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The Nth disappearance of the bullet man, by Juan Ranieri, 2006. Courtesy of Gador.

ARGENTINA: Crisis Brings Opportunity

Boasting three Nobel Prize winners from the life sciences, Argentina has had a long history of innovation. Immigration from Europe at the end of the 19th century saw the genesis of many of the national pharmaceutical companies that today control over 53% of the market. Access to highly qualified and ample scientific human resources provide the fuel for the fire of growth that is currently being experienced by both national laboratories and multinational corporations alike. Realising the potential of this fast moving and rapidly evolving industry, both the public and private sectors are working towards establishing Argentina's reputation as a country capable of producing more than just fine wines and excellent steaks.

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Argentina Report

Argentina faced a devastating economic crisis at the start of the decade, which saw sales in the pharmaceutical sector drop by as much as 26% between 2001-2002. This crisis in many ways shaped the current face of the country's pharmaceutical industry, as many of the multinational companies present in the country scaled back their operations. The larger national companies took advantage of this situation, buying up internationally certified manufacturing facilities that were being hastily sold off by the MNCs. This goes some way to explaining today's dominance of the market by local companies: 71% of Argentinean pharmaceutical production now takes place in national laboratories.

More Argentinean than ever, the country's pharmaceutical industry is now at the turning point of its internationalization strategy, looking to become a producer and exporter of national drugs across both mature and emerging economies. However, in order to achieve this ambitious goal, drugmakers are having to fight preconceptions about the country, sedimented during decades of political instability.

Today, the ranks of research-oriented national laboratories are swelled by a growing number of laboratories that are looking to research as a way to develop niche areas, and distinguish themselves from their competition. Dr Eduardo Franciosi, Executive Director of CILFA (the Association of National Argentinean pharmaceutical companies), explains "our strategic plan builds upon four main pillars to stimulate investment in machinery, new industrial plants, develop export markets and increase investment in R&D. Its aim is to organize the industry and align all our efforts, focusing on the future growth of the sector. This sets future targets, gives visibility for companies to take decisions, and establishes a growth path."

As part of its strategic plan, CILFA identified key strategic export markets for the sector: Latin America, South-East Asia, North Africa and Eastern Europe. Argentine exports have doubled in the last four years, totalling in \$656 million in 2008. Dr Fran-



Ruth Ladenheim,
Ministry of Science
and Technology

ciosi predicts a 15-20% annual export growth rate, and has an export target of \$800 million by 2012, according to CILFA's strategic plan. Helping the national laboratories achieve this ambitious aim is Fundacion Export.Ar, a public-private organisation whose role is to connect the policy decisions of the Ministry of Foreign Affairs with the practicalities of increasing export markets at both a sector and company level. For the pharmaceutical industry, this means commercial intelligence and organising international promotional events.

These plans are the logical conclusion of a wider trend pursued by the Argentinean government in recent years, to lead the country towards a more innovative, value-added economy, less reliant on the traditional staple of primary goods.

In 2007, the Ministry of Science, Technology and Productive Innovation was created, and a well-respected Argentinean scientist and academic, Dr. Lino Barañao, was installed as its first leader. Dr Ruth Ladenheim, Secretary of Planning and Policy at the ministry, explains that the aim was "to better articulate policies for the purpose of using science, technology and innovation as engines of economic development in Argentina." Dr Ladenheim explains that one of the largest responsibilities of the ministry is to help foster the links between basic research and industry. "The various support schemes we have in place encourage universities and research institutions to make joint ventures with companies. This policy has led to a variety of developments, from helping researchers to gain international patents, all the way through to the direct incorporation of research units into businesses."

More than \$150 million USD per year is invested in R&D in Argentina. Ernesto Felicio, Executive Director of CAEME, the Argentinean association for research-based pharmaceutical companies, explains the importance of the investment in what is known as the 'industry without chimneys': "this annual investment implies the hiring of highly qualified staff, as well as the effective and



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Investación para la salud

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clear transfer of technology, which will act as a platform for future generations of Argentinean investigators.” Mr Felicio added that in Argentina, for every 1% increase in investment in R&D, there is a 1.5% increase in the country’s employment rate.

Notwithstanding the level of and desire to invest and export, the pharmaceutical industry is faced by new regulatory restrictions. One of the problems holding the industry back is the slow regulatory timelines administered by Argentina’s National Food, Drugs, and Medical Technology Agency (ANMAT), and patent approvals through the National Institute of Industrial Property (INPI). Created in 1992 with a guiding hand from the US FDA, ANMAT was considered one of the most thorough, knowledgeable and comprehensive in Latin America, and was used as a template for the later creation of ANVISA in Brazil. Fifteen years later, the backlog has been blamed on Argentina’s acceptance as a PICS (Pharmaceutical Inspection Cooperation Scheme) member in 2008 - the first Latin American country to receive this certification. However, the agency has recognised this slowdown as a challenge, and is taking steps to regain ANMAT’s previous reputation by addressing these industry complaints.

With the introduction of Intellectual Property laws in 2002, and the increase in the level of regulation, the government is hoping to both stabilize the regulatory environment in order to attract foreign investment, and move the innovative national industries more in line with international standards. Although prices in Argentina are not officially regulated, there is currently an unofficial system in place, where prices are re-adjusted three times a year in consultation with the various pharmaceutical associations. It is unclear whether this system will be replaced with official pricing regulation or abolished in the years to come.



