reduce costs while delivering the same standard of healthcare, yet the legislation passed in regards to these products is making them unnecessarily expensive. When biosimilar manufacturers have to carry out extensive and expensive clinical trials, after having shown that their product is bioequivalent to an already approved and marketed product, the resulting costs have to be recovered by increasing the prices.

How do you see these changes affecting Argentinian firms?

Well, in my point of view, Amega Biotech is probably the only Argentinian biotech firm that is currently in a position to be able to enter the US market in the foreseeable future. In the pharmaceutical field, there are really only three companies that do the majority of the work that have entered the US with a few very specific products. On the biotech side, Amega is the only player that has the technical capacity, knowledge and the infrastructure needed to meet the demands of the US market, so for us it's now a matter of investing the time and money needed to actually get there.

We've been looking closely at the sophistication and quality of our platforms relative to the standards and we are certainly able to meet them fully or with minimal changes. Currently we are discussing several potential US projects with different partners, and the first submission of one of our products to the FDA was made a few months ago, so in a few years we will hopefully be

actually entering the market. Again, for us it’s not a race to be the first, but to get there in a way that is sustainable so that we can remain and compete in the longer run.

Rogelio Lopez was just appointed as the new national administrator for ANMAT; what advice would you give him if you had the chance?

From what we’ve heard, meaning what is rumoured, Ing. Lopez was appointed to support the government’s broader initiative to promote the domestic development of medications so as to reduce dependence on imported medical products. Of course this directly entails supporting national companies, which sounds great to us at Amega Biotech. We are arguably the most developed company in the country in the biosimilar field and have the most complete platform for drug development, production and sales, so we know we have a lot to gain if and when the Argentinian authorities decide to directly support or invest in national firms. There is the potential for us to do a lot of good for our country, and we would very much like to take this opportunity to do so and to renew our commitment to the development of our country

In 2009, you were still integrating the companies in the Amega group; after five years of hard work, what would you identify as some of the key milestones that Amega has reached in this time?

In terms of international presence, we have managed to become not only an API producer but also a pharmaceutical manufacturer of a wide range of Finished Dosage Forms. We’ve actually had more success entering foreign markets than our own Argentinian market, and are now present in parts of Africa, South East Asia, the Middles East, and many of the former soviet republics. We are also present in nearly all of Latin America through various partnerships.

We’ve also greatly expanded our manufacturing capabilities and today we have three facilities producing APIs, with two more under construction. Most of our finished dosage forms are produced by an affiliated Uruguayan company that is EMA certified, and happens to be owned by Amega shareholders. For some specific formulations and products distributed in the Argentinian market we work with an Argentinian CMO.

The next big step will be launching our own product line under our own brand name. So far, our partner companies have marketed all of our products. For example, in Argentina Bagó is commercializing our Interferon Beta, Elea has our Erythropoietin and all of Bioprofarma’s biosimilars are manufactured using our APIs.

Also, we've been growing in sales and complexity and now we are over 300 people, mainly highly specialized human resources for technical areas.

How does Amega's vertically integrated structure give you the ability to develop the most competitive processes?

First, our platform is based on our own clone development. Today, we have roughly 60 scientists in Process Development Department who have done all of our bioengineering and science; we have not relied on anyone else for scientific support. To develop an efficient process and product, you need to master and optimize every step of the biotech development, and this is our core strength. If you utilize a conventional or standard method for a non-conventional purpose, usually it won't be particularly efficient and these inefficiencies are compounded as when they exist at multiple points in a process. So either you, like us, have the resources and capability to optimize a process or you try and likely fail to compete with an inefficient process.

Second, as a relatively new company in terms of R&D and having only invested in the most modern technologies, our equipment is of a high standard at every stage. As a vertically integrated group, our investment plan can take into account the relationships between technology and processes at different stages to optimize the development and investment, instead of just analyzing individual pieces.

A good example of the benefits of having new technologies and the scientific capacity to develop our own process is our CHO Interferon Beta, which has the most complex and unique production process of all our products. It was very challenging and expensive to develop, but now that the system is up and running, the production process is very efficient in terms of working capital and productivity. Most of the other companies producing CHO products at the moment are still using older technologies that are far more inefficient, with lower and higher production costs.

