

INFORME  
**biocat**

THE STATE OF BIOTECHNOLOGY, BIOMEDICINE  
AND MEDICAL TECHNOLOGY IN CATALONIA

# PORTRAIT OF A SECTOR IN MOTION

2011

Executive summary

Biosciences  
and innovation

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This document is a shortened version of the 2011 Biocat Report, which contains the table of contents, introductory article by Biocat CEO Montserrat Vendrell, and the chapter entitled “Final considerations”, which serves as an executive summary of the publication while it is being translated.

The full English version will be available shortly.

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# PORTRAIT OF A SECTOR IN MOTION



**Montserrat Vendrell**

CEO, Biocat

At the time of publication of the 2011 *Biocat Report* (the second edition of this exhaustive study on the state of biotechnology, biomedicine and medical technology in Catalonia that Biocat conducts biannually) it is important to stop a moment to look back on the milestones that have marked this period. This review provides us with a wealth of information, which paints a picture that at times seems rough, although it also indicates paths that if we can (and do) follow to the end, will allow us to be successful. When the previous report was drafted, we had little information regarding the impact of the global economic crisis on the sector and, in fact, the international statistics showed that in 2008, the worst moment in the financial crisis, turnover in the sector was up 12% (this growth reached 17% in Europe). Over the two following years, this growth slowed or stopped: according to Ernst & Young, in 2009 the total revenue of all publicly traded biotech companies in the United States, Europe, Canada and Australia (\$79,100 millions) fell 9% from the previous year, while in 2010 revenue was up 8% to more than \$85,000 millions. Although the decrease of 2009 was due to temporary conditioning factors (the exclusion of Genentech from E & Y statistics after this biotech firm, the largest in the world at that time, was acquired by Roche), there is a clear change in the trend.

Paradoxically, cutbacks in spending and efficiency measures allowed publicly traded European and American companies to post spectacular growth in net profit in 2009, reaching \$3,600 millions, compared to the \$1,800 millions in losses reported in 2008. Last year, profits were even more spectacular, \$4,700 millions, which has made it possible, for the first time ever in the sector, for a biotechnology company (Amgen last April, in this case) to pay out dividends to its stockholders. Over the two-year period studied, funding received by biotechnology companies also grew spectacularly: the \$23,200 millions obtained in 2009 through various available channels—initial public offerings (IPOs), venture capital and others—showed a 48% increase over 2008 and the figures were even larger in 2010: \$25,021 millions, which puts the injection of capital in the sector at pre-recession levels, according to data from the *Beyond Borders 2011* report by Ernst & Young.

The problem is that 20% of publicly traded biotech companies (the largest ones) receive 83% of all investment in this sector. Furthermore, even in the United States, which makes up 50% of the international biotechnology market, only 30% of all companies in the sector are publicly traded. The rest are, mainly, small companies with less than 25 employees and capital of less than €50 millions (*Unleashing the Promise of Biotechnology*, BIO, 2011). The problems and characteristics of these companies are, clearly, very similar to those in our own sector. Due to their size and the fact that most are in the early stages of development, the logical source of funding

would be venture capital, however the flow of this type of funding towards biotech companies is scarce, either due to the fact that the available capital isn't on par with that of other times or because of a lack of confidence and experience in the sector.

In the United States, the Biotechnology Industry Association (BIO) indicates that venture capital investment in biotechnology totaled roughly €3,700 millions in 2010, 30% lower than in 2007, the year before the crisis began. In Spain, the venture capital and private equity market recovered notably in 2010, after registering decreases of 32% and 48% respectively the two previous years. However, of the nearly €3,500 millions invested, only €27 millions (0.8% of all funds) went to biotechnology companies, in some eighty transactions with an average value of €300,000 (see section 8.5 of this report).

In short, the outlook, despite appearances, shows that access to funding continues to be the main problem facing most biotech companies (both here and in the United States) and that there is a high concentration of resources that, moreover, are not always focused on the most strategic aspects. In 2009, while the sector's profits grew spectacularly, R&D investment in publicly traded American and European companies fell 21% and, despite having reversed the trend, recovery in 2010 was only able to grow investment in research and development by 2%. International analysts explain that the increases in capital that, as explained previously, have been seen over these two years, have gone, in large part, to fund financial operations in large biotechnology and pharmaceutical companies, and not to new entrepreneurial initiatives or to fund growth and research projects in small and medium-sized biotech companies, which make up the bulk of the sector.

## Innovation, ever more expensive

And while the global market continues to be unfavorable to biotechnology SMEs, in the period analyzed pressure has likewise increased continually on large pharmaceutical and biotechnology companies whose activity focuses on red biotechnology (that concerning human and animal health). This pressure centers around four crucial aspects:

Firstly, *the economic crisis has intensified debate regarding the sustainability of our healthcare systems and is causing a downward trend in drug prices around the world* (either through freezing or reduction of reference prices paid by the Administration—as has happened in Spain with four legal decrees approved in 2010 and 2011), which according to sector calculations, has led to a decrease of between 10% and 12% in turnover. According to figures from the Ministry of Health, the decrease in public spending on pharmaceuticals in Spain in 2010 was -2.38%, while in Catalonia this figure was slightly lower, -2.23%. This decrease has been even more pronounced this year: in the first half of 2011, pharmaceutical spending was down -10.6% in Catalonia (-11% in Spain), with a yearly fall (from July 2010 to June 2011) of -8.85% in Catalan spending (-9.42% in Spain). Beyond this decrease in spending, the sector points to delays in payment (with corresponding interest costs of nearly €600,000 per month) as a

burden that threatens the viability of both pharmaceutical companies and distribution networks and pharmacies. And, above all, they warn that, with this growing pressure, it will be difficult to maintain previous R&D investment levels in the pharma sector.

