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Distinguished members of the pharmaceutical and innovative industries,

As General Secretary for Science, Technology and Innovation, I am proud to introduce this special report dedicated to the pharmaceutical and healthcare industry. We consider this communication platform as a great opportunity to display the capabilities of pharmaceutical companies in Spain.

Over the last thirty years, Spain has redefined its outlook on the innovative industries, and has undergone dramatic developments to improve the system for the benefit of all Spanish people. Despite the economic tumult of recent times, Spain is placing innovation at the heart of its investment for all industries across the country.

2014 represents an exciting time for the industry in general; with substantial investment of over €1 billion being made in R&D+i, Spain will be looking at ways to further improve the system that is sustainable for all stakeholders as well as ensuring that the country bolsters its competitiveness both in Europe and worldwide.

Spain has one of the most important developed markets in both Europe and the world. With an excellent base for human resources, strong infrastructure, immense production capacity renowned for high quality and affordable costs, and a natural gateway between Europe and Latin America, Spain represents an important place of investment for regional and global pharmaceutical companies alike.

With this special report on the industry, I invite all members of the pharmaceutical and general innovative community to take a look at the exciting opportunities that Spain has to offer.

Warm regards,

Maria Luisa Poncela
Secretary General for Science, Technology and Innovation
FROM OUTSOURCING TO **RIGHTSOURCING**
development and manufacturing of solid oral dosage forms

CONTACT US!
create more together
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Acknowledgements

PharmaBoardroom would like to thank

Maria Luisa Poncela
General Secretary for Science, Technology and Innovation,

Margarita Alfonsel,
General Secretary of FENIN

Anabel Sanz,
Head of Technology Transfer and Valorization of the Spanish National Cancer Research Center

Regina Revilla,
President of ASEBIO,

Carmen Castresana
Director of the Spanish National Center for Biotechnology

Jaime Malet
President of AmCham Spain,

Walther von Plettenberg,
General Manager of the German Chamber of Commerce in Spain

for their support, assistance and enthusiasm.
Lundbeck es la única multinacional farmacéutica a nivel mundial especialista en el tratamiento de patologías del Sistema Nervioso Central.

En Lundbeck, la búsqueda de nuevos fármacos para el futuro es el eje de todas nuestras actividades.

Nuestro objetivo es investigar y desarrollar fármacos que representen una innovación en el tratamiento de patologías psiquiátricas y neurológicas.

Y nuestra misión es Mejorar la Calidad de Vida de los Pacientes que sufren Enfermedades Psiquiátricas y Neurológicas.
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“We are dedicated to provide valuable medicines to you and future generations”

Almirall is a global company based in Barcelona dedicated to provide valuable medicines through its R&D, agreements and alliances. Our work covers the whole of the drug value chain. A consolidated profitable growth allows us to devote our talent and efforts to research in the respiratory and dermatology areas with a focused interest in gastroenterology and pain. Our size enables us to be agile and flexible so that we can accomplish the purpose of taking our innovative products wherever they are needed.

We are working today for better health tomorrow
Beyond the headlines that heralded the start of the Eurozone crisis that rocked the Spanish economy in 2009, and the austerity measures that followed, the Spanish pharma community has remained pragmatic. “Despite the crisis, Spain is still the fifth biggest European market, and the general conditions to invest are favorable to the pharmaceutical industry,” says Humberto Arnés, director general of Farmaindustria, the country’s association for research-based pharmaceutical companies.
For years, Spain’s pharmaceutical industry had been growing at a rate that would eventually become unsustainable.

The breaking point was reached in May 2010, when public pharmaceutical expenditure reached an all-time high. At that point, “Spain had a similar market size to the UK and Italy with a significantly smaller population. It would have been impossible to maintain that situation, and an adjustment of our market was absolutely necessary,” remarks Arnés of Farmaindustria. “But after this adjustment that has already been made, further reductions to the pharmaceutical industry are not possible, without causing irreversible harm to patients and companies,” he warns.

The Ministry of Health, under the administration of Prime Minister Mariano Rajoy, introduced a series of austerity measures in 2011 designed to curb costs following a series of similar measures made in 2006 and 2007. Most notably, these measures included a 7.5 percent price reduction for all patented medicines financed by Spain’s National Health System (SNS), mandatory prescription by active ingredient, the de-listing of over 400 medications for minor conditions, and the introduction of a ten percent copayment for pensioners and increases of up to 60 percent for employees. As a result of these measures, pharmaceutical expenditure contracted 19 percent for the total market and a staggering 38 percent for the public market. As a country whose pharmaceutical expenditure is 80 percent public, the impact this had on the industry was immense.

“National companies have been affected in that they do not have enough margins to keep up with the R&D investment needed to compete in international markets,” continues Arnés. “Multinational companies have also been affected because they have more difficulties to replace their investments in R&D facilities that could become obsolete. As such, Farmaindustria is working with the Ministry of Health to build a stable framework for the long-term to avoid similar issues in the future by linking the growth rate of the pharmaceutical business to that of GDP.”

On top of the various austerity measures implemented over the last few years, mounting debts by Spain’s health authorities to the pharmaceutical industry had also become critical. Fortunately in 2011, Minister of Finance Cristóbal Montoro recognized this as a critical issue and established a plan to raise EUR 32 billion (USD 44.16 billion) to pay providers in a number of industries, including health.

“This plan provided significant relief for the industry and was very important to demonstrate to our headquarters that the country is going through difficult times but is simultaneously serious about stepping up to its obligations,” notes Andreas Abt, general manager of Roche Spain. “This was very helpful for us and had a big impact on our headquarters and in general for the image of the country.”

**Austerity Measures 2010–2013**

- Introduction of ten percent in co-payments for pensioners and increases up to 60 percent for employees.
- EUR 1 (USD 1.37) fee paid by every patient for each prescription drug.
- Restrictions to National Healthcare Service including exclusion of undocumented foreigners.
- De-listing of 417 medicines for minor conditions.
- Price cuts imposed through revision of reference pricing system.
- 7.5 percent discount on patented medicines financed by the National Health System.
- Rebates applied by pharmaceutical companies to pharmacies have been capped at ten percent for generic drugs and five percent for branded products.
- Mandatory prescriptions by active ingredient.

**NONPROPRIETARY NONSENSE**

The Spanish retail market dropped to EUR 9 billion (USD 11.36 billion) in 2012: sales in pharmacies dropped from 63.5 percent of the total market in 2009 to just 60.7 percent in 2012, according to IMS Health. This drop was due in part to laws implemented that force innovative companies to drop the prices of their brands once off-patent to the same prices as their generic competitors.

“Generics in Spain only represent 18 percent of the total market in terms of value compared to 59 percent of products with patents and 23 percent of products with expired patents,” says Ángel Luis Rodríguez, general manager of Spain’s generic asso-
ciation AESEG. “In terms of units, generics represent 36 percent of market share, while patented brands represent 33 percent and brands with expired patents represent 30 percent. Again, this figure is far from the European average of generic market share of 55 percent.” AESEG has called for a price differential between generics and off-patent brands as well as clearly defined times for patent expirations. The association also defends prescription by INN: “this is very important to AESEG because physicians and pharmacies study pharmaceutical products by INN, and most patients today tend to recognize pharmaceuticals by INN.”

“The average price of medicines has dropped by 25 percent in just three years thanks to short-term price cuts,” says Javier Anitua, general manager of Mylan Spain. “This means that the average Spanish pharmacy has lost its net margin by 34 points over the last five years, with a net margin of less than seven percent. We cannot continue this trend.” Anitua is pushing for new channels of income among Spain’s pharmacies, which are struggling to make a profit due to price cuts. “This involves the preventive role that pharmacies can play through professional pharmaceutical services,” continues Anitua.

“We need to establish an agreement of sustainability for pharmacies and provision of medicine with every industry stakeholder. Innovation needs to come, but to provide that innovation we need to activate the use of generics instead of creating more short-term price cuts.”

Generics timeline

- **30 Dec 1996**: Amendment to the Medicines Act by adding to Article 8 the definition of Generic Pharmaceutical Specialty
- **1997**: Introduction of the first generic
- **13 Jul 2000**: Publication of the Ministerial Order establishing the approval of Reference Prices
- **Dec 2000**: Inception of the Reference Price System
- **29 May 2003**: Modification of the Medicines Act
- **1 Jan 2004**: Entry into force of the Decree that develops the Third Final Provision of Law on Cohesion and Quality
- **23 Nov 2004**: Presentation of the new Strategic Plan for Drug Policy
- **27 Jul 2006**: Publication of Law 29/2006 of July 26 of Guarantees and Rational Use of Medicines and Health Products
- **01 Mar 2007**: Inception of the new Reference Price System
- **26 Mar 2010**: Royal Decree-Law 4/2010 of the pharmaceutical expenditure under the National Health System.
- **20 May 2010**: Royal Decree-Law 8/2010, by which extraordinary measures are taken to reduce the public deficit
- **19 Aug 2011**: Royal Decree-Law 9/2011 of measures to improve the quality and cohesion of the national health system, contributing to fiscal consolidation, and raising the maximum amount of State guarantees for 2011.
- **20 April 2012**: Royal Decree-Law 16/2012 on urgent measures to ensure the sustainability of the national health system and improve the quality and safety of their performance measures.

“Rebélate contra el dolor”

Sociedad Española del Dolor

Instituto mundipharma
The old Spanish healthcare system has disappeared as it had proven to be unviable and unsustainable,” says Luis Cruz, general manager of Spain and Portugal at CSL Behring. “Now we are in the process of switching to a new system that has yet to be formalized. We are trying to keep up with everything, but the process of defining this new system is not an easy one.” CSL Behring, a leader in the plasma protein biotherapeutics industry worldwide, provides hospital-based treatments for a number of rare diseases, all of which are reimbursed by the authorities. “We know that in the future we will not be able to spend in healthcare as much as we have been spending until now,” Cruz admits.

He nevertheless warns: “When new treatments for rare diseases are discovered preventing patients from dying and suffering, we have to generate ‘new expenses.’ The Ministry of Health must make new resources available for these patients who will not only survive, but who will often need these treatments for life.”

“Spain was living in a bubble-like dream in many ways, above what the country and its economic capabilities could deliver,” says Juan López-Belmonte, CEO of Laboratorios Rovi, a Spanish laboratory that has achieved significant growth during the economic downturn. “The recession of 2008 demonstrated across the globe that life is what you generate and what you can spend.”

He notes that companies have adapted quickly to the new conditions: “Consequently, our adjustments have had a lasting effect on all companies. While the pharmaceutical business is fairly stable and regulated, the crisis has forced managers like myself to change our ways of thinking, to restructure our companies to allow for a faster decision-making process and to be more ambitious in R&D programs. Nevertheless, I am very optimistic regarding Rovi – we have prepared ourselves for the future, and the best is yet to come. We have increased our staff from 500 in 2007 to almost 1,000 in 2014.”

The path to recovery may not be easy, but it certainly is not impossible for Spain either. “Thankfully, the worst days are behind us; looking at the future, Spain has incredible human talent, financial reforms in place and a very competitive labor market,” remarks Javier Ellena, president and CEO Spain, Portugal and Greece of Lilly. “The transition from the past to the present has been difficult and painful, but we can be optimistic in that a new cycle is starting from a very healthy base as a consequence of all the measures implemented. Establishing parameters for handling potential innovation will be critical to ensure that the pharmaceutical sector will have a brilliant future in Spain.”

