The Brazilian life science industry

Pathways for growth

pwc

Biominas BRASIL

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Foreword

Brazil has structural and current situational aspects capable of leveraging the development of the life science sector: strong scientific base, leading position in agribusiness and biofuel production, abundant natural resources, growth and aging of the population and ascension of millions of Brazilians to the middle class, increasing demand for and access to health care services. However, capitalizing on these factors will require a proactive and coordinated attitude by members of the public and private sectors and, especially, a long-term vision, which are critical for building a robust and innovative life science industry.

With the purpose of stimulating this discussion, Biominas Brasil and PwC are proud to issue this study, a unique publication for Brazil in light of its analytical and propositional focus. Developed jointly by both institutions, with information obtained from the industry, it combines PwC's global vision and expertise in life sciences, with the profound knowledge of the environment and of Brazilian companies acquired by Biominas Brasil over the last 21 years. In addition to providing statistics about the industry, the report analyzes four pillars of the innovation ecosystem: intellectual property and technology transfer, capital, public policies and qualified human resources. It discusses what lies ahead in the coming years and offers recommendations on how to develop the Brazilian life science industry.

We would like to take this opportunity to express our most sincere thanks to all who contributed to preparing this study, especially to entrepreneurs and executives who gave of their valuable time to answer the questionnaires and participate in interviews, and to columnists, who enriched this report with their vast knowledge and experience.

With the purpose of building impartial and comprehensive analyses reflecting the reality, aspirations and concerns of the industry, we welcome discussions on the principal conclusions of this study and look forward to receiving comments and suggestions at the following electronic address: *estudo@biominas.org.br*

Eliane Kihara
Partner - Pharma Leader
PwC

Eduardo Emrich Soares
Chief Executive Officer
Biominas Brasil

1 Introduction

The Brazilian life science industry is undergoing an unique period in its history. The last five years have been marked by the implementation of industrial policies favoring companies in the health and life science areas, with the approval of non-reimbursable funds, establishment of government programs to support internationalization of the sector and progress in university-industry interaction mechanisms.
The government funding programs, however, have not resulted in significant progress in generating economic value for the companies involved. Industry revenues remain relatively stable, mostly made up of companies with annual revenue of R$1 million or less. The chief difficulties in leveraging growth include internal aspects, such as a clear value proposition, development aligned with the reality of the market, professional management and strategic planning; and external factors, essentially an efficient regulatory process and a more inclusive funding environment.

Despite the modest sales level and small number of jobs generated, Brazilian life science companies, characterized by strong technological content and potential for innovation, can play a fundamental role in the economy. This contribution could range from import substitution and reduction of the trade deficit to development of innovations to meet specific domestic needs, such as diagnostics, vaccines and treatments of endemic tropical diseases, bio-pesticides for very common agricultural blights in Brazil and others. These companies could also solve technological problems and feed the pipeline of medium- and large-sized domestic companies, helping to establish a more competitive industry.

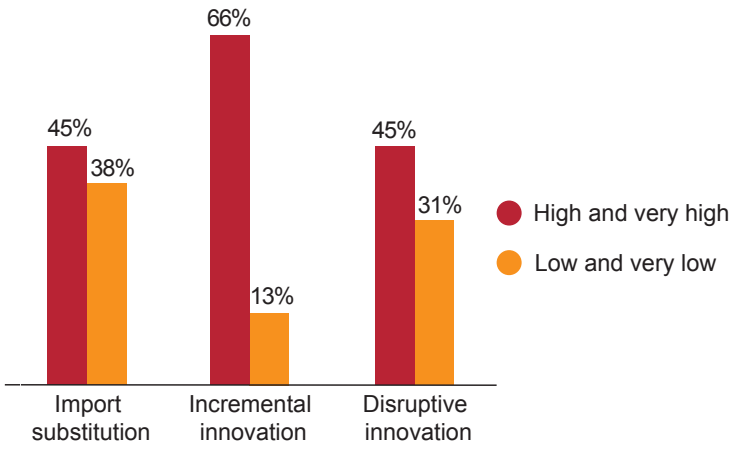
Analysis based on questionnaires answered by 103 industry entrepreneurs revealed the importance given to innovation. Graph 1 shows that 45% of the companies give high or very high priority to developing disruptive innovations, while 66% give high priority to incremental innovations. Graph 2, in turn, reveals that 62.9% of the entrepreneurs consider development and sale of innovative products and services to be the principal parameter for a successful venture.

In order to evaluate their ambitions and references, these entrepreneurs were asked to give examples of successful companies. The respondents very frequently mentioned Brazilian company Alellyx (acquired by Monsanto) and, among the foreign companies, those most often mentioned were Amgen, Genentech (acquired by Roche Pharmaceuticals) and Genzyme (acquired by pharmaceutical company Sanofi), all companies with a strong scientific base and who seek to expand the frontiers of technology.

Therefore, it can be noted that that the majority of Brazilian life science companies are oriented toward innovation. However, this innovative potential has not been reflected in significant or growing economic results.

This study focused on understanding the principal obstacles which have hampered industry progress and evaluating the prospects and paths for growth.

Graph 1 - *On a scale from 1 to 5 (very low, low, average, high, very high), indicate the priority level of your innovation strategy according to the listed objectives*



Source: Biominas/PwC Survey, 2011

Graph 2 - *In your opinion, which of the following parameters reflect a successful Brazilian life science company? (select the two most important)*

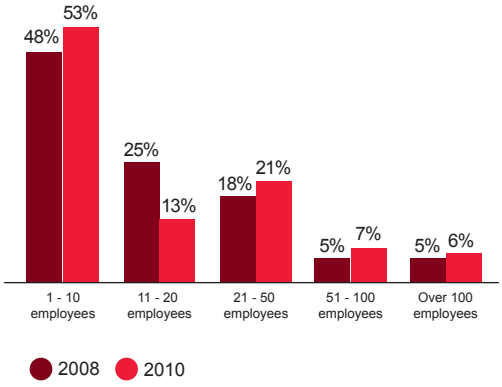
Source: Biominas/PwC Survey, 2011

Industry profile

Geographical distribution of life science companies

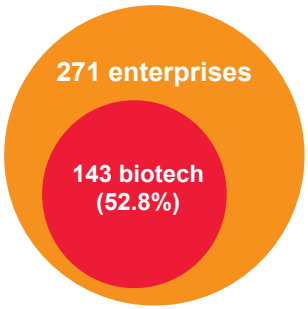
Source: Biominas/PwC Survey, 2011

Companies by number of employees: 2008 vs. 2010

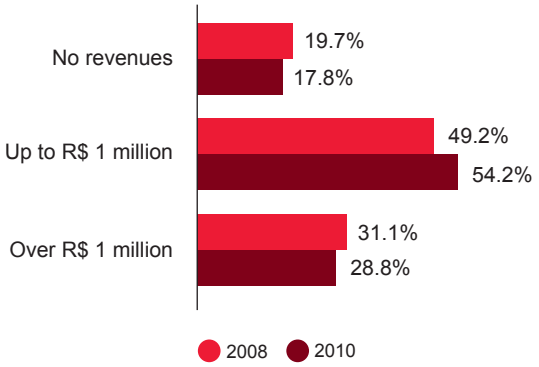


Source: Biominas/PwC Survey, 2011 and Study of the Brazilian Life Science Companies, Biominas, 2009

Biosciences enterprises x Biotech enterprises



Companies by Gross Revenue Classification: 2008 vs. 2010

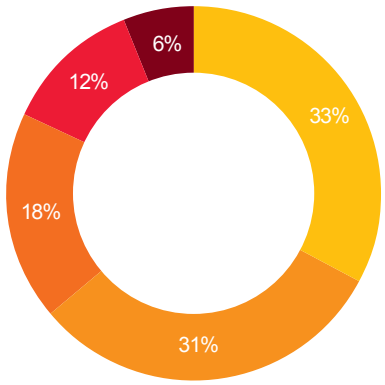


Source: Biominas/PwC Survey, 2011 and Study of the Brazilian Life Science Companies, Biominas, 2009

Most representative states and regions

Region	State	Number of companies	% of Brazil
Southeast (74.9%) **203 companies**	São Paulo	103	38.0%
	Minas Gerais	83	30.6%
	Rio de Janeiro	16	5.9%
South (14.4%) **39 companies**	Rio Grande do Sul	19	7.0%
	Paraná	14	5.2%

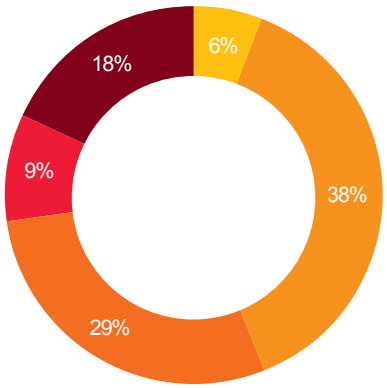
Companies by application



- Human health
- Agribusiness
- Reagents
- Mixed
- Environmental

Source: Biominas/PwC Survey, 2011

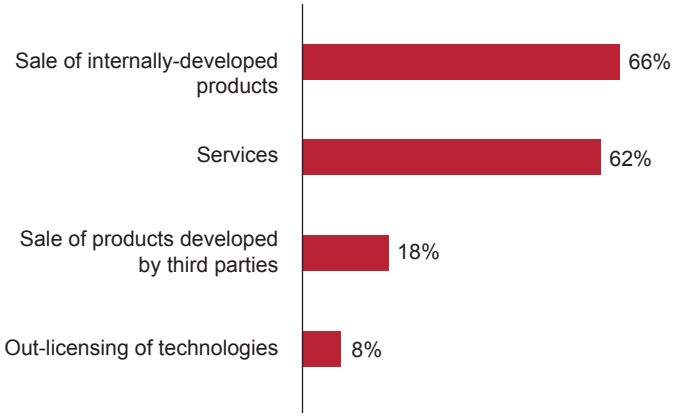
Companies by age



- 2 years or less
- 2 to 5 years
- 5 to 10 years
- 10 to 15 years
- Over 15 years

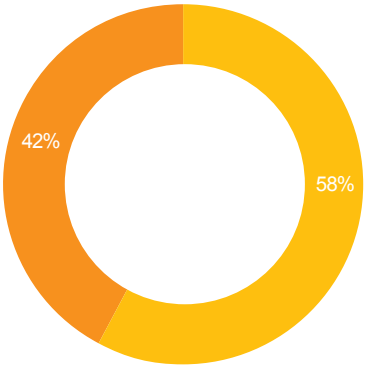
Source: Biominas/PwC Survey, 2011

Brazilian life science company business model



Source: Biominas/PwC Survey, 2011

Exports and services provided to foreign customers

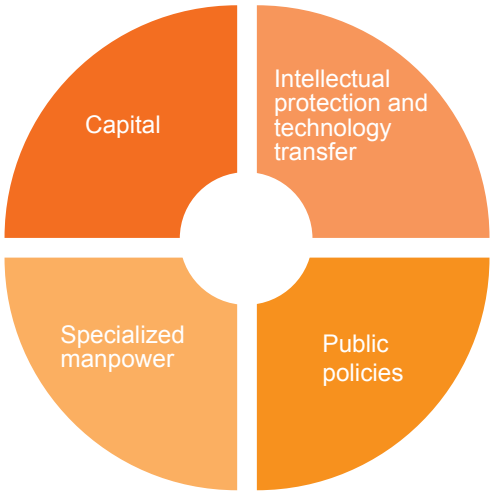


- Yes
- No

Source: Biominas/PwC Survey, 2011

2 The brazilian innovation ecosystem in life sciences

The dynamics in the creation and development of life science companies are influenced by four basic pillars which will be the subject of a more detailed analysis:



2.1 Intellectual protection and technology transfer

Establishing a competitive life science sector requires an institutional environment that stimulates innovative entrepreneurs to assume the high costs and risks inherent to R&D activities. An important instrument in creating a proper environment is the intellectual property (IP) system. IP rights are a fundamental mechanism in fostering technological innovation, ensuring that entrepreneurs, researchers and investors can appropriate their developments and reward creative and financial efforts.

For biotechnology companies especially, patents represent an important element of added value. Considered as their principal asset, a patent portfolio is a decisive factor in raising investment capital, attracting partners and, in some cases, serves as the major source of company revenue.