Top: Ernesto Felicio,
Executive Director,
CAEME



Below: Dr Eduardo Franciosi,
Executive Director,
CILFA

The state-run health system in Argentina is meant to provide access for the whole population, but a parallel system of pre-paid HMOs also exists, making the pharmaceutical sector highly fragmented and complex. Pharmaceutical companies sell to both state-run and private hospitals, and a vast array of small to medium sized regional pharmacies that are supplied through a chain of wholesalers and distributors. This complexity is exacerbated by the fact that whilst Argentina is the 8th largest country in the world geographically, its population is only 40 million, mainly to be found in cities spread across the country. Most of Argentina’s pharmaceutical production takes place in the Buenos Aires region, although there are some laboratories to be found in other areas of the country.

The national industry works very closely with the Argentinean HMOs in order to overcome the challenges of distribution and access in such a vast country. “We cannot leave aside the role the national industry had in securing access to quality medicines at affordable prices for the population. We play a vital role in providing medicines to the main Healthcare Plans, especially to the IOMA and PAMI. The PAMI gathers 4 million retired Argentines, who buy and need medicines throughout the entire territory of our country. This requires an extensive logistics network, a commercial and financial structure, and a vision of securing access and better use of our medicines,” says Dr Franciosi.

Despite its complicated nature, Argentina’s pharmaceutical industry manages surprisingly well, breeding a class of manager that can cope with intricate and dynamic environments. Market growth was 21.6% between 2007-8 up to \$3.2bn USD, and despite the world economic slowdown, growth of 2.5 - 3.5% is expected for 2009. With such a positive prognosis, the country is ripe for venturing overseas.

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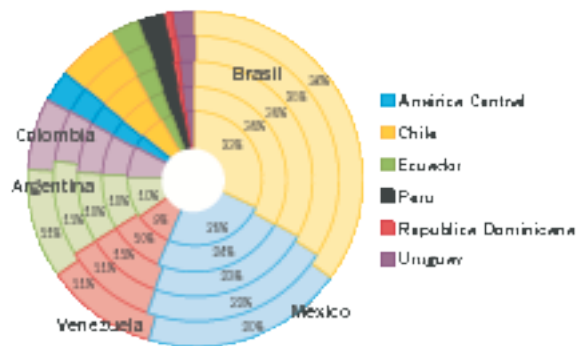
ARGENTINA'S MARKET: From Patagonia To The Pampas

For a market the size of Argentina, this outward-looking approach makes a lot of sense. With a population of 40 million, Argentina is much smaller than the other major Latin American pharmaceutical markets of Brazil and Mexico, with 191 million and 111 million inhabitants respectively. Whilst the large



Left: Javier Lombar, General Manager, IMS Health Argentina Right: Federico Wintour, Managing Director Southern Cone Region, MSD

population size in these countries demands that a lot of production is inward-facing, Argentina is perfectly positioned, both in terms of size and geographically, to serve as a production and administration gateway to the smaller countries of Latin Ameri-



The Latin American Market in Units, 2004 - 2008 Source: abeceb.com

ca: Paraguay, Uruguay, Chile, Bolivia, and Peru. As Javier Lombar, General Manager of IMS Health Argentina explains, "Multinationals tend to take a very large view when it comes to their operations in Latin America, and so one manager can be in charge of the whole region, not just a country. Brazil and Mexico are both fairly autonomous, but when it comes to the rest of Latin America, you need to think in terms of the region, not just particular countries."

Having had a presence in Argentina country for 55 years, MSD decided recently to make Argentina the centre of operations for the Southern Cone of South America. Federico Wintour, head of this new region, predicts that the recent acquisition of Schering Plough will position Merck as the pharmaceutical leader in Latin America, given that the company is able to access even the smaller markets in the region using this regional approach.

Shaking Off Former Prejudices

After decades marked by struggle with military dictatorship, a defeat in the Falklands war, and severe economic difficulties, Argentinean companies have a lot of work ahead to build a reputation abroad beyond the country's extraordinary tennis players and tango dancers. Silvia Macchiavello, President of Temis Lostaló, says that the changing nature of the political and economic situation in Argentina has made establishing such a name internationally very difficult, but that the pharmaceutical sector is one industry that has worked very hard to change this paradigm. Her sister Lucila, Vice President of the company, explains how companies such as Temis Lostaló have achieved this "by being constant, always having the best quality, and keeping our word. Keeping promises is the only way for a company to become credible in another market: more than any other contract. It is also important to foster long-term relationships, both for our partners and for our company."

After satisfying demand in the local market, Argentinean companies are looking to explore foreign markets. National companies

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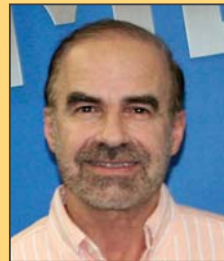
Nycomed's executive management recently stated that "the tremendous growth of the pharmaceutical industry will not occur in either Europe or the United States, but in emerging economies such as Latin America." The company hopes to use the strategies that have proved so successful in Argentina across the region, securing future growth and development.

Luis Ricciardulli is Regional Manager for the Latin American region, and hopes to expand Nycomed's regional platform through a series of long-term investments. Ricciardulli explains how the company has flourished in Argentina through developing fast decision-making processes, and how these lessons are being employed across the region: "Nycomed has an advantage in this market by being a very lean company. Communication is very open between the regional offices and the key decision-makers, which helps the company take advantage of opportunities."

Learning from the national Argentinean companies, Nycomed has been capitalizing on the success of specific products in the market by introducing line extensions, which today forms a key element of Ricciardulli's Argentinean strategy, profiting from products such as Hepatalgina, one of the country's best-recognized OTC brands. By using such tactics, Mr Ricciardulli expects that Nycomed grow faster than the market for at least the next three years.

