HEALTHCARE & LIFE SCIENCES REVIEW

PHARMA BOARDROOM

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BEATING THE CYCLE

ARGENTINA'S PHARMA OUTLOOK, POSITIVE DESPITE ECONOMIC STRIFE

ARGENTINA

March 2015

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ARGENTINA
Beating the Cycle

Argentina has experienced six severe economic crises since the great depression, and as a result, Argentinians have become excellent problem solvers. With extensive scientific and engineering expertise, creativity and ambition, the industry has established a pattern of strong growth in times of plenty, and minimizing losses during periods of inflation and recession, in effect "beating the cycle." Along the way, the top Argentinian labs have developed into a powerhouse pharmaceutical industry that rivals the multinational sector domestically, and has taken a position of leadership in markets across the region.

A Local 's Market

Truly diamonds in the rough, the top Argentinian pharma and biopharma laboratories are forces to be reckoned with wherever they do business. "Argentina is one of the few nations worldwide that has a domestic pharma industry that dominates the international pharma sector in terms of revenue; seven out of the ten top firms are Argentinian, and 60 percent of the market value is sold by Argentinian laboratories," explains Francisco Cervo, the general manager of Elea. Patrice Fuster, the general director of Sanofi Argentina, clarifies that these national companies "are not nationals in the traditional sense, as they are giants; they are regional

companies, exporting their products around the world. They have an extremely strong presence and are very competitive in Argentina, and their brands are incredibly strong." One of these domestic giants, Roemmers, stands significantly above the rest, with more than nine percent of the market, nearly twice that of the next highest grossing competitor, Bagó. Argentia, a company of the Roemmers group led by Esteban Echenique, entered the nutraceutical market after the acquisition of Metabolic Cla and recently incorporated Menarini's products into their portfolio, another example of the dynamism of the Roemmers Conglomerate, lead by Eduardo Macchiavello, CEO, Roemmers. Echenique explains their strategy : "to focus on chronic products, the cardiology area mainly focused on antibiotics, and with our cardio branch our market share grew from the 13th largest to the 8th (and climbing) at this point in time." Argentia is the fastest growing company in the IMS ranking of the 50 biggest companies in Argentina.

This market is also unique within the region, as it has developed as a branded generics market with very low pure generics participation, at just ten percent according to IMS, the lowest level in the region. Norberto Bonaparte, the founder and CEO of Close Up International, explains that "until 2002, physicians could legally prescribe a specific branded product, and today a brand name is usually included alongside the generic name on the prescription." As such, "most labs carry out extensive and dynamic marketing strategies and actions," according to Bonaparte, and Eduardo Neira, country president for AstraZeneca Argentina, says Argentina has a "consumer driven market that pays more interest to brands rather than new molecules," because the brand is seen as a "stamp of quality."

ARGENTINA IN FACTS & FIGURES	
Population (2013)	41.45 million
GDP (2013)	USD 609.9 billion
Total Healthcare spending (2012)	8.5% of GDP
Annual Retail pharmaceutical spending (October 2014)	USD 6.1 billion
Pharmaceutical plants	110
Foreign owned Pharmaceutical plants	17
National Labs share of total market (2014)	57%
OTC share of total market (2014)	10%

The significance of brands to the Argentinian consumer, and the strength of many of the top Argentinian brands, has limited the ability of multinational companies to penetrate the market on their own. According to Ernesto Felicio, the executive director of the research-based pharmaceutical industry association CAEMe, which is celebrating its 85th anniversary in 2015, there has been "an increase in joint initiatives between local and international companies" in recent years; many of these joint initia-

From left: Esteban Echenique, General Manager, Argentia, Alberto Alvarez Saavedra, President, Gador; Luis Rodriguez, Director General, Gador; Francisco Cervo, Director General, Elea

tives have taken the form of product licensing and co-marketing agreements. Mariano Sanchez, lead healthcare partner at KMPG Argentina, explains "the increasing prevalence of distribution and licensing agreements between multinational and Argentine laboratories" is the result of several policies that caused local labs to build "better distribution and marketing infrastructure and [made] investing in manufacturing capabilities in Argentina" less attractive to outside investors.

In today's market, "multinational companies often want to launch products in countries like Argentina, but lack the sales force to properly market the products," Cervo explains. "Since only the top five or six firms have sufficiently large sales teams," he continues, "there are only a few competitors for this [co-marketing/licensing] business that we must contend with overall, across all therapeutic areas." The demand for local partners is so great, that for Gador, "in Argentina, nearly 40 percent of our sales are licensed products at this point," according to the company's general director, Luis Rodriguez.

PHARMACEUTICAL EXCEPTIONALISM

"The pharmaceutical industry has been one of the most dynamic sectors in the Argentinian economy, and is now an engine of economic growth, employment, scientific knowledge and applied technology," says Alfredo Chiaradia, the general director of CILFA, the chamber of Argentinian pharmaceutical industry that recently celebrated its 50th anniversary. "Pharma in Argentina comes from a very rich and deep-rooted tradition, triggered by the early emergence of many national family businesses, many of them now over 100 years in the country. All that was achieved in spite of the frequent volatility associated with the evolution of the economy at large." Janssen's finance director for Janssen Latin America South, Alejandro Smolje, assures that this pattern still continues, saying "in spite of the country's often volatile economy, the industry has enjoyed adequate growth over the past few years."

While the industry has outperformed other sectors in recent years, Mariano Sanchez, the partner in charge of healthcare at KPMG Argentina, points out a few external and structural factors that have contributed to the industries success. "Following the crisis in 2001," he explains, "a significant number of multinational pharmaceutical companies started to sell their production facilities in Argentina," and a few years later the government "put in place the controls on imports that we see today, and instituted the 'national preference' policies in many parts of the healthcare industry." As a result, "some of the larger local companies were able to acquire high-tech manufacturing facilities from multinational companies at liquidation prices, and then were given a privileged position in the market and protected from foreign competition." The pharma industry also benefits from several other governmental support measures, including low rate investment credits awarded for Argentina's bicentennial in 2010 and scientific, engineering and financial support for R&D from the ministry of science and technology, and the national research council (CONICET).

From left: Emb. Alfredo Chiaradia, Director General, CILFA; Ernesto Felicio, Executive President, CAEMe

Offsetting these measures of support however, are the price controls on pharmaceutical products, which have not adequately taken into account the effect of the country's high inflation rate. "For several years, the price of pharmaceutical products in Argentina has been lagging behind the increase of prices of everything else (raw materials, salaries, etc.)," says Juan Pablo Bagó, the general director of Grupo Bagó's pharmaceutical business in Argentina. "With the inflation rate of around 25 to 27 percent per year [over the last four years], prices of medicines have only increased by an average of 14 percent per year," Bagó explains. With profit margins being squeezed, quarterly price negotiations with the ministry of economy and public finance led by Augusto Costa, the secretary of commerce, are of critical importance for vendors, and the chambers representing the industry in these negotiations—CILFA, CAEMe, and COOPERALA—have seen their responsibility increase substantially. However, Daniel Varde, Deloitte's head of healthcare and life sciences for Latin America, notes that while margins "have been shrinking, they are still reasonable," because Argentinian "prices are quite high relative to other countries."

However, as Varde also admits, "surviving in this environment has forced companies to overhaul their strategy, so that they can effectively reduce costs, or at least limit their growth, without losing revenue." Furthermore, he argues that while reducing costs, "it is critical for companies to grow their revenues by launching new products and developing more exports," which provide the added benefit of revenue diversification. However, he also points out the fact that developing these revenues means "there are R&D, registration, and marketing costs that cannot be cut and in some instances, must be increased in the short term." Accordingly, several CEOs have quoted aggressive goals for export growth, with Lab Richmond aiming to exports from 14 to 50 percent of revenue in the short-term, Gador hoping to increase substantially from 20 percent, and Bagó planning on reaching 75 percent from their current level of 45.

The OTC segment is another area that holds a lot of potential for growth in the Argentinian pharma market, as this segment only accounted for 10 percent of total retail revenues in 2012. Bagó says that the share of OTC products will "increase on an annual basis," and that "the current market situation is not due to regulation," but the fact that "very few companies are currently focused on the OTC market." German Heiken, the general manager for Genomma, agrees, and points out "companies like us, mainly focused on OTC products, are quite rare in Argentina." Bagó sees this gap in the OTC market as a key opportunity for the firm's growth, and as such the group is "investing more than ever in this type of product," and he is confident that "in the near future OTC will be definitely one of our leading lines in the Argentinian pharma market."

HEALTH & PHARMA "ARG-ECONOMICS"

Consisting of a patchwork of overlapping insurers, providers, and often-inconsistent systems, the Argentinian healthcare system is closely entwined with the local industry and the incentives of multinational players. In reality, the system is fragmented along more than just geographical lines as there there are three separate systems of healthcare providers: the public systems (managed independently within each province) including public hospitals and health centers, the private health system, and a system of healthcare centers operated by Pami, the Argentinian social security health insurance agency for senior citizens. While Pami and the public system are self-funded, private healthcare services are covered by both private insurance providers and union-based health insurance plans called "obras sociales" or "social work insurance," which are themselves generally outsourced to private insurers. Raul Pistorio, executive director of Farmalink, clarifies that currently, "healthcare coverage level is as follows: 46 percent through agents of social security, 39 percent some of the different services provided by the public sector, and finally about 15 percent the private sector."

According to Mariano Sanchez, partner in charge of healthcare at KPMG Argentina, this fragmentation has reduced the



From left: Eduardo Neira, Presidente, AstraZeneca; Alejandro Smolje, Finance Director, Janssen; Maria Gabriela Pittis, Country Manager, Shire

efficiency of healthcare spending, indirectly contributing to the system's high levels of debt and payment risk for pharmaceutical players. He highlights several structural and procedural inefficiencies, pointing out that when the unions outsource the 'obras sociales' to private insurers, "there is an extra margin generally included by the union," and that "in many cases people are covered by more than one payer, yet there is no harmonization between the systems."

However, despite posing certain risks to the pharmaceutical industry, the healthcare system itself offers an excellent standard of coverage to Argentinians. Healthcare spending was 8.5 percent of GDP in 2012, according to the World Bank, and Brazil and Uruguay are the only Latin American countries to surpass

What does it take to lead in Argentina?

Patrice Fuster, Director General, Sanofi

Edgardo Vazquez, General Manager, Pfizer

Mariano de Elizalde, General Manager, Sandoz

Doing business in Argentina presents a host of challenges that managers do not often face in other markets. Confronted by high and volatile inflation, controls on imports and exchange rates, and a political system with a track record of interventionist policies, they must direct their companies through a sea of uncertainty and around a wide variety of obstacles. When asked what qualities are most needed in a manager for an Argentinian business, Mariano de Elizade, general manager for Sandoz in the south cone, answers "patience and constant flexibility to adapt to daily changes are the most important qualities you have to show," a sentiment echoed across the industry. "Managing a company effectively in this environment of uncertainty can be exhausting, as doing so requires one to continuously ask or suppose 'what if?'," says Luis Rodriguez, general director for Gador, adding that beyond planning for contingencies, "we have to be prepared for all of the above, and thus must be quite conservative."

Multinationals face a particular dilemma in selecting managers for Argentina, as their top talent globally may not be the most suitable for the job. "Learning and understanding all of these challenges and risks would take an outsider months at a minimum," says Edgardo Vazquez, country manager for Pfizer Argentina. He explains that as an Argentinian citizen, his "ability to navigate all of these issues and achieve a reasonable balance between the risks and rewards in Argentina makes me an asset to Pfizer globally." Daniel Varde, healthcare and life sciences partner from Deloitte Argentina adds that "the dynamics here are different and often seem counter intuitive to outsiders," and that "it is usually advisable to make use of local managerial talent."