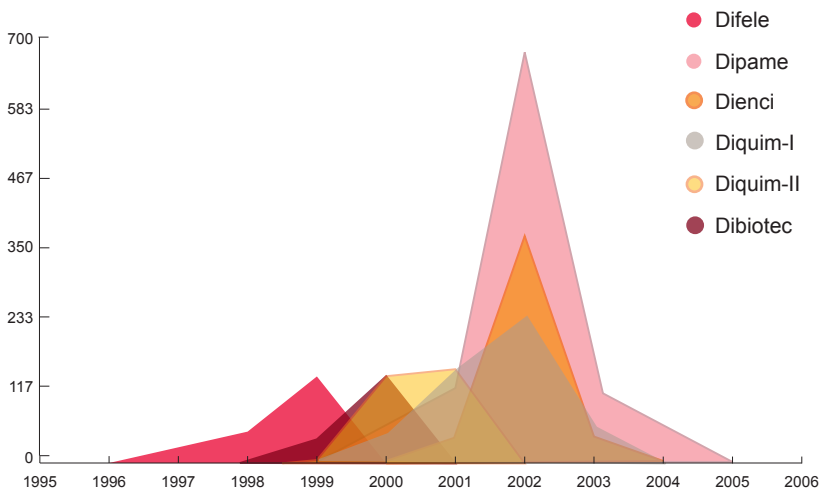
The organ in Brazil responsible for analyzing and judging patent applications is the *Instituto Nacional da Propriedade Industrial (*National Industrial Property Institute) (INPI) and the question is regulated by the Lei da Propriedade Industrial (Industrial Property Law) of 1996 (LPI 9.279/96). Plant variety protection, in turn, is granted by an unique system implemented by Lei (Law) n° 9.456 of 1997.

Even though Brazil has signed the principal international agreements dealing with this subject and respects IP rights, there are three obstacles, frequently mentioned by entrepreneurs, which contribute to discourage private investment:

1. Long patent approval period

As illustrated in Figure 1, the management status report published by the INPI in 2010 indicated a backlog[1] of approximately 9 years to analyze biotechnology[2] patents, 2 years more than the average period of analysis by the Institute (7 years). The longer waiting line in life sciences reflects the small number of examiners and increased demand. Aware of this problem, the INPI increased its number of biotechnology examiners by 230% over the last 5 years, from 19 in 2005 to 44 in 2010. However, the structure is still insufficient. Hiring of new personnel, internal process improvements and cooperative agreements with other patent offices are some of the actions planned with the goal of reducing the total INPI analysis time to 4 years by the end of 2014.

Figure 1 - *INPI backlog statistics by technical area*



Source: Balanços e Perspectivas, INPI (2010)

2. Restrictive patentability criteria

According to the Industrial Property Law (LPI), the following items are not patentable in Brazil: nucleotide and peptide sequences isolated from natural living organisms as such; extracts and all molecules, substances and mixtures such as those obtained or produced from plants, animals or microorganisms found in nature; as well as animals and parts, even when isolated from nature or elaborated by man (except stable and reproducible transgenic microorganisms). Bill 4.961/05 is under analysis by Congress which would change the terms of the LPI, allowing for patenting of the abovementioned materials.

3. Obstacle related to access to biodiversity

Abundant natural resources and an unparalleled biodiversity are comparative advantages which could leverage the development of a competitive life science industry. However, access to biodiversity remains restricted due to Medida Provisória (Provisional Measure) 2.186-16 of 2001 which stipulates that the concession of IP rights depends on approval to access the genetic heritage and associated traditional knowledge, granted by the Genetic Heritage Management Council (CGEN), which is a slow and bureaucratic process.

Another unfavorable item in Brazilian law was recently changed. The LPI establishes that granting patents for pharmaceutical products and processes depends on prior approval by the National Sanitary Vigilance Agency (ANVISA). However, an opinion issued by the Federal Attorney General's Office (AGU) in January 2011 restricted ANVISA's authority to analyze applications. With the AGU's decision, analysis of patentability aspects once again became the exclusive responsibility of the INPI, which should speed up the pharmaceutical patent approval process in Brazil.

[1] Backlog is the expression used to characterize the amount of patents waiting to be analyzed.

[2] As indicated by the Biotechnology Patent Division (Dibiotec).

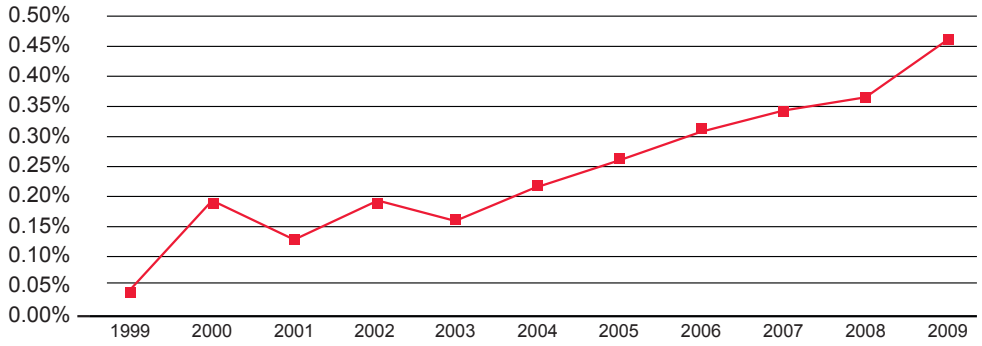
Patent activity in the life science area

Despite the growing amount of scientific production and advances in training qualified manpower, Brazil still performs poorly when it comes to technological production. In this regard, Brazil's participation in the international repository of biotechnological patents remains small (0.45%), despite the fact that it is growing rapidly.

The results obtained from the questionnaires corroborate the existence of a reduced patent pipeline and the trend for growth. 33% of the companies stated that they had patents in the preparation phase for domestic filing and 16% for foreign filing. There was substantial growth in the number of companies with domestic or foreign patents filed; respectively, 44% and 23%[3] .

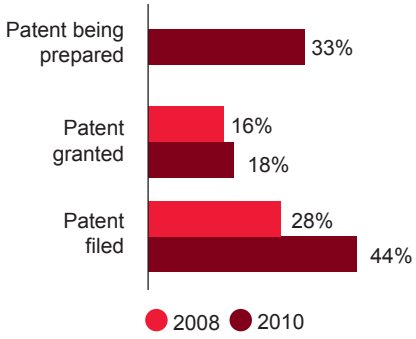
In terms of patent portfolio composition, there are an average of 2.5 patents filed and 1.6 patents granted in Brazil per company; and 2.5 patents filed and 1.4 granted abroad. These numbers are well below those observed in other countries, where companies have more extensive portfolios, made up of dozens and hundreds of patents.

Figure 2 - *Brazil's share of all life science patents filed via PCT[4] (1999-2009)*



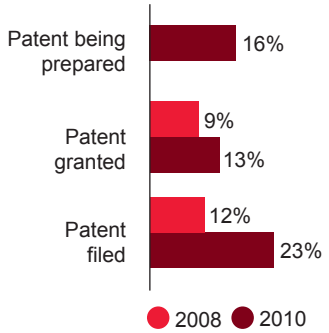
Source: OECD StatExtracts, Complete Data Base, available at: http://stats.oecd.org/Index.aspx

Graph 3 - *Distribution of companies by domestic patent filing status (%)*



Source: Biominas/PwC Study, 2011

Graph 4 - *Distribution of companies by PCT patent filing status (%)*



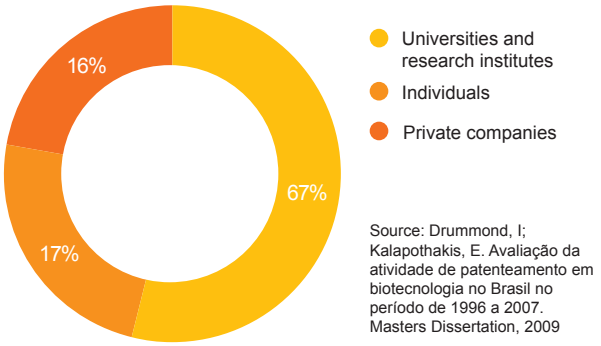
Source: Biominas/PwC Study, 2011

[3] There were a total of 88 answers to this question, resulting in a sample error of 8.5%, and this could be partially responsible for the strong growth in comparison with 2008.

[4] Patent Cooperation Treaty (PCT).

Brazil's small share of international life science patent filings can be attributed to the low level of investments in R&D (1.9% of the 2009 GDP, including public and private investment), the absence of an intellectual property culture and the immature nature of its innovation system, characterized by the concentration of scientists and PhD's at universities and research institutes. The principal classes of life science patent filings at the domestic patent office reflect this scenario:

Figure 3 - *Filings with the INPI in the C12N[5] subclass by resident category (1996 to 2007)*



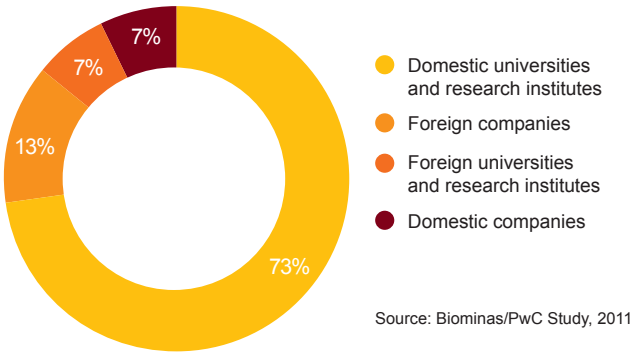
Source: Drummond, I; Kalapothakis, E. Avaliação da atividade de patenteamento em biotecnologia no Brasil no período de 1996 a 2007. Masters Dissertation, 2009

In this context, the establishment of efficient university-industry interactions becomes of vital importance. This process advanced significantly over the last years, pushed forward by the Federal Innovation Law, approved in 2004 and regulated by a Decree of 2005. Among other provisions, the Innovation Law established transfer and licensing mechanisms for technologies generated by Scientific and Technological Institutions (ICTs)[6] and instituted the creation of Technology Transfer Offices (TTOs), responsible for managing innovation policy at the ICTs and the main point of interaction with the productive sector.

Data obtained from companies confirmed this. 21% of the companies indicated that they had patents licensed from third parties in their portfolios, 73% of which were from domestic universities and research institutions.

Despite the fact that the data obtained demonstrates that there is intense interaction between universities and companies in the life science area, there are still items which need to be improved in this relationship. There are great disparities between Brazilian TTOs, especially related to professionalism, organization and experience, which affects the establishment of partnerships and licensing activities. One challenge mentioned by the entrepreneurs which applies to all TTOs refers to the frequent changes in personnel, leading to problems of continuity and rework.

Graph 5 - *Origin of licensed patents*



Source: Biominas/PwC Study, 2011

In fact, it can be noted that the creation of the TTOs, established by the Innovation Law, was not accompanied by an effective human resource policy in the area. The TTO's team is mostly made up of professionals on scholarships and civil servants outside of their normal functions, as this career is not included under the list of functions in the Education Ministry (MEC). The establishment of career plans, salaries competitive with the market and educational and training programs could contribute to professionalize and strengthen these players and, consequently, the efficiency of the interaction of the ICT's with the productive sector.

[5] Subclass C12N corresponds to the International Patent Classification (IPC); propagation, preservation or maintenance of microorganisms or tissues; genetic engineering or mutations and culture media.

[6] The Federal Innovation Law (*Lei Federal de Inovação*) (10.973/04) defines a Scientific and Technological Institution (ICT) as a public organ or entity whose institutional mission, among other things, is to perform basic or applied scientific or technological research activities.

Jorge Ávila

President INPI – National Industrial Property Institute

Zea Mayerhoff

Head of the *Centro Brasileiro de Material Biológico* (Brazilian Biological Material Center)

Perspectives

Since the Brazilian Constitution of 1988 was ratified, the effort to promote Brazilian development has been concentrated on seeking an increasingly favorable insertion of the country's companies and products in world markets. This orientation, essentially focused on increasing the competitiveness of Brazilian industry, has already been present in the changes in intellectual property legislation which have taken place since then. A more active participation by Brazil in building global trade-related governance mechanisms can also be associated to this same period. Brazil had a decisive role in the discussions of the treaties which resulted in the creation of the World Trade Organization (WTO), and observed the impact of internal discussions on its construction. Therefore, signing the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), in 1995, and approving the new Intellectual Property Law (*Lei da Propriedade Industrial*) (LPI) in the following year, were two important and related events, in a trajectory of institutional progress that has not since been interrupted.