By working in Argentina, managers learn about the correct way to handle markets with a high level of volatility and change. "Argentina is a great school for managers," notes Ricciardulli, "because we are forced to become creative. You have to pay attention to so many things here."

Argentina has proved to be a great success story for Nycomed: now they are looking to extend their Latin American achievements through continued commitment to Argentina, and with large investments in countries such as Mexico and Venezuela.



Luis Ricciardulli,
Regional Manager
LATAM, Nycomed



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seem to be split into two rough categories: there are the companies that are looking to gain access to the highly developed markets of Europe and the US, such as Eriochem, Amega Biotech and Sidus, and companies like Rommers, Bagó and Phoenix, who are looking towards other emerging countries. Many Argentine companies, following the strategic plan of CILFA as well as their own tactics, have selected markets in South East Asia, North Africa and Eastern Europe as the most promising regions for success.

Carlos Mayotti, Commercial Director of Phoenix, currently ranked 8th in Argentina, adds that reputation is also crucial in obtaining licenses and partnerships with international companies. Phoenix has succeeded in entering new therapeutic areas such as cardiology and neurology, building on their excellent business in respiratory disease, by licensing and co-marketing products from third parties, and then building their own product lines around these internationally respected brands. Mayotti explains, "This type of reputation is not easy to maintain, especially for an Argentinean company, that has had to deal with the extra challenge of economic instability throughout its history." Evidence for the efficacy of this strategy can be seen in the fact that today, cardiology is Phoenix's most successful line.

However, for Phoenix, achieving respectability to work with



Left: Silvia Macchiavello, President, Temis Lostalo
Center: Lucila Macchiavello, Vice President, Temis Lostalo
Right: Carlos Mayotti, Commercial Director, Phoenix

partners such as Pfizer has always come through building a solid position in the home market: "Phoenix's most important business will always be done in the local market, where the company is known for providing high quality scientific services." Phoenix has achieved this standing through a dedicated, highly trained sales force, and looking for ways to compete at the highest levels of quality production. The acquisition of the Novartis manufacturing plant in 2003 is a prime example of how the company has achieved this. Mayotti explains that the acquisition "has allowed the company to stay at the cutting edge of manufacturing technology and international GMP."

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“Argentina is at the forefront of countries in Latin America for clinical research in terms of training, hospitals, human resources and enthusiasm, which is critical, and has been the key for the region in many ways,” explains Dr Victor Molina-Viamonte, Latin America’s Senior Medical Director for Omnicare Clinical Research, Inc. and President of CAOIC, Argentina’s CRO association.

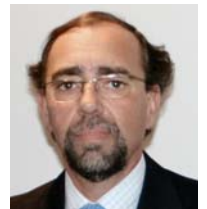
Alluding to the problems that have been recently faced by

Destination	2007\$	2008\$	Variation%	Total %
Brazil	64.1m	80.9m	26.2%	17.9%
Venezuela	36.8m	48.9m	32.9%	10.8%
Uruguay	39.4m	43.7m	10.9%	9.7%
Canada	34.5m	40.4m	17.1%	8.9%
Colombia	23.9m	28.5m	19.3%	6.3%
Chile	26.4m	24.9m	-5.5%	5.5%
Mexico	18.7m	21.7m	15.9%	4.8%
Paraguay	14.6m	18.5m	26.8%	4.1%
Panama	15.6m	17.4m	17.4%	4.1%
Peru	14.3m	16.9m	18.3%	3.7%

Top Ten Argentinean Pharmaceutical Export Destinations
Source: abeceb.com

those looking to carry out clinical research in Argentina, such as slow regulatory timelines, Osvaldo de la Fuente, General Director of Roche Argentina, explains the importance of Argentina for Roche’s R&D network: “Our country has a great potential for clinical trials because of the excellent professional level, the patient’s characteristics, and the fact that research is done with the same quality standards as in Europe or the USA. We are optimistic that the approval times will improve in Argentina and the region, in order to conduct processes in the same time frame as Europe or USA.” Roche Argentina’s R&D department has grown from one person to 35 over the last four years, indicating that these slow regulatory timelines have not discouraged the company from investing in clinical research in Argentina. The direct and indirect pharmaceutical labour force stands today at 27,000 and 100,000 employees, respectively.

Above: Phoenix manufacturing facility
Right: Dr Victor Molina-Viamonte, President, CAOIC and Osvaldo de la Fuente, General Manager, Roche Argentina



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Although the slow regulatory timelines in Argentina are usually compensated for by very quick patient registration times, Dr Molina-Viamonte believes that the industry needs to work together to improve the regulatory situation in the country: "To some extent, clinical research is being threatened in the country by ideology, politics and ignorance... What the CRO industry needs is regulatory officials who fully understand their job, who have received sufficient training, and have a reasonable attitude, in order to help CROs do a job that is very important for the country." Through the CAOIC, this is being resolved through cooperation at a provincial, regional and national level, and all parties are optimistic of a change for the better in the near future.

INTEGRATE AND CONQUER: Cooperation And Co-marketing

For many MNCs, the market influence that they enjoy in other countries is elusive in Argentina, due to the dominance of the national laboratories. Novartis has bucked this trend by making integration with national companies a



Left: Jim Harold, CPO President and Country Head, Novartis Argentina
Right: Raul Massone, President, Massone

priority. Jim Harold, CPO Head and Country President of Novartis Argentina, explains that Novartis sold their plant to Phoenix, with whom they now have a manufacturing agreement. This partnership has worked very well, and now the company manufactures only niche products in Argentina for global distribution, as dictated by global trends. Sandoz, a company that now comes under the Novartis umbrella, has really taken advantage of Argentinean production: "Where exportation is more of a focus is at Sandoz, where we have a state-of-the-art plant for oncology products. Argentina is the worldwide production site for some of Sandoz's key oncology products. Three years ago, the plant was the first to be approved by the FDA for the exportation of oncology products to the USA. As a group, we're very proud of that." says Harold.