“Spain is a great country,” concludes

---

**Top 20 companies by retail sales**

<table>
<thead>
<tr>
<th>Ranking</th>
<th>Company</th>
<th>EUR MAT/14</th>
<th>Incr. (%)</th>
<th>Market share</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>PFIZER</td>
<td>577,356,288</td>
<td>-1.1%</td>
<td>6.3%</td>
</tr>
<tr>
<td>2</td>
<td>NOVARTIS</td>
<td>575,759,940</td>
<td>0.2%</td>
<td>6.2%</td>
</tr>
<tr>
<td>3</td>
<td>SANOFI</td>
<td>425,454,865</td>
<td>0.1%</td>
<td>4.6%</td>
</tr>
<tr>
<td>4</td>
<td>GLAXOSMITHKLINE</td>
<td>417,164,995</td>
<td>2.2%</td>
<td>4.5%</td>
</tr>
<tr>
<td>5</td>
<td>MERCK &amp; CO</td>
<td>406,756,833</td>
<td>-12.7%</td>
<td>4.4%</td>
</tr>
<tr>
<td>6</td>
<td>JOHNSON &amp; JOHNSON</td>
<td>364,496,915</td>
<td>-3.4%</td>
<td>4.0%</td>
</tr>
<tr>
<td>7</td>
<td>ESTEVE</td>
<td>342,537,567</td>
<td>0.5%</td>
<td>3.7%</td>
</tr>
<tr>
<td>8</td>
<td>ASTRAZENECA</td>
<td>340,506,560</td>
<td>-1.4%</td>
<td>3.7%</td>
</tr>
<tr>
<td>9</td>
<td>BOEHRINGER INGEL</td>
<td>319,136,838</td>
<td>-1.5%</td>
<td>3.5%</td>
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<tr>
<td>10</td>
<td>TEVA</td>
<td>311,775,247</td>
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<td>3.4%</td>
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<td>11</td>
<td>CINFA</td>
<td>306,044,258</td>
<td>9.8%</td>
<td>3.3%</td>
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<tr>
<td>12</td>
<td>ALMIRALL</td>
<td>269,668,473</td>
<td>1.3%</td>
<td>2.9%</td>
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<td>13</td>
<td>LILLY</td>
<td>240,774,996</td>
<td>1.1%</td>
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<td>14</td>
<td>FERRER</td>
<td>234,599,476</td>
<td>-7.9%</td>
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<tr>
<td>15</td>
<td>BAYER</td>
<td>231,269,999</td>
<td>-5.5%</td>
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<tr>
<td>16</td>
<td>ASTELLAS PHARMA</td>
<td>175,296,556</td>
<td>5.1%</td>
<td>1.9%</td>
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<tr>
<td>17</td>
<td>NOVO NORDISK</td>
<td>170,743,060</td>
<td>4.9%</td>
<td>1.9%</td>
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<tr>
<td>18</td>
<td>MENARINI</td>
<td>168,885,601</td>
<td>4.6%</td>
<td>1.8%</td>
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<td>19</td>
<td>STADA</td>
<td>145,409,412</td>
<td>3.7%</td>
<td>1.6%</td>
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<td>20</td>
<td>NORMON</td>
<td>144,323,866</td>
<td>10.5%</td>
<td>1.6%</td>
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Source: IMS Health

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**THE SYSTEM IS DEAD, LONG LIVE THE SYSTEM!**

From left: Luis Cruz, General Manager, Spain & Portugal, CSL Behring; Juan López-Belmonte, CEO of Laboratorios Rovi

---

**TOTAL EMPLOYMENT**

\[
\begin{align*}
\text{TOTAL EMPLOYMENT} & = 200,000 \\
\text{Induced Employment} & = 65,000 \\
\text{Indirect Employment} & = 95,000 \\
\text{Direct Employment} & = 40,000 \\
\end{align*}
\]

Source: Farmaindustria

---

**From left: Luis Cruz, General Manager, Spain & Portugal, CSL Behring; Juan López-Belmonte, CEO of Laboratorios Rovi**

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**Javier Ellena, President, Lilly Spain**

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**Spain report**

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**FOCUS REPORTS**

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**SPAIN SEPTEMBER 2014**
Rovi’s López-Belmonte, “and we should keep investing in this country. The best of Spain is also yet to come. We went through difficult times, but the country has done its homework, has grounds for future growth, and will become a success story in the years to come.”

A CHANGE OF PACE

The decentralized nature of Spain’s health system presents its own unique challenges for health-related companies. Regulatory and reimbursement decisions are taken at the regional level, and many rules and regulations can vary from hospital to hospital within a region. While this concept is not new, the crisis has made each community even more stringent about its own laws, which creates a complex environment in which companies operate. As Luigi Antoniazzi, general manager Spain & Portugal of Baxter states, an advantage that this system provides, “is the opportunity to be closer to the patients, which is useful to fulfil the ultimate objective of providing a better service to the population of each region. On the flipside, needless to say, having to deal with 17 regional authorities is quite a challenge. Each one has a unique set of healthcare policies or interpretation of how healthcare services should be provided to citizens.” As part of the adaptation to Spain’s decentralized health system, many managers find themselves placing increased emphasis on the key stakeholders in each region, be it regional health authorities, hospital managers or others.

“We were used to having one strategy for the whole country for each of our business areas,” notes Kristian Hart Hansen, general manager of Leo Pharma Spain. “The first challenge is to understand the differences in the 17 regions and understand the needs of our different customers within each region in order to...
be able to adapt our plans and strategies to each stakeholder in each region.” Hart Hansen notes that when the environment changes like it has in Spain, a whole revamp of strategy is required. “If you manage to do that — which is not easy here in Spain as well as in other countries — the opportunities will arise,” he says. “The question is, do you dare to do it? One thing is certain: you need to move from a national to a regional perspective in terms of everything you do; there is no one-product strategy for Spain anymore. We are not there yet, but it has been an exciting part of the journey and it will continue.”

“We have returned to a focus on science rather than just the relationship,” remarks Rogelio Ambrosi, general manager of Merck Spain. “We have changed our organization from only having sales reps or key account managers to a mixed organization where our people actually promote the products. Companies today talk at great length about science, patient benefits and health economics, along with other departments like market access or government affairs. Merck has ensured that its products are available for all Spaniards by working directly with the responsible people in each region, from the minister and regional counselors to hospital managers. Spain is one country; where you live should not make a difference for accessing medications. There are stark differences in each community, and this is perhaps less to do with money as it is about how they organize themselves to make this happen. Merck Spain has changed its organization from only having sales reps or key account managers to a mixed organization where our people actually promote the products.”

Merck Spain has made significant efforts to increase its foothold in Spain. As the only multinational with three produc-

The medical technology sector in Spain has a market size of EUR 6.8 billion (USD 9.38 billion). 90 percent of the 720 companies that sell medical equipment are SMEs and account for about 40 percent of the industry’s turnover, while a mere eight percent controls 60 percent. This stark contrast is largely due to the strong investments made by multinationals, while many of the smaller, local companies rely on the export of their products to generate revenue.

Just like the pharmaceutical industry, the medical technology industry has also been subject to a number of problems. Margarita Alfonsel, general secretary of the Spanish Federation of Healthcare Technology Companies (FENIN), says that for 20 years Spain has been challenged to eradicate negligence and standardize payments. “This stems from a lack of government accountability, but has been exacerbated by the financial economic crisis and its subsequent intense illiquidity and lack of funding for companies,” notes Alfonsel. “Over the last five years, major cuts in public budgets have caused companies to change their operating expenses, both in the pharmaceutical and medical device areas,” says Daniel Carreño, CEO Spain & Portugal of General Electric and President of FENIN. “In some cases, 90 percent of business has disappeared for some companies compared to 2007. The last two years have been slightly better, but the negative trend continues. In 2013, the average growth rate of the medtech sector was between five and six percent, and while some subsegments are starting to recover like dental or ophthalmology with slight growth, most sectors are still falling.”

“Thankfully, the government has been quite responsive in this matter as of late by launching the payment plans to suppliers involving extraordinary mechanisms for payment of outstanding invoices,” continues Alfonsel. “From 2012 until today the industry has claimed back more than EUR 6.5 billion (USD 8.97 billion). Through published or pending publication of a legislative package of commercial debt law, law of electronic invoice, bill of transparency and good governance, we believe that the government will achieve its goal to eradicate delinquency and standardize payments, essential for the sector to work with certainty and stability.”
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<td>302</td>
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<tr>
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<td>419</td>
<td>ROVI-LISBOA</td>
<td>9:35</td>
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<tr>
<td>LH</td>
<td>1122</td>
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<td>9:35</td>
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<tr>
<td>LH</td>
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<td>ROVI-ATENAS</td>
<td>9:35</td>
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<tr>
<td>LH</td>
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<td>ROVI-VIENA</td>
<td>9:35</td>
</tr>
<tr>
<td>AF</td>
<td>1701</td>
<td>ROVI-ROMA</td>
<td>9:40</td>
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<tr>
<td>AY</td>
<td>822</td>
<td>ROVI-LA PAZ</td>
<td>9:40</td>
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<tr>
<td>AA</td>
<td>071</td>
<td>ROVI-QUITO</td>
<td>9:45</td>
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<tr>
<td>AF</td>
<td>743</td>
<td>ROVI-MEXICO DF</td>
<td>9:45</td>
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<tr>
<td>LH</td>
<td>1116</td>
<td>ROVI-AMMAN</td>
<td>9:45</td>
</tr>
<tr>
<td>DL</td>
<td>023</td>
<td>ROVI-CARACAS</td>
<td>9:50</td>
</tr>
<tr>
<td>GA</td>
<td>892</td>
<td>ROVI-SANTIAGO</td>
<td>9:50</td>
</tr>
</tbody>
</table>
Vaccines: Building a Sustainable Business

As Europe’s leading vaccine manufacturer, Sanofi Pasteur MSD has the widest portfolio in the continent, and has vaccines to cover 20 of the World Health Organization’s priority infectious diseases across all age groups. Spain, however, required a rethink of strategy when the crisis hit. “Because of the configuration of Spain’s public health business, almost all purchases go through tenders,” explains Ricardo Brage, the company’s vice president Spain. This process allowed the Spanish government to squeeze prices, hitting vaccine companies hard. “The government started to introduce a centralized procedures to aggregate purchases, starting with flu vaccines, significantly pushing down prices,” he continues. “This was compounded by the fact that payments are often late in Spain.”

In order to rebuild a sustainable business, Brage shifted the company’s business model away from the public sector, which he has reduced from 70 percent of Sanofi Pasteur’s Spanish business in 2011 to 55 percent today. “The company has shrunk and rebuilt but has become more competitive and the culture is different. But it certainly seems to be working. We have been able to look at different markets while maintaining the same level of sales in the last three years,” Brage explains. “We are still here and we will provide vaccines to the population. But we also need to reassess our business model and adapt it in terms of size and position.”

“In 2012, Spain’s government undertook major economic reforms to help labor markets, contain the deficit and regain the confidence of international markets,” says Maria del Coriseo, CEO of export and investment agency ICEX. “This meant that our risk premium decreased, and our public and private financing costs for the whole country became more reasonable and affordable. Companies made great efforts too, continuing to invest in R&D and process innovation, obtaining their own brands, and generally maintaining flexibility and reliability while offering quality post-sales services. By the end of 2012, Spain had consolidated and also increased its exports by 38 percent, bucking the trend in surrounding countries. Today, the number of companies exporting is 50 percent higher than compared to three years ago. Companies with previous international experience became more focused in markets outside the European Union.”