The discussions on the creation of the WTO and preparation of the LPI were directed based on the principle of precaution. The starting point was a legislation designed to facilitate acquisition of mature technologies at low cost, and the objective was to build a business environment favorable to technological cooperation and innovation. But no one was yet aware of the country's real potential. Brazil worked so that there would be flexibility in TRIPS, and used that in its legislation. At the same time, it agreed to make the different forms of protection for chemical-based pharmaceutical innovation mandatory, but questioned the requirement to protect biologically-based innovations through patents, making optional protection for the advances of the then nascent modern life science industry.

The protections established were widely used in designing the Brazilian legislation, which in almost every regard followed the minimum requirements put forth in TRIPS, mainly concerning items eligible for patent protection. Thus, all materials and substances found in nature, in Brazilian Law, are not considered as inventions, even if these substances have been isolated and purified, were the object of research initiatives, and such research work has indicated properties which can characterize them as bases for development of products with high social significance or economic value.

Protecting Biotech inventions is not an obligation which we must observe, but it could very well be the sovereign choice of a Brazil which desires to extract value from its rich biodiversity in a sustainable and inclusive manner

It is evident, under these conditions, that shy private investment has been directed towards prospecting the economic potential of the Brazilian biodiversity.

Fortunately, since then, many things have changed on the Brazilian economic scene. In recent years, economic development policies have focused more directly on promoting innovation, and intellectual property has become an important instrument of public policy to enhance the business environment and build competitiveness. At the same time, Biotech has been underlined, with ever greater emphasis, as a strategic priority which could represent a mark in Brazil's insertion in industries with great technological dynamism.

The sustainable use of biodiversity to obtain products aimed at the well-being of society is defended by almost everyone in all business circles of the government today, and all are aware that this requires heavy financial investment and a broad range of technical-scientific collaboration efforts. Everyone agrees without any question that bringing together technical and financial resources, both public and private, and sharing risks and markets are necessary requirements for the industry's development. And no one questions the need for a robust system to protect intellectual property, able to provide the necessary legal security to attract investment and ensure the minimum institutional conditions necessary to celebrate technological cooperation contracts and divide benefits.

It is evident that Brazil has advanced considerably in establishing the basis for a dynamic innovation system in recent years. The country which built a solid and diversified industrial sector and developed a highly-qualified basic research and graduate level educational system, today, has motivated entrepreneurs and highly-qualified researchers and technicians ready to participate in intense R&D activities in companies of almost any kind and technological area. Perfecting the PI system is a consequence of this favorable situation, and a necessary condition to continue advancing in the direction of an increasingly active participation in markets with highly dynamic technology.

In government's efforts to strengthen this area, institutional conditions have evolved to stimulate business's response to R&D needs based on industries.

In recent years, legal security on PI rights has improved and will continue to do so. Protection of intellectual property rights has become more effective, as the structure of the organ responsible for granting PI rights in Brazil, the INPI, has been radically redesigned. The significant increase in the number of employees, principally with the hiring of highly-qualified researchers, in addition to the continual modernization of the operating system, are examples of recent structural advances in the institution. This effort is also reflected in INPI's work with the Brazilian judiciary system, aimed at contributing towards consolidating PI jurisprudence in favor of innovative Brazilian companies.

Despite these advances, there are still barriers which need to be overcome, and many of them are in the field of Biology. These barriers are not restricted to industrial property legislation, but also pervade the legislation of access to genetic heritage and other regulations, frequently pointed to as weak points of a system which inhibits industry development. For this reason, recently, these issues have been the subject of intense discussion by civil society, the Government and also within the scope of the Brazilian Congress. The INPI and the Brazilian authorities responsible for promoting investments have made an effort to listen to the legitimate needs of people willing to perform R&D activities in Brazil or in partnership with domestic research laboratories, which have brought important changes. But these discussions still need to go more deeply. Especially, there needs to be a broader understanding about the role of intellectual property and paths indicated which lead to building more favorable conditions for investment and technological collaboration.

Today we have sufficient maturity to ask ourselves what is and what is not convenient for Brazil, regardless of what has been established as mandatory in the international legal framework. Protecting Biotech inventions is not an obligation which we must observe, but it could very well be the sovereign choice of a Brazil which desires to extract value from its rich biodiversity in a sustainable and inclusive manner. Brazil is on the way of becoming a power in the field of innovation and it is an inescapable fact that life science and the sustainable use of Biodiversity are present in this new configuration.

Rubén Dario Sinisterra

President of *Fortec* (National Forum of Technology Transfer and Innovation Managers)

The University-Company Interaction: A Challenge for Brazil's Sustainable Development

In the last five years, there has been a considerable increase in level of interaction between universities and industries as a result, on one hand, of the accumulation of knowledge at Brazilian universities and research centers, and on the other by the efforts and the need of Brazilian companies to insert themselves in the new scenario of the knowledge economy. However, we still face important challenges ahead in order for industry to gain the dynamism and efficiency of mature national innovation systems.

The new knowledge economy brought new challenges for universities, whose principal mission is anchored on three basic pillars: training of very high-level manpower, research and continuing education which today are not sufficient to participate actively and proactively in consolidating national innovation systems.

This situation could not be different in Brazil, where universities and research centers are responsible for at least 80-90% of all knowledge generated in the country. This reality is the result of a policy of consolidation of post-graduation education and research in Brazilian universities, through CAPES (Coordination of Higher Education Personnel Improvement) programs to support and evaluate post-graduation programs and the sector funding program which strengthened groups and research networks like the national science and technology institutes, promoted by the MCT (Science and Technology Ministry), CNPq (National Council of Scientific and Technological Development) and the state FAPs (Research Support Foundations), in strategic and intensive areas such as: medications, life science, energy, materials, nanotechnology, chemistry, information technologies, engineering, agribusiness and others.

Today Brazil invests roughly 2% of its GDP in science, technology and innovation, graduated some 37,000 master degree recipients and 12,000 PhD's in 2010 (although only 25% of these are in the private productive sector) and produces approximately 2.1% of world knowledge. However, patent production is still very low, corresponding to only 0.2% of world production.

The new knowledge economy brought new challenges for universities, whose principal mission is anchored on three basic pillars: training of very high-level manpower, research and continuing education which today are not sufficient to participate actively and proactively in consolidating national innovation systems.

These numbers still reveal our current challenge, which is to consolidate the Brazilian national innovation system. When we analyze patent origin, we observe that they are still very concentrated in Brazilian universities and research centers, which also showed an important increase in patent filings from 941 in 2006 to 2313 in 2009. Royalties received by these institutions in the technology transfer process totaled US$101 million between 2006 and 2009. Despite these advances, which attest to the dynamic nature of the technology transfer process in Brazil, it cannot be said that there is an efficient and dynamic process yet to appropriate and create innovative new processes and products for society to generate sustainability and greater competitiveness for the country.

Together with this process, we can observe a consolidation of new organizations responsible for disseminating the culture of innovation, intellectual property and technology transfer, with the mission of maximizing the effect and spreading the role of universities and research institutions in cooperative activities with the public and private sectors. On the state and regional levels, the state and regional networks of Technological Innovation Nuclei (NITs) stand out, and on the national level, the National Forum of Technology Transfer and Innovation Managers (FORTEC), created in 2006 with 43 associates is prominent, after the Brazilian Innovation Law (Lei 10.973) of 2004, which today includes approximately 200 NIT's.

Analyzing the results of the university-company interaction using one of the indicators, the transfer process of independently-developed technologies, and those coming from universities and research centers, we find in the market products like the recombinant vaccine against canine leishmaniasis sold by Hertape-Calier from technology developed by the UFMG (Federal University of Minas Gerais) and the anti-inflammatory medication Acheflan sold by Aché from technology developed by the UFSC (Federal University of Santa Catarina). We also find diagnosis testing technologies for diseases, medications and vaccines, in the laboratory stage, in pre-clinical and clinical stages in humans, for treatment of disease in a wide variety of areas such as cardiovascular, cancer, high blood pressure, yellow fever, AIDS, tuberculosis, Chagas disease, malaria, influenza and others. On the other hand we also find a large concentration of technologies for production of ethanol and biodiesel as alternative energy options from life science processes. These are great opportunities for the domestic and international markets.

Despite this promising scenario, still lacking are: a better absorption of master degree and PhD recipients in companies, establishment of long-term research and development programs in partnership with universities, establishment of basic and applied research inspired, funded and monitored by groups of companies, generation of spin-offs aimed at intensifying the innovation process in the Biotech area, for example, the creation of new long-term training programs to seek solutions for immediate problems and future needs of Brazilian companies. Thus, it is necessary to continue strengthening the interaction between universities and companies as a way to guarantee increased sustainability, competitiveness, job creation, income, wealth and well-being for the Brazilian population.

2.2 Capital

Funds availability is one of the key elements required to develop the life science industry given the long product development cycle and high cost involved, especially for applications related to human health. The principal available sources of funding for Brazilian life science companies can be summarized as follows:

1. Reimbursable funds: loans and financing, which must be paid off within a pre-determined period, plus interest and monetary correction. This includes public funds (e.g. BNDES[7], FINEP[8]) and private (e.g. Commercial Banks).
2. Non-reimbursable funds: grants and donations, generally in the form of public requests or calls for grant proposals. Amount received does not have to be paid off. Includes public sources (e.g. FINEP, State Research Support Foundations (FAPs), such as FAPESP and FAPEMIG, CNPq[9]) as well as private (e.g. non-profit organizations, like the Bill and Melinda Gates Foundation).
3. Internally-generated funds: capital from shareholders and retained earnings on the company's activities.
4. Investors: this includes several different types, including angels, seed capital, venture capital and private equity. They vary as to range of investment and development stage of the companies invested in. They acquire equity interest and look for a substantial return for when they exit the venture. They include public sources (e.g. BNDESPar, CRIATEC[10]) and private (e.g. private investors, like FIR Capital and Burrill & Company[11]).
5. Corporate partnerships: funds obtained from cooperative agreements between companies. This can take on different formats, including R&D partnerships and joint ventures.

When defining their fund raising strategy, entrepreneurs usually focus on three main criteria: items to be financed (expansion of production capacity, R&D, working capital, etc.), accessibility to available sources of funds (offering guarantees, counterparts, attractiveness and investors) and cost of capital (interest and rates). Table 1 suggests some additional criteria and compares the main sources of financing:

[7] The National Social and Economic Development Bank (BNDES), a federal public company, at present is the principal instrument of long-term financing for investments in all segments of the economy, with a policy which includes social, regional and environmental dimensions. (www.bndes.gov.br)

[8] FINEP - *Financiadora de Estudos e Projetos* ("Brazilian Innovation Agency") is a public company connected to the Science, Technology and Innovation Ministry (MCTI). The ability to finance the entire Science, Technology and Innovation system, with both reimbursable and non-reimbursable funds, as well as other instruments, gives FINEP a strong power to induce innovative activities, which are essential to increase industrial competitiveness. *(www.finep.gov.br)*

[9] The Scientific and Technological Development Council (CNPq) is an agency of the Science, Technology and Innovation Ministry (MCTI) whose purpose is to foster scientific and technological research activities and train manpower for research work in Brazil. *(www.cnpq.br)*

[10] See Box 1.

[11] See Box 2

Table 1 - *Comparison of the principal forms of financing*

Comparison criteria	Forms of financing				
	Reimbursable funds	Non-reimbursable funds	Internally-generated funds	Investors	Corporate partnership
Risk sharing	-	+++	-	+++	+++
Gaining know how	-	-	-	+++	+++
Accelerating development	++	+	+	+++	+++
Funds availability	+++	++	+	+	++
Dividing profits	-	-	-	+++	+++
Dilution of equity participation	-	-	-	+++	-

Key:

-	Absent		The higher the better
+	Low		The lower the worse
++	Average		
+++	High		

Source: Biominas Brasil, 2011

Comparison criteria

Risk Sharing: evaluate if the form of financing allows for division of technological and/or commercial risk of failure with a third party.