While many multinationals such as Pfizer have taken this approach, a few such as Sanofi have not. Patrice Fuster, general manager of Sanofi Argentina, points out that the HR cycle and company culture must be taken into consideration. "Some companies run a shorter cycle, in the hopes that new blood and fresh ideas will stimulate growth," he says. "Others prefer a longer cycle so that their country manager has the opportunity to build a local network and put down roots in the local community and provide an aspect of stability." In an environment that puts a high premium on creativity and flexibility, bringing an outsider with a fresh perspective and who is less constrained by knowledge of the barriers and obstacles in the Argentinian market can present certain advantages, as long as their management team is able to provide the necessary local knowledge and experience.

this level of spending, at 9.3 and 8.9 percent respectively. "Access to medicine in Argentina is among the best in the world," explains Hugo Sigman, CEO of Grupo Chemo and its parent company Grupo Insud. "On one hand, there are many national programs that help the population to receive medicine, such as Plan Remediar, which supplies 40 million free units to health centers around the country, as well as Plan Nacer. The government delivers free medicine to 100 percent of people with AIDS, chagas, and other illness. Additionally, if you are a patient in a hospital you receive free medicines. Today, there are 18 compulsory vaccines in Argentina that are free, universal and obligatory. All citizens with pensions receive free medicines or medicines with minimal cost."

Regarding access to innovative and high-cost treatments specifically, "many Argentine citizens today have access to specialty or high technology products due to a solid reimbursement system," explains Alejandro Smolje, the finance director for Janssen Latin America South. "Through HMOs, more than 70 percent of the population has access to these high tech products. This is not unique, but certainly different from the situation in many other Latin American countries." Smolje also adds that Janssen has "been able to launch new, innovative and high-quality products on numerous occasions due to an emphasis on a long-term strategy focused on unmet medical needs," and Eduardo Neira, country president for AstraZeneca Argentina concurs, saying "market access in Argentina is outstanding: we are often among the first countries [worldwide] when it comes to new drug releases."

Among the innovative and often high cost treatments that the Argentinian healthcare system is able to provide, the government has recently made progress with regards to orphan drugs for rare diseases. "Argentina passed a law in 2011 that is still being implemented, which explicitly requires the private and social insurance organizations to provide support for rare disease treatment," explains Gabriela Pittis, the general manager for Shire Latin America South. Furthermore, recognizing the "phenomenon unique to rare diseases, which is that through Internet research and participation in patient associations, the patients quickly come to know far more about their condition" and its management "than most of their physicians, health

Dr. Raul Pistorio, Executive Director, Farmalink

management organizations, and regulatory authorities." The same law "created a central committee, which includes patients as members, to coordinate activities such as neonatal screening and patient registries." Overall, she concludes, "progress in Argentina is moving more quickly than in many other countries in the region, and current treatment standards are very high."

NEXT STOP ON THE EXPORT EXPRESS; FIRST WORLD MARKETS

According to Federico Trucco, CEO of Bioceres, Argentina's "strong tradition in biological sciences" is a key factor behind the success of the country's domestic pharma companies at the regional level in recent years. As "the only country in Latin America with three Nobel laureates in the field," the country has a large "pool of talent, who lead in biopharmaceuticals because of their renowned expertise," that the pharma and biotech industry has recruited heavily from. Antonio Bouzada, president and founder of Eriochem, reinforces this claim by saying that "our biggest asset is our strong pool

Figure 2: Ranking of Top 20 companies

		Volume	Share volume	USD Sales	Market Share
1	Roemmers	55,879,630	8.11%	$554,108,756	9.08%
2	Bayer	45,238,857	6.56%	$212,347,002	3.48%
3	Gador	30,270,402	4.39%	$267,888,456	4.39%
4	Elea	29,245,217	4.24%	$260,442,964	4.27%
5	Bagó	28,307,312	4.11%	$288,268,967	4.73%
6	Montpellier	25,305,491	3.67%	$198,799,360	3.26%
7	Genomma	22,936,368	3.33%	$81,822,326	1.34%
8	Pfizer	21,415,673	3.11%	$165,559,249	2.71%
9	Casasco	19,752,175	2.87%	$250,913,980	4.11%
10	Baliarda	19,106,937	2.77%	$214,235,175	3.51%
11	Investi	18,176,596	2.64%	$146,074,588	2.39%
12	Andromaco	17,658,563	2.56%	$118,313,009	1.94%
13	Nutricia Bago	17,459,310	2.53%	$64,989,379	1.07%
14	Bernabo	17,450,849	2.53%	$134,492,723	2.20%
15	Boehringer Ing	17,427,972	2.53%	$135,800,593	2.23%
16	Raffo	17,379,050	2.52%	$229,850,428	3.77%
17	Mead Johnson	16,973,145	2.46%	$27,014,100	0.44%
18	Ivax Argentina	13,474,176	1.96%	$181,638,793	2.98%
19	Cassara	11,786,065	1.71%	$41,158,796	0.67%
20	Glaxosmithkline CH	11,505,028	1.67%	$43,998,194	0.72%
	Top 10	297,458,062	43.17%	$2,494,386,235	40.89%
	Top 15	385,631,352	55.96%	$3,094,056,526	50.72%
	Top 20	456,748,816	66.28%	$3,617,716,837	59.31%
	Total market	689,106,095	100.00%	$6,099,971,049	100.00%

Source: IMS Health Argentina (oct 13 to oct 14 data) Retail Market

Regional Leadership Beyond the Private Sector

The state-owned laboratory Hemoderivados, which is part of the National University of Cordoba, is a unique public institution. One of the most technologically and scientifically advanced institutions in Argentina, Hemoderivados produces a broad portfolio of plasma products, injectable generic pharmaceuticals and bone tissue products. Hemoderivados currently has several biotech protein products in the pipeline, including recombinant factor IX, thrombin, fibrinogen and fibrin glue, as well as other generic pharmaceuticals, tissue products, and organ conservation liquids.

Catalina Massa, Executive Director, UNC Hemoderivados

Most remarkably, the public laboratory is currently a critical source of blood-protein products for several countries outside of Argentina. The executive director of Hemoderivados, Catalina Massa, explains that "the social role of Hemoderivados has two somewhat separate aspects: one is to produce expensive medicines at a more affordable price, the other is to produce medications that are not currently being produced by anyone in our country, or in the region," while the ultimate goal of the organization "is to help the south cone region of Latin America reach self-sufficiency for plasma and blood products." At present, the organization exchanges plasma for plasma products with Chile, Uruguay and Ecuador, with 35,000kg of the roughly 140,000kg of plasma that they currently fractionate coming from these countries. Hemoderivados is currently in the process of signing a new plasma exchange agreement with Paraguay that should be finalized by the end of the year.

Laboratorios Hemoderivados, Cordoba

"I think it is quite clear that there is significant potential for mutually beneficial cooperation on other issues," says Massa, giving the example of the organ conservation liquids that the lab is currently developing, as there is currently no producer of these products in the region. "Once we develop enough capacity to meet Argentina's needs, our next objective will be to meet the demand for the region, while cooperating with their own health authorities."

of human resources, and the cultural commitment to excellence in work; business might not be the most efficient or professional in Argentina, but when people are expected to meet a certain level of quality in their work, they meet it," allowing this company and many others "to achieve and maintain the standards necessary to export to some of the more regulated markets."

Carlos Grzelak, General Manager, Glenmark

Trucco also says that he believes the industry's core strength has been in "producing existing technology at a lower cost with high quality," and "pursuing state-of-the-art pharmaceuticals to generate competitive production platforms," and Bouzada hopes that "in the future, we will be able to leverage these strengths [in production technology] and take a strong position as generic players in the more regulated markets." "The problem for the other markets," he says "is that our products are neither the cheapest, nor the very highest quality." This trade off has encouraged many Argentinian firms to pursue niche product types and difficult-to-produce products, including added-value generics, also known as super-generics, and biosimilar APIs and products, as their higher operational costs are less of a disadvantage in these underserved and technologically demanding areas.

At present, "the main destination for our exports is clearly the Latin American market," says Alfredo Chiaradia, the general director for CILFA, before adding "despite that, Argentine products reach almost every corner of the world," mentioning Southeast Asia, Eastern Europe, parts of Africa, Lebanon, Pakistan and Kazakhstan as important markets for the industry. "In terms of export growth, the last years have seen the value of our exports increase about 15 percent per year," according to Chiaradia, and "in 2013 total medicines exports reached a level of USD 900 million."

The next step for many firms, which they are just beginning to reach, is to enter the US and EU as generics and biosimilar players. While many labs are currently FDA and EMA compliant, only a few have actually been officially certified. Eriochem is one of the few, having received its FDA certification letter in October 2014, and is currently the only national laboratory in Argentina with FDA certification for injectable products. Lab Richmond is one of those on the cusp, as the company recently built a new plant that, according the president Marcelo Figueiras, has "the latest technologies and complies with international standards required for the production of pharmaceutical products according to PIC/S GMP," and "is prepared to [be] certified by the EMA and the US FDA." Similarly, Edgardo Taraciuk, vice president of Tuteur Argentina, explains that the firm's "state-of-the-art" plant has applied for EMA certification, along with several other labs.

Of course, among the most sophisticated laboratories in the country are the 17 plants owned by multinationals. Despite the economic and political risks that have discouraged many foreign companies from investing in the country, the excellence of Argentinian scientists, chemical engineers, and other professionals has convinced several firms to develop or acquire plants in the country that supply their regional or global operations.

Sanofi's plant in Mirador

Among these firms are Sanofi Pasteur, AstraZeneca, Glenmark, Catalent, GSK, Pfizer, and others. Eduardo Neira, country president for AstraZeneca, explains that the company's Argentinian facility produces "many injectables and everything related to the anaesthesia line," as well as "different types of ointments and creams," in addition to several other products manufactured in the country via a third party. Glenmark's global oncology business is actually based in Buenos Aires, which "serves as the hub for development, manufacture and distribution of injectable oncology drugs for the entire organization," according to country manager Carlos Grzelak.

AN INNOVATIVE MODEL FOR INNOVATION

What is Argentina's biggest barrier to true innovation? "Argentina doesn't have enough capital to adequately invest in R&D without taking unreasonable levels of risk," says Mauro Bono, President of Savant, "although we arguably have the required scientific expertise." Furthermore, most Argentinian firms have very limited access to global capital and credit markets due to the economic and political risk that foreign investors must carry. Local laboratories must face these same risks, and thus are relatively conservative in their investment projects in general, with two of the most innovative firms in the country, Gador and Bagó, investing only four and five percent of their revenue in R&D respectively. As such, in the past innovation has been limited to incremental product innovations, and process innovations on the manufacturing side.

These instances of innovation, as well as other more radical research projects that Argentinian firms are currently involved in, have been achieved under a unique collaborative model. Since companies are unable to fund high-risk pre-competitive research, the public sector, namely the ministry of science and technology, "has filled that gap in terms of providing significant funding for pre-competitive research," explains Federico Trucco, CEO of Bioceres. This funding is distributed through two different mechanisms: first through public research organizations including national universities and the Argentinian National Scientific Research Council (CONICET), who often collaborate closely with the private sector for R&D, and through government grants for specific projects.

CONICET employs over 8,000 researchers, and is filing an increasing number of patents each year, with 42 applications in 2010, 79 in 2011, 93 in 2012 and 94 in 2013, with 26 percent of all patents in the field of 'health'.

Beyond patents, technology, and early-stage research, public organizations also provide private companies with human resources in many cases. "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," explains Francisco Molinari, CEO of Amega Biotech, referring to national universities, such as the National University of Litoral and National University of Cordoba,

two organizations that they currently have projects with. In return for this assistance, Amega "helps them with their research strategy and provides them with certain technology or biological samples."

Eriochem is leading a particularly intriguing project at the moment, for which they have enlisted the assistance of Amega Biotech and the National University of Litoral. Antonio Bouzada, president and founder of Eriochem, explains that the "idea relies on the fact that many types of cancer tumors preferentially absorb a particular cholesterol lipoprotein as they grow due to a mutation on one of their receptors." Eriochem is "seeking to imitate this lipoprotein using biotechnology, which is the step that Amega Biotech is helping with, so that we can then attach a chemotherapy drug to it, our leading candidate being docetaxel." There have also been recent initiatives to stimulate and facilitate collaboration in Argentina, such as the inaugural Bio Argentina event in October 2014 hosted by the chamber of biotechnology, which brought together over 900 professionals from across the industry to discuss the strategic future for Argentina's biotech industry, and serve as a platform for researchers to present research proposals to the chamber's member companies.