For Ignasi Biosca, CEO of local pharmaceutical group Reig Jofre, focusing on international markets was the key success factor for the company, which has managed to do everything from acquiring international companies like Bioglan in Sweden in 2009 to obtaining FDA approval to market its sterile penicillin-based antibiotics in the US in 2013. “The key point for Reig Jofre is to innovate new products that can be manufactured and marketed by ourselves in those markets.
where we have direct presence, or through our network of more than 180 partners, licensees and distributors in more than 52 countries worldwide,” Biosca states.

“Instead of growing through business units in every country, we have been growing through a network of partners to whom we offer every new product that Reig Jofre develops. In that sense, we are slightly more focused on the development side of R&D+i. We try to develop both real innovation, but also products that are not necessarily a new chemical entity but rather some developments or improved formulations or new indications for existing molecules that can be successfully marketed in each local market.”

**THE RESEARCHER’S DELIGHT**

“The pharmaceutical sector is the leading industry in R&D in Spain,” says Maria Luisa Poncela, general secretary of Science, Technology and Innovation for the Spanish Ministry of Economy, who believes that the industry needs to increase its investment in Spain even more. “Ten years ago, foreign pharmaceutical companies were investing in research in Spain but mainly in the later phases of drug development. At present there are big companies investing in Spain that entirely develop a drug here, from the preclinical phase until the last phase of clinical trials.” Currently, the pharmaceutical industry invests roughly EUR 1 billion (USD 1.38 billion) annually in Spain; “this is a great path for Spanish knowledge and science, because many physicians of different hospitals are involved, as well as researchers of Spain’s leading institutes.”

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“Spain is ranked tenth worldwide for production of science, measured in terms of publications and papers,” notes Emilio Lora-Tamayo, president of the Spanish National Research Council (CSIC), the third biggest of its kind in Europe and ranked first in Europe in terms of output of papers and patents. “In the last ten years, we have tried to emphasize approaching translational focus of our biology and biomedicine activity, ranging from our very first steps in a biological molecule or chemical sources to the end of the clinical process to treat different diseases. This is particularly important in the fields of neurological, chronic and rare diseases.”

Spain currently invests 1.4 percent of its GDP in research; Lora-Tamayo wants to see this number increased to two percent. “The importance of this figure is that the majority of this investment effort is made by the public sector,” comments Lora-Tamayo. “The private sector in Spain is far below the European average, and needs to make a much stronger effort.”

One of the most notable examples of Spain’s research prowess in the life sciences is the Spanish National Cancer Research Center (CNIO). “Considering such a structure takes time to develop, CNIO is an impressive institution given that it is only ten years old,” comments Anabel Sanz, head of technology transfer and valorization at CNIO. “In 2013 CNIO partnered with companies to develop novel drugs through applied programs. The two very first novel products entirely developed at CNIO through our drug discovery platform have been licensed to companies that can help us take these products forward into the clinical stages of drug development.”

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CNIO is ranked as the number one research center in Spain in terms of scientific production in cancer, and number two for high impact on cancer publications worldwide. “We publish more than 200 papers per year and in particular we have been increasing the number of publications with high impact, considered to be highly influential in their fields, since 2010, up to a 22 percent increase in 2013,” says Sanz.
Catalan Competitiveness

As a region, Catalonia is quite impressive in terms of its research capacity: Joan Guinovart, director of the Institute for Research in Biomedicine in Barcelona (IRB Barcelona), notes that the region on its own ranks third in Europe, behind the Netherlands and Sweden, for the number of grants provided by the European Research Council per million inhabitants. “IRB is a member of a network called the Research Centers of Catalonia (CERCA), which belongs to the Catalan Government,” states Guinovart. “This is a body that brings together a new type of research center that does not fit the traditional rigid structures common to Spain over decades.” Combined with a Catalan government-owned agency designed specifically for international recruitment, the region’s system “has maintained the same policy of attracting and recruiting the best international talent through open calls for over 15 years and the impact has rapidly become evident.”

“The Catalan government has really bet that innovation is the future for competitiveness; they have devoted large amounts of money to protect research,” says Luis Serrano, Director of the Center for Genomic Regulation (CRG). The next step, according to Serrano, is to take this high-quality research to the next level. “Governments need to keep their investments in science and technology alive during such times to push the economy, and innovation is critical for this,” he remarks. “Now Catalonia has globally competitive institutes in terms of research, but like the CRG they need to become competitive specifically in tech transfer and translational medicine. Publishing is great and our access to EU grants has been superb, but at some point we need to start returning value to the society that finances us.”

A history of cooperation

The American Chamber of Commerce in Spain (AmCham Spain) and the German Chamber of Commerce in Spain were both founded in 1917, during the First World War. Throughout the 20th century, both organizations were instrumental to the development of commercial relations between their respective countries and Spain, and investments between Spain and the United States and Germany continue to this day.

AmCham’s total membership contributes to 24 percent of GDP in Spain, and the healthcare industry plays a significant role in this contribution: 50 percent of the entire investment in the pharmaceutical industry in Spain is represented by American companies. Despite the crisis in Spain, American support in Spain for the industry remains unaltering.

What makes Spain such a great market in which American companies can invest? Jaime Malet, president of AmCham Spain explains: “Spain’s GDP is the same as Mexico’s, slightly smaller than Brazil’s but larger than Russia’s. Therefore, the Spanish market opens up many opportunities. Secondly, Spain has an incredible infrastructure that makes it one of the most important logistic platforms in the world. Thirdly, Spanish people have incredible managerial skills, which are very useful for the growth of small, medium and large companies, both local and international.”

“One of our basic focuses for the next three years will be small and medium sized companies in sectors of fast growth capacity,” says Malet. “Among them, biotechnology is at the top. Spain therefore has a real capacity to develop this sector. There is an excellence among many Spanish biotech companies that are comparable to similar companies being developed in Boston or Silicon Valley, and we do not see many places in Europe with such incredible development. AmCham will help as much as possible in this regard.”

Similarly, the German Chamber of Commerce in Spain has played a substantial role. The organization was critical to the introduction of a number of German companies into Spain between the 1970s and 1990s, including the pharmaceutical industry. Walther von Plettenberg, general manager of the chamber, notes that recent restructuring in the labor market have helped to recuperate ten years of lost productivity in just three years. “This has made our member-companies more competitive,” says von Plettenberg. “They can produce the same with less cost, so the basis is better. Secondly, exports have been growing tremendously in Spain and our German companies are good players in the export market too. This is also true for the pharma sector. A couple of German pharma companies have centers of excellence in Spain for a specific product or process, acting as a worldwide reference center, producing for the whole world, or their process is being imitated by facilities elsewhere because they know how to do it best.”
WITH GREAT RESEARCH SHOULD COME GREAT COMMERCE

Spain has the sixth largest number of registered biotechnology companies worldwide. “The high quality science that exists in Spain helps to create that environment, and certainly the good funding that existed in the past also contributed,” says Carmen Castresana, director of the National Biotechnology Center (CNB). “In fact, for many years, Spain was a great place to create startups in general and as such there was higher international visibility for science and research. But funds have also been cut for biotech companies in recent years, just like the research institutes. There also used to be money in every university campus nationwide; science parks and incubators were being created for small enterprises. We are still waiting for recovery phase to begin.”

Have you ever wanted to know how much time you have left to live? Life Length, founded in 2010, is the only company in the world that offers a technology that can measure an individual’s “biological age” using a biomarker that measures the percentage of short telomeres (tips of chromosomes) in individual cells, which provides great insight into cellular ageing. This “Telomere Analysis Technology” (TAT) became a reality after five years and EUR 20 million (USD 27.6 million) invested in research, technical studies and development at CNIO.

“85 to 90 percent of all adult cancers escape the limit that causes cells to become senescent because they endogenously express telomerase (enzyme that repairs telomeres), allowing them to continually divide and metastasize rapidly, essentially meaning that every cell in that tumor is immortal,” says Stephen J. Matlin, CEO of Life Length. “If a pharmaceutical company were able to inhibit the expression of telomerase in those cells, this could potentially be a blockbuster drug that addresses almost all human cancer. Pharmaceutical companies now need to figure out how to deliver such a target with a technology that measures whether your potential molecules can slow telomerase expression, which means screening compounds. Life Length offers that testing service to the industry.”

This service has become an object of fascination with society. “The idea of biological age as expressed by this genetic biomarker, which is a very precise and objective measurement of the ageing process, is very appealing to physicians and patients worldwide,” explains Matlin. Given the worldwide recognition and interest in the technology, Life Length has established 13 partnerships with diagnostic laboratories around the globe. “This model is proving to be successful, as we can also take advantage of these labs’ commercial infrastructure to sell our TAT to physicians.”

“We believe that the TAT test has the potential to become a biomarker on par with cholesterol testing, which is the largest biomarker in the world today by sample volume and revenue,” Matlin says. “Our vision is that Life Length’s test will become an increasingly standard part of preventive healthcare over a period of time, as well as a test used by cardiologists, oncologists, infertility doctors and endocrinologists, among others, because of its correlation to all these diseases.”
Mª Teresa Orozco is one of 382 million reasons for change

People with diabetes need control over their condition to prevent complications. That is why we have developed the industry’s most comprehensive insulin portfolio, the world’s leading GLP-1 treatment and the most widely used injection devices. With comfortable, innovative treatments on their side, Mª Teresa Orozco and others with diabetes are able to live longer, healthier lives.

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In July 2014, the Spanish pharma sector received international media attention when Almirall transferred the rights of its respiratory franchise, a key component of the company’s portfolio, to AstraZeneca in a deal worth up to USD 1.22 billion. Eduardo Sanchiz, CEO of Almirall explains the decision: “Ultimately we have to be careful for a company our size; launching new products requires a very substantial investment in the short-term for both R&D and commercialization, while establishing in new countries is also quite a financial undertaking.”

“You have to determine how far you can go without financially overstretching yourself. Internationalization has played a key role in obtaining our current position, and has made us ready to maximize new product opportunities.”

Sanchiz replaced Jorge Gallardo as CEO of Almirall in 2011, and in 2013 the company underwent an important restructuring in terms of defining the company’s direction and priorities, primarily focused on Almirall’s pipeline of new products. “The percentage of products in a portfolio that come from external sources has increased significantly in recent times,” continues Sanchiz. “R&D is a very difficult part of the business to tackle, as you are never fully in control and results can be unpredictable; thus you need to supplement internal efforts with external efforts. Consequently, you need clarity regarding where those efforts are focused. As such, we align our business development initiatives together with areas where we also have strong R&D interests.”

“Local R&D will ultimately lead to exports of products that benefit the trade balance in the country, and keeping significant essential goods in an area like pharmaceuticals can help as well,” Sanchiz explains. “I would like to see more of that taking place in Spain. This country enjoyed good market growth before the crisis, but we are still behind other markets when it comes to creating an environment for national champions. There needs to be some strategic support from the state towards moving in that direction.”

“I think we need to have a much more stable and predictable healthcare environment before such a push can occur. There is a need for a higher recognition of the value of pharmaceutical companies in Spain in terms of being a magnet for attraction and development of highly educated professionals,” he concludes.