Gaining know how: evaluate if the form of financing allows for adding additional competencies to the company.

Accelerating development: evaluate if the form of financing induces acceleration of development.

Funds availability: evaluate the supply of this type of funds in the domestic environment.

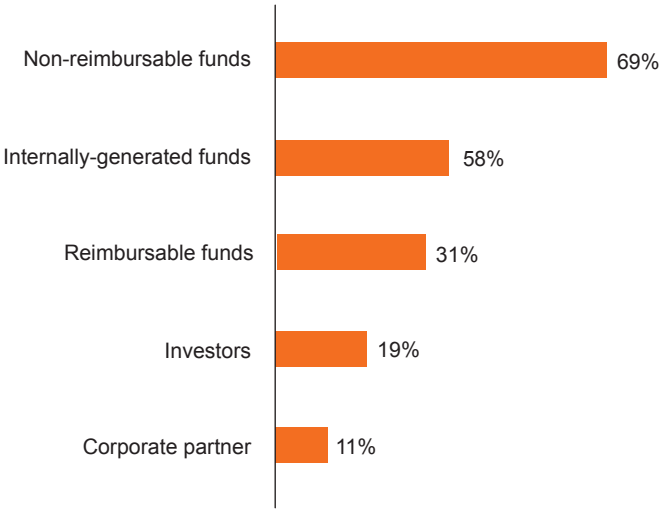
Dividing profits: evaluate if the financial results are shared with third parties.

Dilution of equity participation: evaluate if the form of financing leads to dilution in equity participation.

The comparison demonstrates the attractiveness of corporate partnerships and investors, who stand out in criteria such as dilution of risk, adding know how and accelerating development. The partnerships are also interesting as they do not bring about dilution in equity participation and given their greater availability domestically as compared with venture capital and, therefore, will be the subject of a more detailed analysis in Section 4, *Partnering for growth*.

The survey applied to the companies mapped the most accessed funds sources and the profile of the investments. As demonstrated in the graphs below, a preference for non-reimbursable and internally-generated funds can be observed, at the expense of corporate partnerships and investors, meaning that the reasoning presented earlier has not been applied by companies.

Graph 6 - *Indicate the principal sources of funds for Research & Development activities at your company (select up to two options)*

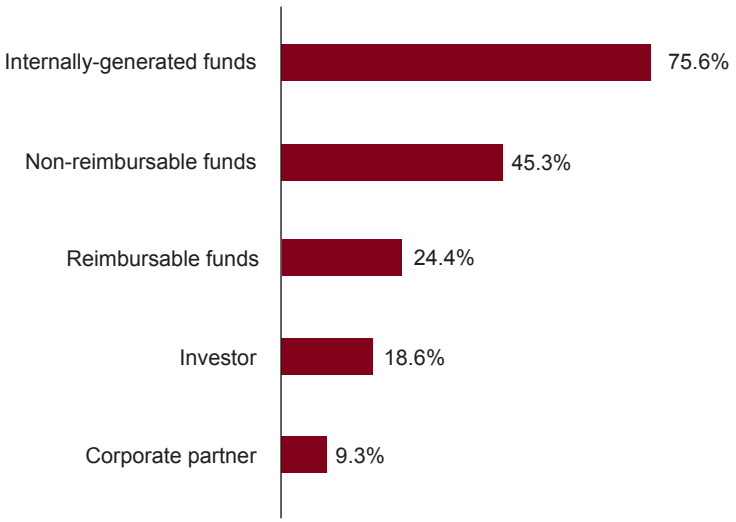


Source: Biominas/PwC Study, 2011

Graph 7 - *Excluding Research & Development activities, what were the main investments and cash outlays made by the company in 2010? (select up to two options)*

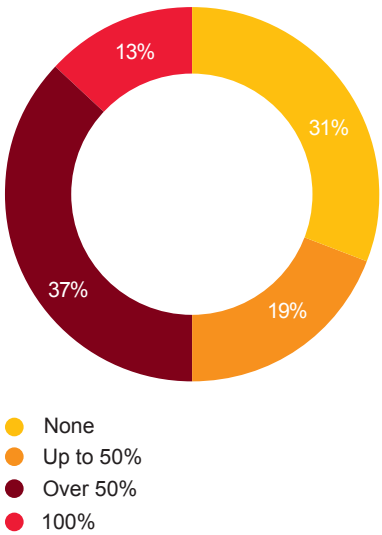
Source: Biominas/PwC Study 2011

Graph 8 - *Indicate the principal sources for financing this investment (excluding R&D)*



Source: Biominas/PwC Study, 2011

Graph 9 - *What was the approximate percentage of government funds to R&D investment?*



Source: Biominas/PwC Study, 2011

On the total amount invested in 2010, the sum of the 79 open answers reveals a total of R$52.4 million, an average investment of R$ 670,000 per company, 43% of which applied to R&D expenditures. Even though the high percentage of R&D expenditures demonstrates the technological and innovative character of the industry, the absolute amount of investment is very small in comparison to that invested by life science companies in other countries.

The data reveal the importance of government investment in financing R&D and other forms of investment made by national life science companies. In half of the companies, government funding represented over 50% of the investment in innovation, reaching a level of 100% for 13% of these companies.

The predominance of public funds and internally-generated capital as the primary, if not the only, sources of funds, has important implications for the industry. Capital from investors and private partners comes together with managerial support, strategic direction and networking, which are crucial for technological entrepreneurs. In addition, these players are more careful in the selection process, especially with regard to the company's growth potential and business model.

The principal non-reimbursable programs and forms of government financing accessed by domestic companies over the last five years and their characteristics are presented in Tables 2 and 3.

Table 2 - *Principal government programs with non-reimbursable funds accessed by Brazilian life science companies*

Institution	Program	Limit	Fundable Items	Counterpart	Frequency	Examples of Grantees
FAPESP	PIPE	**Phase 1:** Maximum R$125,000 **Phase 2:** Maximum of R$500,000	Supplies, Machinery and Equipment, Outside Services, Research Scholarships, Project Presentation Expenses	**Phase 1:** Develop internally at least two-thirds of the project (in activity cost) **Phase 2:** Develop at least 50% of the activities	Continuous flow	Gentros, Verdatis, Velly-FARM Biomateriais
FINEP	PAPPE	R$ 100,000 - R$ 400,000	Exclusively in operating expenses: human resources, specialized consulting services and supplies	Variable	Request for Grant Proposals	Bioclone, Cenatte Embriões
	Subvenção	Minimum of R$500,000 and Maximum of R$50 million	Expenses directly related to R&D: operating expenses, services, supplies, equipment and real estate rental	5% - 200%	Request for Grant Proposals	Quantas Biotecnologia, BIOMM, Gentros, Recepta Biopharma, Bionext
	Prime	R$ 120,000	Qualified human resoruces and specialized consulting services	Minimum of 5%	Request for Grant Proposals	Imprenha, Bioaptus, Bioclone, NeuroAssay
CNPq	Rhae	R$ 300,000	Scholarships which must be directly related to the object and activities of the project	Minimum of 20%	Request for Grant Proposals	Imunodot Diagnósticos, Biocod, Veritas Biotecnologia, Verdartis

Source: Biominas Brasil from data provided by the respective institutions, 2011

Table 3 - *Principal government programs with reimbursable funds accessed by domestic life science companies*

Institution	Program	Maximum	Fundable items	Counterpart	Grace Period	Amortization	Rate	Guarantee
FINEP	Inova Brasil	From R$1 million to R$100 million	Everything, except land and vehicles	Minimum of 10%	Technological innovation - 36 months Innovation Capital - 24 months Pre-Investment - 24 months	Technological innovation -120 months Innovation Capital - 96 months Pre-Investment - 96 months	Technological innovation -4% per annum Innovation Capital - 5% per annum Pre-Investment - 8% per annum	Bank bond letter, liens, pledges, chattel mortgages of property and real estate, blockage of accounts and guarantees
	Juro Zero	R$100-900,000, limited to 30% of Previous Calendar Year's Gross Operating Revenues	Items directly or indirectly related to technological innovation activities	Minimum of 10%	No grace period	Up to 100 months	No interest charge, company only pays for the variation of the IPCA inflation index.	20% of the amount financed in the form of Personal Bond from company owners or named representatives
BNDES	Profarma - Produção	Minimum of R$1,000	Everything, except land and vehicles	Minimum of 10%	Up to 36 months	Up to 120 months	TJLP (Long-Term Interest Rate (~6% per annum) + BNDES Remuneration (1%)	Lien, pledge,fiduciary property, bond, guarantee or collateral reserve
	Profarma - Inovação	Minimum of R$1,000	Everything, except land, vehicles, working capital and business management costs	None	Up to 60 months	Up to 80 months	Fixed rate of 4.5% per annum	Lien, pledge,fiduciary property, bond, guarantee or collateral reserve

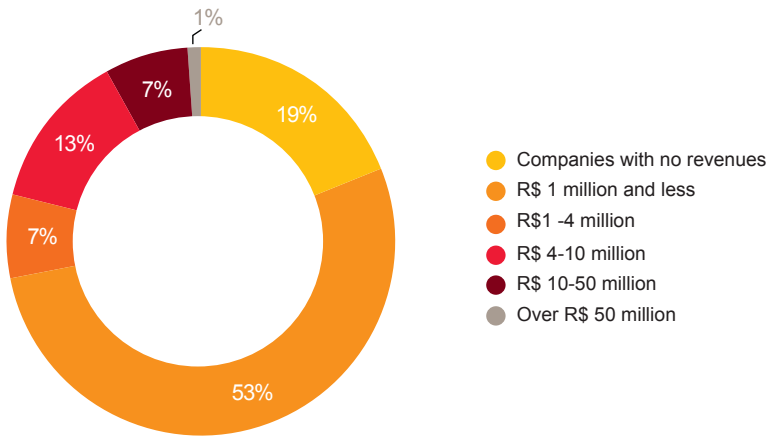
Source: Biominas Brasil from data published by the respective institutions, 2011

The interviews held indicate a high level of satisfaction among entrepreneurs regarding the non-reimbursable programs currently available. Negative points involve uncertainty concerning date of the public requests for grant proposals and program continuity, which make corporate planning more difficult.

With regard to the reimbursable programs, accessibility is more difficult due to the requested guarantees. As can be observed in Graph 10, the industry is made up most of very small and small companies, 19% of which have no revenues and 53% have revenues of R$1 million or less, which makes access to credit more difficult. The impact of this limitation tends to get worse as companies advance in the development stages of their products and start to demand funds for investment in infrastructure, working capital, marketing and sales.

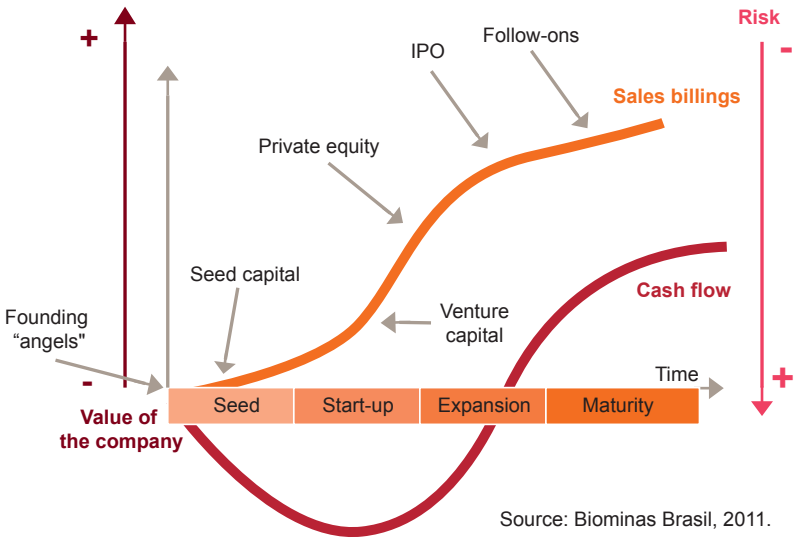
Another characteristic of the Brazilian market is the scarcity of private investors willing to put funds into the life science area in the initial phases of development and expansion. The American biotechnology funding model, described below, is frequently mentioned as a reference and has been duplicated with relative success in several countries. It consists of several rounds of venture capital investment, including angel investors, seed capital, venture capital and private capital, followed by the process of going public on a stock exchange (Initial Public Offering or IPO).