Mr Harold believes that one of Novartis' most successful strategies in Argentina has been to work together with the



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national companies in order to better integrate into the market. “Where Novartis Argentina has slight differences to Novartis Worldwide is the way we relate to the national companies. We currently have a number of marketing agreements with different national companies. These range from exclusive marketing deals to co-marketing. For example, we have a co-marketing agreement with Montpellier, a division of Bagó, for Galvus, Novartis’ oral diabetic that was launched at the end of 2008. This means that we have two brands of the same drug in the market, and gives us an additional voice in the market that only a national company can provide.” Mr Harold sees this as an important element of brand strategy in a country like Argentina, where, because of the number of branded product copies on the market, partnering with a large national company is an important tactic to be considered, and a way to succeed despite the idiosyncrasies of the Argentinean market.

Partnering strategies do not just help MNCs to gain market share, but can also help national companies to reach export levels that would not be possible otherwise. Massone is a local company that has also found partnering to be an indispensable part of their strategy. Massone is a very niche company: their sole product is Gonadotropin, and as one of the very few companies in the world that manufacture this infertility treatment, they have been able to export the product globally: today, 95% of Massone’s production is exported. This accomplishment has been made possible by a very productive partnership with Ferring, who distribute Massone’s product worldwide. Raul Massone, President and son of the founder of the laboratory, explained that the company had initially had an unsuccessful partnership with an Italian company, but that the new partnership had turned his fortunes around: in 2001, he was able to buy back the shares and become the sole owner of Instituto Massone. “Although our past experience working with a sole company was not successful, this relationship is excellent. Massone realizes that only one company is needed: the right company,” Massone retorts.

Looking for More Nobel Prizes

Argentina prides itself in having had the first Spanish-speaking scientist to ever receive the Nobel Prize in Chemistry in 1970, Luis Federico Leloir. Over 30 years later, his legacy is finally being understood by all relevant stakeholders and the possibilities resonate in the ears of the pharmaceutical business community.

The Argentinean government has recently begun undertaking efforts to link businesses with Argentina’s famed research institutions, for mutual profit. Pfizer Argentina recently announced that it would be collaborating with the Leloir Institute on research into Parkinson’s disease. Jesús Loreto, Pfizer’s General Manager in Argentina, explains the reasoning behind this collaboration was “to work on something that might be commercially successful: obtain the patents, get funding, and generate more money to invest in other research areas. That’s something that Pfizer believes in, and other multinationals are now following our lead.”



Far right: Instituto Leloir

Above left: Jesus Loreto, General Manager, Pfizer Argentina,

Above center: Fernando Pitossi, Treasurer, Instituto Leloir,

Above right: Abel Guillermo Di Gilio, Business Director, Elea

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The fact that Pfizer was the first multinational company to engage in this type of PPP will doubtless improve their frequency in the years to come. Fernando Pitossi, Treasurer of the Leloir Institute and project leader of the collaboration with Pfizer, explains that it has not only opened the minds of big pharma, but also researchers who may have been reluctant to enter into projects with large companies: "The partnership has broken preconceptions. Pfizer is a huge multinational pharmaceutical company, and the Leloir Institute is based in Argentina, a developing country. Although the institute is renowned, the scale of our two operations is completely different. The alliance has helped to change the vision of how possible it is to interact with a multinational company without being hurt in any sense."

He also explains how much this collaboration has started to change the nature of the pharmaceutical industry in Argentina: "As a result of this alliance becoming public knowledge, the national pharmaceutical companies are looking at research, and also talking with multinationals, discussing possible synergies and partnerships. The national companies tend to do most of their research in-house, and when they want new skills and resources they would rather buy a company than collaborate. This is beginning to change, because when research reaches a certain scale, companies need to collaborate. This is true even for companies like Pfizer."

Elea is a national company that is investigating other forms of PPP available in Argentina, and capitalizing on them to great effect. The company has an agreement with CIPEIN, an army-related institution, in order to research and develop solutions for lice. As a result of the collaboration, Elea today has 70% of the market in this area. Abel Guillermo Di Gilio, Business Director of Elea, tells us "Elea would not be able to proceed at various stages of research without these partnerships. We provide both scientific and economic support for the progress of these researches." These high levels of scientific dedication have showed in other areas of Elea's achievements, and combined with the rest of their business model, have allowed them to reach very high levels of growth and product release: "Elea's strategic planning, focus, and targeting is very sophisticated; it's the only way that a company could have fifty products in promotion like we have at the moment."

The Common Good

The presence of multinational pharma companies in a developing market like Argentina does not only serve to bring innovation into the country and service previously unmet medical needs, but can also provide vital help when a country needs it most. This was shown during the Argentine economic crisis at the turn of the decade, when Novartis was inundated with requests for pharmaceutical donations. It set up a programme called Novartis Comunidad, in collaboration with two NGOs, Caritas and Tzedaká, in order to ensure that the sections of the

population that were the most at risk during the crisis were provided free access to the medicines they needed. Although the crisis is now over, the programme still exists, and complements a range of projects that Novartis Argentina has undertaken in the community.