“Spain has invested a great deal of capital in this area, and ranks fifth in Europe and seventh worldwide for scientific production,” comments Regina Revilla, president of Spain’s biotechnology association ASEBIO. “Many of the key opinion leaders in the health area in Spain today chair the governing boards of a number of leading research institutes in the country as well. Considering where Spain was in the beginning of the 1980s, when the country was being assisted by the World Bank to develop technologies, we have come a long way. It may have taken a long time, but Spain is finally developing incredibly groundbreaking products and with stronger intellectual property protection.” The fruits of some biotech companies in Spain are finally beginning to blossom as well; local company PharmaMar’s groundbreaking marine drug Yondelis is on the brink of approval by the FDA, while Roche established a partnership earlier this year with Oryzon to co-research, develop and commercialize inhibitors of Lysine Specific Demethylase-1, an epigenetic modulator that regulates gene expression.

Spanish companies and research institutes are also placing a large emphasis on personalized medicine. “Spain’s strength in the development of biomarkers is outstanding for the creation of an interesting and innovative healthcare system, particularly in the areas of hematology and oncology,” comments Revilla. “Combined with Spain’s program involving the public purchase of new technologies, the opportunities to improve clinical outcomes and reduce costs are endless. Considering there is really only one buyer of such technology in Spain, the public, we can really develop these purchases in-house for innovative technology, covered with government funds”.

**WHERE THE BUSINESS IS**

While Spain has never built a global pharmaceutical giant like their close neighbours in France, UK, Germany or Switzerland, the ecosystem in Spain has certainly allowed for strong growth despite the country’s financial crisis. With over 3,000 clinical trials being conducted in 800 hospitals across the country combined with its low-cost appeal, Spain is still a very attractive place for companies to invest in for research and production.

“Spain’s efforts in R&D, manufacturing, marketing and intellectual property have continued as normal in the last few years,” says Antoni Esteve, director of Esteve. “The real problem...
is the way which these assets are managed and prioritized. Much of the country’s issues depend on public services that establish their criteria regarding how many resources they deserve compared to others, and the government needs to confront this. Essentially, this is not a crisis of the sector, but an economic crisis that impacts the health sector. Accordingly, as the pharmaceutical industry we are obliged to rethink how our products may play a role in this new environment.”

For those multinationals that have not invested in manufacturing or R&D products, the market still offers plenty of ways to still be a potent player in the game. “We commit to R&D by using Spanish resources to invest in local and European projects,” says Alberto Martínez, general manager Spain & Portugal of Mundipharma. “We also have partnerships with local product suppliers based in Spain, such as Alcaliber (morphine and oxycodone API suppliers), and Inke (formoterol exclusive worldwide supplier). The growth and development of local pharmaceutical companies like these are also dependent on the development of companies like Mundipharma Spain.” Mid-sized companies like Mundipharma cannot always afford to establish R&D or manufacturing capabilities in Spain. Nevertheless, Martínez is optimistic about his affiliate’s efforts to contribute what it can. “We hope the authorities will recognize our firm commitment with innovation, with a growing contribution to the Spanish GDP and towards a sustainable healthcare system.”

In 2013, Spain finally balanced the trade of pharmaceutical products at EUR 10.7 billion (USD 14.76 billion) through companies’ increased activity in third-tier markets and general internationalization (Source: Farmaindustria)

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<td>(p) Provisional data from the aggregation of the last 12 months leading to October 2013: Source: Secretary of State of Trade</td>
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Kern Pharma is one of the leading local generic companies in the Spanish market today, with over 150 generic products and 400 presentations in the market. Founded in 1999 as part of the Indukern Group, Kern Pharma has set many milestones in a short period of time. “Since we belong to a family-owned group that already had activities in the veterinary and API sectors, we have very good sourcing capabilities of API and we know the patent situation very well,” says Raúl Díaz-Varela, CEO of Kern Pharma and President of Spain’s generic association AESEG. “Kern Pharma has its own development, production and commercialization, and as a vertically integrated company we consider ourselves capable of bringing new products into the market. As a relatively new company we were the first to launch new molecules into the market and in some cases related to new technologies, sometimes based on pre-filled syringes or with controlled substances hard to acquire. While we participate in some areas of innovation, our main target is to bring as many products to market as possible, largely in the generics area.” Aiming towards that goal has paid off; with a seven percent share of the generic market, in terms of units Kern Pharma ranks third for the generic market and fifth for the total market in Spain.

Díaz-Varela also points to the company’s competitive production as a key strength; Kern Pharma’s production plant in Terrassa is ranked among the top five in Spain in terms of number of units produced. “Some companies do not focus so much on their own production, but we consider this as a strategic perspective of Kern Pharma and that is why we continue reinvesting in new areas and facilities and sometimes in new technologies as well,” he says. “We consider having our own production to be a big advantage. Customers feel confident in our system of quality and how we work when they come to visit our facilities. This is especially true when we can demonstrate our capacity for both producing our own products and for third parties of very well-known companies; we maintain the same quality system and competitiveness. Furthermore, we place great emphasis on volume to remain competitive.”

Strength in Numbers

Raúl Díaz-Varela,
CEO, Kern Pharma

Packaging of Kern Pharma’s products

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The actual production of pharmaceutical products and forms offers a significant portion of business as well, as a remnant of the Francoist-era push for the industrialization of Spain, particularly in the chemical area. “Spain has historically had a huge infrastructure in pharmaceuticals and chemicals, as well as APIs and finished dosage forms,” says local contract manufacturer Medinsa’s CEO Joachim Teubner. “The country is building upon this as a competitive advantage. Today, price is one of the most important criteria when deciding on contract manufacturing or in-house manufacturing. Given that there are usually benchmarks, you have to be competitive in your pricing. The government has made some adjustments during and after the crisis, especially for labor laws, which will enhance Spain’s positioning for foreign companies to use this country as a hub for manufacturing their products. This change will strengthen Spain’s direction and I am optimistic that the country’s current infrastructure will grow.”

Newcomers to this area also have an enormous slice of pie to take. One such example is Aplicaps, a local manufacturer of soft-gelatin capsules, founded in 2008. “The Spanish market is big but everyone is playing in it, both local and multinational companies,” comments José Luis Martín Guinea, CEO of Aplicaps. He sees an immense opportunity available in the Spanish market for this niche. “Many companies in Spain are essentially commercial and their problems are mainly located in R&D and the manufacturing of their products,” he says. “Once we reach our customers’ trust it is very likely that they come to us for other projects. 30 percent of our sales are met in other product ranges, and some of our best clients ask us to solve other issues for which we have the capacity to undertake. We then sign deals with other companies specialized in the area of expertise required and they eventually collaborate under our responsibility and supervision to realize the product ordered.”

TOO MUCH JAMÓN

“5.3 million Spaniards suffer from diabetes,” says Erik Lommerde, vice president Spain & Portugal of Novo Nordisk. “This is much more than the average ten percent, so it is more severe in Spain than many other countries, particularly in Europe. This is linked to Spain having the highest obesity in Europe, a key driver of Type 2 diabetes. This will not fade either; obesity rates will only worsen. More importantly, only half of the people with diabetes are diagnosed. The challenge for those being diagnosed then is to receive the right treatment.”

In terms of diseases, diabetes represents the highest cost for the Spanish government (eight percent of the total health budget) and is certainly a priority. “The problem is that they do not see the whole picture, which includes aspects like hospital costs or late complications due to a poor control of the disease,” continues Lommerde. “If they see the whole picture, then diabetes medication will cost less than ten percent. But because it is politically very interesting to talk about the cost of drugs, short term objectives, and not interesting to talk about late complications that you might prevent ten years from now by providing education, you will see a lot of focus in Spain and Europe on medication.”

In order to change this, companies like Novo Nordisk have decided to work much more with Spain’s autonomous communities to teach and train individuals to live healthier lifestyles. “The challenge is that there is a lack of trust in the pharmaceutical industry by people, despite our intention to do well,” Lommerde concludes. “Many in Spain do not understand that if we do nothing, we will make much more money in the future because the number of diabetes cases will skyrocket. I hope the government sees that Novo Nordisk takes Spain very seriously. This should allow us to work together to tackle the burden of diabetes and to ensure we have innovation in the market. We can do this because the quality of clinical research in Spain is outstanding and there are enough patients. Because Spain is good in research, Novo Nordisk quite often chooses this country for early phases of research.”
Solid and Sustainable Collaborations

For Antoni Esteve, director of Spanish heavyweight Esteve, Spain has not suffered a crisis in the health sector, but rather a crisis of the social economic environment in which health providers and benefi cers have to reconsider priorities so that the social service of health provision can be afforded and maintained sustainably.” Considering pharmaceuticals, change has not been dramatic,” comments Esteve. “Spain’s efforts in R&D, manufacturing, marketing and intellectual property have continued as normal in the last few years. The real problem is the way which these assets are managed and prioritized. Much of the country’s issues depend on public services that establish their criteria regarding how many resources they deserve compared to others, and the government needs to confront this.”

The same principle applies to research for the company. “New criteria regarding how products should be financed indicates a clear message about how innovation will be valued or perceived by payers,” says Esteve. “We do not have to change our scientists, research structure or managing model. But we do have to seriously reconsider how we can demonstrate the value proposition of innovation so that it is perceived enthusiastically upon reaching the marketplace. Economic pressure generated by crisis has forced industry to adapt and be more efﬁ cient in responding to what society expects from us.”

International partnerships are also key for Spanish companies wanting to grow, given the lack of a truly global Spanish pharma player. Most notably, Esteve started operations in China with ZHP, and set up a second plant in the country (Esteve Huayi Pharmaceutical) in 2009. “Creating partnerships in countries like China requires many skills that can be developed internally, and for larger companies with short-term pressures, establishing such relationships can be challenging,” continues Esteve. “This is why our ability

ESTEVE KEY FACTS AND FIGURES:

- Founded in 1929
- 2,300 employees
- 12% of employees engaged in research
- International expansion began in 1954
- Presence in 60 countries
- Total sales for 2013: EUR 818 million (USD 1.06 billion)
- International sales for 2013: EUR 448 million (USD 579.5 million)
- R&D investment in 2013: EUR 60 million (USD 77.6 million)
to establish solid and sustainable collaborations is truly one of Esteve’s strengths, both in terms of business units and culture. Open innovation and collaborative research are key to maintaining good research, and having partners or other stakeholders that support your efforts because they believe in you and want to participate creates real added value.”

Ultimately, it is up to pharmaceutical companies themselves to bring about recovery in Spain rather than waiting for the health authorities to act, according to Esteve. “Government has other priorities and problems to take care of, especially for research and innovation,” concludes Esteve. “Therefore, I think it is time that pharmaceutical companies, as actors in the health sector, take their own role and help to create this ecosystem through our initiatives and proposals to society. A society needs to believe that innovation is a key driver in order to be competitive in a knowledge-based economy.”
According to Enrique Samper, President and CEO of NIMGenetics, Spain was historically inactive in the area of biotechnology and biomedicine up until the 1960s, and thus the country has traditionally relied on other countries in this area. “This area of research is not embedded into our “genes” like it is in the Anglo-Saxon culture,” he says. “We are a bit myopic in terms of looking at the future. The government needs more expert vision, as well as clear examples as to how science and technology can be transferred into economic wealth.” Samper had the opportunity to study in the United States, and the level of entrepreneurship and general awareness of science and technology is markedly higher there than compared to Spain.