Graph 10 - *Gross revenue by company*



Source: Biominas/PwC Study, 2011

Graph 11 - *Life science company development line and funding mechanisms*



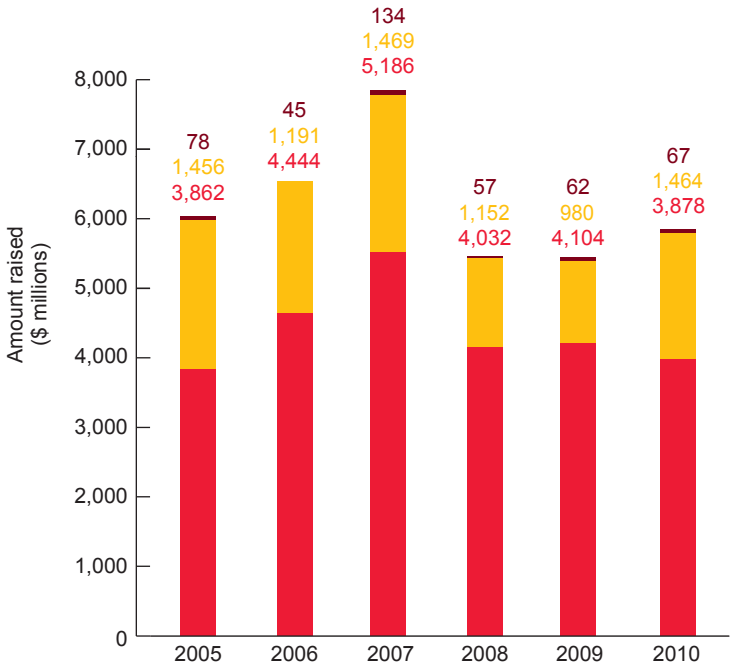
Source: Biominas Brasil, 2011.

However, two crucial components of this model are absent in Brazil, specifically:

1. A vigorous venture capital industry familiarized with the life science industry, specifically, with its long development and return cycles;
2. A developed capital market and investors informed about the growth potential of life science companies.

According to information obtained in the electronic domain of the *Comissão de Valores Mobiliários* (the Brazilian Securities and Exchange Commission) (CVM), the total amount raised by Brazilian life science companies by means of registered funds over the last 10 years is estimated to have been R$100 million, similar to the amount raised by companies in the Asia-Pacific region in 2010. More relevant than comparing absolute values is to compare the amount per investment operation. The average amount for operations in the Americas was US$17 million, in Europe US$14 million and Asia-Pacific US$11 million, while in Brazil this amount was US$1 million, far below the typical demand for investment in the industry.

Figure 4 - *World venture capital investments in life science over the last 5 years*



Number of operations

	2005	2006	2007	2008	2009	2010
Americas	183	213	228	214	209	225
Europe	100	87	108	103	89	104
Asia-Pacific	9	8	11	6	5	6

Source: Yang, W. Nature Biotechnology, vol. 29 (2), February 2011

The principal venture capital fund which has leveraged life science companies in Brazil is CRIATEC, a seed capital fund made up of funds from the BNDES and the *Banco do Nordeste do Brasil* (BNB). In the last 2 years, seven investments in innovative life science companies were identified in the CVM data base, five of which made by CRIATEC (Box 1).

A new fund focusing exclusively on life science ventures is in the final structuring phase and will enter into operational phase in the second half of 2011 (Box 2).

Box 1. CRIATEC, Seed Capital Fund

CRIATEC is a seed capital fund created based on a national call promoted by BNDES, co-managed by Antera and Inseed, whose investors are BNDES itself and the Banco do Nordeste. The objective of the fund is to invest in and develop nascent technology-based companies with high growth potential.

Funds injections can be as much as R$1.5 million per company in the first round and up to R$5 milllion in subsequent investments. Criatec also participates in management, adding market knowledge and strategic business management, in order to drive the company's development. In addition, the fund adds an extensive networking, which generates innumerous opportunities to the companies invested.

According to information from Robert Binder, National Manager of CRIATEC, up to August 2011, the fund had invested in 28 companies and is in the final phases of investment in five more. 30% of its portfolio is made up of investments in the life science industry. With regard to the obstacles to the growth of domestic life science companies, Robert mentioned that regulatory difficulties, the lack of long term capital and the amounts to be invested in the human health sector constitute barriers which are difficult to overcome. The technology push of small- and medium-sized Brazilian companies could be the main driver of development. In his opinion, companies need to focus on niches and areas where Brazil has competitive advantages, like technologies to use biomass and natural resources.

Box 2. Burrill Brasil I Fund

The American capital management firm Burrill&Company, global leader and pioneer in investments in the life science area, is establishing a venture capital fund focused on this segment in Brazil.

According to Gabriela Cezar, Burrill Director for Latin America, the Burrill Brasil I Fund, with a target value of US$200 million, should begin operations in the second half of 2011. As of August 2011, the investors are: BNDES, FINEP, the Multilateral Investment Fund (Fumin/BID), Pfizer USA, Nossa Caixa Desenvolvimento, CAF, Investe Rio and Life Technologies.

According to Gabriela, search of potential investment targets is being actively pursued and covers all segments of life sciences and company sizes. Companies like Cobalt Biofuels and Chromatin Inc., both from the area of bioenergy, are part of Burrill &Company's world portfolio of investments and reflect the profile of companies of the group, which also has a significant focus in the health care and pharmaceutical sector.

This analysis shows the limited funding environment for domestic life science companies:

1. The non-reimbursable governmental programs available this far only allow funding for the research &development phases of specific projects (in addition to being connected to the publication of official requests for grant proposals);
2. Funding programs from governmental institutions have attractive interest rates, but are difficult to access due to the required guarantees;
3. Nearly 70% of the companies either have no revenues or they are less than R$1 million, which means they do not generate sufficient cash for reinvestment;
4. There is a very limited number of private investors willing to invest in this area;
5. Public offerings are simply not a realistic proposition for most of these companies.

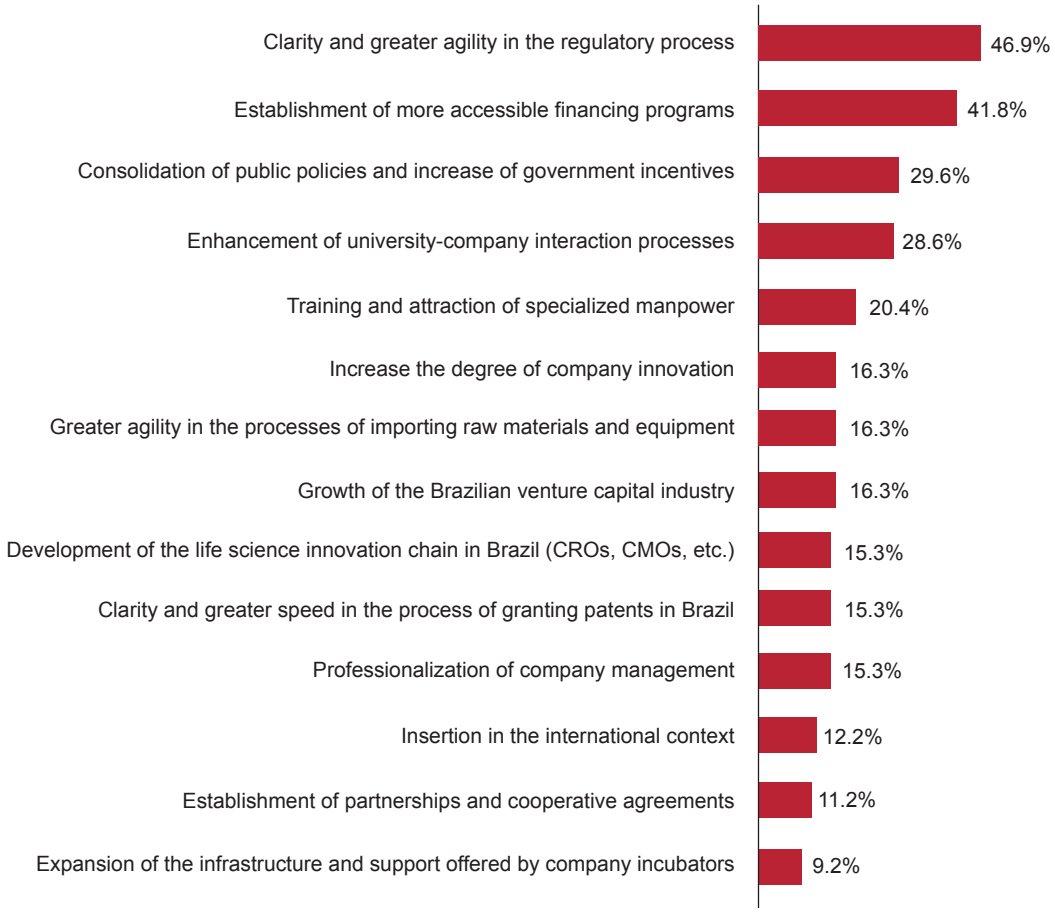
In order to survive and prosper under these conditions, domestic companies must structure creative business models, including virtual and collaborative models, and use corporate, domestic and international partnerships more efficiently, not only to raise funds, but also to join capabilities and share risks, as will be discussed in Section 4 "Partnering for Growth".

2.3. Public policies

Considering the high technological risk and long development cycle, life science companies require a favorable business environment which stimulates private investment. Just as important as having support and incentive mechanisms is their continuity and the establishment of long-term policies - one of the weak points in the Brazilian environment. Equally important is articulating different public players and the overall view of the chain, from development to taking a competitive product to the market.

The importance of public policies in the eyes of businessmen is clear in the question below:

Graph 12 - *Which of the following topics represent critical success factors for the Brazilian life science industry during the next two years? (select the three most important)*