Another way in which companies here are helping the community and their business alike is through setting up educational programs. This is the case of Novo Nordisk, which is acutely aware of the diagnosis problem related to diabetes in Latin America. Although 70% of the company's sales in Argentina come from diabetes, 50% of sufferers remain undiagnosed. Flavio Devoto, General Manager of Novo Nordisk in Argentina, explains that the company is involved in numerous projects



Above: Basic research at the instituto Leloir

Flavio Devoto, General Manager, Novo Nordisk Argentina



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dedicated to the education of patients, physicians and the general population about diabetes, hoping to increase diagnosis rates. Some of these projects have been suggested by employees within the affiliate; indeed, the company encourages all who work there to participate in the development of the business: perhaps one of the reasons that it was declared the 'best place to work' in Argentina last year, and has been in the top ten of the list for the last six years.

Education definitely helps companies like Novo Nordisk to gain market share in developing countries like Argentina, but within such a niche it is equally, if not more important to have high quality products. "In the diabetes market, both patients and doctors want to have products with very high quality, and very good delivery devices. This is important, because in the insulin market, it is not simply about drugs, also having good devices in order to ensure that the patient follows the treatment. Good compliance rates is one reason why Novo Nordisk is the market leader here in Argentina," explains Devoto.

Staying On Track Pays Off



Alejandro Serafino,
Finance and
Administration
Manager, Poen

As in many countries, Argentina's top producers are the laboratories that produce in high volumes in many therapeutic areas. As a result, many laboratories in the country have had to find niche therapeutic areas in order to compete, with their own brand of speciality products. Poen is an excellent example of a company that has succeeded in a niche segment of the Argentinean market. Dedicated to the production of ophthalmologic products for over 80 years, the company today enjoys a 27% market share, placing it second in the rankings of ophthalmologic

units sold. By concentrating on the local market initially, Poen was able to release between four and five products a year. Alejandro Serafino, Administration and Finance Manager, explains that "today, Poen has a broad product line, complete and updated, covering all known diseases in ophthalmology." This strategy of concentrating on a niche

Critical Mass For Critical Therapies

Baxter's progress in Argentina is a direct result of their strengths in haemophilia, renal and hospital product areas. However, as Marcelo Rozas, General Manager of Baxter Argentina explains, this success could not be achieved without the support of the healthcare sector: "The government healthcare plan covers 100% of critical diseases. In addition,



Marcelo Rozas,
General Director,
Baxter Argentina

there is strong commitment by HMOs in Argentina to cover critical therapies such as haemophilia and dialysis, which enables companies like Baxter to launch innovative products like our plasma-free recombinant factor VIII, or products for diabetic patients who need dialysis."

With an annual turnover of \$60 million, and placed 25th in the national rankings, Argentina is considered as one of the Baxter group's most promising emerging markets, having experienced double-digit growth for the past four years. However, there is room for improvement in certain areas, and Baxter is doing everything it can to help change the situation.

Treatments such as peritoneal dialysis, which can considerably improve the quality of life for renal patients, have only 5% penetration in Argentina. "Keeping in mind that in other countries this treatment accounts for up to 30% of all dialysis treatments altogether, there is an opportunity to improve patients' quality of life by developing PD in Argentina," says Rozas.

With a team of clinical coordinators, Baxter organises training, workshops and conferences on these treatment options for the healthcare community, in order to improve awareness. This is combined with a close relationship to the government and the HMOs in the country. "If we put together high quality products, ongoing medical education and lower-impact treatments from an economic point of view, the result is a renal community with a better quality of life."



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segment has been very successful for Poen, and allows them to compete with multinational companies in their home market.

The habit of staying on track has proven extremely worth it, so the next stage in the evolution of this strategy won't be to diversify product lines, but to expand into international markets. Serafino says that the next goals for the company are to stabilize their product sales in Latin America, and attempt to expand their operations in both Brazil and Mexico. He believes that Poen's brand and reputation will easily translate to these markets: "Argentine physicians frequently travel abroad to receive training or work in different clinics, and use our products as they do here in Argentina. Thus, we maintain an identity as a company and brand."

This niche approach has also worked for Marcelo Figueiras, President of Laboratorios Richmond, a local company specializing in HIV, oncology and CNS products. The lab was the first in the world to produce branded oncological generics, and today is one of the four labs chosen by the Argentine government to produce Oseltamivir to cope with the H1N1 crisis. The specificity of their product lines means that a lot of Richmond's production is aimed towards the Argentinean government. Figueiras acknowledges the importance balance between being partner of choice for the gov-

ernment, whilst at the same time diversifying the business: "The fact that we sell our products not only to the Ministry of Health but also as prescribed medicines is a unique position in the country.

We have to recognize that the government health plan is very good, in the sense that the program gives all patients free access to medication, which directly affects the HIV market and is in turn beneficial for Richmond. Today however, Richmond's focus is towards the international development of non-infringing processes, bioequivalence studies and production; and directing these assets to higher regulated markets like Europe." By 2010, Richmond expects to be directing 50% of its production to foreign markets. "It is crucial for Richmond's objective to always be first to market with our generics: every time a patent goes off we



Marcelo Figueiras, President, Laboratorios Richmond, Catalina Massa, Executive Director, UNC Hemoderivados

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have to be ready to be the first to react and enter this particular market. We can now challenge the originator more effectively as we have developed the expertise of supporting our own non-infringing processes. This gives Richmond an edge.”

Almost all of the pharmaceutical laboratories in Argentina are privately owned, which makes UNC Hemoderivados stand out, as it is state funded: part of the University of Cordoba, it functions as a distinct business unit. One of the few Argentinean production facilities to be found outside of the Buenos Aires region, UNC Hemoderivados is focused on the production and development of blood derivative products. Catalina Massa, the Executive Director of the business, stresses the unique role that the company plays in both Argentina and Latin America. Through toll fractioning agreements with other Latin American countries, UNC Hemoderivados produces blood derivative products both for Argen-

tina and other countries in the region.