Nevertheless, a few shining examples of technology combined with entrepreneurship have paved the way for success in some instances in Spain. Samper has been President and CEO of local genetic diagnostics business NIMGenetics since 2011. The company was created in 2008 with extremely limited funds and thus in difficult conditions. “Essentially, we wanted to put all the know-how that Spanish scientists have and translate that into a company that creates value through providing better genetic diagnostics wherever we can reach,” Samper comments. “Our goal is to make genetic diagnostics useful, affordable and widespread. We believe that having a genetic diagnostic result early on in the pathology will have a very significant impact on the lives of people and this includes the affected patient, the patient’s family, the doctor and the global health economic system wherever we are.”

Because of the comparatively small environment in Spain for venture capital in the tech area, NIMGenetics relies on recurring cash flow to generate the majority of revenues for growth. “There are a set of investors in NIMGenetics that have been very faithful to us,” says Samper. “So far yet we do not have an institutional investor, but we have grown from zero to 35 people and about EUR 4 million (USD 5.5 million) in revenue this year with only EUR 600,000 (USD 828,000) in total capital invested in NIMGenetics. This has been also supported by a series of public organizations in Spain like CDTI and ENISA. These groups provide us with small grants and loans, for another million Euros or so. Still, we have been very capital-efficient because this growth would have cost at least threefold in the US with our talent.”

Many current diagnostic tests for genetic disorders require patients to undergo a series of tests in hospitals for months or years, particularly when the pathology is not clear as to the cause of the disorder. NIM Genetics aims to change this. “We provide a very specific tool in which we provide a correct diagnostic, identifying the cause of the problem very quickly and precisely,” says Samper. “We are currently undergoing some
pharmacoeconomic studies for our microarray technology; NIMGenetics often finds the genetic cause quickly, providing clinically relevant results in a few weeks, rather than going through different tests for years.”

One such product is Trisonim, which was commercialized in 2012 in collaboration with the Beijing Genomics Institute, and provides extremely precise information about the occurrence of eight different chromosomal syndromes. “NIMGenetics was the first company to put this type of product into the market, and it has been revolutionary,” recalls Samper. “The advantage of Trisonim is its ability to read the complete sequence of the DNA of fetal DNA in maternal blood. Competing products read small fragments of the genome called single nucleotide polymorphisms (SNPs), which are informative for very large chromosomal syndromes (i.e. Down Syndrome), but less so for smaller syndromes, of which there are many.”

NIMGenetics has also focused on maintaining an aggressive internationalization strategy in order to maximize its commercial potential. The company partnered with the Instituto de Medicina Genómica (IMEGEN) in Valencia to consolidate its international presence in Latin America. “Together, we will go to Mexico, Colombia, Peru and Chile with a combined portfolio of 1400 genetic tests, and we stand a good chance to become a leading player,” Samper notes. “In India, we have signed a letter of intent which is a first step into the service contract agreement with one of the largest laboratories of clinical diagnostic and pathology laboratories in the country. That will be a very powerful synergy. In both Latin America and India, the technology has not been fully commercialized, so now is the time to enter these countries.”

Growth for NIMGenetics has been about 75 percent CAGR for the last six years, and Samper’s aim is to grow 100 percent per year, a goal certainly easy for a startup but increasingly difficult with each passing year. “We will focus on international markets as we already have significant presence in Spain, where we can have a market share of 25 percent for our tests,” concludes Samper. “Spain will continue to be a place of growth, but our greatest opportunity is international. In five years’ time, we hope to be recognized as significant partners in the genetic diagnostics field across five continents.”

“Spain will continue to be a place of growth, but our greatest opportunity is international. In five years’ time, we hope to be recognized as significant partners in the genetic diagnostics field across five continents.”
PharmaBoardroom: What have been some of the key successes of this department in terms of innovation over the past couple of years?

MARIA LUISA PONCELA: The Ministry of Economy has developed a new national strategy and plan for science and innovation, which is focused on societal challenges. The first set of these challenges we have to define is centered on health. We are now developing this plan and we have published open calls for implementing this strategy. Approximately 25 percent of all applications received have been focused on health and health-related aspects both in applied science and in the frontier of knowledge. This open call is made for public and private consortia to develop and make research and innovation for companies in which we can apply knowledge originated from universities and research institute for various topics including health, transport and energy, among others.

PB: How can the innovative public procurement process help foster innovation?

MARIA LUISA PONCELA: The Ministry is strongly promoting the process of innovative public procurement (IPP). According to OECD, the US, Canada and Spain are the top three countries for pushing IPP, and health in particular has had a warm welcome in this area. For example, two hospitals in Galicia currently use IPP, which combined represent a large portion of the €200 million being invested in this idea. But to develop IPP the government needs to communicate to society, companies and researchers that it would like to buy new technologies or innovative services. This involves everything related to hospitals, physicians, nurses, and administrative people as a part of defining IPP, how they would like to introduce innovation in this procurement.

PB: You have said that Spain needs to double its investment in R&D+i, particularly in the private sector. How much of a role do you think the pharmaceutical industry needs to play in that investment?

MARIA LUISA PONCELA: The pharmaceutical sector is the leader in R&D in Spain. When I say it is necessary to double our investment, undoubtedly I would like to see the pharmaceutical sector play a leading role. We have a network of hospitals where physicians engage in a high level of research and have the potential to achieve great things here. Looking back ten years ago, foreign pharmaceutical companies were investing in research in Spain but mainly in the later phases of the development of a drug. But at present there are big companies investing in Spain that entirely develop a drug here, from preclinical until the last phase of clinical. This is a great path for Spanish knowledge and science, because many physicians of different hospitals are involved, as well as researchers of Spain’s leading institutes.
PB: What is the potential for Spain’s biotech sector to grow?

MARIA LUISA PONCELA: I think the potential of these companies is enormous. The products that they develop usually have the objective of being sold to big pharma, and such products are developed with a very high quality of research. This quality research is interesting big pharma, as many developments have a current focus on personalized medicine. For example, the Spanish genomics company Oryzon recently closed an agreement with Roche to research and develop a drug for a specific cancer, which was strategic for both companies.

The Ministry of Economy is encouraging these developments in the biotech sector not only to open calls that we have here, but to provide loans to the companies to do such things. Our strategy is focused on capital risk. We are closing agreements with different initiatives from different financial institutions, not only from Spain but also from countries like the United States, who has invested with government funds and capital from financial institutions for the equity of biotech companies. We need to give them loans to invest in research but private equity is fundamental as well.

PB: What would you like to have achieved for Horizon 2020, and where can we expect to find Spain in terms of being a competitive country in innovation?

MARIA LUISA PONCELA: We are supporting our agents strongly in order to fulfill the objectives of Horizon 2020 because it mainly provides money in open calls in a very competitive environment between researchers. Successful open calls provide the capital necessary not only to engage in research but also ensure high quality innovation and a strong positioning for receiving EU grants. This is a very good opportunity to achieve that level of excellence because only the most excellent proposals will be financed. It also provides the opportunity to internationalize the teams and increase the network with international agents. The Ministry of Economy also supports companies to go to Horizon 2020 because we recognize that we have strong teams with dedicated people researching in Spain that just need the international exposure to succeed.

I believe that Spain’s researchers in the pharmaceutical and biotech sectors have enough good quality and excellence to be leaders in many of those proposals, and they are doing so at present. Spain is ranked fifth in Europe for winning open proposals in consolidation grants. That means our research is truly excellent. We will continue to be ambitious and try to do even better in our ranking for grants. Leaders in Spain will become leaders in Europe.
R&D in Spain: Promising and Profitable

PharmaBoardroom: How do you perceive the R&D infrastructure of Spain today?
BERTIL LINDMARK: Almirall is the first pharmaceutical and the fourth biggest investor out of all sectors in Spanish R&D. We invested 18 percent of the company’s sales in R&D in 2013. We cover all R&D phases from initial hits to registration of a new drug. However, a country of this size should have more companies spending even more than Almirall has. Spain has the necessary infrastructure to support R&D based business and to make this type of industry promising and profitable. The quality of secondary and tertiary education in Spain is very high. Maybe Spain is on a curve that lags slightly behind other parts of Europe. Nevertheless, the Spanish government is working hard with the industry to promote R&D based industries, and to enable funding at the national, European, and global levels.

PB: What are Spain’s strengths in the pharmaceutical/medical research area?
BERTIL LINDMARK: I am impressed by Spain, and in particular Barcelona, for its level of medical education and profession. The way hospitals are organized and the way people become experts in different therapeutic areas is a strong point for Spain and Spanish medicine, based on the country’s traditions. Barcelona has a respiratory network and looking at pharmacoepidemiology, and preclinical and pharmaceutical R&D, we can easily find expertise throughout the country.

PB: What have been some of the most important achievements in terms of R&D since you joined?
BERTIL LINDMARK: We have been able to modify and evolve the R&D area into a more dynamic and agile organization. This required the invigoration and modernization of the management and leadership style in Almirall’s R&D, and allowing a new generation of leaders to progress. Additionally, Almirall has enjoyed successes providing innovative products to patients around the world like Eklira® Genuair®, Constella® and Sativex®. Before I came, the company had been investing in these products which are fantastic but difficult to bring to the market. Furthermore, we have developed and industrialized the production of a best-in-market multi-dose dry powder inhaler, named Genuair®, a twice daily LAMA (long-acting antimuscarinic), which helps patients with COPD to breathe easier.

The way hospitals are organized and the way people become experts in different therapeutic areas is a strong point for Spain and Spanish medicine, based on the country’s traditions.
PB: How important is the R&D strategy in Almirall compared to big pharma?
BERTIL LINDMARK: 64 percent of our products come from our own R&D, which is a high rate in the industry. If you look at where big pharma products really come from, only about 20 percent originate from the company itself. Almirall employs a dual strategy of high market penetration and excellent quality through our R&D products and third party drugs. With our R&D compound aclidinium for COPD we are second LAMA to enter into the market in Europe and the US, which is impressive for this size of a company based in Barcelona. Constella and Sativex are unique first-in-class licensed products, the first one for irritable bowel syndrome with constipation and the second one for spasticity in multiple sclerosis. We do continue to invest in R&D but are constantly on the hunt for meaningful products that can add to our portfolio.

PB: What is the typical strategy for Almirall in terms of how it engages with clinical centers and how you attract patients to participate here and abroad?
BERTIL LINDMARK: Small specialized studies like SAD/MAD and early phase trials in dermatology often go to specialized centers. We recently finished a MABA program, which is another exciting respiratory product. It is a bi-headed molecule that creates two activities in one molecule which makes it possible for a triple combination when you add a steroid. We are one of the few companies in the world that has such a molecule. For larger trials we look for large contract research organizations to help carry out these complex trials.

PB: Almirall has one research center here in Barcelona and two in Germany. What is the strategic importance of each of these centers?
BERTIL LINDMARK: The molecular brewery is here in Barcelona. This center has very good chemists and preclinical pharmacologists, as well as the core of regulatory and global clinical development with biostatisticians and clinical operations. One center in Germany focuses on dermatology through reformulation and topical formulation innovation, repositioning drugs and reformulating known molecules into topical treatments. We currently research a topical combination therapy for psoriasis, in one formulation which brings down the side effects of steroids on the skin and increases their potency. The second German center, Sofotec, focuses on inhalation technology. There we have engineers focused on the characteristics and patient friendliness of the inhalers, and how they and the drug formulations we use compare to other product.