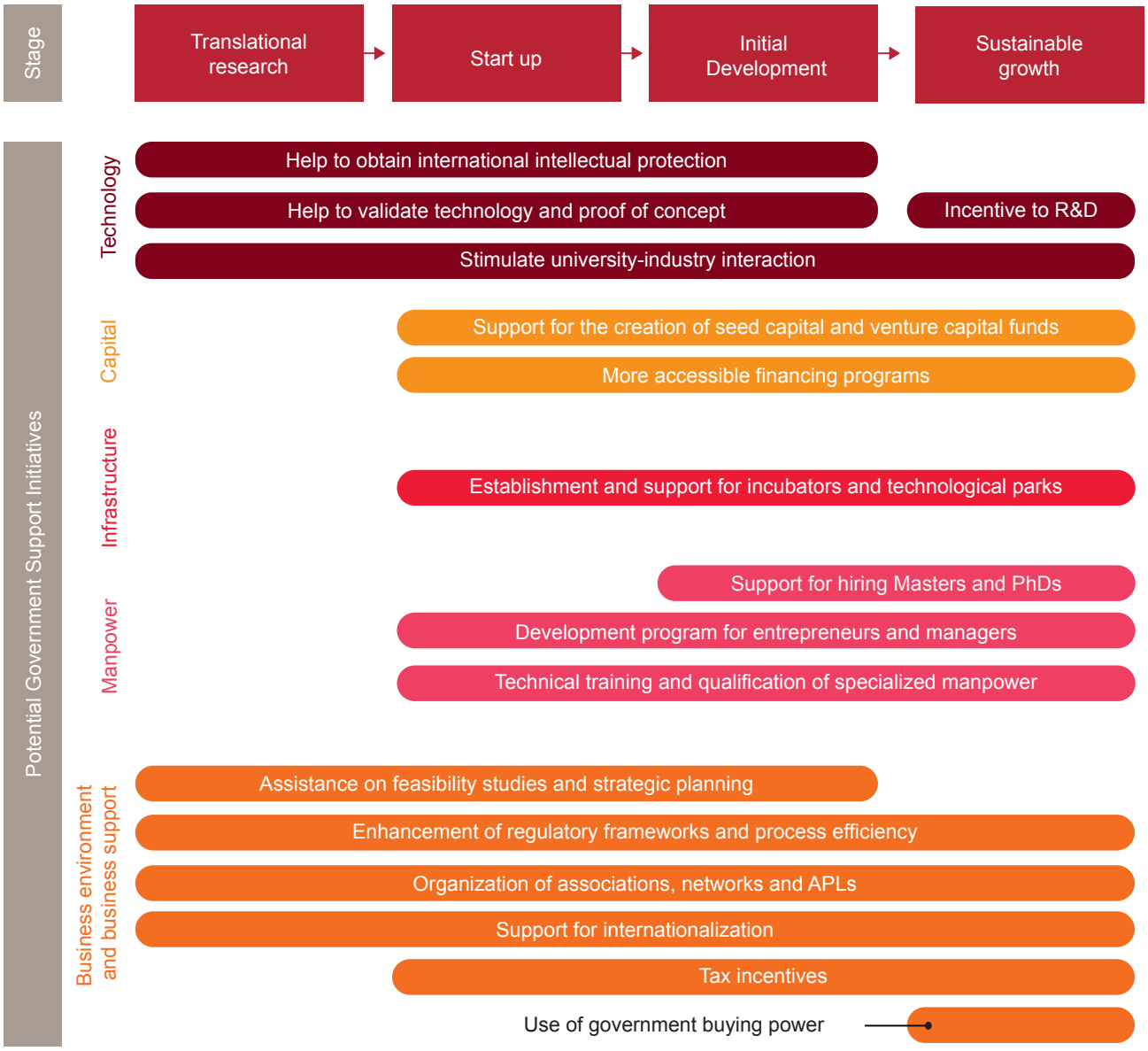
Source: Biominas/PwC Study, 2011

The different spheres of federal, state and local governments can articulate several actions and programs in order to stimulate this industry, as has been observed in countries like the United States, Canada, France and Australia.

The diagram below summarizes the different areas in which government can act in relation to the stage of development of life science companies and is based on identified initiatives in different countries.

The principal actions demanded by entrepreneurs in interviews and questionnaires make up this picture and will be discussed point by point.

Figure 5 - *Potential government-supported initiatives vs. company development stage*



Source: Biominas/PwC Study, 2011

Technology

In order to strengthen the technological platforms of domestic companies, the most critical stages are fostering intellectual protection, especially international, and validating and obtaining proof of concept. This type of government support becomes vital in companies' earlier stages, in order to make them able to attract private partners and investors. Economic grant programs and public request for grant proposals to foster innovation in companies has played this role in the life science area, however support for intellectual protection should be expanded.

Establishment of a legal framework which is favorable to the interaction between universities and companies, as well as issuing public requests for grant proposals giving special treatment to this type of cooperation and efficient technology transfer mechanisms, thus favoring the innovation cycle, strengthening the technological base and innovative potential of domestic companies. Important progress was obtained in these areas with the Federal Innovation Law (*Lei de Inovação Federal*) and subsequent state laws

Capital

The main government contributions to the funding environment are related to support in creating seed capital and venture capital funds which invest in the life science sector; offering attractive lines of credit associated to risk guarantee funds; and expansion of non-refundable programs, subject to enhancements in the follow up mechanisms and establishment of an annual calendar for publishing requests for grant proposals or a constant flow of project analyses.

With regard to the first point, FINEP has been taking actions since 1999, with the creation of the INOVAR program in partnership with Fumin/BID[12], which involves fostering the creation of investment funds and holding several forums to bring together companies and investors. The BNDES also plays an important role in this area through the BNDESPar, its division responsible for implementing investments in companies and funds with equity participation.

[12] The Inter-American Development Bank (BID) is the principal source of multilateral financing and knowledge for sustainable economic, social and institutional development in Latin America and the Caribbean. The BID Group is made up by the Inter-American Development Bank, the Inter-American Investment Corporation (CII) and the Multilateral Investment Funds (Fumin). The CII concentrates on financing medium- and small-sized companies, while Fumin promotes the growth of the private sector with investments and non-reimbursable technical cooperation operations, with emphasis on microenterprises. *(www.iadb.org)*

Infrastructure

The demand for specialized infrastructure is one of the chief bottlenecks in the industry and one of the large problems faced by domestic companies. From the significant incubation statistics we can conclude the fundamental role performed by these players in the process of creation and initial development of life science companies. However, there are few domestic incubators with the proper infrastructure to meet industry requirements. Regardless of their level of specialization and quality of infrastructure offered, most have already reached their maximum capacity and have waiting lists. The long development cycle and maturation of companies in this industry make for not very encouraging prospects in this area.

The government programs should emphasize the strengthening and expansion of the network of incubators specialized in the life science area and in the professionalization of the support offered, preferably in partnership with private entities, in addition to investing in the establishment of technological parks, which could house newly-formed companies and R&D centers for medium- and large-sized companies, creating an environment favorable for mutual fertilization.

Manpower

In the human resource area, government actions to stimulate hiring of people with master's degrees and PhD's could improve the supply of specialized manpower for the industry. To this end, it should include financial incentives (offering scholarships), career advancement (greater weight given to technical research and interaction with the productive section as evaluated by CAPES[13]) and tax incentives to hiring companies.

Regarding qualification, technical and business development programs could be developed together with the National Industry Confederation System (CNI) and State Industry Federations (including the member systems SENAI, SENAC and IEL), and with the Brazilian Service of Support to Microenterprises and Small Companies (SEBRAE). The Local Productive Arrangements (*Arranjos Produtivos Locais*) which consist of industry clusters fostered by the government, could also perform an important role in preparing successful entrepreneurs.

[13] The Coordinating Organ for University-Level Personnel Development (CAPES), part of the Education Ministry (MEC), plays a fundamental role in expanding and consolidating stricto sensu graduate degree (masters' and doctors') programs in Brazil. Responsible for evaluating graduate programs, it defines specific quality indicators to be applied for each field of knowledge. *(www.capes.gov.br)*

Business environment and support to companies

Public policies should essentially provide a favorable environment which stimulates economic growth and private investment. In this regard, the most strategic and most impacting action for the life science industry consists in enhancing regulatory frameworks and promoting greater clarity, speed and efficiency in the analysis and approval process.

An example of a regulatory framework which inhibits private investment relates to the RDC 315/2005, which regulated biological product registration. RDC[14] 315 did not specify any clear distinctions between new and not new biological products, also known as biosimilars, in terms of the level of requirements, which hampered development in this area. The regulatory framework was recently improved with RDC 55/2010.

Another example of a segment suffering from the lack of a clear regulatory framework is that of bio-pesticides. Despite the great potential to impact Brazilian and global agriculture with a pest and disease control process that is less aggressive to the environment, using biological processes, domestic life science companies developing such technologies have been facing long approval processes with the competent government organs, subjected to broad legislation regulating agrichemicals.

The use of tax incentives and the government's buying power also are mechanisms which have been widely discussed in Brazil.

Among the tax incentives, an agreement made in August 2011 between the *Frente Parlamentar Mista das Micro e Pequenas Empresas* ("Mixed Parlamentary Front for Microenterprises and Small Companies) and the federal government will result in reduced federal, state and municipal taxes, by changing the rules for the simplified tax treatment regime known as the *Supersimples*.

[14] Resolution of the Collegiate Directors (RDC).

With the agreement, the first level of annual revenues of up to R$120,000 increases to R$180,000, with a tax rate of 4%; the second level now includes companies with revenues of up to R$1.8 million, with a tax rate of 9.12%; while the highest level now includes companies billing up to R$3.6 million and the applicable rate becomes 11.61%. These rules will become effective starting January 2012 and will benefit Brazilian life science companies as a large portion of the companies in the industry falls within these categories.

Tax incentives for innovation established under the so-called "*Lei do Bem*" ("the Law of Good"), in turn, have not benefited the industry, as the great majority of the companies use the "Presumed Earnings" (*Lucro Presumido*) tax regime, not included within the scope of this law. In addition, a large portion of the investments made by the industry in innovation came from non-reimbursable funds obtained through public requests for grant proposals.

As for the use of government buying power, Decree (*Decreto*) 7.456, published in August 2011, regulates the application of a preference margin for domestic manufactured products and services as well as compensating commercial, industrial and technological measures or access to favorable financing conditions included in Law (*Lei*) 8.666/93. It also created the *Comissão Interministerial de Compras Públicas* (Inter-Ministerial Public Purchases Commission). In short, the decree considers the State's buying power as an instrument of public policy and establishes the preference for products and services manufactured and developed in Brazil, as opposed to those of foreign origin, allowing a price differential of up to 25%. Decree (Decreto) 7.456, however, does not permit immediate application of that benefit. In order for that to happen, a specific decree must be established defining which products will receive the benefit, the preference margins and other conditions to apply government buying power.

Finally, as for the company support mechanisms which could be provided by the government, the following items were listed: assistance in developing feasibility studies and strategic planning, essential prerequisites to improve project quality and professionalization of domestic companies; organization and strengthening of associations, networks and Local Production Arrangements ("*Arranjos Produtivos Locais*") (APLs), which are efficient mechanisms to promote gains in competitiveness from the exchange of experiences, networking and use of synergies; and support for internationalization, an essential component in the life science industry, from the early stages of technology development.

Diana Jungmann

Intellectual Property Program Coordinator
Confederação Nacional da Indústria
(National Industry Confederation) – CNI

Life science: a sector with a future for Brazil

The world life science scene is no longer exclusively a privilege of rich countries and Brazil, together with India, China and South Africa, are starting to become part of it. Business success stories have already begun to circulate in the market, including abroad, giving visibility to the growth potential of the so-called Brazilian Biotech industry.

The characteristic profile of biotech is a knowledge-intensive industry which absorbs highly-qualified manpower; requires large investments in research and development (R&D); is highly regulated by the government; has a long new product development cycle and, when these products are successful in the market, offers high returns on the investments made.

According to a recently-published study, in Brazil the industry is made up of fewer than 300 small companies focused on the areas of human and animal health, reagents, agriculture, environment and bio-energy. Brazilian biotech companies are still in their infancy. Most have been created by the entrepreneurial efforts of scientists, with no experience in business or in marketing. The majority of these companies is located in university incubators, mainly concentrated in the Southeast region of Brazil, and depends on government financing (FINEP, CNPq and BNDES).

Worldwide, the industry is expanding, is profitable and sells hundreds of billions of dollars annually. Therefore, there is no room for amateurism and to be competitive, the Brazilian Biotech industry cannot merely focus on the domestic market, but will have to participate in the global "bio-economy".

In order to grow and create wealth, Brazil needs to define how it will integrate the life science industry value chain. Worldwide, the industry is expanding, is profitable and sells hundreds of billions of dollars annually. Therefore, there is no room for amateurism and to be competitive, the Brazilian Biotech industry cannot merely focus on the domestic market, but will have to participate in the global "bio-economy". So, the challenge is great.

The Brazilian regulatory structure in the life science area is extensive, but inefficient. Today there are contradictory rules which limit access to Brazilian R&D, at the same time that there is improper appropriation of our biodiversity. Consequently, the lack of the proper public policies to foster industry development creates legal uncertainty for doing business, thus causing huge losses for the country.

The life science industry is a dynamic and innovative sector, and, for this reason, it is essential that Brazil make a strategic and competitive analysis of the leading markets; define the possible trends and impacts of the global industry on the country's development; identify the industry's critical needs and how to meet them; develop an articulated and future vision between government, universities and industry to make the right choices and bets in designing an industry strategic plan and, finally, create an agenda with an integrated vision to execute and communicate the advances obtained in leading the growth of the Brazilian biotech industry to society. This seems to be the logical path to follow.

Exercising its role in defending the interest in developing the competitiveness of Brazilian industry, the Confederação Nacional da Indústria – CNI, at the beginning of the year, through the Mobilização Empresarial pela Inovação (Business Mobilization for innovation) – MEI, presented a substantive, practical and viable agenda to create a more favorable environment for innovation in Brazil to the government. The agenda applies to several technology-intensive business sectors. Among the points considered as priority, the following are highlighted as having immediate needs: training of qualified manpower; improvement of the legal framework for innovation to expand government incentives and investment; structural R&D projects; sectorial innovation programs; an innovation policy and improvement of the intellectual property system (PI).