BOLD BIOTECH BUSINESSES

As one of the areas in which Argentina's pharmaceutical sector is more competitive globally, biotech has been the most exposed to global trends. Alfredo Chiaradia, the general director of CILFA, expects that "in terms of the type of products we export, we follow the global trend in the expectation that by 2016, half of the top-selling drugs in the world will be of biotechnological origin. In 2012, six of the twenty bestsellers were from this source," compared to only two in the year 2000. However, another key global trend, being changing regulatory standards and demands, has also had a significant effect on the structure and strategy of Argentinian biotech firms.

From left: Francisco Molinari, CEO, Amega Biotech; Hugo Sigman, CEO, Grupo Insud; Mauro Bono, President and Founder, Savant; Santiago Garcia Belmonte, Chairman, Biosidus

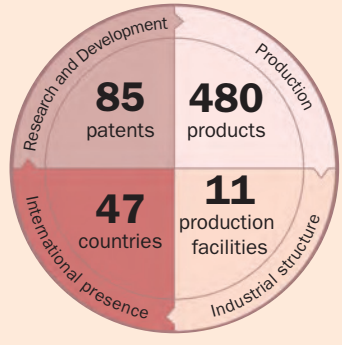
Argentinian Multinationals on the Horizon?

There are few Argentinian firms that truly have the potential to become multinationals. Several are strong regional players in Latin America, with operations across the continent, and others export products worldwide to as many as 40 or 50 countries, but generally lack fully-owned affiliates in non Latin American markets. Close Up International and Grupo Bagó are two of the few Argentinian firms that have the potential and ambition to become truly global players.

Juan Pablo Bagó, General Director Pharma, Bagó

Close Up was "the first company in the world to provide audits and reports in the prescription market," and its "internationalization process began right after the foundation of the company in 1968, when we challenged ourselves to go to Brazil and Mexico," says the founder and president of the company, Norberto Bonaparte. Today, the company audits prescriptions in Latin America and Spain, and develops and manages CRM systems for customers around the world, in roughly 70 countries. Bonaparte continues, saying that while "Close Up is a well-respected company throughout Latin America and has a wide percentage of coverage in the region," the company's goal "is to expand globally, especially in the northern hemisphere."

Norberto Bonaparte, CEO, Close Up



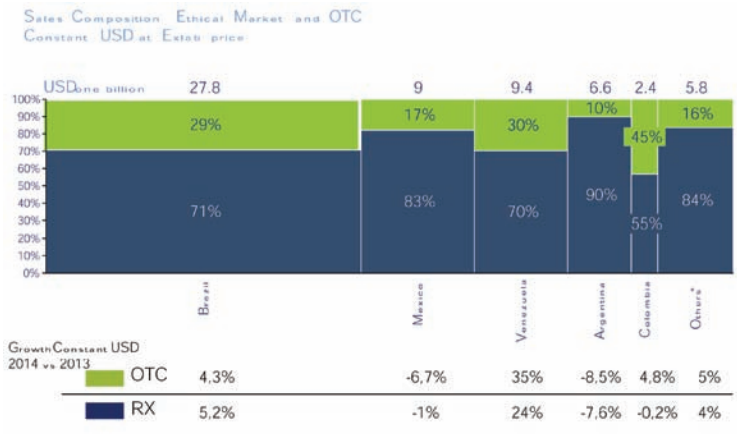
Key figures of Bago group

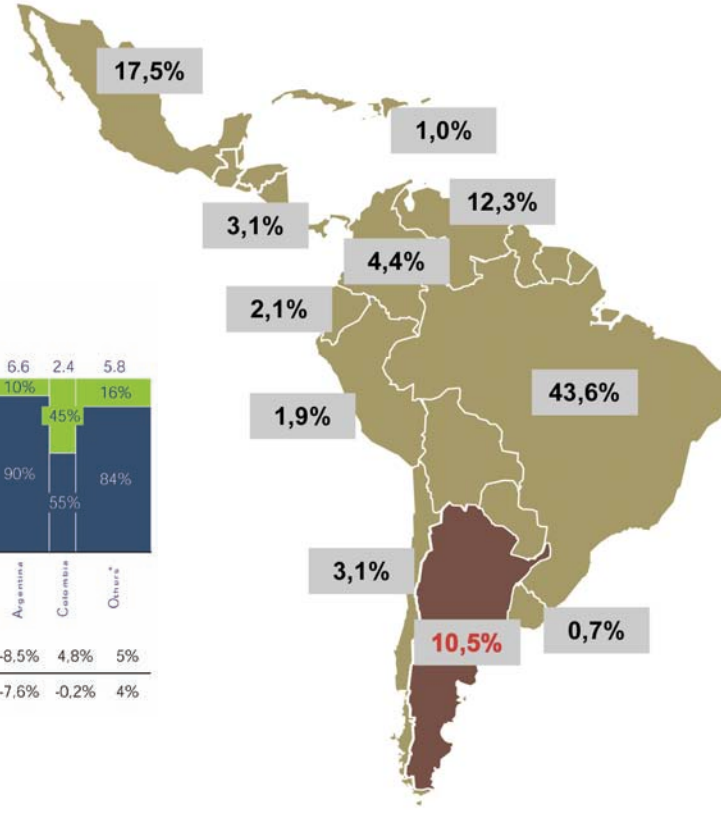
Bagó, a strong regional player with 18 affiliates across Latin America and plants in Argentina, Bolivia, Chile, Uruguay and Mexico, also has a significant presence in other parts of the world. The firm currently has four affiliates outside of Latin America, in Pakistan, Russia, Sri Lanka and Ukraine, with 11 manufacturing facilities strategically distributed between Argentina, Bolivia, Brazil, Chile, Colombia, Pakistan and Uruguay. Juan Pablo Bagó, general director for the group's pharmaceutical business in Argentina, says that the group currently envisions "a turnover of 75 percent coming from international markets" within the next five to ten years. Furthermore, being one of the few Argentinian companies to have discovered a new molecular entity (talniflumate, in the late 1960s) the holder of 85 patents developed over 15 different countries, and having achieved USD 1 billion in sales in 2012, Bagó is the perhaps the only Argentinian pharmaceutical company with the potential to develop a blockbuster drug that could catapult them into the global top 50.

"Regulatory standards are increasing worldwide, so regardless of whether we choose to compete in developed markets or emerging markets, we face increasing levels of scrutiny," explains Santiago Garcia Belmonte, president of Biosidus. Francisco Molinari, CEO of Amega Biotech, agrees that "regulatory burdens on final dosage form manufacturers, in even the most unregulated markets, have increased substantially," and points out that in many cases, this has caused clients to demand "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.'"

With these new demands from their clients, both firms have had to take a new strategic direction. "Previously, we placed the most emphasis on our transgenic animal research for API production," explains Belmonte, "and in 2010, we made the decision to focus more on final-dosage forms and recombinant proteins." Amega Biotech, which operated primarily as an API producer until five years ago, has similarly become "a pharmaceutical manufacturer of a wide range of finished dosage forms." The two companies' strategies differ at this point however. Amega Biotech is working hard to enter the US and EU markets, while Biosidus's "core objective is to become the leading biosimilars in emerging markets," according to Belmonte.

Argentina's position in Latin America





Source: IMS PM Sep 2014– pharmaceutical channel, Prices Ex Lab

Countries	Sales 2014 (Billion USD)	Growth% 2013 to 2014	CAGR 2010 to 2014
Brazil	27	5%	9.18%
Mexico	9.0	-2%	2.41%
Venezuela	9.4	27.5%	7.62%
Argentina	**6.6**	**-7.7%**	**8.59%**
Colombia	2.4	2%	6.76%
Chile	1.5	-1.4%	7.14%
C. America	1.8	3.6%	8.15%
Ecuador	1.2	7.1%	8.1%
Peru	1.0	-7.5%	6.66%
Dom. Rep.	0.5	4.7%	6.25%
Uruguay	0.4	8.8%	2.89%
Total LatAm	60.8	14.3%	14.8%

The Economic Elephant in the Room

"We are a country of cycles," explains the president of Lab Richmond, Marcelo Figueiras. "Every ten years we have a crisis. Our current crisis is not as bad as the one in 2001. Its magnitude is manageable." Amid occasional patches of negativity, pessimism, and disgruntlement with current government policy, Figueiras's attitude and optimism for the near future predominate.

Mauro Bono, president and founder of Savant, sees this propensity for volatility as a consequence of an impatient and short-sighted culture. "Usually, our country only plans for the next two or three years, maybe ten when they are intentionally taking a longer view," he explains, "and this isn't enough." Unable to dedicate themselves "to larger goals and acting with the stability necessary to build up to them over longer periods of time," he says that Argentina generally tries "to jump straight to our objectives at full speed, in only a few years." While the country often makes "huge progress for a few years," the eventual result is always "high inflation and economic problems as the costs catch up with the progress."

There is no doubt that inflation is high and there are economic problems at present. Inflation was quoted at 21.4 percent for the period of January through October by the national institute of statistics and census (INDEC), however the official opposition has published estimates for year-end inflation as high as 41.1 percent, a similar level to the 40 percent inflation rate usually quoted for 2002. Both the government and opposition agree however, that the monthly inflation rate has fallen significantly since its peak of 3.6 percent in January 2014, with October estimates ranging from 1.2 to 2.5 percent. Currency controls are also particularly tight at the moment, as the country is struggling to balance payments in the wake of a roughly 35 percent decrease in the price of soy, the country's largest export, although as an exporting industry, the pharmaceutical sector has not been the worst affected. The severity of these issues has been further exacerbated by Argentina's recent technical debt default, the second default in 13 years, which has limited the governments ability to borrow and promoted inflationary spending, and prompted fears that the country is facing a crisis of similar severity to the 1998-2002 "Argentinian Great Depression."

Marcelo Figueiras, president, Laboratorios Richmond

However, as Figueiras explained, this is far from the case. At the height of the last crisis in 2001, unemployment reached 25 percent in 2001, while today it hovers around 7.5 percent according to INDEC, and GDP growth in USD terms has been flat, shrinking half a percent in Q4 2013 and Q1 2014, before growing 0.9 percent in Q2, according to the OECD. In 2001, the national healthcare system collapsed under USD 700 million of debt, while it is still functioning smoothly at present. With the new possibilities for resolution of the sovereign debt situation following the expiration of the RUFUS clause in December 2014, many people are confident that although 2015 may be difficult for businesses, by 2016 the country will enter a new cycle of growth.

Promoting National Policy in a Federal System

In March 2002, amidst an economic crisis and national healthcare emergency the then Minister of Health Gines Gonzales Garcia declared "Argentina's health system is in agony… What is lacking is money, not drugs. Our country has the best pharmaceutical industry in Latin America. The problem is that the state and the medical insurance firms owe the system about one billion pesos (around USD 700 million)." Having extended this massive line of credit to the both public and private insurers who covered millions of Argentine patients, wholesalers and pharmacies eventually had to stop providing medication at the subsidized rates, cutting off access to essential medications. Simultaneously, the public healthcare system itself, composed of individual provincial institutions, struggled to provide basic healthcare services in many regions, and average uninsured patients actually lost access to the universal healthcare to which they were constitutionally entitled.

Five months later, in August 2002, Argentina's federal government started to fight back by passing the Health Emergency Act. Simultaneously, the Ministry of Health created the national **Plan Remediar** to address those patients who had lost access to their medication, and in the process created what is now the largest free drug program in the world. Mauricio Monsalvo, the current national coordinator for Plan Remediar explained that "When this program started, we purchased and supplied 21 different drugs to 2500 health centers, and in 2004 we extended our portfolio to 50 products and worked with 5000 health centers. Currently, we work with 7000 public health centers (primary care) covering the 79 different medications we currently provide." Over the last ten years, Plan Remediar has also developed additional roles, as "today, Remediar finances, procures, stores and distributes these 79 drugs to primary healthcare facilities and public health centers across the country. We are also used as a public logistics operator by a variety of other Ministry of Health programs, so we distribute many more medications than just those that we procure."