PB: What do you look for in a partner? What synergies can Almirall offer?
BERTIL LINDMARK: Our inhaler and the series of compounds we have in respiratory provide many opportunities for inhaled therapy. We have one of the best pipelines globally for inhaled bronchodilators. In dermatology we have a series of oral and topical products that have unique niches and features. Furthermore, we have the chemistry that allows us to create compounds that travel to the lung, stay there, and provide efficacy in the lung. We can transfer this knowledge to understand how we can make molecules that penetrate the skin, stay in the skin and do the efficacies locally.

Aa country of this size should have more companies spending even more than Almirall has. Spain has the necessary infrastructure to support R&D based business and to make this type of industry promising and profitable.
Fighting against the abandonment of R&D in Europe

PharmaBoardroom: Could you provide our readers with an overview of IRB?

JOAN GUINOVART: I am the founding director of the Institute for Research in Biomedicine, which was created in 2005 by the Generalitat de Catalunya (Catalan Government) and the University of Barcelona. IRB Barcelona is located in the Barcelona Science Park, which is part of the main Science and Technology Campus of the UB. IRB occupies a prominent position in a rich landscape of research centres of excellence, universities, hospitals, scientific infrastructures and pharmaceutical companies, all with a focus on the life sciences.

IRB is a member of a network of the CERCA research centres that belong to the Catalan Government. CERCA is a body that brings together a new type of research centre that does not fit the traditional rigid structures common to Spain over decades. These centres are characterised by highly flexible and dynamic structures and they are subjected to evaluation. This model thus contributes to generating internationally competitive science. Thanks to such a structure, IRB is able to apply a flexible international recruitment strategy that is not typically used by universities.

This has given rise to a flexible system through which to attract and recruit talent while generating research centres that allow international scientists to integrate comfortably. Furthermore, despite new governments coming and going, the research centres and ICREA have continued to develop under different administrations. The Catalan system has maintained the same policy of attracting and recruiting the best international talent through open calls for over 15 years, avoiding endogamy, and the impact has rapidly become evident.

PB: What is the competitive strength of the Catalan research community in the European context?

JOAN GUINOVART: Catalonia is ranked third, behind only the Netherlands and Sweden, in the number of ERC grants per million inhabitants. A good indicator of the usefulness of the ICREA recruitment system is that many of the ERC grants went to researchers holding ICREA positions.

PB: The Institute has strength in many areas like cell and developmental biology, molecular medicine, chemistry and oncology. How are you able to engage in so many areas?

JOAN GUINOVART: IRB brought together outstanding individuals from various fields to work towards a unified goal of conducting multidisciplinary projects that address important biomedical problems affecting our society. IRB indeed has a unique combination of structural and computational biology, chemistry, and biology; this profile is uncommon and it opens a strategic window to gain insight into basic molecular processes in health and disease and provides unprecedented potential for the translation of basic biomedical research into innovation.
The founding fathers of IRB deliberately put together people from different backgrounds in order to foster opportunities to talk and collaborate. This form of communication is strongly encouraged at IRB. Our chemistry is essentially chemical biology, meaning chemistry that ultimately has an application or provides a way to understand a biological problem that you might use for a biological target against a disease. Structural and computational biology offer very different tools.

We also have an emphasis on oncology, which is focused primarily on the study of metastasis, this being one of the major health problems as 90% of cancer patients die as a result of the spread of this disease to vital organs.

**PB:** IRB has a produced number of spinoffs over the last decade; what has been IRB’s entrepreneurial capacity to generate commercial entities from the research produced here?  
**JOAN GUINOVART:** Early after the foundation of IRB, we set up a Technology Transfer Office to optimise the translation of our discoveries and knowledge into benefits for society. Therefore, since its very beginning, IRB has been committed to developing an entrepreneurial culture, encouraging and supporting its research community in this endeavour. Our Technology Transfer Office works with researchers to ensure the identification of commercial opportunities for their discoveries. This office is also actively engaged in entrepreneurial training initiatives to provide researchers with key business skills.

**PB:** What are your expectations for the near future, as Spain finally begins to recover from its recession?  
**JOAN GUINOVART:** I am afraid that I have to criticise the research policies of some European governments. They have aban- doned science and have shown no interest in investing in such a strategic field for many countries, including Spain. It gives the impression that politicians do not appreciate the benefits of having a modern, strong and well-organised science system. They perceive research as a consumable, not as an investment. In contrast, Catalonia has demonstrated that only small changes—as commented before—that do not require a huge financial investment can nurture the scientific environment. The benefits of this policy have become evident in less than a decade, and we already have a strong and competitive system. In this regard, there are centres that have weathered the crisis. An example is IRB, and in general the centres included in the Catalan science system.

Another strategic issue to ensure a viable future refers to technology transfer and capital risk. In this regard, we also need a revolution in the mentality of the business sector that will bring about an appreciation of the value of investment in science. Barcelona has two of the top five business schools in Europe (IESE and ESADE), with whom IRB has established close ties, thus allowing some postgraduate students to work with our Technology Transfer Office on their dissertations. Bringing together young people who excel in business and first-class scientists will breed a novel business culture that will favour economic growth.

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The benefits of manufacturing in Spain

PharmaBoardroom: What durable changes has the crisis brought to the pharmaceutical sector overall?
ANDREAS ABT: Even before the crisis, a change in the sector was necessary. From the perspective of industry and Roche in particular, we are in the business for the long-term. This requires a sustainable model and that was what the sector and us too were demanding. Spain has one of the highest per capita consumptions of medicines, especially in primary care, which is perhaps not always scientifically necessary. As such, we will see significantly reduced growth momentum for the coming years. The challenge is that access to innovation is significantly delayed.

PB: What were some of the personal changes you had to make, having arrived just before the crisis started?
ANDREAS ABT: The total pharmaceutical market has experienced a 20 percent contraction. Roche had to adjust its structure due to government measures imposed, including a seven and a half percent price discount in 2010 that hit everybody. We also lost an important product in primary care. Since then, we have tried to weather the storm, so turnover has decreased less than the market. Of course we have also given priority to getting paid, since accounts receivable were reaching unsustainable levels. Spain owed Roche a significant amount at the end of 2011 in unpaid bills between our pharmaceutical and diagnostics divisions. Thankfully, the current government established a plan to raise €32 billion to pay providers in a number of different industries under the leadership of Budget Minister Cristóbal Montoro. This plan provided significant relief for the industry and was very important for this affiliate in order to demonstrate to our headquarters that the country is going through difficult times.

PB: What can the private sector do to ensure that private investment in R&D is happening, and what is Roche doing in this regard?
ANDREAS ABT: One of our key challenges is proving that Spain attractive for us to maintain our investment. With a stable scenario, we can commit to the country. Roche nevertheless sustained a strong image in the country; we have kept our annual investment of €46 million in R&D solid, and this has not changed prices of our products. In 2012 and 2013, 18,000 patients were recruited in Roche Spain’s hospital care portfolio for 270 clinical trials in

Between 2012 and 2017, we will invest almost €50 million in manufacturing facilities, and thus these centers will be at the cutting edge of the latest technology.

Andreas Abt, MANAGING DIRECTOR – ROCHE SPAIN
over 200 hospitals using more than 50 new molecular entities. Therefore, the current reimbursement issues need to change, as they are not justifiable for patients, doctors and companies in a country like Spain.

**PB:** What are the competitive strengths of Roche Spain’s manufacturing facilities?

**ANDREAS ABT:** Not only do Roche Spain’s facilities have very highly qualified people and a great management team, the company is actively investing in them. Between 2012 and 2017, we will invest almost €50 million in manufacturing facilities, and thus these centers will be at the cutting edge of the latest technology. Essentially it is a mixture between people and investments. We also have a global IT service center with over 300 employees, one of the few such hubs that Roche has worldwide, and we are expanding this facility as well.

**PB:** Roche recently joined ASEBIO, and also recently entered into an R&D partnership with local genomics company Oryzon. What do these activities communicate in terms of Roche’s commitment to the industry?

**ANDREAS ABT:** Roche is a biotech company, albeit a very big one. In fact, it was one of the first companies to really bet on biotech. It took a long time, but the company’s focus and passion for personalized medicine has resulted in a number of amazing products and today almost every R&D project has a biomarker. It is a strong signal in the sense that the biggest biotech company in the world has joined Spain’s biotech association. We are committed and obsessed with innovation, which we will look and strive for wherever we can find it. Oryzon is a testimony to that pursuit, as well as the quality of the Spanish R&D. It is the first time that Roche chooses a Spanish company to partner with and it is yet again proof of how much we believe in alliances for research, just as much as we commit to in-house projects.

**PB:** With so many investments, do you think Roche is leading the way for other big pharma established in Spain to invest in the country?

**ANDREAS ABT:** We are. We invest a lot and have demonstrated a significant commitment to the country, as long as the market keeps certain attractiveness. But we are committed to Spain and we are not here for the short term. We will not make rash decisions just because of a crisis or fluctuations in the market. Roche is not the only one but is probably one of the better cases or role models for Spain that exists.

**PB:** What are your expectations for the pharma industry as an investor in the country’s research capacity, and what role will Roche play in the next few years?

**ANDREAS ABT:** I think Spain is a very important and attractive pharmaceutical market, and I am convinced it will stay that way. Some markets might grow faster but Spain will remain a key market worldwide. Roche is a leading pharmaceutical company in the world and Spain, and we want to lead in the contribution to the country’s sustainability. We are convinced that certain things must change, and we cannot sit idly by; we want to be a very active player, partner and leader of this change through new ideas and initiatives.
Adapting to increased complexity in European markets

PharmaBoardroom: This affiliate runs an important manufacturing facility that exports to 123 countries worldwide. How much does this plant represent in terms of global exports?

JAVIER ELLENA ARAMBURU: Our facilities in Alcobendas only manufacture and package oral dry products, but as of June 2014, we will start packaging a totally different line of products that were formally part of an operation conducted in Germany. This decision will help the plant to replace some of the volume lost as well as maintain volume for the next few years. More importantly, we will start operating differently. Lilly has already brought new technology to Spain that is very well aligned with the profile of the majority of molecules in our pipeline, where we will focus less on traditional compounds and more on biologics.

PB: In January 2014, Spain became the first country worldwide to authorize Amyvid, a radiopharmaceutical that significantly improves the diagnosis of Alzheimer’s. What are your expectations for Amyvid in terms of sales growth and health outcomes in Spain?

JAVIER ELLENA ARAMBURU: We were very proud of being the first country to receive approval and reimbursement of Amyvid. This product will gradually standardize the diagnosis approach for Alzheimer’s through more efficient use of resources and more accurate treatment of patients, particularly those bordering between dementia and Alzheimer’s. We will see rapid growth in the use of Amyvid not just in daily clinical practice for this very specific patient population, but also in clinical trials for potential new molecules being developed for Alzheimer’s.

PB: What do you perceive to be the real outcomes of the recent protocol between Farmaindustria and the Ministry of Health?