Within the scope of PI, it is important to stress the emphasis of MEI's agenda on the life science industry. Brazil is considered to be a "mega" bio-diverse country. It is estimated to house 13% of all species existing on Earth, and the most surprising thing is that only 10% of this natural heritage is known today. Thus, stimuli for innovation based on the use of our biodiversity, in accessing the genetic heritage and traditional knowledge require a profound revision of the legal framework, which must begin with the immediate removal of the obstacles present in current legislation, that represent a major barrier to the country's technological development. Among Brazil's great opportunities in this century are the development of knowledge and exploration of its life science potential. The Industrial Property Law (Lei de Propriedade Industrial) must be updated, allowing patent protection for inventions related to living organisms, so that knowledge can be transformed into assets with marketable value, generate economic and social benefits and stimulate private investment in these sectors

The CNI believes that business has a role to contribute along with government towards building strategic public policies so that the country can innovate, compete and develop itself, creating wealth for all Brazilians.

2.4. Specialized human resources

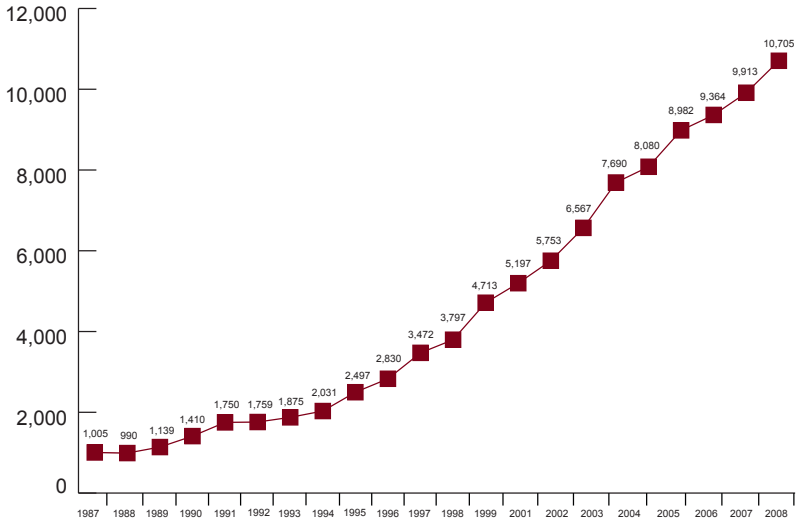
The life sciences industry development requires manpower specialized in diverse knowledge areas and disciplines, as molecular and cell biology, microbiology, chemistry, physics, bioprocess engineering, bioinformatics, medicine, statistics, technology transfer and commercialization, intellectual property, regulatory issues and bio-business management. The interdisciplinary labor force is fundamental and must be stimulated since the biotechnological innovation emerges from these areas integration.

On the last couple of years, Brazil significantly improved scientific production and specialized human resource graduation. The number of doctors degrees tripled in the last 10 years, reaching 11,000/ year in 2008, meanwhile the country participation in the scientific articles publication reached 2,7% in 2008 from 0,8% in 1992, as showed on Figures 6 and 7. Besides the quantitative increase, the area of PhD graduation must be evaluated, and so the education quality and national scientific production impact.

In 2010, the "Centro de Gestão e Estudos Estratégicos" (Management and Strategic Studies Center, CGEE) published a study that examines the demography of the Brazilian techno-scientific basis[15]. The evaluation of the knowledge graduation areas share by the total doctorates degrees in 2008 revealed that 42,2% of the PhDs graduated in the life sciences segment, being 18,3% in the health area, 12,3% in agro sciences and 11,6% in biologic sciences.

Regarding the post graduation education quality, it has been observed that, in healthcare area, approximately 70% of the doctors programs received 3 or 4 grades on CAPES evaluation, level considered average, meanwhile in biological sciences this share is 50%. The agro sciences highlights with almost 70% of the programs graded above 5.

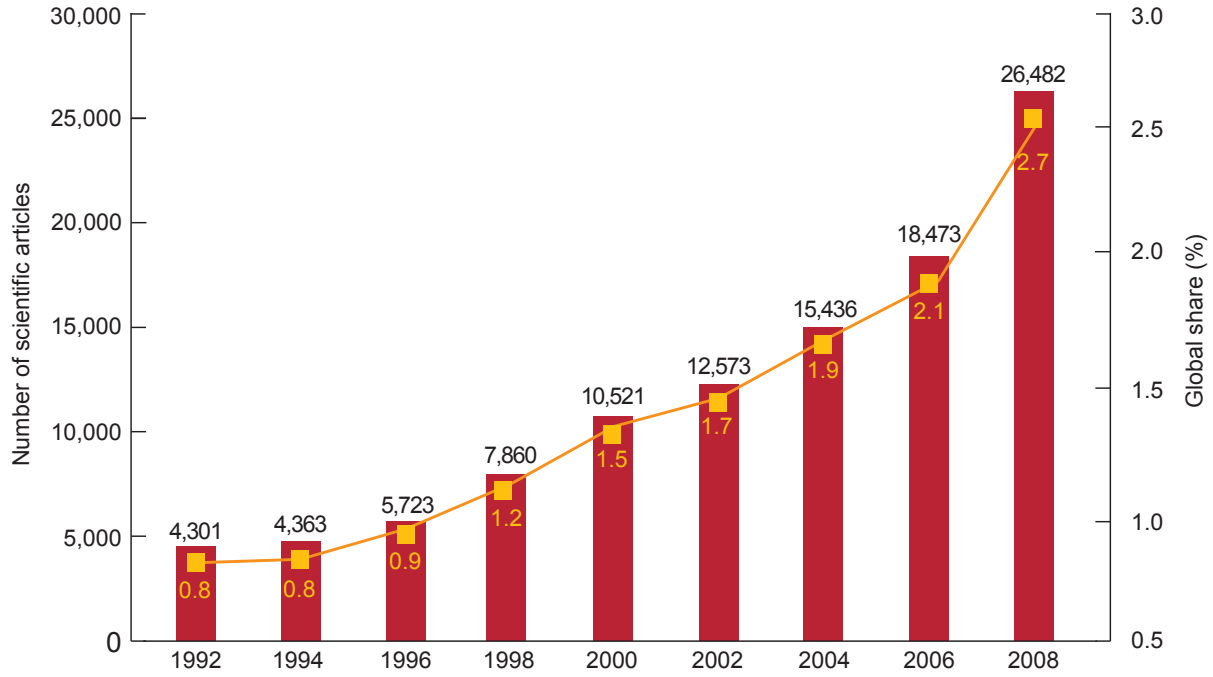
Figure 6 - *Evolution of doctorate degrees granted per year in Brazil, 1987-2008*



Source: Centro de Gestão e Estudos Estratégicos, Parcerias estratégicas - edição especial, vol. 15, número 31, Dezembro 2010

[15] Doutores 2010: estudos da demografia da base técnico-científica brasileira - Brasília, DF: Centro de Gestão e Estudos Estratégicos, 2010.

Figure 7 – *Scientific articles published in magazines indexed by authors from Brazilian institutions, 1992-2008*

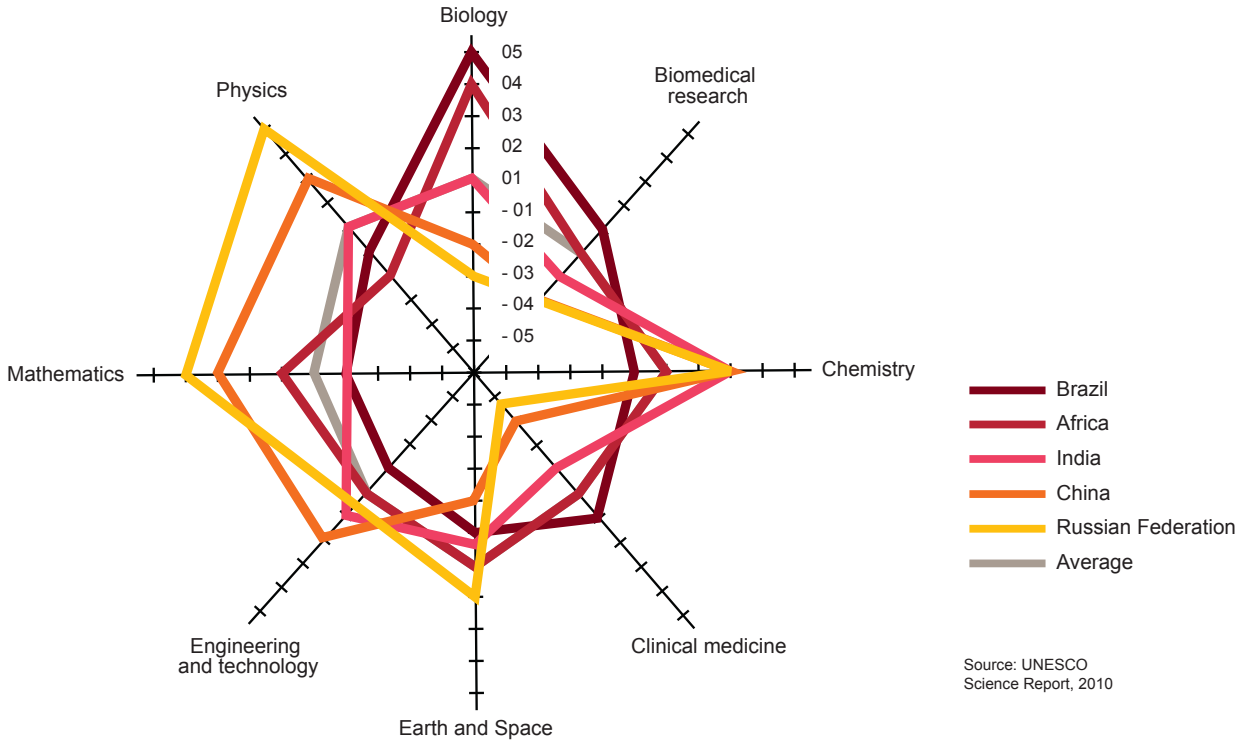


Note: Part of the growth could be attributed to the inclusion of new journals to Thomson Reuters Web of Science, especially in 2008.

Source: Relatório UNESCO sobre ciência, 2010

Regarding specialization in specific scientific disciplines, Figure 8 indicates Brazil's position compared to BRICs (Brazil, Russia, India and China) and Africa. According to UNESCO report, the scientific specialization differences reflect the inclination and country profiles. It is highlighted the well-marked Brazilian performance on the biological area, stimulated by the abundance of natural resources and biodiversity, and good positioning on biomedical research and clinical medicine. On the other hand, it is observed the Brazilian deficiency in engineering and technology, basic areas for translating scientific knowledge in economic development.

Figure 8 – *Scientific specialization, BRICs and Africa, 2008*



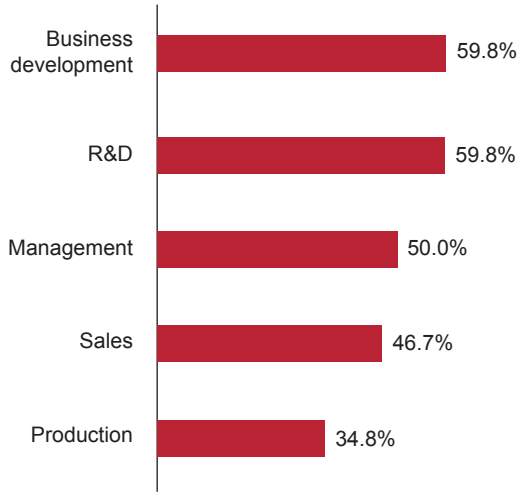
Source: UNESCO Science Report, 2010

In the last years Brazil established critical mass in the genomics, stem cells, regenerative and neuroscience areas, where it has contributed with growing shares of the world scientific production. Additionally, the country reaches highlighted position in the specific segments: knowledge generation about neglected tropical diseases, being responsible for 20% of the articles published in the world about tropical medicine and 12% in parasitological study; and agro biotechnology, being not only the second biggest country in cultivation areas dedicated to genetically modified plants, but also detains expertise in new variety generation based in molecular methods.