At the same time, there is *growing competition from generic drugs*, both due to political pressure to lower the cost of public healthcare and to the nature of the market itself. In this sense, 2012 is considered a key turning point, as patents that have fueled growth of various large pharmaceutical companies will expire in this year. Astra Zeneca, Eli Lilly, Forest, Glaxo-SmithKline, Johnson & Johnson and Merck have marketed products with patents that will expire next year, which account for turnover of between \$1,000 and \$3,000 millions per year. The biotechnology arena has also felt increased pressure from the generics market (in this case, biosimilars), with countries like India leading production. According to the IMS Institute for Healthcare Informatics, the biological drug market totaled \$138,000 millions in 2010 (one sixth of the global pharmaceutical market), of which \$311 millions were from biosimilars (0.22%) This institute predicts that, over the next five years, the biologicals market will reach \$200,000 millions (with a yearly growth rate of between 6% and 9%) and that biosimilars will account for between \$2,000 and \$2,500 millions (between 1% and 1.25%).

This reflection leads us to the third pressure factor: *accelerated growth in the markets of countries with emerging economies* (the so-called *pharmergent* countries) and, in particular, China. The forecast for growth in the pharmaceutical market of this Asian giant (between 25% and 27% in

2011) is five times higher than that of the global market. In fact, as shown in figure I-1, despite positive progress in the global biopharmaceutical market, growth rates have shown a downward trend since 2003, and the most optimistic forecasts put it between 3% and 5% annually.

Meanwhile, China (whose GDP grew 10.9% in 2010, compared to a 2.9% increase in the OECD and only 1.7% in the European Union) has jumped from ninth to second in this market, just behind the United States, in only four years. The 58 venture capital operations closed in China in 2010 accounted for a total investment of \$1,013 millions, with an average of \$21 millions per operation and up 319% from 2009. Half of all companies that went public around the world in 2010 were Chinese and, in the life sciences arena, 33 initial public offerings (IPOs) were closed, valued at nearly \$6,000 millions (*China Life Science 2010: A Giant Leap Forward*, China-Bio, 2011).

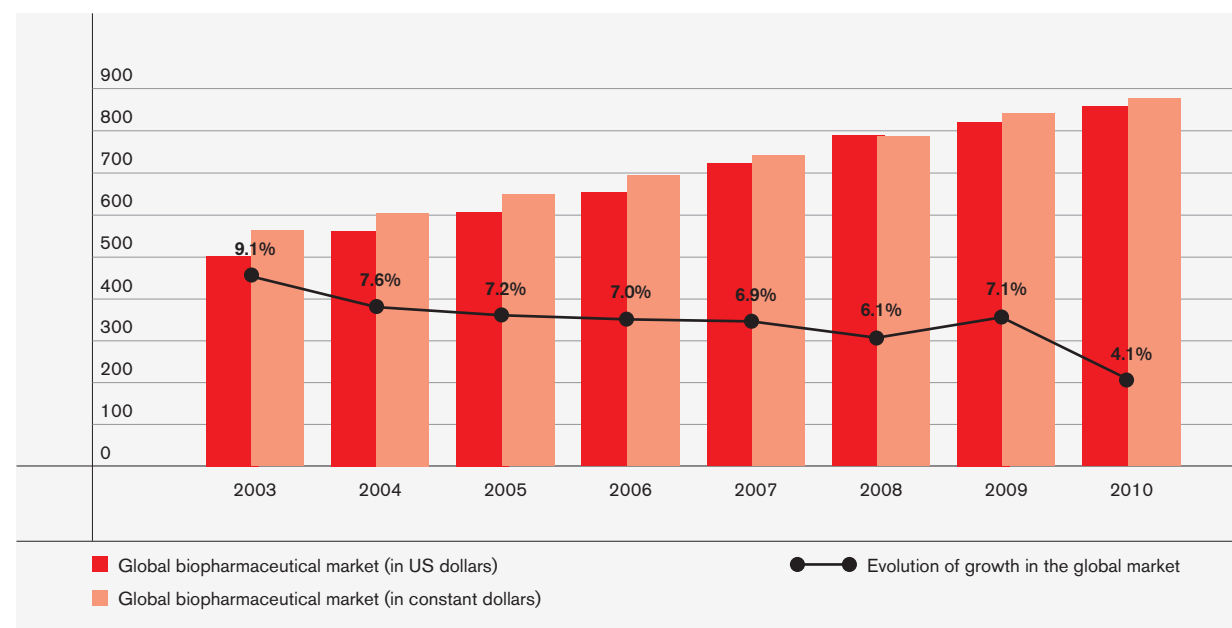
To these important figures, we must add the fact that all large pharmaceutical companies (Astra Zeneca, GSK, Pfizer, Lilly, etc.) have opened R&D centers in China. This is both to take advantage of the growing research capabilities of Chinese universities and researchers and of advantageous production costs in this country and to facilitate access for new products that may come out of these centers to a market of 1,000 million people.