In the longer run, the creation of this national free drug program had consequences that were perhaps unforeseen. In Argentina, healthcare is one of the most important political issues across the section, and provincial governments hold strongly to their authority of the public health intuitions that they control. Yet, by providing drugs for free to the system, Plan Remediar developed an instrument of influence over the public health centers, and have since been able to encourage the professionalization of healthcare administration across provincial boundaries. For instance, Plan Remediar has orchestrated an "ambitious training program for inventory management that focuses on the storage of medicines, pharmacovigilance procedures, definition of demands, processing stock shortage conditions, inventory reconciliation procedures, forecasting future demand, and a few other areas. This new health center culture that we are fostering is very innovative for Argentina, as most government departments still don't record what drugs they provide; until recently there was no proper registration of the drugs inside the health centers."

Martin Sabignoso, national coordinator, Sumar/Nacer

Mauricio Monsalvo, national coordinator, Plan Remediar.

Plan Nacer is another program that was founded in the wake of the healthcare emergency that has evolved into an instrument of national healthcare policy. It was founded in 2004, with the initial providing "public health insurance to uninsured pregnant women and children under the age of six," as the national coordinator Martin Sabignoso explains. By providing formal insurance with defined benefits to Argentinian's who were technically already covered by Argentina's "universal healthcare system", Plan Nacer (which was absorbed by Plan Sumar in 2012) sought to improve the quality and accessibility of public health services that were delivered by the pub-

lic health centers. By using "an innovative 'pay for performance' model that provides incentives to the provinces and health care centers to promote better access and quality of health services," Plan Nacer/Sumar was able to establish influence over the public health centers, and the provincial ministries of health that they were usually funded by. The funds the program provides to the public health centers are allocated by their own staff (instead of by the provincial Ministry of Health), empowering them to decide how to best improve their ability to provide healthcare to their patients. Further funding was tied to the actual provision of services, or results, to incentivize the health centers to encourage mothers to enrol themselves and their children in the program.

The program has been astoundingly successful, helping to cut the infant mortality rate from 14.4 to 11.9 per 1000 between 2004 and 2011, and evaluations have shown that the program has succeeded in increasing average birth weight, lowered the probability of very low birth weight babies, reduced early neonatal mortality, and increased Apgar scores. Plan Sumar's success has been audited and lauded by UCLA Berkley and the World Bank, who have publically recognized the success of the program. At the core of this success lies the program's collaborative model and their efforts "to create space to build consensus and harmonize treatment standards, so it is critical that we include the provinces in our planning and prioritization process."

Similarly to Plan Remediar, Plan Sumar also confronted the poor management practices that were holding the public back, although in a much more direct way. Sabignoso states that the program's "main challenge was to develop new management skills, and a more professional management culture at all levels of the public system: national, provincial and facilities level… Our goals are quite demanding and constitute a significant challenge to the status quo, as we require everyone to learn new procedures, operational standards, and a new philosophy, all of which force individuals to work much harder to achieve the same productivity, albeit at a significantly higher quality."

Perhaps most indicative of the impact that the two programs have had is the impact they have had directly on provincial politicians. Sabignoso is proud to say that his organization is now respected as a source of intellectual leadership within the healthcare community, and has had enough success in "shifting the mentality towards public healthcare, [that] now the provincial governments have added the term 'good practices' to their vocabulary and some of their legislation.

Key figures on Programa Sumar and Programa Nacer

1 Programa Sumar has **9 million** beneficiaries who represent **90%** of the program's target population. In total, **11 million** people all over the country have received health coverage from Programa SUMAR and Plan Nacer.

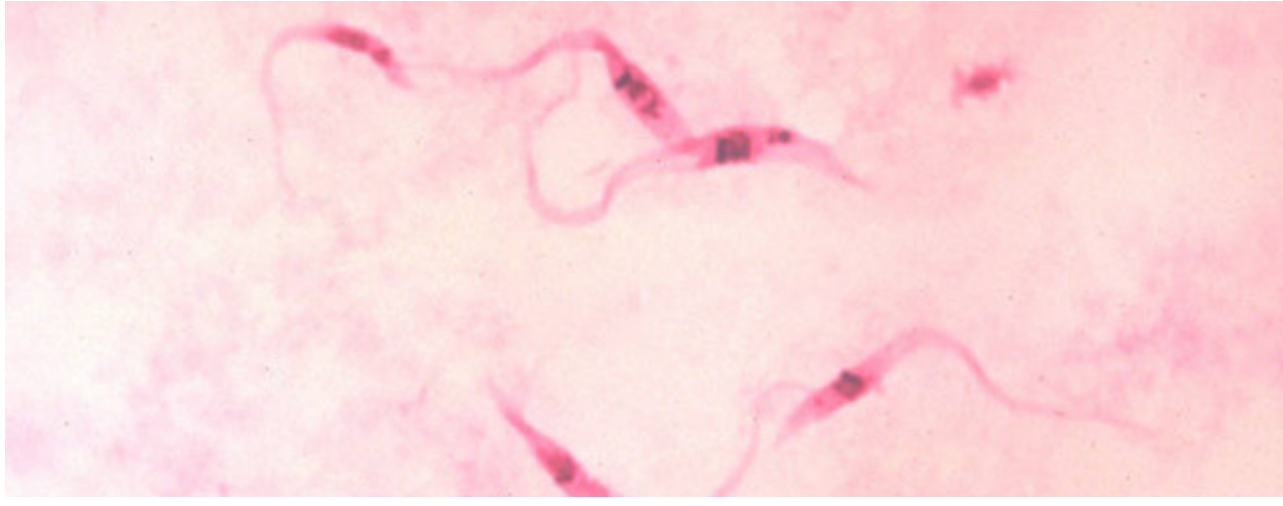
2 The Program has invested over **USD two billion** in the provinces on capitation payments, medical equipment, vehicles and human resources training.

3 The Program has financed about **52 million** healthcare interventions and practices in **7,500** public health centers throughout the country. Additionally, thanks to an improvement in billing systems, **78%** of billing is made on-line, which has become a real-time monitoring network of the levels of effective coverage for each Program beneficiary.

4 Thanks to the coverage offered by Plan Nacer and Programa Sumar more than **5,000** children have received congenital heart disease surgery since 2010, with a reduction in waiting times of **80%** in comparison with 2009, and an improvement in diagnostic opportunity of **46%**. In 2013, Programa Sumar expanded coverage for the full treatment of congenital heart disease for children up to 10 years of age and adolescents between 10 and 19 years of age.

5 The Program is the mandatory health coverage for the beneficiaries of the Universal Child Allowance scheme and the Universal Pregnancy Allowance.

Argentina: Leading the Fight Against Chagas



Chagas disease, caused by the protozoan parasite Trypanosoma cruzi, is a potentially life threatening illness afflicting 8 to 10 million people worldwide. Latin America is home to the vast majority of Chagas patients as the disease is most commonly transmitted through contact with the faeces of triatomine insects, also known as 'kissing bugs', which are endemic to 21 different countries in Latin America. Acute symptoms are often absent or mild, and if left untreated a chronic infection causes cardiac disorders in up to 30 percent of patients, and digestive, neurological or mixed complications. In later years, the parasites progressive destruction of the heart can lead to sudden death or heart failure.

Two treatments exist for Chagas disease, benzidazol and nifurtimox, both with near 100 percent efficacy if administered soon after infection, but diminishing effectiveness as the length of the infection increases. Due to nifurtimox's more severe side effects, benzidazol is the preferred treatment.

In 2003, Roche Pharmaceuticals, the originator and primary manufacturer of benzidazol, transferred the technology to LAFEPE, a Brazilian public laboratory. As awareness and understanding of Chagas disease increased over the following years, demand for the drug drastically increased putting pressure LAFEPE, who lacked adequate support from the Brazilian ministry of health. When stocks of benznidazol that had been produced by Roche prior to the technology transfer expired in November 2010, a long foreseen global shortage began in earnest, leaving thousands of infected patients without any available treatment.

In response, the **Mundo Sano Foundation** and **Chemo Group** developed their own benznidazol formulation with the support of Argentinian public laboratories and the Argentinian ministry of health. **Laboratorio Elea** manufactures the final formulation while Maprimed handles the production of the API, and the product was launched under the name Abarax in 2012. Argentinian scientists participating in two different international forums for tropical diseases in 2012 announced that the product was the product of a public-private partnership, and that the lab would soon be able to begin exporting Abarax to other endemic countries. Today, Elea is the primary producer of benznidazol worldwide, and has developed adult and paediatric dosage forms.

Several other Argentinian laboratories have entered partnerships with the objective of developing a vaccine for the prevention of Chagas disease. In May 2014, the French pharmaceutical giant **Sanofi** has contributed a "chemical library" of 2000 molecules considered to be potential candidates for new Chagas disease treatments to a cultured Trypanosoma cruzi toxicity study being conducted by the Argentinian National Scientific Research Council (**CONICET**). Back in 2007, the Argentinian laboratory Gador announced a partnership with the British firm PepTcell (now SEEK) to develop a T-Cell vaccine for Trypanosoma cruzi.

A CRO South-Spot

Clinical trials are by far the most prevalent pharmaceutical R&D activity in Argentina, and is a major Latin American hub for the multinational CRO industry. "Argentina is well respected when it comes to clinical trials," says Eduardo Neira, country president for AstraZeneca and CAEMe's vice president, explaining "companies like AstraZeneca play an important part in clinical research here because of the quality of the professionals and the research centres we have in Argentina." Alejandro Smolje, finance director for Janssen Latin America South, adds that "because of Argentina's high education level, the excellence of physicians, and world-class research centers, we have been able to truly develop a solid clinical trial structure here. Argentina is one of Janssen's key countries for the organization's R&D strategy."

Research models vary from company to company, with different levels of reliance on CRO resources. "Janssen runs a global clinical operations unit here," says Smolje, one which is lead by their own research team but reliant on outsourcing resources from CROs such as Icon Clinical, and AstraZeneca also has a local "clinical trial organization [that] reports directly to AstraZeneca's clinical research head," according to Neira. Sanofi's local clinical research unit consists "of 250 FDA approved medical sites with over 3,000 patients enrolled in clinical trials," according to general director Patrice Fuster.

Mirroring the global trend of clinical trial outsourcing, the vast majority of clinical trials are carried out by the major multinational CROs, who all have relatively large offices in Buenos Aires. "If you look at the development of clinical research in Latin America, Argentina has always been a leader," says Pablo Hammerschmidt, senior director of clinical trial management for Icon Clinical Latin America. Hammerschmidt continues, saying "the market is significantly more evolved here in the sense that there are more sites that have been developed specifically for clinical research, a good supply of well trained and experienced staff, as well as the proper processes and infrastructure in place. Another aspect is the size and accessibility of patient populations, which can be recruited effectively through the public health system, and the level of regulatory oversight and inspections has always assured that trials are conducted properly and safely." All of these factors, coupled with relatively low costs, contribute to Argentina's attractive clinical trial environment.

Pablo Hammerschmidt, senior director of clinical trial management for Icon Clinical Latin America

Wanda Dobrzanski, president of the Argentinian chamber of clinical research organizations (CAOIC)

However, Argentina currently has some competitive disadvantages as well; as Wanda Dobrzanski, president of the Argentinian chamber of clinical research organizations (CAOIC), explains "the [start-up] timeline compared to other markets is slower and less predictable than in some other markets, and we haven't seen any improvements recently. This is preventing us from competing effectively with other countries in the region." Hammerschmit adds that "we cannot contribute much to preliminary or early results because of this," but he hopes that an "initiative underway between ANMAT and the industry to develop and launch an electronic submission system," will improve the situation.

The other distinguishing feature of the Argentinian clinical trial market, as explained by Hammerschmidt, is "better patient retention, which is another strength of Argentina; in general, clinical trial patients stay enrolled longer on average than in other countries." Both he and Dobrzanski agree that Argentina has an excellent medical training system that develops high quality doctors that patients trust, and this trust has a large influence over a patient's decision to enrol, and remain, in a trial. As a result of these two factors, Argentina is most competitive in long-term studies, where "having higher patient retention rates is particularly valuable," as Hammerschmidt explains. "Argentina is a strong participant in such studies," he continues, sometimes enrolling more than 50 percent of all patients recruited in Latin America for particularly long-term studies.