JAVIER ELLENA ARAMBURU: The real intention of this agreement was to reinforce the commitment of both sides to collaborate in key aspects, which involve continuing to deliver innovation and making that innovation accessible to patients. This is a critical moment for the industry. When the reference price system was approved last month through a Royal Decree, the government announced that the criteria for pricing and reimbursement would be ready by late 2014 or early 2015. This decree will determine how new brands or molecules will be assessed in terms of usefulness, how they will be funded, and how this innovation will be made accessible. It will set the framework for the next decade, and it is a top priority for innovative

It is not just about having more molecules; it is about playing a game, where winning involves healthier patients.

Javier Ellena Aramburu, President & CEO Spain, Portugal and Greece – Lilly
pharmaceutical companies. I am convinced that the only way this will happen is through frank and formal dialogue, productive collaboration, and a common objective that ultimately serves patients.

PB: As head of Spain, Portugal and Greece, what are some of the organizational changes that you are employing to navigate these harsh times?

JAVIER ELLENA ARAMBURU: We have a twofold strategy of delivery and transformation; doing both simultaneously is not easy. Delivery has involved introducing several measures to adjust the organization according to the reality we are facing in all three countries. We needed to change the business substantially through the introduction of many measures while still being able to deliver on our commitments and to achieve our goals. This is critical because the funds we are receiving today are being used to clinically develop more than 60 molecules. As success is vital, Lilly has devoted about 24 percent of sales to R&D in 2013, probably the highest among the top 30 companies worldwide in relative terms. About ten molecules are in Phase III and several are in regulatory processes both in the US and Europe.

In terms of transformation, regardless of whether Europe or the world recovers previous growth rates, the paradigm is completely new. To succeed and create this transformation, we need to define key elements and capabilities and then create more efficiencies. It is not just about having more molecules; it is about playing a game, where winning involves healthier patients. This game requires more and different work to launch a drug successfully compared to launching drug a decade ago. Today, the focus is on clinical evidence and demonstrating meaningful and concrete value propositions. This means truly proving the value of how new medicines can help patients and our public system to maintain its quality with greater sustainability. That is why this recent protocol is so important. When I talk about increased complexity, it is due to having many more stakeholders in this country. The industry needs to understand what is needed and expected not just from the Ministry of Health, but also the Ministries of Economy and Industry. Innovation is not about producing more brilliant molecules, but rather impacting lives and determining how new medicines can improve efficiency and the standards of the NHS.

PB: What role will the pharmaceutical industry play in the reconstruction of Spain’s economy, and how will Lilly contribute?

JAVIER ELLENA ARAMBURU: I am convinced that Spain will recreate a good macroeconomic environment in which to operate. This must require more activity in something other than tourism or construction. Spain needs to be much more intense in the use of technology and creating the right environment to attract investment related to knowledge, and specifically biomedicine or bioindustries in the health sector. The number of biotech companies that have been established and have succeeded in Spain has skyrocketed in recent years. If Spain can create this environment for “bio-investments” in different fields, the country clearly has a huge opportunity to attract European talent. Generally speaking, the country needs to define what it wants and to identify the key growth engines to accelerate the recovery of the economy.
Managing in Times of Crisis

**PharmaBoardroom:** You became general manager of Baxter Spain & Portugal in 2011. What steps did you take to ensure you could continue selling products and maintain sales growth?

**LUIGI ANTONIAZZI:** Given the significant shift in the market, we needed to perform an in-depth analysis to find a strategy moving forward, especially since we quickly realized it was not going to be a temporary change.

Baxter is strongly anchored in select therapeutic areas, such as haemophilia, chronic renal disease or nutrition. Within those, the company has a clear leadership position and thus we try to communicate to prescribers, payers and policy makers at regional and national level the value our therapy offering represents for patients and how it contributes to a more sustainable healthcare system. The conversation, especially with payers, must go beyond therapy costs; we must also look at the value an innovative company like Baxter can provide to patients’ quality of life and how it can help improve the efficiency of the healthcare system. In spite of the significant cost-reduction measures, we contributed to maintaining reasonable access to the therapies we provide for patients.

**PB:** Does Spain’s decentralization necessitate different strategies to target each autonomous community?

**LUIGI ANTONIAZZI:** One advantage is the opportunity to be closer to the patients, which is useful to fulfil the ultimate objective of providing a better service to the population of each region. Needless to say, each region has a unique set of healthcare policies or interpretation of how healthcare services should be provided to citizens. Consequently, we have invested in our market access organization and built stronger relationships with the regional authorities to demonstrate to them the value we can provide in each therapeutic area.

**PB:** Could you tell us a little bit about your manufacturing sites in Spain?

**LUIGI ANTONIAZZI:** We employ around 300 people at our fluid plant in Huesca where we produce non-PVC intravenous solutions. Not only does it serve the local market, but by exporting 80 percent of what it manufactures it is also an important economic driver in the region. We are proud that we can export Spanish technology and products to the rest of the world.

**Clearly, we have been impacted by the government’s cost reduction measures, but we did not have to go through huge restructuring or downsizings as a result. These are very difficult times for our teams and it is important to keep them not just motivated, but to build and unite the team around a single goal.**
of Europe. As Baxter, we would certainly be willing to consider investment opportunities in Spain moving forward, provided the right conditions are put in place.

**PB:** As the Spanish market continues to flounder, has this facility had to step up its game in terms of using exports as a means of providing sales for this affiliate?

**LUIGI ANTONIAZZI:** Our plant in Sabiñánigo needs to be very competitive in terms of its manufacturing, technology and efficiency. That has been the focus of this plant, and thanks to the investments made over the years, Sabiñánigo is one of the most efficient and automated plants we have in Baxter’s European network.

**PB:** Does Baxter’s presence in Spain today reflect the objectives that you set out when you first took over this affiliate?

**LUIGI ANTONIAZZI:** Baxter Spain is on the path to realize the strategy that was set out three years ago. This is a continuum. We set objectives and we revise them. We have strengthened our position in all key segments and therapeutic areas. We have made significant progress in our Renal Division with the acquisition of Gambro. This has allowed us to complete our product offering, which includes all types of renal replacement therapies, be that for patients treated at home or in the hospital. This is a good example of how we believe we can add value. In our Renal Division in Spain, we have a vertically integrated service offering. We can offer products for hemodialysis, peritoneal dialysis or acute dialysis, but also services related to the treatment of dialysis patients, given the fact that we also operate several dialysis clinics in Spain.

**PB:** How do you maintain company morale in times of crisis?

**LUIGI ANTONIAZZI:** Clearly, we have been impacted by the government’s cost reduction measures, but we did not have to go though huge restructuring or downsizings as a result. These are very difficult times for our teams and it is important to keep them not just motivated, but to build and unite the team around a single goal. We continue to communicate clearly on our vision and strategy and provide a healthy and friendly work environment. I am pleased that Baxter Spain’s efforts were recognized with the “Great Place to Work” award. We continued to invest in developing and training our team: last year alone we invested more than 10,000 hours in training. We continue to invest in developing the skills we need and in developing our talent, so that we are even better prepared to address the challenges ahead.

**PB:** Where will Baxter Spain be in the next few years?

**LUIGI ANTONIAZZI:** You will see a company that has clearly evolved from where we are today. One of the great advantages and challenges we have at the same time is a strong product portfolio and a pipeline that will allow us to bring new, innovative products to the market. This will drive revenue growth and provide great professional development opportunities. Baxter will evolve and grow on the basis of its strengths as an organization and its innovative products. For the rest, we will continue to assess different options how to best drive innovation and deliver value to all our stakeholders.

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*We are proud that can we export Spanish technology and products to the rest of Europe.*
Predicting life

**PharmaBoardroom:** The study of telomeres and telomerase is relatively new. What is the global interest in this subject as a scope for commerce?

**STEPHEN J. MATLIN:** Before we started Life Length, we spent over a year doing very careful market research to effectively look at this very issue. This incredibly powerful technology which we call Telomere Analysis Technology® (TAT®) measures telomeres, found on the tips of chromosomes. One market for this was a tool for academic research, such as scientists and doctors investigating whether there is a causal relationship between telomere loss and telomere attrition and disease. The second was a tool for industry as a companion biomarker in current and developing products to determine whether drugs, nutraceuticals, vitamins, active ingredients in creams and cosmetics, or even how food affects the rate of ageing as expressed by telomere attrition and rate of loss.

As an example, 85 to 90 percent of all adult cancers escape the limit that causes cells to become senescent because they endogenously express telomerase (the enzyme that repairs telomeres), allowing them to continually divide and metastasize rapidly, essentially meaning that every cell in that tumor is immortal. If a pharmaceutical company could inhibit the expression of telomerase in those cells, this could potentially be a blockbuster drug that addresses almost all human cancer. Pharmaceutical companies now need to figure out how to deliver such a target with a technology that measures whether your potential molecules can slow telomerase expression, which means screening compounds. Life Length offers that testing service to the industry.

Other examples include characterization of cell therapy and regenerative medicine products where our technology is providing a much needed quality control tool and services to nutraceutical or pharmaceutical companies that want to show that their drug, supplement or even yoghurt may slow or reverse the loss of telomere, reverting the ageing process. This makes our technology relevant for many sectors.

The third market area that we originally did not anticipate is that society is fascinated with this technology’s concept. The idea of biological age as expressed by this genetic biomarker, which is a very precise and objective measurement of the ageing process, is very appealing to physicians and patients worldwide, who want to adopt our test as an innovative biomarker of health.

**PB:** What is the global academic interest in telomeres for researching this life-changing technology?

**STEPHEN J. MATLIN:** There are more than 17,000 peer-reviewed papers published on telomere biology and its relationship to just about any disease. For example, in cardiology there are more than 600 publications that show that short telomeres correlate to higher cardiovascular risk and death from CVD. Patients in the first quartile of the shortest telomeres may have eight times the risk of dying from heart attacks. Consequently, Life Length is beginning to work...
with cardiologists who use our test as a companion biomarker to provide a richer insight in terms of a predicative and measure of disease and to take proactive, preventive action.

**PB:** Life Length’s diagnostic is also ten times more precise than similar products. How was this technology developed?

Existing technologies used to measure telomeres are actually semi-quantitative, often imprecise, and dependent on lab technicians’ experience. After five years and approximately €20 million invested in research, technical studies and development for a technique that measures telomeres individually, we realized this really was a quantitative and qualitative step forward over current technology. In late 2010, the Botín Foundation, the Spanish government and I put together a company that would license the technology from the CNIO to which we would pay royalties, generating a return for Spanish society. Since then, the technology has evolved dramatically as we have industrialized and scaled it for commercial use.

**PB:** Apart from working with academia and industry, what is the global commercial strategy to sell this technology to physicians or the general public?

**STEPHEN J. MATLIN:** The concept of biological age has always been around, but Life Length has a scientific and objective basis that can be correlated to this biomarker of telomeres. As a result of media exposure, we received many thousands of e-mails worldwide from people wanting to measure their telomeres; individuals, physicians and institutions and corporate clients. In order to get samples from all corners of the globe to Madrid we started working with big diagnostic labs in each country, who became local partners that transferred blood samples from the physician’s office to a lab. Life Length began building partnerships with major diagnostic labs worldwide, many of whom contacted us, and we now have 13 such partnerships. We believe that the TAT test has the potential to become a biomarker on par with cholesterol testing. Our vision is that Life Length’s test will become over a period of time an increasingly standard part of preventive healthcare as well as a test used by doctors and specialists because of its correlation to many diseases.