The fourth element that must be taken into consideration is *the progressive increase in the price of biopharmaceutical innovation*, which is the result of what is known as the innovation gap: while investment in research for new drugs has quadrupled since the 1990s (in 2010 it was \$49,400 millions, according to the 2011 *Burrill Report*), the number of new drugs approved by the FDA (Food and Drug Administration) has been cut in half (21 in 2010). This increase in the price of innovation is leading to new business models, in which large pharmaceutical companies maintain large international collaboration networks with cutting-edge research centers and biotechnology companies that work on state-of-the-art research lines. Appropriate connections with these networks may be a key element over the coming years for the development of our biocluster.

In the biomedical arena, which continues to be the main activity of most research groups and companies in the BioRegion, as demonstrated in chapters 7 and 8 of this report, we must also take into account the global outlook for medical technology production and the changes underway in this area. Specifically, the study *Pulse of the industry 2011* by Ernst & Young on the techmed sector, published just at the conclusion of work on this report, highlights a trend toward a new business model, in which communication with the end-customer, which moves from being a passive patient to an active consumer of medical technology, will become progressively more important.

Global turnover of publicly traded European and American companies (436) totaled \$315,900 millions in 2010 (up 4% from 2009), of which nearly 4% was invested in R&D (\$12,400 millions). Innovation in this field has led to a progressive convergence with biotechnology (particularly regarding in-vitro diagnostics and bionanomedicine), which finds here a

Figure I-1 Evolution of the global biopharmaceutical market (in thousands of millions of dollars)



Source: IMS Health Market Prognosis, March 2011

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place for research applications with a much shorter time to market. And, indeed, some areas for future development, like telemedicine, which bring devices to the patient, will demand this change in perspective that is beginning to become apparent and that is both a challenge and an opportunity for companies in the sector.

### **Broadening horizons**

In these first pages of the *map of challenges and opportunities* this article aims to be, we have sketched out the main changes, difficulties and barriers that are conditioning the biomedical arena. However we mustn't forget that there are development opportunities in biotechnology beyond this area.

Food, clean energy and environmental conservation and recovery are three areas in which biotechnology must play a key role. Improving agricultural and livestock species through seed and embryo selection, reducing and controlling disease in species for human consumption, improving sustainability of agricultural production in adverse environmental conditions (drought, poor soil, plagues, etc.) and identifying the most productive non-food species for biomass are just a few examples of the contributions green biotechnology is currently making in a situation with increasing demographic and environmental pressures.

The UN calculates that there will be more than 8,300 million people on the planet by 2025 and, by that same date, the OECD predicts that energy demand will have increased by up to 50%. For many analysts, the response to this demand for energy (which the public, moreover, requires to be clean) lies, mainly, in biofuels. The race to address these social requirements has already begun: Brazil is positioning itself as the great worldwide supplier of biomass (which is essential to producing biofuels), which, according to OECD calculations, tripled in the period between 2000 and 2007, and will see similar growth before 2017, with the South American giant as the second manufacturer in the world after the United States (*The Bioeconomy to 2030*). The 2011 *Burrill Report* predicts that the biomass value chain (from agricultural farmers through biorefineries) may come to generate turnover of \$224,000 millions by 2020 (see figure 7.15).

The introduction of bioprocesses in industry in a variety of sectors (which can substantially reduce contamination from production) and bioremediation (which allows for recovery of contaminated environments using microorganisms) are growing fields of applied biotechnology and, as explained in chapter 8 of this report, offer new market opportunities that we must take advantage of.

### **The outlook at home**

In reviewing large-scale international trends, however, we mustn't forget the specific changes that have come about in our country since 2009 and which, naturally, delimit our playing field in facing growing challenges. The direct impact of the crisis on the Spanish and Catalan economies was delayed in comparison to the international scene, as have been signs of recovery. We have already commented on the pressure cutbacks in health-

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care spending have put on the pharmaceutical sector, but budget restrictions are affecting the whole hospital system and, inevitably, will continue to affect the sector as a whole over the coming months.

There have also been changes to the legislative framework, as will be discussed in chapter 4 of this report, with new laws on Sustainable Economy and Science, which establish a new framework for technology transfer and an active role on behalf of research bodies in valorizing research, increasing flexibility of researcher participation in creating and managing public companies. The new Spanish Law on Science recognizes the capacity of autonomous communities with exclusive competence, as is the case of Catalonia, to regulate their own research centers. As the authors of chapter 4, Ignasi Costas and Alberto Ouro, point out, this is an opportunity to respond to the needs of our centers and drive research of excellence in our country that we can't let pass us by. Modifications to the governing system of research centers introduced through the Law on Fiscal and Financial Measures of 2011 to reinforce their autonomy, also covered in-depth by Costas and Ouro, are just the first step.