A regulatory expert : Gerardo Daskal, Technical Director of Isophar

Could you please introduce Isophar to our readers?

Our mission is to cover the regulatory compliance needs of the pharmaceutical industry that they are willing to outsource. We help many companies by ensuring that their short term investments will not go to waste because they "didn't know" about the new legislations and policy trends; in short, we want to anticipate those trends so that companies can make investments that will help their businesses succeed in the long run.

Gerardo Daskal, technical director of Isophar

When we started, we only offered services in only one of the areas that we currently work within, validations. As we gained experience, we branched out into facility design and clean room design, which are now our main areas of operation.

What would assess as Argentina's relative strengths and weaknesses in terms of technical capabilities?

I would say the industry's strength lies in the people and experience that make up the industry, as well as the specific technologies that we have developed in biotech. For instance, we also excel in helping to develop newer biotech industries in other areas of the world through partnerships and technology transfers, and the recent flourishing of biotech businesses operating API incubators can give us a better picture about the level of expertise that we have attained.

In terms of areas of development, I see statistical tools as our greatest weakness; we also need to bolster our engineering and technical areas. These process aren't necessarily "bad" but the tools and infrastructure can certainly be improved.

Ing. Lopez was just made the new administrator of ANMAT; what do you think he will bring to the regulatory environment, and how will Isophar respond?

I knew engineer Lopez a few years ago, he's from San Juan, he was the director of a company called Productos Médicos (Medical Products); he helped local manufacturers and businessmen to develop and transform local businesses, helping to drive the expansion of the national pharmaceutical industry. He has political notions for many technical and scientific areas.

ISOPHAR also has a political vision in addition to its purely technical vision; we'd like to see a new law that would require locally manufactured pharmaceutical products, molecular pharmaceutics and APIs to be registered and approved in Argentina, regardless of where they are to be sold.

Indian Companies in Argentina: Trade Winds

Perhaps the most significant regulatory change of 2014 in the Argentinian pharmaceutical market took place in August, when **India was added to the list of now 27 countries from which final dosage form pharmaceutical products can be imported to Argentina**. While the import of APIs from India was previously allowed, the importation of Indian pharmaceutical products was not permitted. Given the price-competitiveness of many Indian manufacturers, and the open interest of several large Indian manufacturers, such as Pharmexcil, Glenmark, Torrent and Cadila, it seems likely that this policy change will result in a significant change to the structure of the Argentinian market. Of course the challenge for these companies, even those with established businesses in other Latin American countries, will be to build brand recognition in Argentina's pure-branded generic market.

Glenmark Pharma was the only Indian company with an established presence in Argentina prior to this change in policy, as the affiliate has an EMA certified (FDA pending) plant and "serves as the hub for development, manufacture and distribution of injectable oncology drugs for the entire organization," according to the country manager, Carlos Grzelak. As a local producer, Glenmark was beginning to participate in the local market prior to the policy change, and had some modest sales of their injectable oncology products. Grzelak explained that since his assignment to Argentina in January 2014, his main responsibility has been "to develop the local sales and marketing operations and expand the portfolio to take advantage of the potential in the Argentinian market," something that will certainly be facilitated by his affiliates new ability to supplement their portfolio with products imported from India.

Carlos Grzelak, general manager, Glenmark Argentina

Given the unique features of the Argentinian market, namely the importance placed on brands, the strong local industry, and the resulting low participation of non-branded generic products, it seems likely that the Indian competition will find it difficult to build market share in Argentina. However, if their significantly lower prices do prove be attractive to patients, pharmacists, physicians, or public institutions, this minor policy change could result in major changes to the Argentinian pharmaceutical market.

Savant - Argentine Rising Star

Mauro Bono is the man with the plan. Since Bono and his partners founded Savant in 1993, they have shown the Argentinian industry that it is "possible to build a successful pharmaceutical company from the interior of the interior," something quite noteworthy in Buenos Aires centric Argentina; it is widely said across the country that while god may exist everywhere, he only answers in Buenos Aires.

Mauro Bono, president, Savant

More recently, the lab has begun to make waves with their ambitious export strategy and aggressive investment plans. Starting in 2011, Savant began construction on a new, more advanced facility that has doubled the firm's production capacity, and includes the only Argentinian owned soft gel plant in the country, as well as new corporate headquarters and commercial offices in Buenos Aires. The firm has had remarkable success in financing the expansion, managing to raise amounts in the region of AR$ 30 to 40 million several times through promissory note issuances, which have often been oversubscribed due to the firms strong balance sheet and A+ debt certification from Evaluadora Latinoamericana.

The firms current five year plan, Bono explains, "is to quadruple our business in the next five years," while reaching "20 percent of revenue in exports by 2020," a large step from the firms current exports which lie between 10 and 15 percent. To achieve this aggressive growth, the firm is rationalizing its various product lines and brands under the master brand Savant, developing a new commercialization model for their relatively young prescription business, and developing their export business in markets outside of Latin America such as Vietnam.

Leadership in Regulatory affairs

In addition to the country's regional leadership in terms of quality of healthcare, patient access to innovative medications, and rare diseases, Argentina's food and drug regulatory agency ANMAT is a regional leader in several respects. "Since its creation in 1992, ANMAT has performed activities intended for the regulation, monitoring and control of health products and has consolidated and positioned itself as a national and international reference authority since it inception," says the former national administrator Carlos Chiale, adding that ANMAT was one for the first five countries to be designated as a Reference National Authority for drugs by the Pan American Health Organization. As such, several other Latin American countries have looked to Argentina's ANMAT as a model for the development of their own regulatory institutions in the past.

Carlos Chiale, national administrator, ANMAT

At present, the organization is continuing this legacy of leadership as a full member of the Pharmaceutical Inspection Cooperation Scheme (PICS) since 2008, promoting GMP development and implementation across the region. ANMAT has also taken a leadership role in fighting drug counterfeiting and tractability systems, and has recently helped Colombia and Ecuador to develop and implement their own tractability systems. Furthermore, Chiale notes "Argentina hosted the first reference authorities forum on drug traceability in 2013, in which authorities from the US, Turkey, the United Kingdom and the European Union took part," and will chair the WTO group for international collaboration on strategies against counterfeit drugs.

As new challenges and trends confront the world, ANMAT is likely to continue take on new issues, leading the response of a portion of Latin America. At the very least, Argentina's excellent market access will ensure that ANMAT is forced to find regulatory solutions for radically new biopharmaceutical products before other administrations in the region.

Manufacturing Technological Standards

Daniel Juncal, CEO - BAS&IS

PharmaBoardroom: **How advanced are the most advanced Argentinian systems relative to the "leading edge" of automation technology?**

DANIEL JUNCAL: Several years ago I had the opportunity to visit a few plants in the U.S., and while I was impressed by the size of many of the plants and systems, I didn't see any operations or capabilities that were beyond the level of complexity seen in Argentina. We use the same hardware, software and sensors, so the sophistication of the systems here is very similar. There were some differences in terms of design and applications, primarily because Argentinian's like to have dedicated or unique systems for some processes, and the activities of the pharmaceutical industry here are different and don't include as much R&D activity.

PBR: **What are some of the solutions and methods of navigating the Argentinian macroeconomic environment?**

DANIEL JUNCAL: For many firms, focusing on exports can be a good method of reducing your exposure to the Argentinian economy, however for us this option is somewhat limited. Exporting products is not an option for us, however we are able to sell our services sometimes in other countries where our suppliers don't have existing partners. A much more important strategy for us is to have future cash flows secured by service contracts and long-term relationships. This way, there is a relatively stable predictable portion of our business that we can rely upon even when we have no customers investing in new automation systems, because even in adverse economic times it is cheaper to maintain systems and equipment properly than it is to repair they stop working correctly.

The most challenging aspect for us is the import restrictions as it makes it difficult for us to provide certain delivery dates to our clients. A few months ago this put us in a difficult situation as our client needed their system up and running by September 30th and a few weeks ahead of that date we didn't have the needed equipment. Luckily, we were able to use a Siemens industrial system that Siemens Argentina had in stock and we were able to use it; in the end, this presented us with an opportunity because this was the experience that prompted us to become certified as Siemens Industrial integrators.

Medtech in Argentina

Relative to the innovation friendly and marketing heavy pharmaceutical industry in Argentina, the market for medical devices is somewhat less developed. While Argentina ranks as the fourth largest pharmaceutical market in Latin America, it comes in at fifth place for medical devices, and according to Ricardo Sanchez Moreno, the regional director for Medtronic in the south cone, "the rate of medical device implantations per million is still well below the number of implant done in the US or Europe in every category."

Sanchez explains that "at present, there is good coverage in the cardiac stimulation and interventional cardiology areas, and we are starting to see good coverage of transcatheter aortic valves," indicating by omission that coverage of some of Medtronic's products in the spinal, neurological and diabetes are reimbursed less consistently by the public health system.

Knowledge of medical devices is similarly spotty among physicians, according to Sanchez, while "there is a core group of physicians who follow advancements in the industry extremely closely and are well aware of new technology developments and product launches," there is also "apparent that we still have a lot of work to do in this regard as low awareness is one of the factors which contributes to the lower penetration rate of some therapies in Argentina compared to more developed markets." However, Sanchez does emphasize that "all of our minimally invasive surgical technologies have been extremely well accepted here in Argentina," something he attitudes to the "open-minded and innovative mindset" of Argentinian surgeons that is in part a legacy of the innovative spirit that lead René Favaloro and Julio Palmaz to invest the bypass surgery and coronary stent respectively.

Ricardo Sanchez, General Manager, Medtronic Argentina

Nova Argentia on Growth & Castling

While many multinationals have been quick to defend their commitment to the Argentinian market during this period of economic turbulence, a few others, the Italian laboratory Menarini among them, have decided that maintaining a local affiliate is no longer a sustainable strategy. Over the summer of 2014, Menarini finalized their decision to close their Argentinian affiliate and began the process of licensing out their products to local companies. According to pharmabiz.com, the first package of products that were licensed out had previously generated up to USD 8.3 million in previous years, and ten-year commercial licenses were awarded to the highest bidder. Several labs showed interest in these licenses, including Elea, Bagó, Craveri, and Spedrog Caillon, however in the end it was Roemmers that won the competition over the summer of 2014, and as a result Roemmers's Rofina will be taking over the distribution of these products from Disprofarma.

Esteban Echenique
general manager
Argentia

In August, Esteban Echenique, the general manager of Nova Argentia, a part of the Roemmers group of companies, announced that Argentia "will soon incorporate Menarini's products into our portfolio." Having recently "started to develop some other lines like gastroenterology [and] pain," several of Menarini's products, such at the anti-inflamatory Enantyum, will support the firm's broader goal of expanding into areas beyond antibiotics and cardiology. Overall, Echenique is "very positive and confident when I think about future" he explains, primarily because "Argentia has many good products with almost no market share: there is a lot to develop and plenty of space within the market to grow." Furthermore, Echenique highlighted the fact that "in the 70s Argentia was in the top five in the market," although by the time Roemmers bought it in 2005 it had fallen to 40th place; today the firm is "25th in value and 20th in volume," and Echenique's "goal is to bring back Argentia to the top ten companies in Argentina."

Unfortunately for Echenique, he will likely have to accomplish this feat without further licenses from Menarini. According to Fransisco Cervo, general manager of Elea, Menarini has indicated "that they would like to license some other products to us in the near future," and several other firms have indicated continuing interest.

PHARMA BOARDROOM

Bagó's Blueprint

PharmaBoardroom: **2014 marks the 80th anniversary of Laboratorios Bagó, a company founded by your grandfather and developed by your father and uncle. The company is a market leader in Argentina but also in Latin America, and its products are present in 47 countries. How did Laboratorios Bagó perform in 2013 and what is the outlook for 2014?**

JUAN PABLO BAGÓ: Laboratorios Bagó was born in Argentina and it has grown along with the country. Since its foundation in 1934, it has been permanently committed to its vision: to build a state-of-the art pharmaceutical company and to achieve excellence in healthcare. In Argentina we have three companies, Bagó, Montpellier and Bioprofarma. Laboratorios Bagó is ranked second in the market while Montpellier is holding position number six. On top of that, Bagó group also partly owns Nutricia Bagó, Disprofarma - our own logistics company - and several other non-pharma companies.