As well as looking at this production from a business perspective, Massa is keen to stress the social role that the laboratory plays: upon its creation, it was the first blood derivative plant in the region, and today works hard to create self-sufficiency across the continent. This is frequently encouraged through technology transfers. “An example of proposed exchange of technology or biotechnology is the signing of a framework agreement with Cuba. UNC Hemoderivados will transfer some technologies currently in use in our production process, but cannot fund the project with money. To find a solution that benefits both countries, it was proposed that this be done through a technology exchange agreement, as Cuba has extensive experience in biotechnology and UNC Hemoderivados has a need for implementation of future projects.” Through cooperation across the region, the labora-

tory is working both to improve access to vital blood derivative products, and increase its own capacity to develop new processes and medicines. The state-run model has been applied in Chile, Uruguay and Ecuador to date, showing that the project is both scalable and valuable.

From Beef To Biotech



Famous for its juicy beef steaks, paid at premium prices over the world's steak houses, Argentina is now captivatingly working to replicate its success in agribusiness innovation and put made-in-Argentina biomedicine on the menu.

Part of the Sidus group, Bio Sidus is regarded by many as the pioneer of Argentinean biotechnology. Formed as an independent company in 1983, Bio Sidus has established its national and international reputation through its work with cell cultures and bacterial fermentation. Marcelo Argüelles, President of the Sidus group and Bio Sidus, believes that the future for the company lies in the production and development of transgenic animals. “The company currently produces three target therapeutic molecules in the milk of Holstein and Jersey cows: one line which produces human growth hormone, one for bovine growth hormone, and one which produces human insulin. This has taken a very high level of investment over the last ten years, and we hope to receive approval for the use of the human growth hormone in both Argentina in Brazil in the very near future. Bio Sidus have twenty cows at the moment that produce human growth hormone,

Success is a journey, not a destination

Bio Sidus relies on the talent of the Argentine scientists and develops biotechnology for over 25 years. Exports biotechnological products for human use to more than 40 countries:

- * r-hu-EPO
- * r-IFN α 2b
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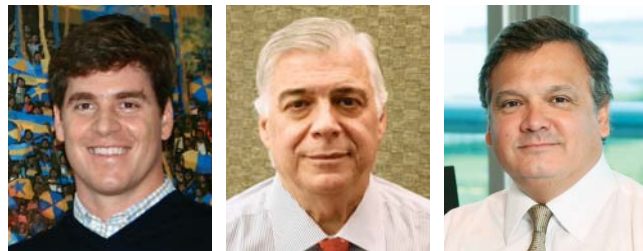
Develops technology through its works in transgenic animals and gene therapy.

and these are enough to produce all the human growth hormone currently being used in the world.” Developments such as this and the White Genome Project, which aims to isolate, identify and characterize Antarctic bacteria for medical use, are flagship projects that show the potential for Argentinean biotech companies on the world stage. The company sells its products in over thirty non-regulated markets across the globe, but has the long-term vision of reaching the US and Europe with its products, once conditions in those markets for biogenerics change: a goal shared by most of the biogeneric producers in Argentina.

Many companies see the development of biological drugs as the next step forward in their development. 49% of the biotechnology companies operating in Argentina are specialised in the area of human health, accounting for 78%, or \$98 million USD of the sector’s total sales. There are a number of existing biotechnology companies in Argentina that offer different models of how this business can be developed. Amega Biotech was created in 2005 as an umbrella organisation, combining various established biotechnology companies from across the value chain: Gema Biotech, well established in biological research and production, and two smaller Argentinean companies, who were focusing on APIs. As Francisco Molinari, CEO of Amega, notes, “These companies did not have the volume or resources to grow to the next level in terms of investment, in-

frastructure and regulatory status. By joining all these companies together under one umbrella, Amega Biotech became a stronghold in the biotechnology sector for the region in a very short period of time.” The company today produces 8 APIs in various iterations, and has claim to an industry first: they have been producing generic EPO since 1998. Molinari believes that the Argentinean biotechnology

market has a lot of potential, especially for its future expansion into more developed markets. “Argentina needs to stop being afraid of expanding and exposing



Left: Francisco Molinari, CEO, Amega Biotech, Center: Marcelo Argüelles, President, the Sidus Group and Bio Sidus, Right: Edwin Harvey, General Manager, Biogen Idec Argentina Facing page: Bio Sidus’ Transgenic Cattle

BIOGENERICS: Friend Or Foe?

The debate over the introduction of biogenerics into regulated markets in the US and Europe is one that is close to the heart of the Argentinean biotechnology sector. Originator companies argue that in cases where biotechnological processes are involved, the process used should be identical to the patented original in order for a treatment to claim true biogeneric status. However, innovative Argentinean companies such as Cassará, Bio Sidus and Amega Biotech, who are all working on producing biogeneric products, are eager to demonstrate that identical proteins and antibodies can be created using different processes. They believe that the sooner this conclusion is reached by international regulatory authorities, the sooner these life-saving drugs can be introduced to global markets at more affordable prices.

Argentinean companies are showing that new processes to create treatments such as erythropoietin, human insulin and monoclonal antibodies are stable, successful and affordable. First world markets offer a lot of potential business for these companies, as well as the chance to demonstrate to the world that the Argentinean pharmaceutical sector is capable of revolutionary innovation. Regulatory and legislative reform is on the horizon, but the influence of the major US and European pharma companies who want to see their patents protected for as long as possible in order to fund future innovation means that this debate is set to continue, for the short-term at least.