At this point, we must remember, however, that, as Vice-President of CataloniaBIO Ricard Munné points out in his article in chapter 3 of this report, the Spanish government missed its chance to rectify, in the Law on Sustainable Economy, some of the specific problems hindering development of the biotech sector. The measures requested included improved conditions for R&D activities with regard to business taxes, recognition of the sector's specific characteristics (like negative balance statements in the initial stages of development) in order to benefit from tax benefits that, otherwise, are unattainable, the Law on Patronage, or the creation of tax incentives to encourage biotech companies to join the Alternative Stock Market (MAB), are all measures designed to improve funding tools in the sector (one of the key aspects, as we have seen) and ones that must be implemented in the not-so-distant future.

Even so, the Law on Sustainable Economy does have a positive aspect: the national government's commitment to promoting innovative public procurement (IPP). According to data from the European Commission, public procurement in the EU-15 totaled more than €2.1 billions in 2008 (17.23% of the GDP). The same year in Spain, Administration contracts surpassed €48,500 millions, of which 20.7% was from the General State Administration, 46.2% from autonomous administrations and 15.2% from local administrations. According to announcements from the Spanish Government, the aim is for 3% of all procurement in 2013 (some €650 millions) to go to innovative technology, a goal that, if met (and we must demand that it is), could be an important boost for our sector.

We mustn't forget the importance, both for public research and business, of the start-up of new scientific facilities over the period of time covered by the 2011 *Biocat Report*, like the Alba Synchrotron and the National Center for Genome Analysis, or the fact that Catalonia has six Campuses of Excellence (more detailed information on which is provided in chapter 6).

## Responding to challenges

Chapters 7 and 8, and shortly in the final considerations, cover the potential of research groups and companies in the BioRegion of Catalonia in the fields discussed. Of these we must highlight the increased capacity of our research groups and companies in terms of advanced phases of therapeutic product development (clinical phases) and, as a result, a significant deepening of the Bioregion's pipeline (285 products); a pipeline of more than 300 medical technology products, 169 of which are in the production stage; the consolidation of oncology and the nervous system as the top therapeutic research areas and priorities in terms of patent applications; the significant increase in public/private partnerships; growth of green biotechnology (above all regarding functional foods, nutritional supplements and nutrigenomics) and of white biotechnology (with a spectacular leap forward in bioprocesses); turnover of more than €15,000 millions and capitalization of nearly €2,400 millions; nearly 20,000 new patents (for more than 3,000 inventions) over the past 10 years.

The chapter on the human resources employed by the sector deserves specific note. The ample response obtained in the survey Biocat carried out in December 2010 (230 of the 435 groups and 208 of the 450 companies) has given us a highly accurate image of employment in the Catalan biotechnology, biomedicine and innovative medical technology sector, which increases figures forecast through available nationwide surveys. Organizations in the BioRegion of Catalonia employ more than 29,000 people (22,000 in companies and 7,981 in research groups) 18,000 of which carry out R&D tasks (including researchers and technical personnel).

However, beyond the assets the sector itself has amassed (gained through much commitment and more than one personal sacrifice), we must wonder if adequate measures are being taken to drive a sector that offers so much potential.

Other countries are taking active steps to this end. In mid-September, US President Barack Obama took advantage of the signing of new patent legislation to announce that the US Government is preparing an ambitious plan to drive the bioeconomy that will be set in motion in January 2012 and which aims to "harness biological research innovations to address national challenges in health, food, energy, and the environment." According to the White House, this new plan will include legislative changes and measures to drive the labor market in the sector and encourage increased public/private partnership to foster translational research, thus bringing scientific progress to market and, in short, to the people.

This new plan is part of a large number of measures adopted by the US Government over the past months in order to stay on track with competitiveness, which include the American Invents Act (a new patent law that simplifies the process of registering new inventions and introduces a series of measures designed to facilitate intellectual protection of discoveries and inventions from universities, small companies and entrepreneurs) and the Final Company Capital Formation Act, passed in early 2011 with the aim of facilitating access to the capital market for R&D-intensive small and

medium-sized companies. These measures are in addition to those already in place, like the Therapeutic Discovery Project Program and the obligation to devote a percentage of federal research funds to start-ups programs (see chapter 8 and *Final considerations*), which brought \$2,500 millions in public funds to the sector in 2010.

In India, the *Biotech Industry Partnership* program gives donations and soft credit to companies specializing in high-risk research, which has led to sector growth of roughly 20% per year (BIO/ Ernst & Young). In China, biopharmaceuticals has been declared one of the seven key industries in the twelfth Five-Year Plan and 160 programs are currently underway, devoting more than \$150,000 millions to early-stage research and marketing new drugs (ChinaBio).

Massachusetts has shown that political impulse and public support are key to the development of the biotechnology and biomedical sector. This US State has more than 80,000 life sciences workers and is one of the benchmark clusters in the world in terms of the production of new drugs: its 400 biotech companies produce 1,100 biotechnology drugs (8% of the global portfolio). And, even more significant, the number of life sciences workers in Massachusetts rose 42% from 2001 to 2008, while more than 56,000 jobs were lost in other sectors.