2013 has been an outstanding year for Bagó in all 47 countries, spanning America, Africa, Asia and Europe, where we develop and sell pharmaceutical products. Argentina's performance, however, has been affected by the country's current economic distress Although our company's dependence on Argentinean revenue has been, and still is, decreasing, it accounts for about 45 percent of our turnover today. Therefore, we are putting in place some initiatives to try to minimize future macro economic impacts.

For several years, the price of pharmaceutical products in Argentina has been lagging behind the increase of prices of everything else (raw materials, salaries, etc). With inflation rate in Argentina of around 25 to 27 percent per year, prices of medicines have only increased by an average 14 percent per year.

On the other hand, in Latin America and in the rest of the world where we are exporting today, the outlook for 2014 looks very bright, specifically in terms of growth and profitability.

PBR: **The bulk of international revenues come from Latin America where you also have several production facilities. Should we expect to see more international development in the coming years, and what would be your target markets?**

JUAN PABLO BAGÓ: Bagó's intention and prediction is still to work and to operate thinking that our future growth should come from the Latin American markets. There are three countries in which we have the potential to grow even better than in other areas, which have been consistently high: first comes Brazil, where

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Juan Pablo Bagó, GENERAL DIRECTOR PHARMA ARGENTINA - BAGÓ GROUP

our performance has been incredible in terms of profitability, but there is still huge room for improvement; second is Colombia, which is the same as Brazil; and third is Venezuela, a market which we are not present today. Venezuela is the only market in Latin America where we donít sell any kind of products. Here, although we are not planning to enter in the short-term, at some point in the future, in our strategic plan, Venezuela is a country to cover.

Last but not least, briefly speaking about our manufacturing plants, we have in Mexico, Chile and Argentina our main manufacturing facilities which are mainly the source of production for most of the markets on which we are present.

PBR: **What are the trends that will shape the local pharmaceutical market in the coming years and how is Laboratorios Bagó preparing for this?**

JUAN PABLO BAGÓ: In the next six to ten years, the environment of the Argentinian pharmaceutical industry, isolating all the macroeconomic issues, will very closely follow the pharma evolution happening today in developed countries. What we expect to see is a decrease in the importance of the massive prescription market, mainly due to the fact that the source of new innovative products is drying up in big traditional markets. New products arenít coming up except in particular areas like neurology, some products for Alzheimer's and diabetes. What we are seeing today is that in many important categories like hypertension or pain, no innovation will come. In a way, there is very little push to add value. It is quite simple and logical: when companies cannot innovate more, the competitive variable becomes price.

The growth of the industry will therefore come from other market segments. One of them is the OTC segment. Compared to other Latin American markets, Argentina has a very small share of OTC products. This will increase on an annual basis. The current market situation is not due to regulation, only that very few companies are currently focused on the OTC market. Laboratorios Bagó already has an OTC line, and today we are investing more than ever in this type of products. Considering the price situation in Argentina today, investing in OTC products may not look like the best strategy but again, crises in Argentina are always transitory and in the near future OTC will be definitely one of our leading lines in the Argentinian pharma market.

The current market situation is not due to regulation, only that very few companies are currently focused on the OTC market. Laboratorios Bagó already has an OTC line, and today we are investing more than ever in this type of products.

The second and most important growth area will be speciality products: products aimed a targeting unmet medical needs substantially suffered by small populations. This is the market segment that has been growing the most and it will keep on growing in the future, driven by innovation. Obviously, this will pose a challenge to the payers as these are expensive products. Laboratorios Bagó, thanks to its strong financial skill, has been able to be focus on speciality products during the last six to seven years. Our group considers this segment as a crucial avenue of growth.

PHARMA BOARDROOM

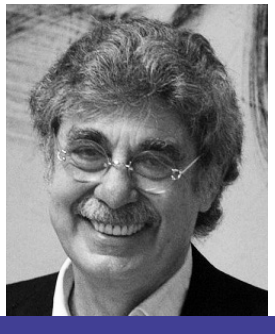
Consolidating Biosimilar Leadership

CHEMO

PharmaBoardroom: **Could you give to our readers a brief overview of the group's activity in pharma today?**

HUGO SIGMAN: Chemo operates across the entire pharmaceutical value chain, delivering specialized expertise and experience in scientific research, development, manufacturing, sales and marketing of a wide range of active pharmaceutical ingredients (APIs), finished dosage forms (FDFs) and branded pharmaceuticals, both for human and animal health in all major therapeutics (cardiovascular, gastroenterology, central nervous system, anti-infective, respiratory, women's healthcare and ocular healthcare).

The pharmaceutical business, still the largest of the group, has three areas: the generic area knows like Chemo who works B2B activity; the Exeltis line of products, with its own brand and a commercial and sales organization present in 46 countries, and the biotechnology arm mAbxience, specializing in research, development and production of biosimilars and the discovery of new products for the treatment of cancer. The active pharmaceutical ingredients of mAbxience are manufactured at the pharmADN plant, specialized in biotechnology.



Hugo Sigman, CEO - GRUPO INSUD

In Argentina, Grupo Insud is a partner in Elea Laboratories, which has over 70 years of experience in pharmaceutical research and production, in Biogénesis Bagó, which runs a world-class facility for foot-and-mouth vaccine production, and in Sinergium Biotech, a pharmaceutical company focusing on research, development, production and distribution of highly complex immunization and biotechnology products. At Sinergium Biotech's last-generation plant, mAbxience performs the formulation and fill and finish operations of the biotech products manufactured at pharmADN, in an exclusive facility that is compliant with the highest international standards and good manufacturing practices (GMPs).

Chemo's activity is organized in three synergistic business areas: industrial, branded and biotech, with over 5,000 professionals in more than 44 countries, across four continents, ten state-of-the-art manufacturing facilities, nine specialized R&D centers, 12 commercial offices and 33 pharmaceutical affiliates, serving 1,150 customers in 96 countries around the world.

PBR: **Your latest move was the acquisition of a biopharmaceutical company in Spain, Genhelix, by mAbxience in June 2014. What will this acquisition bring to the group and how important will biosimilars become for the future of Insud?**

HUGO SIGMAN: The acquisition of Genhelix is very important news in terms of consolidating mAbxience as a biosimilar leader in Spain, and it will allow us to move forward in our strategy for manufacturing products that meet the highest quality standards and for obtaining significant cost savings. Our aim is to expand our manufacturing capacities in other geographical areas through a plant that will enable us to strengthen our market opportunities in Europe and Asia. Thanks to the technology used, we can considerably increase productivity as well as reduce manufacturing costs, which in

turn may lead to EUR 1.5 billion in savings through the use of biosimilars that the authorities are hoping for between now and 2020.

With the incorporation of Genhelix, the Chemo group is strengthening its global presence in Spain, where it already had commercial offices in Barcelona and Madrid, R&D centers in Azuqueca de Henares and León, and manufacturing plants in Alcalá de Henares, Azuqueca de Henares and León. This represents its first industrial presence in Spain in the area of biosimilars.

The problem with biological products is the price, which is often prohibitive for the majority of the population. Today, a new biological product costs between USD 60,000 per year per treatment to USD 200,000 per year and per treatment. Biosimilars could help to dramatically reduce the cost of these treatments.

PBR: **A recent milestone was the decision to launch flu vaccine production in Argentina with the creation of the Synergium Biotech consortium, which entails a full technology transfer from Novartis. You were invited to speak to the UN about this new approach of collaboration between big pharma, the state and private interests. How has this experience been?**

HUGO SIGMAN: The experience with Novartis wasn't easy in the beginning, but progress today is very smooth and cooperative. At the end of the day, Novartis sent many people to inspect our factory and they were absolutely surprised at our quality standards. On top of that, some of our people will train at Novartis headquarters for some months. Furthermore, we are also partnering with Pfizer. We are extremely glad to have working experience with European and American multinational giants.

What is the room and future for a midsize group like Insud in today's world and how can the company compete with both big pharma and upcoming competitors from countries like China that are receiving huge financial, scientific and political support from their government?

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Our future is brighter than ever! I personally think that today we still have good opportunities in biotech, despite very aggressive competition from countries like China: I actually believe there will be plenty of opportunities for our company in these countries.

Public Research Supporting Private Development

CONICET TRANSFERENCIA TECNOLÓGICA

PharmaBoardroom: **Could you please explain to our readers the main activities that have been put in place by your technology transfer office?**

SANTIAGO VILLA (SV): The first CONICET office was created in 1958; however, its work has changed so drastically over time that CONICET today is nothing compared to what it was like back then. Today, CONICET strives to provide concrete solutions and answers to meet the scientific and technological needs of Argentina, and the world at large. Under the umbrella of CONICET, the main areas of focus of the technology transfer office are patents, agreements, on-site research, advisory services within the public and private sectors, start-ups and joint ventures, and high-level technology services. CONICET is Argentina's leading scientific and technology research institution.

MARIANA BERENSTEIN (MB): We created an entire department for "technology offer" open to companies so that they can come and ask for anything that they might need from patented technologies, know-how, infrastructure, high technology services, etc. They can take a patent or they can ask for support in a particular area, or solutions to an issue that they might be having. Furthermore, our operational processes are standardized, but our services are highly personalized.

PBR: **What is the structure of CONICET?**

SV: CONICET is divided into 13 different scientific and technology centers—what we call CCTs—and two multidisciplinary research centers. These regional centers, or offices, enable decentralization and the direct management of 192 research centers and institutes. It is interesting to note that 90 percent of all CONICET centers are managed jointly with national universities, which greatly encourages postgraduate learning.

PBR: **What is your assessment of patent protection in Argentina?**

SV: It is standard in relation to the level of technology patents. If you go to the Supreme Court, you will not find more than 50 cases in the last twenty years. Having said this, everything here reaches the Supreme Court, unlike in the US. In Argentina, we do not have many IP problems, interferences, infringement trials, etc. so I cannot give an accurate assessment based on these few cases that have reached the Supreme Court. It is also important to note that Argentina is more interested in exporting our knowledge. Argentina is an important market for certain areas of technology, but it is not important for every area. We are always looking to export our knowledge abroad—to Europe, the US, and Asia for example.

After organizing several different trade missions, what is your opinion when it comes to assessing the level of what Argentinean companies are providing in places like China and Singapore?

SV: Generally speaking, we have good feedback from these markets. It is tricky because in truly important markets like China, the problem is not our capabilities, products and services, but rather the amount and scale that need to be fulfilled.

Santiago Villa, GENERAL MANAGER OF TECHNOLOGY TRANSFER OFFICE AT CONICET
Mariana Berestein, GENERAL COORDINATOR OF TECHNOLOGY TRANSFER OFFICE AT CONICET

PBR: **What are the key indicators to ensure the success of the technology transfer office?**

SV: The problem is that we have many different models here. Every year-end we have a different key indicator, but what remains important for us is to have continuously clear processes and transparency. It is important for us not only to maintain efficiency, but also transparency. That is a key indicator for us. Every area of our office is now under a standardized process, we have set rules for everyone and everything to follow.

Another indicator would be our number of agreements. It is really an indicator of activity and something that we focus highly on. For the future, we will put more effort into acquiring more international partners and increasing international activity.

PBR: **What is your strategy for increasing the number of international partners?**

SV: In order to focus more on business development and international partners, Conicet has recently taken the strategic decision to create a new Managing unit for strategic technology projects so that we can coordinate efforts on selected or more advanced projects in activities that, today, further exceed the capabilities and mission of the OTT. In other words, we would work on a small structure with high impact. One of the key indicators in the future would be the success, or not, of this strategy.

PBR: **What is lacking in Argentina that would foster more innovation and technology in the country?**

SV: You have to build the basis of negotiation with people who are willing to do that. So, for example, new management in companies—more flexible, younger managers—would be one way to accomplish this. At the end of the day, the most important change has to come from the mindset of people; it has to be a cultural movement. Another aspect would be a change in law and taxation; it does not necessarily always have to come from the businesses themselves.