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itself. Up until now there have not been many cases of Argentine products or innovations recognized on a global framework. This is due to our informal market, which needs to be formalized through regulations and time: a whole learning curve for Argentina." Currently, only 23% of Argentina's biotech exports are destined for the US and Europe.

Rather than adopting the vertical integration model, Cassará Biotech has chosen another path. "Our business model is to make alliances rather than acquire companies, and grow alongside partners that have strengths in new and different areas," explains Jorge Cassará, business developer and part of the second generation of Cassarás in the company. By following this method, the business is able to expand into many different therapeutic areas: today, the company has the broadest portfolio of any biogenerics company in the world. "The company has technology platforms in bacteria, mammalian cells, in yeast and now in plants. From this starting point, it is very easy to cover many products. There are not many companies that all these technologies together in one place, and that is the reason that Cassará can cover so many products."

Ten years after initially launching products in Latin America, Biogen Idec has recently established offices in Argentina. Edwin Harvey, Managing Director of this new operation, explained

why the country has so much potential for multinational biotech companies, pointing out the excellent human resources, and high regulatory standards for biotech. On top of this, he points to excellent potential for conducting clinical trials in the country, something he believes is crucial for biotech companies looking to produce at the highest level of quality. Mr Harvey believes that the time is right for Argentinean biotech companies to showcase their achievements on the international stage, saying "the local companies will have an excellent opportunity to show that we have good scientists in Argentina, and good products. We have a high quality of scientific research and development in Argentina, and the fact that the government is supporting the biotechnology sector will prove to be a big help."

National Giants Position Themselves For The Future

The Argentine market is dominated by the names of the big local players: Roemmers, Bagó, Gador, Phoenix, Elea, Bernabó. One might be tempted to assume that their strategies for hegemony are all very similar; this is far from the case. Different histories and origins have influenced the aims and visions of these companies over the last century. Alberto Alvarez Saavedra, President of Gador, notes "Gador is perceived in Argentina in a different way to some other national companies. Our founders had experience in pharmaceuticals for many years. They brought with them the traditions of a European pharmaceutical company. The vision has always been to have a company based on quality products, with the objective of solving human health issues." This commitment to solving serious medical conditions permeates all levels of Gador, from the development of molecules in its R&D department to its recent collaboration with a British company to find a cure for Chagas disease.

Top 20 Ranking of Argentine Pharmaceutical Companies

Local Currency		Units	
TOT	TOTAL	TOTAL	TOTAL
	MAT MAY/09		MAT MAY/09
1	Roemmers - (88) 8.3%	1	Bayer - (134) 7.8%
2	Bago - (176) 5.3%	2	Roemmers - (88) 7.5%
3	Bayer - (134) 4.8%	3	Bago - (176) 5.9%
4	Ivax Argentina - (187) 4.2%	4	Elea - (161) 4.1%
5	Elea - (161) 3.8%	5	Gador - (83) 4.0%
6	Gador - (83) 3.5%	6	Montpellier - (71) 3.2%
7	Sanofi Aventis - (102) 3.2%	7	Pfizer - (99) 3.1%
8	Pfizer - (99) 3.1%	8	Ivax Argentina - (187) 2.9%
9	Phoenix - (136) 3.1%	9	Boehringer Ing - (54) 2.8%
10	Montpellier - (71) 3.0%	10	Andromaco - (46) 2.5%
11	Casasco - (92) 2.7%	11	Casasco - (92) 2.2%
12	Raffo - (103) 2.6%	12	Raffo - (103) 2.2%
13	Baliarda - (97) 2.5%	13	Baliarda - (97) 2.1%
14	Glaxosmithkline Ph - (77) 2.4%	14	Phoenix - (136) 2.1%
15	Novartis Pharma - (88) 2.3%	15	Bernabo - (84) 2.0%
16	Boehringer Ing - (54) 2.3%	16	Sanofi Aventis - (102) 1.7%
17	Roche - (46) 2.0%	17	Roche - (46) 1.6%
18	Beta - (101) 2.0%	18	Novartis Pharma - (88) 1.5%
19	Bernabo - (84) 1.9%	19	Glaxosmithkline Ph - (77) 1.4%
20	Andromaco - (46) 1.9%	20	Beta - (101) 1.0%
	Others (335) 35.0%		Others (335) 38.5%

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Source: IMS Argentina (May/2009)



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**Left: Eduardo Macchiavello, CEO, Roemmers
Right: Alberto Alvarez Saavedra, President,
Gador.**

Roemmers is truly one of Argentina's pharmaceutical giants: established in 1921, the company has topped the country rankings for the last 25 years. Eduardo Macchiavello attributes this success to the fact that "the company has a consistent and consolidated way of working; with a very strong focus in the promotion of our products and relationships we have with

physicians." He believes that "being strong on sales is the key to success in the Argentinean market." According to IMS, the Roemmers group has a 13% share of the total Argentinean pharmaceutical market. However, this dominance has not come easily. During the economic crisis, the company was hit hard, and the owners of the group decided that serious changes needed to be made. The Roemmers family took a step back, and Mr Macchiavello took over the daily running of the company. Explaining why the restructure was necessary, Macchiavello notes that "One of the biggest challenges that face family owned companies is that if mistakes are made, it can be very difficult to take responsibility for them. This was one of the biggest changes that needed to be made at Roemmers: as CEO, I was put in place

to take big decisions and also shoulder the responsibility. The Roemmers family is still present on the executive board of the company, and they are consulted on every major strategic decision. Previously, these decisions had been taken without due attention and study, and this was one of the aspects of the company I wanted to change when taking charge."