However this growth isn't just a lucky coincidence. It is a direct consequence of important political and economic efforts. In Boston, the Massachusetts Life Sciences Center (a body similar to Biocat) manages a fund of \$1,000 millions for driving the biotech sector. With the \$217 millions invested between 2008 and 2011 in research bodies and companies, they have leveraged \$715 millions in private investment and have created more than 7,000 new jobs.

Catalonia has 20.5% of all biotechnology companies in Spain, but the proportion is higher if we take into account their economic weight, as with an estimated turnover of €15,600 millions, they account for 29.4% of the national total. It is also the most dynamic community, creating 23% of all new biotech companies started up in 2010 and, as demonstrated in the first call of the Severo Ochoa Program for Centers and Units of Excellence (where Catalan research centers obtained 50% of all grants awarded) and as has been seen in the European Research Council grants for some time now, Catalonia is a leader in research. And all of this wealth comes from local initiative with strong ties to the Catalan productive fabric, as shown by the fact that only 16% of businesses in the BioRegion are affiliates of multinational companies.

This foundation can grow and spearhead Catalan economic development, if the appropriate conditions are met and the necessary efforts are made by all political and institutional authorities. The first thing that must be done, naturally, is to address the weakness detected in the BioRegion's own productive and research fabric and to tackle determinant aspects that largely go unseen, like training in business management for scientific entrepreneurs, professionalization and specialization of the upper-tiers of management, and driving international mobility. But this will all be insufficient if



measures aren't taken that involve both a political and economic commitment on behalf of the Administration. There are four key aspects that must be strengthened over the coming years:

- I Maintaining investment levels in research is key and this must be a nationwide strategic priority followed by all institutions and political parties. However it is just as important to make the funds invested more efficient: we need large, competitive projects, the best in their field, and it is essential to avoid duplicity and dispersion of resources.
- II Facilitating business start-up and growth by eliminating bureaucratic hurdles and implementing fiscal measures that take into account the specific characteristics of the sector and foster funding. It is key to increase deductions for research investment and to facilitate access to financial funds without requiring guarantees that would make this impossible. Mergers and acquisitions must also be encouraged, allowing companies to reach the critical mass needed to compete in the global market.
- III The Government of Catalonia must act as a driving force for innovation, using its public procurement power actively and must ensure that innovative Catalan companies' participation in the country's public procurement process is in line with their scientific leadership. As a country, we cannot allow our investment in research to generate knowledge to manufacture a new drug or diagnostic system to then not be introduced into our healthcare system due to a lack of unified criteria among departments. We must take a coherent stance in all of our research and economic-promotion policies.
- IV Finally, we must drive internationalization. Our efforts must be focused on both establishing research and development collaborations and on marketing products and advanced services.

### **Innovation and competitiveness**

Steps forward in these four lines will put us in a position to take advantage of the opportunities biotechnology offers. However we must be aware that if we want to make the most of our potential, we can't do it alone. As we have seen in these introductory pages, the playing field is global and competitors are large and powerful. We have made a conscious effort not to include comparisons to other European countries because Europe must be, above all, an arena for collaboration and not competition.

This was the understanding of the European Commission when, in 2008, it launched the European Institute of Innovation and Technology (EIT), a project that aims to drive European competitiveness by fostering the alignment and partnership of higher-education bodies, research centers and companies around a series of thematic focal points that the EIT considers to be key.

Before giants like the US and China, Europe seems to be a fragmented territory where it is difficult to structure strong projects in the technologi-

cal arena. The EIT aims to address this reality by promoting the creation of large public/private consortia that integrate the three areas of the knowledge triangle (higher education, research and innovation). These consortia are organized into networks (the Knowledge and Innovation Communities, KICs) that in every node, each located in a different country, bring together these three arenas. The EIT selects the KIC for each theme from those that present a bid in the corresponding call for proposals. So far, three calls have been held (sustainable energy, climate change and information society) and the three winning bids in the 2009 call for proposals formally created consortia in 2010. The next call for proposals (which could be opened in 2012) is expected to include one or two thematic focal points related to health/life sciences.

Europe is committed to the EIT and the BioRegion of Catalonia is committed to Europe. Therefore, Biocat has been working intensely since 2009 to create the conditions that will allow for a winning bid for the health/life sciences KIC headed by Biocat. This is Biocat's commitment but it is also a commitment on behalf of Catalonia, which will be successful if it includes active participation of all the key stakeholders (large and small companies, universities, business schools and research bodies). And the payoff could be significant: multiyear projects, averaging €100 millions per year, with 25% of funds contributed by the EU.

Consistent support from all of the country's decision-making arenas, in addition to the commitment shown every day by research bodies and companies, will allow us to project Catalonia towards the top of the ranking in European biotechnology, making small steps forward today large leaps towards the future.

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## 10. FINAL CONSIDERATIONS

The final goal of all the work that has gone into the 2011 Biocat Report — responding to a detailed survey, on one hand, and analyzing and evaluating the data obtained, on the other— is to measure the evolution of the biotechnology, biomedicine and medical technology sector, to detect its strengths and potential, and to identify the challenges that must still be addressed. The final goal is to make this sector a driving force for innovation and the economy in Catalonia, a goal that will also require appropriate policies and measures to foster long-term consolidation.