**PB:** How do you plan to expand the company further?

**STEPHEN J. MATLIN:** We currently bring all samples worldwide to our lab facilities in Madrid. During 2015, we intend set up a lab in the US, our biggest market, and to establish about five labs in strategic locations around the world in the coming years. We will continue to use our lab in Madrid as the R&D hub to improve our technology and to process European samples here, while other facilities will function as production labs to deliver results to clients.
Structural improvements to improve Spain’s competitiveness

стеа�ма: Spain has a highly talented workforce and offers low-cost production capacity. How can the country leverage that as a means of promulgating economic recovery and growth?

DANIEL CARREÑO: We had these attributes before the crisis and this is why we were one of the world-leading countries in these markets. Due to the crisis, Spain has undergone important structural change, created a stronger financial system, and implemented a new labor law that provides flexibility. As a country we are much more competitive internationally. Today, Spain has high class productivity, at the top level of OECD countries, with an average lower cost of 30 percent. In the last 18 months, we have seen huge foreign direct investment coming back to the country. Combined with solid infrastructure, top-class universities providing access to a talent pipeline, transport facilities, high speed trains, and hospitals to name a few, the structure of this country has become much more competitive.

PB: GE specializes in so many areas, and in Spain you are able to engage all of them, a unique situation in the country. What is the relevance of Spain for the organization?

DANIEL CARREÑO: Based on different performances, Spain is one of the top 15 economies in the world. Much more importantly, due to export activity and in some sectors like EPC, half of the top 25 companies in the world are Spanish. Considering project deals influenced from Spain through these Spanish companies worldwide, the importance of Spain for GE ranks fifth or sixth globally.

PB: How have you ensured that GE demonstrates value over cost in Spain, given that budgetary concerns and cutbacks in public spending might mean buying products from cheaper regions?

DANIEL CARREÑO: This is our ultimate goal and requires creating long-term solutions rather than systems or products that fix needs quickly. GE has a privileged outlook of technology evolution, and by sharing such information with customers, we can address their long-term needs. Given our more than 60 year presence in Spain, GE can try to find alternative financial models to partner in a different manner knowing that our clients are short on capex these days. Therefore the organization looks for more opex-driven formulas that help them go through a tough time. Long-term value also plays a key role in this strategy. GE is the only company that produces most of the items that ultimately build healthcare systems and we can secure a continuous upgrade of those systems.

Spain has undergone important structural change, created a stronger financial system, and implemented a new labor law that provides flexibility. As a country we are much more competitive internationally.
PB: The decentralized nature of Spain is difficult for getting products into each autonomous region. Have you changed your strategy in terms of key account managers versus salespeople?

DANIEL CARREÑO: One of the benefits of being the leading company is that GE’s installed base helps to provide the service that we have committed. We have people in most of the Spanish provinces, and this physical presence helps us in most regions. We try to leverage common services as much as possible, delivering the benefits of this standardization combined with the close contact through being officially present in those countries. But the system obliges key account managers and phone service managers to ensure we are close to customer needs.

PB: What steps have you taken to ensure that the payment time for hospital-based products is reduced?

DANIEL CARREÑO: In June 2012, the government paid EUR 30 billion (USD 38.74 billion) through a public payment plan that reduced debt to almost zero, and sales outstanding dropped to 250 days. Pending invoices in the medtech sector today are about EUR 1.1 billion (USD 1.42 billion), and the average number of days outstanding is 150. Additionally, there have been a couple of other measures put in place such as electronic billing, and a centrally administrated mechanism to enforce regional payments. This is one of the positive consequences of the crisis; on top of our past problems, a major crisis of liquidity has forced the government to make the ecosystem more sustainable.

PB: What are some of the most important issues on your agenda today as president of FENIN?

DANIEL CARREÑO: The medical technology sector in Spain consists of over 1,000 companies generating nearly USD 9 billion in value, USD 2 billion of which belongs to exports. The medtech sector has grown more than 21 percent over the last four years; while it certainly drives Spanish industry, there has been a big decline in the domestic market over the last few years. Spain was a leader in innovation for many years from the new technology introduction perspective to create new ways of doing business. Spain was also one of the first countries to establish public-private partnerships, and the market here was always ahead of volume in terms of the healthcare sector.

Over the last five years, major cuts in public budgets have caused companies to change their operating expenses, both in the pharmaceutical and medical device areas. In some cases, 90 percent of business has disappeared for some companies compared to 2007. The last two years have been slightly better, but the negative trend continues.

PB: How do you want to position GE in Spain for the upcoming years?

DANIEL CARREÑO: We want to be seen as a partner that helps customers through holistic solutions linked to the country’s reality, provided by the strong footprint that we have after so many years here, and where we can leverage the wide range of our portfolio plus the financial strength that we have as a conglomerate that can help our customers to find and customize solutions that otherwise they could not afford.
Art Against Stigma

For Danish mental health company Lundbeck, helping improve the lives of those with neurological diseases goes far beyond providing medicines and psychological support to patients. The company’s foundation is responsible for the creation of an international art exhibition called “Art Against Stigma,” a gallery of 62 paintings selected from 500 works by artists from 19 different countries that has moved from country to country.

The collection includes work by both professional artists and patients with mental diseases to demonstrate that art and mental health are not synonymous, contrary to popular belief. “This exhibition aims to arouse admiration for the artistic creation of people who have suffered or are suffering from a mental disorder,” says Juan José López-Ibor, former president of the World Psychiatric Association and director the exhibition in Spain. “Its ultimate goal is to help their dignity as human beings to be recognized, as it is often hurt by the stigma that hangs over the disease, sufferers and even their relatives.”

Xavi Martí, general manager of Lundbeck Spain, says that when the gallery came to his country the company did not hesitate to make full use of the opportunity. “We used the paintings in some regional and national congresses, spending a few days in each city with patients and doctors,” Martí recalls. “We invested in a great deal of publicity for this event, trying to demonstrate that mental illnesses actually hinder artists’ full potential.”

Additionally, the affiliate, in partnership with patient associations, psychologists and neurologists, is also host to a competition for short films about mental health (SNCFILM), in which a jury selects three submissions to highlight as part of spreading awareness, highlighting a different disease each year. “Every artist perfectly illustrates how caregivers and families around patients suffer, to show how conditions like depression or Alzheimer’s affect those around patients,” continues Martí. “Cinema is a great vehicle for communication, a story told with pictures story brings rational and emotional messages to society, and makes each of us react differently. Cinema has the power to move and stir our conscience, as the majority of society has never experienced stories like these.”
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Dr. Pilar Najarro
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Legal challenges in pricing and reimbursement in Spain

PharmaBoardroom: What is the main legal challenge the health industry is facing in Spain?

RAQUEL BALLESTEROS POMAR (RBP): Regulatory uncertainty: since approval on July 26, 2006, Spanish law on medicinal products and medical devices has been amended at least once a year, and sometimes twice (2013) or, even, three times (2010), the majority of these amendments implemented directly by the government by means of urgent royal decree laws and subsequently confirmed by the Spanish parliament. These amendments have been related to highly sensitive issues, like pricing and reimbursement, crucial for pharmaceutical companies to take their market and investment decisions and strategies in the short and long term. In addition, some of these annual amendments, initially so urgent, have kept undeveloped by secondary legislation for years, producing additional doubts and uncertainties on their scope and enforcement (for example, the Spanish ministry of health has been preparing a draft of royal decree on pricing and reimbursement for almost last three years; this royal decree is expected to be approved by the Spanish cabinet before the end of 2014).

PB: Why is the regulatory framework so complex in the Spanish health sector?
RBP: It has to do with the territorial organization of the Spanish state, divided into 17 different autonomous regions. To ensure equal health and pharmaceutical care conditions for all Spanish citizens in all regions, the Spanish central government is the only one entitled to produce legislation on the basis of the healthcare and the pharmaceutical system as well as the only one to take decisions on the public funding of medicine and medical devices. Regional governments, in their turn, are entitled to produce legislation developing such national basic regulation, as well as to enforce it, providing (and paying) health and pharmaceutical care to patients through regional hospitals and healthcare centers.

PB: Has the recession to do with this regulatory complexity?
RBP: Absolutely. Recent regulatory uncertainty is an outcome of the recession, since the last amendments to medicinal product and medical device regulations have mainly aimed at reducing public expenditure in healthcare. In addition, regional governments, responsible for acquiring and paying the products needed to provide healthcare services, have adopted a wide number of measures to reduce their cost. Some of them have consisted in changing their financing or dispensation conditions, being out of the scope of the competences of the regional governments, since those changes are reserved to the

“Risk-sharing formulas, used for years in UK and Italy, are perfectly possible in public funding decisions in Spain.”
exclusive competence of the central government.

**PB:** Have these regional measures invading exclusive competences of the central government been reviewed by the courts?

**RBP:** Yes, a number of them. For example, the decisions of two regional governments, Catalonia and Madrid, to impose on patients in their respective territories the payment of one euro per medical prescription, were declared null and void by the Spanish constitutional court by judgments on May 8, 2014 and May 29, 2014. The decisions of another regional government, Andalusia, to restrict the dispensation of certain medicines exclusively to hospitals, excluding their supply through pharmacies (with the consequent savings of pharmacies margins) have been also annulled by the Andalusia high court in judgments on March 17, 2014 and May 12, 2014. Finally, the decisions of the Andalusia government to call competition proceedings to select just a number of medicines or medical devices to be publicly funded per category and for certain periods (the so called “subastas andaluzas”) have been challenged by the central government before the Spanish constitutional court, which has not delivered a final judgment yet.

**PB:** How will the new directive on prices of medicines impact on pricing and reimbursement proceedings in Spain?

**RBP:** It will depend on the final wording of the new directive amending directive 89/105/CEE, but it should dramatically change our pricing and reimbursement proceedings, not only in terms of shorter length, but especially in terms of more transparency and predictability. Until now, financing and reimbursement decisions have been produced with poor publicity, contradiction and motivation, and with poor chances for pharmaceutical companies to defend their interests or to negotiate. The Spanish ministry of health should take into account the new transparency requirements resulting from the proposal of directive when drafting the royal decree on pricing and reimbursement that is expected to be approved before the end of 2014.

**PB:** Is there room in Spanish legal system for new funding formulas based on cost-sharing or risk-sharing agreements?

**RBP:** Yes. These agreements have been already used by certain Spanish regional governments like Andalusia, Valencia or, specially, Catalonia, for the public procurement of medicines and medical devices. In the last months, the Spanish ministry of health has been negotiating this type of agreement with two pharmaceutical companies (Merck and Gilead) but not for public procurement but for public funding decisions, reserved to the competence of the central government. Risk-sharing formulas are perfectly possible in public funding, used for years in the UK and Italy, whose experiences should be taken into account.

**PB:** Just some days ago, Juncker made public his new team of commissioners, jointly with certain organization changes in DG SANCO. Has there been impact for Spain?

**RBP:** It is interesting that the EMA and some units dealing with marketing authorizations and quality of medicines have moved from DG SANCO to DG Enterprise and Industry, depending on the new commissioner of internal markets. This movement should intensify European Commission support for the European pharmaceutical industry and, in particular, to free movement of medicines across Europe. In my view, this is definitely interesting for Spain, in light of recent restrictions put by Spanish authorities to the placement of certain biological products (vaccines) on the Spanish market, infringing EU principles and regulations. New EC should take action with regard to this infringement.
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