We created an entire department for "technology offer" open to companies so that they can come and ask for anything that they might need from patented technologies, know-how, infrastructure, high technology services, etc.

A New Day For Orphans

PharmaBoardroom: **Is the Argentinian system able to reliably diagnose and treat rare diseases?**

GABRIELA PITTIS: Argentina passed a law in June 2011 that is still being implemented, which explicitly requires the private and social insurance organizations to provide support for rare disease treatment, and which created a central committee, which includes patients as members, to coordinate activities such as neonatal screening and patient registries. There is a phenomenon unique to rare diseases, which is that through Internet research and participation in patient associations, the patients quickly come to know far more about their condition than most of their physicians, health management organizations, and regulatory authorities, and as a result many patient organizations are working with authorities to determine what an ideal rare disease treatment system would look like. For real progress in this field, meaning better solutions for the patients foremost, all of the stakeholders must collaborate and share their experience and expertise in the issues. Here at Shire, we invest a lot in medical education to play our part in informing physicians so that the diagnosis process can move more quickly, which is of course better for the patient, but also important for the healthcare system so that expenses related to hospitalizations, symptomatic treatment, and fruitless diagnostic tests.

PBR: **How would you describe the progress in this area?**

GABRIELA PITTIS: There certainly is progress, but it is slow. The perceived speed changes depending on your perspective, so from a regulatory or governmental position things are probably moving at a reasonable pace, but at Shire we always try to put ourselves in the patientsí shoes since they have the most interest in the healthcare systemís treatment and things move much more slowly when you are the one affected by the disease. That said, the progress in Argentina is moving more quickly than in many other countries in the region, and current treatment standards are very high, so in this regard the Argentinian healthcare system is evolving and innovating strongly.

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Gabriela Pittis, SOUTH CONE GENERAL MANAGER - SHIRE

PBR: **Major milestones since you joined in 2007?**

GABRIELA PITTIS: Changing our commercialization model from a patient-by-patient system to full-scale local commercialization was very significant. Shire made material investments in people and capital here, and as a result we are able to maintain strong relationships with local insurers, regulatory authorities, physicians and patients. This permanent presence is very important, as it allows us to increase access to treatment for currently undiagnosed or untreated patients through educational outreach and ongoing dialogues with the other local stakeholders.

PBR: **Could you give us an overview of Shireís R&D activity in the Argentina?**

GABRIELA PITTIS: Our R&D activity in Argentina is limited to clinical research, as our NME investigation is centralized mainly in the USA, but we have been running clinical trials here for several years. Currently, we are running trials for four different drugs. The regulatory environment here is very good for clinical trials as the regulations are very clear, the standards are very high, and the infrastructure is very high quality and comparable to facilities in the U.S. and Europe. The approval process for new biological products is predictable if somewhat slow at times, usually 12-18 months, although there have been occasional delays due to evolving approval standards, and there is no fast track option in Argentina like there is in some other countries, such as Chile.

Perito Moreno Glacier

Global Top Dog's Local Strategy

PharmaBoardroom: **How have Pfizer's goals for Argentina changed over the last few years, and what is your strategy for moving forward?**

EDGARDO VAZQUEZ: Since we divided our business into three global business units, instead of having one core strategy, we now have several local strategies. Each group has their own priorities, and in the case of the innovative products and oncology group, the strategy is to take advantage of the healthcare system, which is quite strong and is able to provide innovation to patients quickly and efficiently. In the last 24 months we were able to launch five different products for very specific types of diseases: Axitinib for advanced renal cell carcinoma, and Crizotinib for lung cancer, Tofacitinib for rheumatoid arthritis, Apixaban to reduce the risk of stroke & blood clots in people who have atrial fibrillation and Tafamidis for the treatment of Transthyretin Familial Amyloid Polyneuropathy. The comments weíve received from patients for many of these drugs have been extremely enthusiastic, including of course some cases where theyíve gone from expecting to die within a matter of months to being told they have a year or two, or even three or five years of life remaining. For some patients, our products are a dream come true, and this is something that the Argentinean pharmaceutical market should be very proud of: that we are able to bring innovation to patients and give them years of life that they otherwise would not have. At the same time, we have a responsibility to control our appetite for profits and work to support and protect the healthcare system.

The strategy for our established products group is quite different. In this area, we are focusing on providing Pfizer's typical high level of quality in certain therapeutic areas and maximizing the tools offered to the physician, at a very competitive price. When inflation is taken into consideration, many of the products in this division are priced more competitively than they have ever been, something that is necessary in this market due to the surfeit of good quality generic medications.

In the case of vaccines, our strategy of working with a local company to supply our innovative vaccines to the National Immunization Program (NiP) of the Ministry of Health has been very successful. We were very lucky to find a partner in Grupo Insud and Laboratorio Elea that was willing to invest a significant sum to build a plant, and completed construction in a year and a half. This has allowed us to move a portion of our production to Argentina, and now Argentinean physicians are vaccinating Argentinean children with vaccines made in Argentina, achieving the expected results in terms of prevention. Thanks to this agreement, Argentina becomes the only country in Latin America, and one of the few in the world, that has the ability to develop this vaccine.

PBR: **Since we were last in Argentina, Pfizer has made some noteworthy investments in the country. Could you please give us an overview of how these resources have been used?**

EDGARDO VAZQUEZ: We have made some significant investments in our manufacturing division in the last five years, totalling USD 27 million that

Edgardo Vazquez, COUNTRY MANAGER - PFIZER ARGENTINA REGION

were used primarily to increase our capacity so that we can keep up with the increasing market volume. We also made a larger investment in our R&D division, nearly USD 60 million over the last five years. This has been spent primarily on some Phase II and III clinical trials for a few of our innovative products. When you include the expenditures we made setting up our new offices here in Buenos Aires, weíve invested nearly USD 100 million in our Argentinean business over the last five years.

Part of the USD 27 million was used to refurbish our manufacturing plant, which had originally been built by a local company, which we bought as part of the Pharmacia acquisition in 2003. Itís a mid-sized site that has a reasonable degree of flexibility, and after spending a few years producing a wider variety of products, we realized it would be far more profitable to limit its production to a few specific areas; now a few areas has become just tablets. The plant is now capable of producing up to 1.6 billion tablets per year in medium sized lots and we have been producing about 800 million a year on average for the last few years, even more when we win contracts from the public Plan Remediar, which has given us quite a lot of volume. The rest of the investments in manufacturing were for in quality control and packaging. We spent USD 5 million building an advanced laboratory with some specialized equipment for testing for biological products, as there are not many labs capable of performing this type of analysis. Last year our new fully automated packaging line was opened, which has given us enough capacity on that side for the foreseeable future.

As for our R&D investments, they have primarily gone towards independent research reports. We were in need of some better research and data regarding the Argentinean market in general, to aid our decision-making process and to satisfy a few investors who had come to us with requests for detailed information on Argentina that we didnít have. Some clinical trials were performed in Argentina for a few speciality products that Pfizer has under development, which are all within the six therapeutic areas that Pfizer is focusing on globally; vaccines, central nervous system, cancer, rheumatoid arthritis, cardiovascular and rare diseases. Argentina is a very competitive market for R&D in terms of physician quality, physician cost, regulatory burdens, research costs and patient cost. In fact, the country is ranked high internally by Pfizer, and as such we have made a concerted effort to develop our R&D capabilities here in the country.

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PHARMA BOARDROOM

The IP Quest, and Shaping the Clinical Trials Agenda

PharmaBoardroom: **Worldwide, AstraZeneca holds seventh position in the rankings while here in Argentina it is not in the top ten. Could you explain us why don't we see AstraZeneca in the top ten, and what is your positioning in the Argentinean market today?**

EDUARDO NEIRA: AstraZeneca currently holds 19th position in Argentina. Why aren't we in the top ten? This is mainly explained because of the lack of patent protection. In a lot of countries where you have relatively new products in the top 20 best-selling products, here in Argentina you have products that have more than 25 years in the top 20. This is more a consumer-driven market that pays more interest to brands rather than new molecules. New molecules are easily copied by companies, which at the end requires an extra effort for MNCs like us. Products in the top ten in other markets have as many as 15 to 20 copies here in Argentina. The market here is very fragmented, with a large number of players ñ and for companies that base their sales on copies, it is a very attractive market. Nevertheless, I am honoured to say that there are also plenty of molecules that have been investigated and developed by AstraZeneca here.

PBR: **How is AstraZeneca deepening its footprint in Argentina outside of sales and marketing?**

EDUARDO NEIRA: As I mentioned before, AstraZeneca has a top quality manufacturing site outside Buenos Aires called Haedo manufacturing plant, 23km far away from our office in the capital. At that manufacturing site we currently produce many injectables and everything related to the anaesthesia line, being leaders in that segment. On top of this, we produce different types of ointments and creams, and do all the local packaging for all our products. Moreover, we manufacture certain products via a third party, using local manufacturing facilities.

PBR: **What do you think about Argentina's potential to become a regional hub for clinical studies?**

EDUARDO NEIRA: Argentina is well respected when it comes to clinical trials. Companies like AstraZeneca play an important part in clinical research here because of the quality of the professionals and the research centers we have in Argentina. Our scientist excellency is part of our signature. At the end of the day, we do a lot of work at our clinical research site, with products either at Phase II or Phase III. These and other initiatives have helped Argentina gain this reputation as an outstanding clinical research hub.

It is important to mention that our clinical trial organization here reports directly to AstraZeneca's clinical research head. They are currently involved, as I mentioned, in Phase II and Phase III trials for products that will be launched in 2016-2020. We have a devoted team working very hard on that.

PBR: **If you had the chance to spend five minutes with the Minister of Health, Dr. Manzur, what would you tell him as the country president of AstraZeneca Argentina?**

EDUARDO NEIRA: To benefit the country we have to improve our patent protection system, as our patent protection model is very weak. Although some-

Eduardo Neira, COUNTRY PRESIDENT - ASTRAZENECA ARGENTINA - SOUTH CONE

times it looks the MNCs want to patent everything, this is absolutely not true. The government has to consider and promote better patent protection conditions, given the huge amount of money that we are investing to enhance patient health with new treatments and new molecules.

On the other hand, this government has been doing a lot in order to repatriate scientists and is working very hard to enhance investigation in Argentina. Moreover, the government has been able to deliver an incredibly good and aggressive vaccines calendar, the best in all Latin America. In several senses, they are doing an outstanding job but when it comes to the MNCs, they are not giving the chance to the companies that are investing in Argentina and creating things. For instance, some investigators have to go to the US in order to be able to get patent protection to their inventions that are refused in Argentina, which, at the end of the day, is against the interests of the country, not just international players like us. The government has an important backlog and it is almost not granting patents at all.

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Operation site of AstraZeneca in Haedo


AstraZeneca's offices

PHARMA BOARDROOM

Smart Drug Nanocarriers

ERIOCHEM S.A.

PharmaBoardroom: **Today, Eriochem is a vertically integrated company producing both APIs and final dosage forms; when you started the company, what was the strategy you followed to develop the business into what it is today?**

ANTONIO BOUZADA: In the year 2000, Eriochem was founded and it launched its first product. Our name reflects our initial purpose, as Eriochem is an amalgamation of the words Entre Rios Chemical, and from the beginning we produced both APIs and finished dosage forms. As a small company, we had to use our limited resources efficiently and develop the more critical products first, and at the beginning APIs were often more important than finished dosage forms; we had a small API plant that started producing vinorelbine, and later on oxaliplatin and then melphalan. In 2004 the FDA approved this API plant for the production of vinorelbine, and later the other APIs were approved.

After a few years, this pattern changed and we began to focus more on developing our finished dosage forms. Even though this was our long-term plan, when the APIs prices started to fall rapidly in the mid 2000s, we decided to accelerate our plan and to begin working more on the finished dosage forms. After that, we limited development of new compounds to those that were of strategic importance to our firm, such as the polymer that we use for our microcapsulation process.

PBR: **Eriochem is already selling products in around 49 countries; what's the next stage in your geographical expansion strategy?**

ANTONIO BOUZADA: Our export strategy has three stages. First, we entered the relatively accessible markets, in terms of regulations and territory/culture. Of course, that meant most of Latin America first, with several larger south east Asian countries (Indonesia, Philippines and Thailand) coming next. The second stage was the European market, where we introduced our first finished dosage product in 2010.