Over the two years that have passed since the 2009 Biocat Report, many changes have come about in the international arena, as well as in our country: the financial crisis, changes in government, modifications to the rules of the game in the sector, and more, but one phrase that can sum up everything that has been analyzed and discussed in this report is that, despite the complex environment, Galileo's words still ring true: *eppur si muove*. The sector has grown and advanced in many ways, but there is still much work to be done before it is truly solid.

In addition to analyzing public research and business activities through the data collected in the Biocat survey —which has been contrasted throughout the study with economic and employment data from a variety of benchmark international reports—, this second edition has also incorporated other collections of relevant data in order to achieve a realistic portrait of economic and innovation activity in the BioRegion. Specifically, analysis has been carried out as to the protection of knowledge and patent portfolios in the sector (chapter 9).

We must say, however, that public data specific to this sector is still fairly limited. Furthermore, better coordination is needed among the institutions that carry out analyses in these fields, as the same organizations are often asked to provide similar information multiple times. We reiterate Biocat's willingness to collaborate in making the data-collection process more efficient and in increasing the coherence of the information available, minimizing the impact on organizations that receive these requests.

From a methodological point of view, we must note that this second report has grown in both the number of organizations evaluated and in the level of

participation seen in responding to the survey sent out in December 2010, which was one of the things we requested in 2009. Regarding the business arena, the sample was extended to include new companies that have been started up over the past two years and support companies, with a total of 450 surveys sent; public research was covered through 435 consolidated research groups (CRG); and we have chosen to survey research groups instead of centers in order to bring our analysis closer to the main knowledge generators. Participation has been high, with nearly a 50% response rate (46.2% of companies and 52.8% of research groups) and has included organizations from throughout the region. The sample size and high participation rate are noteworthy facts that have allowed us to extrapolate the data and make coherent estimations.

### Breakthroughs in the BioRegion

Since 2009, the number of stakeholders in the BioRegion has also grown considerably, which has led to a 40% increase in the number of organizations included in the Biocat Directory. Part of this increase is due to new start-ups, with an average of 12 new companies per year, a figure that puts Catalonia among the leading European regions in this regard, with Berlin and Oxford, and makes the BioRegion of Catalonia the driving force for the Spanish biotech sector, with 23% of all new companies created in 2010. Only 16% of companies in the sector in Catalonia are affiliates of multinational companies, which fosters the firm establishment of this highly innovative fabric in the area. Catalan biotechnology companies make up 20.5% of the nationwide total, but their economic weight is proportionally higher, as their total estimated turnover for 2010 was €15,600 millions, accounting for 29.4% of the national total. Furthermore, capitalization of Catalan companies in the sector has tripled over the past two years and in 2010 reached €2,357 millions, mostly from private sources.

In the political arena, the increase in organizations registered in the Biocat Directory has mainly been due to the incorporation of consolidated research groups that work in the field of life sciences and the creation of new facilities. Groups that carry out research in the areas of activity of the BioRegion of Catalonia make up nearly half (40.4%) of all CRGs (1,078) recognized in the last call for grant proposals held by the Government of Catalonia 2009-2013 (SGR 2009), a percentage that is highly indicative of the weight of biotechnology and biomedicine in the generation of knowledge in Catalonia and of its strategic importance for the country.

In terms of new large-scale facilities, the creation of the CNAG (National Genome Analysis Center) in 2010 is noteworthy, with a joint investment from the Spanish and Catalan Governments of more than €30 millions. This center's location in Barcelona recognizes Catalonia's research potential in genomics, where 57% of all groups and 25% of companies use omic techniques as a research tool and habitual technology. New initiatives have also sprung forth from the university arena, including the international campuses of excellence (ICE). Catalonia has six of these campuses, with funding of roughly €68 millions in the last two calls for proposals, which is between 20% and 30% of all resources devoted to the ICES in Spain.

Biomedicine continues to be the predominant field of research in the BioRegion (58.7% of R&D companies work in red biotechnology and 45.5% in medical technology, 54.3% of CRGs work in red biotechnology and 22.6%

in medical technology). Research into new therapeutic products, followed by medical devices and in-vitro diagnostics are the focus of most work done in both groups and companies. Moreover, Catalonia concentrates 26% of the national generics market.

Over these two years, R&D capacities and the number of products generated by organizations in the BioRegion have also grown and evolved. In 2008, most biopharmaceutical companies had research capacities and products focusing on the discovery phase, while 50% of these companies currently have the capacity to conduct phase I clinical trials and have 71 therapeutic products in this phase (25% of the 285 therapeutic products in the BioRegion's pipeline). This allows us to declare that we are very close to making an important qualitative leap in the value of these projects —decreasing risk and increasing price—, which will undoubtedly be highly relevant in bringing about economic movements in the sector and in increasing its visibility as well as giving it an image of maturity and consolidation that is key to fostering investment and partnerships.

The same occurs with techmed companies, which have 323 products in various stages of research and 169 in production. Moreover, the CRGs show significant activity not only in basic research but also in the early stages (72 targets and 31 products in the discovery stage), projects that will be able to be transferred to companies in the future.