Macchiavello's vision for the future of Roemmers takes into account the drying up of drug pipelines globally. He sees that if the company wants to bring something new to the international markets that are part of the company's plans for expansion, it will have to try to innovate in new areas. "Roemmers is focusing on R&D, working on drug associations, and the combination of different drugs into multipills, which we believe will be the next big advancement

Survival Of The Fittest

In Argentina, there is a new generation of family pharmaceutical businesses developing, with their eyes firmly set on efficiency and quality. When Juan Craveri, businessman and hugely successful triathlon runner, took over the family business, he saw that if he wanted to turn the 120-year old Craveri into a successful modern pharmaceutical company, a lot of changes would need to be made. "Craveri was a very small company in a very big industry. We had to make changes in order to compete" says Craveri. "It was very important for us to correctly define ourselves." This redefinition started with the retraining of his staff, and included the building of new facilities and a complete corporate rebranding. Soon however, Mr Craveri realised that in order to fuel his desired rate of growth, more would have to be done. After adding contract manufacturing to their generics business, Craveri's next step was to look to bioengineering. In 2007, the company received approval for the first bioengineering clinical trials in Latin America.

However, the biggest change has been the way in which Mr Craveri has developed the company from a small family business into a successful corporate enterprise. Putting an end to nepotism in the company, he is clearly proud of the fact that today, there is potential for anyone in the company to rise to the top. The success of this strategy speaks for itself: during Q1 2009, IMS tracked Craveri's growth rate at 37%. The 'Iron Man' still wants more: "Every day, I receive offers to buy the company. I turn them down, one by one, telling them that I am looking to buy companies, not sell."



Juan Craveri: Finishing the ULTRAMAN World Championship, Hawaii 2008

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for the pharmaceutical sector. Once we have the necessary regulatory approval for these new drugs, it will be a lot easier to enter new markets, as we will have something new to offer.”

Elea has developed very rapidly since 2002, when the company integrated products from Parke Davis into its portfolio. Originally known as a women's health company, Elea is now known for its expertise in cardiology and neuroscience, releasing 50 new brands into the market in the space of four years. The company hopes to grow in the future by continuing to work with multinational partners, and developing their product lines. “Finally,” adds Mr Di Gilio, Business Director of Elea, “we're very carefully but solidly starting the introduction of new biological products in some niches related to diseases like cancer or neuropsychiatric diseases. Those segments are characterized by having a very low number of patients, and very high costs of treatment.” Still, Mr Di Gilio believes that “Elea's biggest asset is a very professional, business-oriented team, with an optimistic vision for future growth.”

What's Next, Boss?

A new generation of Argentinean managers are willing to break from tradition and change perceptions of the industry, and more and more companies like Craveri (see box) have realised the importance of changing management style in order to bring success. It is clear that in Argentina's rapidly evolving pharmaceutical market, companies cannot simply rely on their past successes and well-established family names.



Roemmers Plant Mataderos

Roemmers is an excellent example of how even market leaders need to ring the changes in order to ensure continued growth.

Even today, the vast majority of Argentinean labs are still family owned. At Laboratorios Richmond, Mr




Roemmers Offices in Olivos


Figueiras is hoping that the company will become one of the few Argentinean pharma companies to become listed, approaching the London Stock Exchange in order to initiate an IPO, which he hopes will fuel the future growth of the company at an international level. With a dedicated management team selected for their strengths in each particular role, Figueiras believes his responsibility is “to plan the future of the company, and where we are moving to, but how we get there on a daily basis is up to them, and so I depend on my team. In order to succeed in Argentina, the fundamental attributes of any management style are dedication, hard work and empowerment of the people.”

Amega Biotech's umbrella organisation is an unusual arrangement for an Argentinean company. Mr Molinari says that the project could never have succeeded with the approach commonly seen in Argentina: “our approach to this project was to strategically multitask, which meant a lot of risk, but also the only way to do it in such a small period of time.” As a result, he has created a company that has achieved a lot in a very small period. “Amega Biotech is exposing to the world a different activity and a level of technology in Argentina, surprising many regulated countries.”

One of the clearest sensations when investigating the Argentinean pharmaceutical market is a feeling that incredible



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Manufacturing Your Own Success

Julio Scardigli, the President of IBC, and General Manager of Dromex turned his vision into reality despite adverse economic conditions. As he notes, "If we had waited to have a favorable economic situation to advance our projects, maybe we would not have ever started." Today, both IBC and Dromex stand as entrepreneurial success stories, with a global vision for the future that is a testament to abandoning the traditional model.

Both companies occupy very important niche segments. Dromex was a pioneer in Argentina's API market, today also representing European API manufacturers in Mexico and Brazil, with plans to expand this service globally, capitalizing on the high demand for top quality APIs within the region. Scardigli saw that there was a need for integration in the Argentinean market, and turned the lack of APIs in the country into a successful business idea.

The same entrepreneurial skill led to the creation of IBC, which provides a much-needed contract manufacturing service for multinationals and national labs that can compete with international production standards, and manage complex processes such as lyophilization. By taking a close look at the Argentinean market, Dr Scardigli has taken a large step to completing the value chain within the industry, and has simultaneously consolidated the creation of two highly successful service providers.



Julio Scardigli,
President of IBC and
General Manager
of Dromex

change is just around the corner. High levels of predicted growth, coupled with a new dynamic of innovative and professional management, only serve to complement the excellent levels of scientific activity, and enthusiasm for changing people's preconceptions of the country. Argentinean managers are well trained in surviving the tough economic periods; they are eager to show that given the opportunity, Argentina is capable of producing much more than just skilled soccer players.

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