Stage three, which we are working on at the moment, is the US. This initiative is well underway as our main pharmaceuticals plant was approved by FDA just a few weeks ago; our plan is to begin by introducing our simple generics first, followed by our super generic products in a few years. In fact, our plant is the first Argentinian firm to be approved by the FDA for the production of injectable products.

PBR: **Could you elaborate on your strategy for your generics and supergenerics business?**

ANTONIO BOUZADA: One of our reasons for moving more aggressively towards final dosage forms was that we had developed some specialized skills and capabilities of particular value in that business. These capabilities include our lyophilisation techniques, cold-chain production infrastructure, and eventually our patented microcapsulation process that allows the production of sustained release injectable products. Using these techniques, we are able to develop 'super-

Antonio Bouzada, PRESIDENT AND FOUNDER – ERIOCHEM

generic' products, or generics that include some incrementally innovative features or delivery mechanisms.

Our finished dosage form strategy somewhat reflects our legal background to some extent, and relies upon these specialized skills. Generally, the generic industry operates within a box in which no one begins working on a particular product until the originators patent begins near its expiry date, and as a consequence companies tend to look only at those patents which are close to expire for possible opportunities. Our goal at Eriochem is to find patents that we can bypass by applying or developing a new technology to a patented compound so we can get a few years ahead of the generic competition and be the first company to launch a generic version. Thus, we are continuously searching for opportunities and we keep an eye on relevant pharmaceutical patent challenges.

Our first product, which is an example of what been mentioned above, is the lyophilized docetaxel that was filed for registration with EMA in 2009. Unfortunately, Teva was able to get the patent cancelled in 2011, at least three years before its original expiry date, opening up docetaxel to the entire generics industry so we didn't benefit from our privileged market position for as long as we had hoped.

PBR: **I understand you are collaborating with Amega Biotech and National University of Litoral to develop "smart nanocarriers". Could you tell us a bit about this project?**

ANTONIO BOUZADA: The project involves developing a lipid nanocarrier for cytostatics, such as docetaxel. This carrier will be an analog to human low-density lipoprotein, and can enter cells through endocytosis via LDL receptors. As malignant cells reproduce rapidly, they need and absorb much more cholesterol than healthy tissue to build new cell walls, to the extent that certain malignancies over-express receptor cell surface densities by more than 100 times. By attaching a cytostatic to an LDL analogue, direct absorption by malignant cells is dramatically increased, and contact between the cytostatic drug and healthy cells is decreased, lowering their secondary effects. Currently, there is no pharmaceutical product on the market that uses this cellular receptor, the specific enzymatic pathway that our research-subject uses to disassemble the lipid nanoparticle and the active drug intracellularly. Thus, this project represents a radically new treatment option for malignant cancers, and is patentable internationally. This nano/biotechnology could also be used as a platform for other drugs and other diseases related with higher r-LDL surface densities.

Thus, this project represents a radically new treatment option for malignant cancers, and is patentable internationally. This nano/biotechnology could also be used as a platform for other drugs and other diseases related with higher r-LDL surface densities.

So far the progress and results have been very positive; some of our tests have shown that this new delivery platform increases "in vivo" the activity of the docetaxel significantly. The great thing is that the finished product is very small, about 40 nanometers in diameter, and have the specific protein for transitosis via LDL receptor across the blood brain barrier. The most exciting part is that this isn't just only a product, but a platform for drug delivery. However, this is the first stage of the research, not a product development; that it is many years away. We also have several other research sub-projects and ideas tied to this platform, that are in their starting phases or that we are waiting to begin.

Breaking Biotech

AMEGAbiotech

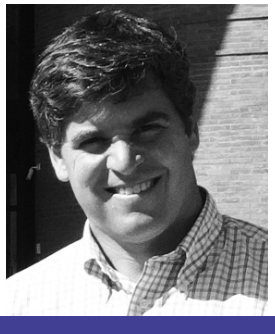
PharmaBoardroom: **How would you describe the current state of the Argentinian biotech sector, and the changes that is it undergoing?**

FRANCISCO MOLINARI: 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 arenít 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 ìrules of the gameî 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.

PBR: **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?**

FRANCISCO MOLINARI: 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



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.

Francisco Molinari, CEO - AMEGA BIOTECH

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 wonít stop being contenders any time soon. A lot of the current competition is starting to fall away and these are the ìvirtual biotech companiesî, 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.

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

FRANCISCO MOLINARI: 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. Iím 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.

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On Finding Growth While Margins Shrink

Deloitte.

PharmaBoardroom: **With the current inflationary pressures to reduce costs, why should firms continue to hire Deloitte as a consultant?**

DANIEL VARDE: Pharmaceutical companies are facing some very significant pressures at the moment as the ministry of economy controls the prices of their products, and at the same time, prices have risen by more than 35 percent since the beginning of the year. Surviving in this environment has forced companies to overhaul their strategy, so that they can effectively reduce costs, or at least limit their growth, without losing revenue. At the same time, it is critical for companies to grow their revenues by launching new products and developing more exports, so there are R&D, registration, and marketing costs that cannot be cut and in some instances need to be increased in the short term. While a company could attempt to do their own analysis in-house, Deloitte has extensive experience in this regard and is able to analyze and prioritize different options for cost minimization and business development much more efficiently and accurately than our clients can themselves.

However, it is important to realize that despite the current issues, Argentina is still a very attractive pharmaceutical market for pharmaceutical companies, and is quite large with over USD 6.3 billion in sales according to IMS. Furthermore, prices are quite high relative to other countries, and as such pharmaceutical companies have enjoyed healthy profit margins in the past, and while they have been shrinking, they are still reasonable.

PBR: **Which global healthcare trends are visible in Argentina, and what are some of the trends unique to Latin America?**

DANIEL VARDE: The Argentinian market is unique in the sense that many multinationals have a much weaker presence here than they do in other similarly sized companies; Sanofi for example is the highest grossing pharmaceutical firm in Latin America, but only ranks 23rd in Argentina according to IMS. This is largely because we have some very relevant and significant local players such as Roemmers, Bagó, Elea, Gador and others, and in fact, local firms collectively have a 55 percent share of the pharmaceutical market. Local firms have about 90 percent of the medical supply market, and 100 percent of the health insurance market, and this large domestic industry insulates us from the global market to some extent.

However, we are obviously affected by global trends, and the primary impact is the rising cost of healthcare. There are a few different components to this, and the aging population with increasing healthcare needs is the first among them. The second is the evolution of the pharmaceutical industry itself, the movement from traditional pharmaceuticals to more innovative fields, meaning biotechnology for the most part, that has been seen at the global level for several years. Argentina developed its pharmaceutical and healthcare industry around generic

Daniel Varde, HEALTHCARE AND LIFE SCIENCE - DELOITTE LATIN AMERICA

companies, and was able to produce most 'typical' medications and treatments domestically while importing some innovative products; as the 'typical' treatment has become more advanced, we have had to import an increasing proportion of innovative products and APIs, which has of course increased healthcare costs. The 'biotech trend' itself has begun in Argentina, with companies such as Biosidus and Dr. Sigmanís Grupo Chemo leading the charge, and it is possible that we will catch up a bit in terms of healthcare costs in future years. Furthermore, we've always had to import medical technologies (sometimes used or not the latest technology) as we donít have much productive capacity in this field.

Argentina is huge geographically, but the market is very different from the others. The biggest challenge is financial, as the provincial governments donít have enough money to adequately fund their respective public healthcare systems. To compensate, there have been a number of different cost saving programs, such as Plan Sumar and Plan Remediar implemented at the national level. Plan Sumar aims to reduce long-term costs by improving healthcare services and preventative measures, while Plan Remediar and PAMI, the social security healthcare provider, reduce costs through bulk purchases if RX products at the national level.

PBR: **What lessons has Deloitte Argentina learned from the challenging business environment here, that Deloitte could benefit from globally?**

DANIEL VARDE: In Argentina, it is especially difficult to replicate strategy that is successful in other countries. Strategies can't be simply localized, meaning implemented and slightly adjusted, as they can in many countries, and instead must be significantly altered or even replaced to be successful here. The dynamics here are different and often seem counter intuitive to outsiders, and as such what works elsewhere doesnít here, and sometimes what works well here will not work elsewhere. So this is my advice; try to understand the local environment, what the currents and dynamics are, and develop strategies and solutions from this frame of reference. Understanding the environment well enough as an outsider can be very difficult, and thus it is usually advisable make use of local managerial talent.

Surviving in this environment has forced companies to overhaul their strategy, so that they can effectively reduce costs, or at least limit their growth, without losing revenue. At the same time, it is critical for companies to grow their revenues by launching new products and developing more exports, so there are R&D, registration, and marketing costs that cannot be cut and in some instances need to be increased in the short term.

A Well-Endowed Partner

PharmaBoardroom: **Since 2009, Elea has advanced from fifth to third place in the Argentinian pharmaceutical market. What have been the key tactics that have lead to this success?**

FRANCISCO CERVO: The first important event was the acquisition of a product line from Merck, as the deal included 140 sales reps and more than 20 brands, covering approximately 190 products. Once the deal was signed, there was the challenge of integrating the two businesses, as well as the two work forces, as the Merck and Elea business cultures varied significantly. With respect to our portfolio, some of these products helped us to build and strengthen our position as the first ranked company in gynaecology, and helped us to establish a strong presence in the diabetes market. Since diabetes is the fastest growing disease in Argentina, at 35 percent per annum, acquiring some of these global brands from Merck was very significant because now several of them are some of our best selling products out of our 400 different brands, with Glucophage ranking in our top 20 brands.

Since 2009, we have substantially increased the size of our sales force and now we have the largest sales force in the country with nearly 300 reps. We have also had several very successful product launches in our OTC line, and built a strong ophthalmologic line through acquisition and we are now the third largest player in the Argentinian ophthalmology market. In fact, Elea is currently ranked number one in the ënew productsí category by IMS.

PBR: **Why is Elea the partner of choice for multinational pharmaceutical firms, and how successful has this business area been for Elea in the last five years?**

FRANCISCO CERVO: Multinational companies often want to launch products in countries like Argentina, but lack the sales force to properly market the products. Since only the top five or six firms have sufficiently large sales teams, there are only a few competitors for this business that we must contend with overall, across all therapeutic areas. As I mentioned before, we have the largest sales force in the country with 300 reps covering every region in Argentina, from Tierra del Fuego to the Bolivian border, and are also 50 percent owners of Disprofarma, the largest pharmaceutical distributor in Argentina.

Most of the business we get is in areas that we already have a strong portfolio in, and as such we have part-

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Francisco Cervo, GENERAL MANAGER - ELEA

nership agreements with Pfizer for some gynaecology products, Novartis for a few vaccines, and others; in total, we have licenses from six of the top ten global pharma companies, and we are always looking for more such opportunities. We recently were in negotiations with Menarini to acquire their Argentinian portfolio as they have closed their local office, and while these brands went to Roemmers in the end, Menarini has told us that they would like to license some other products to us in the near future.

PBR: **What does your current pipeline look like overall, and what direction would you like to take with new projects?**

FRANCISCO CERVO: Overall, we are managing to invest about 10 percent of our revenue in R&D, which is being mostly focused biosimilar drugs, in the oncology, rheumatoid arthritis and ophthalmology areas. The other big category is OTC products, as we are currently the second largest OTC manufacturer in Argentina.

Another field that holds a lot of potential is the insulin market, as currently there are only a few big insulin producers worldwide, and in Argentina the only players are Novo Nordisk, Sanofi, and Eli Lilly. We are currently investing in developing a new plant for insulin production in Argentina, and we hope that in a year and a half we will be starting to build a strong position in Argentina, and the rest of Latin America

There is a phenomenon unique to rare diseases, which is that through Internet research and participation in patient associations, the patients quickly come to know far more about their condition than most of their physicians, health management organizations, and regulatory authorities, and as a result many patient organizations are working with authorities to determine what an ideal rare disease treatment system would look like.


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