In addition to this growing transfer potential, collaborations between organizations in the BioRegion and various public or private partners have tripled since 2009, mainly due to aid policies from public bodies like ACCIÓ and CDTI, which prioritize joint research projects with investments of more than €1 million, which ensures that projects will be larger in size and have more partners. Catalan consortia have received €125 millions in investments through the 7th Framework Program since it was set in motion in 2007, accounting for 28.05% of all funds received in Spain (1.94% of the total granted by the European Union).

In biomedicine, the most common therapeutic areas continue to be oncology and diseases of the central nervous system, both in groups (27% and 28% respectively) and in companies (27% in each area). In the case of oncology, it must be noted that Catalonia carries out research covering the whole value chain: with basic research groups in universities, basic and translational research in hospitals, with small innovative companies and large pharmaceutical and diagnostics companies. This is a great opportunity for the country, if interests are aligned and synergies and partnerships encouraged. Prioritization of oncology and the nervous system is in line with the global needs detected by the WHO and with global trends in public and business research. However, professional investors (Biotech Investor Perception 2011) warn of the risk of saturation in supply for a limited market volume in many of the pathologies researched in these companies and groups. Oncology, which continues to be an attractive area for investment, seems to escape this problem, making Catalonia's capacities a good bio-economical opportunity, if interests are aligned.

Despite the predominance of biomedicine, it must be noted that there is an important presence of white biotechnology research (which is the focus of 39.1% of the CRGs and 47.1% of R&D companies) and green biotechnology (32.6% of CRGs and 28.1% of R&D companies).

On one hand, growth in the world population (estimated to reach 9,000 millions by 2050) and increased demand for energy (expected to rise 50% by 2025) increase both the political and economic value of biotechnology's contribution to food production (more productive and resistant crops, more nutritional foods, less livestock lost to illness, etc.), energy production (biofuels), manufacturing consumer products (biological drugs and enzymes with a variety of applications —cosmetics, food, textiles, etc.— using bioprocesses) as well as the environmental impact of human activities (biotreatment). On the other, white and green biotech have huge potential for reorienting traditional sectors and, in the Catalan sector, offer interesting territorial diversification opportunities for economic development, mainly in Lleida and Tarragona, as discussed in chapters 7 and 8.

In two years, activity in bioprocesses has tripled, now making up 23% of all industrial biotechnology activity versus 8% in the 2009 *Biocat Report*. Nevertheless, Catalonia doesn't have the capacity to industrialize bioprocesses under the MBP (manufacturing best practices), which reduces the BioRegion's competitiveness. Proof of the critical value given to this line of research in Europe is the €57 millions invested in Ireland to create the National Institute for Bioprocessing Research and Training, which is considered a key piece of the country's development strategy.

In green biotechnology, research on food is the main interest of both groups (19% working in this field) and companies (22%), probably due to its connection with health. In the business arena, the agrifood industry's weight in the Catalan economy, which in 2009 generated €20,000 millions in turnover, and its GVA of €4,300 millions (12.7%) lead to this increased interest in food. In this sense, research focuses on functional foods, nutritional supplements and nutrigenomics, fields which in Catalonia —with its strong biomedical and omic sciences research and important agricultural and agrifood sector— can become an important incentive for economic development, along the lines of what has happened in various countries in the Baltic region (Finland, Sweden, Poland, Germany and Denmark) with the creation of the BaltFood cluster, which brings together universities, research bodies and companies, or what is being done in the Netherlands with Food Valley.

Another positive aspect revealed in the 2011 *Biocat Report* is the growing evolution of inventions related to biotechnology, biomedicine and medical technology products, which over the past 10 years have generated a total of 19,531 patents for 3,014 inventions. This positive evolution shows a peak for inventions in 2005 and for patents in 2006, coinciding with the first years of activity of companies started at the beginning of the decade and the creation of Research Results Transfer Offices (RRTO) at universities, which have played a key role in driving the protection of intellectual property in public research. Emerging lines in the portfolio of patents generated in the BioRegion show interest in oncology, the nervous system and the endocrine system, and point to growing attention paid to functional foods.

Regarding employment, an estimated 22,000 people work in companies in the BioRegion, 11,000 of which carry out research. Specifically, consolidated research groups employ 7,981 people, 92% of which work in research. It is a sector of highly qualified professionals, both in the public and private spheres —40% of those working in the sector are doctors—, which requires stability due to the high level of specialization and capabilities needed. This explains the high percentage of fixed contracts in companies in this sector

when compared to others: 47.3% versus only 7.5% temporary contracts. In the public research arena, the number of temporary contracts is clearly higher, making up 24% of all contracts, to which must be added a large number of interns (37% of personnel at CRGs), who are often forced to go to other countries to further their scientific career and in few cases join companies.

### Unavoidable challenges

Nevertheless, despite the steps forward noted in previous paragraphs and as indicated at the beginning of the report, there is still much work to be done, mainly in technology transfer, internationalization, generating critical mass and improving the availability of public and private funds to drive research and business development, which are all challenges previously discussed in the 2009 *Biocat Report*.

Regarding technology transfer, the capacity for knowledge generation of our universities is still disproportionate to business start-ups and the production of inventions and patents. Thus, while Catalan scientific excellence is recognized on both national and international levels and the country (which only makes up 0.1% of the world population) generates 1% of all indexed publications in the world —64% of which are from universities—, the public sector has only generated 26% of start-ups (19% from universities) over the past years. Furthermore, the public sector has only generated 10% of all inventions over the past 10 years and, in the past two, organizations from the public sector have only applied for 14% of all new patents requested in the BioRegion. These figures are truly low if we take into account the budget and personnel available in the public arena.