In 2009, Amega was selling 8 different APIs in different iterations, and now you are selling 16 individual compounds. What were some of the biggest challenges you faced in developing these new APIs?

With regards to the scientific development, our newer products have been increasing difficult to develop as they have been much more complex molecules than some of the smaller ones we worked on in our earlier years. Working on larger molecules is far more demanding in terms of analytics as well, as you must constantly check, optimize and fine-tune your molecules during the development process. This has slowed down the pace of development substantially, and we won't

be able to introduce new molecules at the pace we have.

What has driven your transition from an API focused firm to one that now produces finished dosage forms?

At first, our focus was on APIs because the there was strong demand for APIs. That has changed as the regulatory burdens on final dosage form manufacturers in even the most unregulated markets have increased substantially. Clients are now relying on and demanding a lot of information and analysis from API producers that is pharmaceutical in nature, as they can't handle these challenges themselves. Now our clients are asking us for the 'complete solution'.

We've also started manufacturing medical devices for the delivery of our products too. After we entered the final dosage form market, we realized that our products were at a competitive disadvantage because the originator products came with very nice, customer friendly auto-injector pens while patients using our products had to use a large uncomfortable syringe. We started looking at the auto-injector market and saw that for the quality of device we were looking for, prices are still very high and we thought we could develop our own device in house at a more attractive cost. So, we started an engineering project with a partner company and now we have two of our own auto-injectors; a fixed dosage injector that is already approved in Argentina and is being sold by Bagó, and an adjustable dosage injector that has been submitted for approval in Argentina.

Was there a substantial challenge making this transition in terms of business relationships and distribution?

On the business side, we have been building up our client base and partnerships for ten years now, and we are quite happy with the relationships we currently have. In most cases they are just as happy to buy finished products complete with dossiers from us as APIs, so our distribution network hasn't really changed. Registering products in any market is slow, but once the product is developed and ready to be submitted and you have found the partners you need, the only work that remains to be done is waiting.

At the moment, we have a variety of products submitted for registration in roughly 50 different countries; we are very excited to start getting these registration approvals so we can start opening up our sales and to benefit from a greater degree of economic freedom.

How does Amega make use of Public-Private partnerships as a platform and support structure for innovation?

We were born as a partnering company and we've been always keen to share our projects with other capable organizations and knowledgeable individuals, as we are extremely efficient and capable in some areas but don't have the manpower or expertise for others. Public research institutions are some of our best partners and we've invested a lot of time in helping them develop their capabilities and better understand the biotech regulatory environment so that in the future we can rely on them more.

Currently, we have projects ongoing or starting with both UNC Hemoderivados and the Universidad Nacional del Litoral in Santa Fe. In general, they help us by carrying out some of our development work for us so we don't have to carry the entire load ourselves. In return, we help them with their research strategy and provide them with certain technology or biological samples. Usually, this exchange involves us sharing some early stage work not yet commercially viable so that they can develop an improved bioprocess that could work at the commercial scale.

That said, despite all the benefits and successes that public-private partnerships have demonstrated in Argentina, there is still a lot more the government could do to promote innovation and research. As I've said before, funds are always scarce in Argentina and the government could help their own institutions and the private sector a lot providing more stable and predicable funding to projects that they have a stake in and improving our access to credit. There also needs to be better dialogue between potential partners in early stages so that the proposals are more realistic than many have been in the past; when a project doesn't result in a product that can be commercialized, it generates a lot of disappointment and destroys trust between the different participants.

In 2009, you said that Amega was your dream; today, what is your dream for Amega's future?

At that time we were probably 100 people, and now we're around 300, with a similar increase in revenue. We've achieved a lot in terms of process development, product launches, business development, on every side really. Being an Argentinian, I am very flexible and can always adapt to reality, so whatever comes our way I'm sure we will be able to deal with it and get to our objective. That objective is the global market, and becoming a player at that level would make us a truly global player. We're already most of the way there, with products registered in dozens of countries. At this point, the furthest ahead I am looking is getting our first product into a developed market like the US or Europe, and we're already on the way. The next step would be entering these markets under our own brand and with a wider variety of products.

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