In terms of internationalization of the sector, although 48% of research groups collaborate with organizations in the USA—a significant figure—, presence of Catalan companies in the American market (10%) and the number of companies with partnership agreements in the USA (24%) are still far from the desired level, taking into account that this is the top drug market in the world (with 50% of global business turnover) and that it is among the most important countries in bioenergy and food —despite the importance of Japan in this last field. The low international repercussion of Catalan inventions, from both the public and private spheres, is also a negative point, as 90% of all inventions generated in Catalonia have never been cited.

Another unresolved issue is the mobility of human capital, both to other countries and to other types of organizations. This phenomenon is practically non-existent among personnel in companies (6%) and still scarce in research groups (only 27% have mobility programs) and, as a result, there is a lack of international contact networks that can be key for satisfactory future development of research and business.

The lack of professionalization in management is also an important factor limiting growth, because it makes it difficult to attract the necessary capital. The study shows that 61% of all company founders in the sector are on the executive team, generally occupying the position of CEO but often carrying out more than one function at the same time. This doubling of roles, in addition to a lack of training and experience in business management, is particularly negative.

Reaching a sufficient critical mass, as a sector and as business units, is still a decisive shortcoming if we aim to compete in the international arena. Most companies are still very young and small —37% are microcompanies—; there have only been timid attempts to start up business associations; despite an increase in collaboration, we are lacking public/private synergies; there have been no mergers or acquisitions over the past two years; and most organizations have generated less than 5 patents in the ten years studied for this report, which is indicative of the fragmentation of research and the lack of a strategy backing inventions presented and their positioning in the market.

To all of this we must add the lack of available capital, both public and private. The number of companies specializing in investment (15% of those in the sector) is still very low, which makes it difficult to attract international investors, as they can't yet find appropriate partners in the local financial arena. This weakness will surely affect the outlook for the sector in 2012, as the search for new investment, as shown in chapter 8 of this report, is a priority for more than 60% of companies. This can be explained by the fact that projects underway are at a stage of development in which there is a substantial jump in financial need: going from needing hundreds of thousands of euros in capital to needing millions, which can't be covered by public funds. These funds, created mainly as seed capital, can account for up to 40% of funds received by start-ups. Furthermore, access to public capital is still an obstacle that requires guarantees and backing that don't fit with the economic model of this sector and requires urgent changes to fiscal codes.

Over the coming two years, the public Administration's role will be key, as a driving force for this sector and for business innovation by implementing a robust public procurement system. Likewise, signs from the sector aren't positive: statistics from the Ministry of Health show pharmaceutical expenditure in Catalonia fell 2.23% in 2010 and in the first three months of 2011 the decrease was -9.57%. This reduction in investment in drugs is the result of decrees that have lowered the reference price or forced doctors to prescribe generics, which have been hotly contested by the pharmaceutical industry. We must remember that 38.2% of all drugs are subject to reference prices and the resulting decrease in global turnover directly affects the companies' investment and human capital capacities. In fact, in 2010 internal R&D expenditure dropped 1.7% in biopharmaceutical companies, which can neither serve as driving forces nor invest in co-development projects with SMEs, which is what is needed to drive the sector.

In short, we can say that the sector has moved forward over these two years, despite the crisis and the difficulties inherent in an economic model based on risky, innovative products with long and costly development times, but that benefit society as a whole. However, the great challenges are still the same as two years ago, in an even more difficult economic climate and with a view to growing financial needs, both to ensure business development and competitiveness and to drive public projects of excellence that feed back into the whole system.

It is therefore necessary to make a decided, long-term commitment, as has been done in countries like the United States and Germany —the top biotechnology markets in the world—, which have maintained their commitment to R&D&i and, in particular, to the biosciences, despite the recession, as they understand that this sector is key to innovation and the generation of

employment. Specifically, the USA has started up innovative fiscal policy measures, like the Therapeutic Discovery Project Program (TDPP) —with a total value of \$1,000 millions—, which allows biotechnology companies to convert up to 50% of their fiscal obligations in capital to fund their activities. In 2010, 2,923 biotechnology companies with less than 250 employees benefited from this program. Another measure established that at least 2.5% of all federal research funds must go to start-ups, which injected \$650 millions in small biotech firms in 2010 from the \$32,000-million budget of the National Institute of Health (NIH). According to the Batelle Report/ BIO State Biosciences Initiatives 2010, the measures taken by the federal and state governments in the USA have been able to curb the steep fall in venture capital investment in the biomedical sector, which was down more than \$5,000 millions from 2008 to 2009. On the other hand, public investment in the sector increased more than \$2,500 millions in the same period.

These examples show that political action has been key in keeping the United States at the head of the biotechnology market, just as public action is proving determinant in the strong growth seen in emerging markets like Brazil and China.

Taking into account the data in this report, Catalonia has a good foundation. It will be key for public and private stakeholders to play their cards well in order to drive growth in the sector and in the country.



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