Despite solid scientific basis, the education and human resources attraction are still key success factor for the sector, accordingly showed by 20,4% of the research respondents (Graph 12, Page 26).

The greatest bottleneck nowadays is concentrated on the availability of researchers able to act on the development area, converting knowledge in technologic innovation, and professionals with multidisciplinary competences and background to act on knowledge commercialization, accordingly research data (Graph 13).

Graph 13 – *Percentage of companies with high or very high demand for specialized manpower in specific areas*

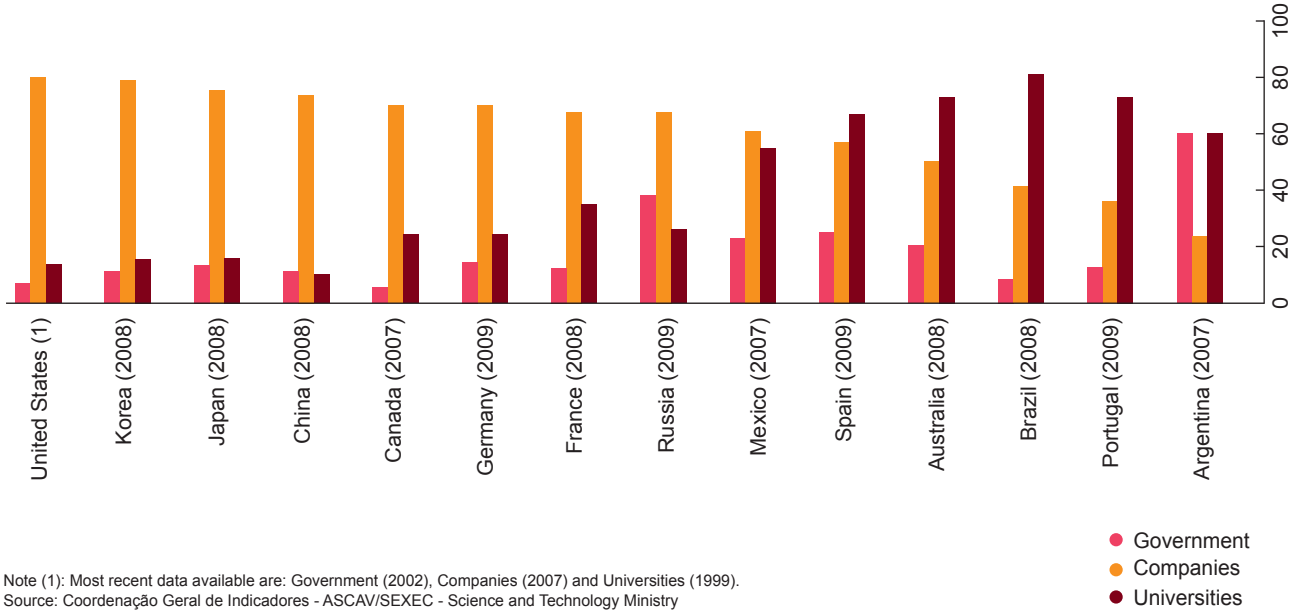


Source: Biominas/PwC Study, 2011

Becomes evident the demand for Business Development (BD) professionals (59.8%), especially due to the company's current stage of development and the importance of attracting investors and strategic partnerships. A good BD professional should have deep knowledge of the commercialization process and technology development, technical and commercial expertise, and background with negotiating partnerships and investments.

Regarding the lack of R&D professionals, the concentration of researchers in the Brazilian academic environment should be noted (Figure 9). Comparing with other countries, it is observed that the situation is the opposite of the United States, Korea and Japan, where the percentage of researchers allocated in companies is superior to 70%.

Figure 9 – *Distribution of Full-time researchers, by institutional group (%)*



Note (1): Most recent data available are: Government (2002), Companies (2007) and Universities (1999).
Source: Coordenação Geral de Indicadores - ASCAV/SEXEC - Science and Technology Ministry

The low technological and innovative intensity of domestic industry is one of the factors that explain this situation. The shortage of opportunities in business directed PhD's toward careers in teaching and academics, resulting in a shortage of researchers able to perform R&D work and industrial production in the current stage of expansion of the life science industry.

The capability gaps vary accordingly to the application area (human health, environment, industrial, agribusiness, etc.), however, some transversal competences are rare, with highlight for the lack of trained professionals to work on the scale-up of biotechnological process, which affects various segments of life sciences industry.

A specific demand that emerges in the biopharmaceutical sector is capacitated professionals for the development of biosimilars, as testing and validating of new therapeutic-prophylactic and diagnostic approaches. The recent movement indicates that the investments of the national pharmaceutical industry will be directed with greater strength, primarily, to the establishment of partnerships with international players of the biosimilars arena involving importation and afterwards nationalization of the production through technologic transfer. The establishment of know-how for the production of biosimilars should leverage later investments on innovative products development originated from universities, research centers, national biotech companies and through international scouting for opportunities.

Study conducted by the World Bank in partnership with "*Confederação Nacional da Indústria*" (National Industry Confederation) (CNI) and published in 2008[16] revealed the worrying picture of the national education system, that despite providing virtually universal access to basic education, needs a quality improvement, targeting the formation of a manpower provided with conceptual reasoning, skills for critical analysis and problem solving, in other words, able to compete in a knowledge based economy.

[16] RODRIGUEZ, Alberto; DAHLMAN, Carl; SALMI, Jamil; Knowledge and innovation for competitiveness in Brazil. Washington, DC: The International Bank for Reconstruction and Development; World Bank, 2008.

Another study published by CGEE[17] in 2010 analyzes the present panorama and proposes measures to enable Brazil to overcome the hurdle of forming human resources in science, technology and innovation strategic areas. Referencing the conclusions of the human resource work group from the Biotechnology Competitiveness Forum, the study lists the main suggested actions, among them:

- Stimulate interdisciplinarity, specially during undergraduate studies, facilitating the access to different classes and promoting the interaction between the different knowledge areas.
- Offer classes and extension courses in innovation management, technology commercialization, intellectual property and bio-business management.
- Induce the creation of professional master's degrees, with industry interaction;
- Improve the offering of master's and doctorate degrees programs oriented to the development of biotech products and processes;
- Stimulate the participation of companies in the development of dissertations and theses;
- Stimulate cooperation and international mobility.

The interaction with the productive sector will be essential to align supply and demand, as well as assuring an education process that includes best practices for translating scientific knowledge into technologies and products. The incentive to living abroad (international exchange), focusing on worldwide excellence centers, will also be important to accelerate the national learning curve, establishing mechanisms and incentives to attract and repatriate the Brazilian researchers with prestigious positions abroad. In this matter, the first step was taken by the Brazilian government with the launch of the Science without frontiers program in August 2011.

The science without frontiers is a program that intends to promote consolidation, expansion and internationalization of Brazilian science and technology, innovation and competitiveness through international exchange and mobility. The program projects the concession of up to 75,000 scholarships in four years to promote exchange, through two main directives:

- Increase of Brazilian students and PhDs, of diverse levels, in institutions of excellence abroad;
- Stimulus to attracting young talents and top-notch researchers to Brazil, devoted to science, technology and innovation.

Ultimately, incentive mechanisms to the scientific and technological career should start on basic education and be extended to PhD degree, improving the number and the value of the master's and doctorate degree scholarships in order to stimulate continued education.

[17] Formação de recursos humanos em áreas estratégicas de ciência, tecnologia e inovação - Brasília, DF: Centro de Gestão e Estudos Estratégicos, 2010.

3 What lies ahead

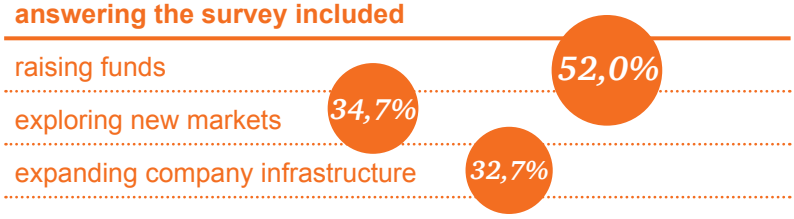
Brazil is currently a leader in agribusiness and in the production of biofuels, areas which could benefit a lot from biotechnology processes. The country also has other aspects related to structure and current economic conditions which could leverage this industry's development: a strong scientific base, abundant natural resources, growth and aging of the population, the ascension of millions of Brazilians to the middle class, increasing access to health care service and demand for sustainably-produced food.

However, as discussed in Section 2, the current business environment has imposed several obstacles to the progress of life science companies in Brazil, ranging from the difficulties in raising funds to regulatory and tax issues. Graph 14 indicates what interviewees believe to be the principal challenges which need to be overcome by Brazilian life science companies over the next two years.

Graph 14 - *Among the following topics, which will be the greatest challenges for your company over the next two years (choose the three most important)*

Source: Biominas/PwC Study, 2011

The three principal challenges mentioned by entrepreneurs answering the survey included



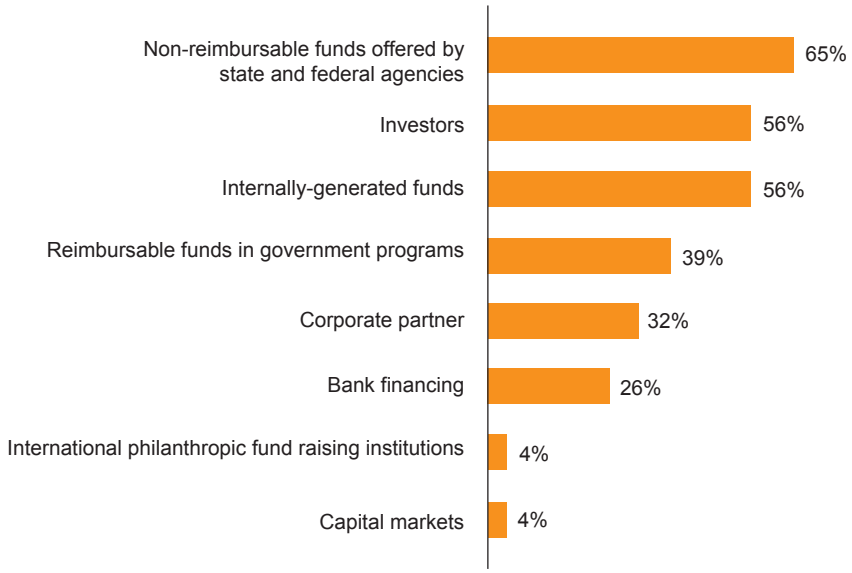
The priority given to establishing or expanding infrastructure reflects two main aspects. First, companies are currently in the development stage where they are expanding their activities. Second, it reveals increasing difficulty in finding incubators with adequate physical capacity and available space, as well as the desire to establish their own infrastructures outside of the incubators. For larger industrial scales, companies have problems to establish adequate infrastruture, which meets the requirements of regulatory organs. Normally, it takes companies years to obtain project approval, complete construction and make necessary registrations. Likewise, Brazil currently has few technological parks in operation.

It was also noted that in some cases the need to explore new markets comes from lack of success on the initial company product and service lines and a change in strategic direction which arose from that experience. Some companies mentioned during the interviews that they began their commercial activities based on technology developed in an academic environment and, after entering the market, found that it did not meet customer needs. In other cases, these companies are interested in venturing into new opportunities and/or wish to obtain gains from economies of scale and scope.

However, the greatest challenge to be overcome in the coming years, according to those responding to the survey, refers to raising funds (52.0%). Graph 12, Page 26, indicates that establishing more accessible programs (41.8%) was chosen as the second most important critical factor of success in the life science industry. Access to capital is frequently presented as a challenge for this industry with high R&D costs associated with the limited funding environment, as described in Section 2.2.

When questioned about which would be the three main sources for these funds (Graph 15), most of the interviewees indicated they expected to obtain them from non-reimbursable programs offered by state and federal funding agencies (65%). Funds to be obtained from investors and capital from the partners were also prominently mentioned, both by 56% of interviewees. This data demonstrates that companies will continue to seek government support, but highlighted the increasing importance of private investment, which correlates with the changes in the profile of items to be financed and in the greater amounts.

Graph 15 - *From which sources does your company expect to obtain these funds? (select the three most important)*



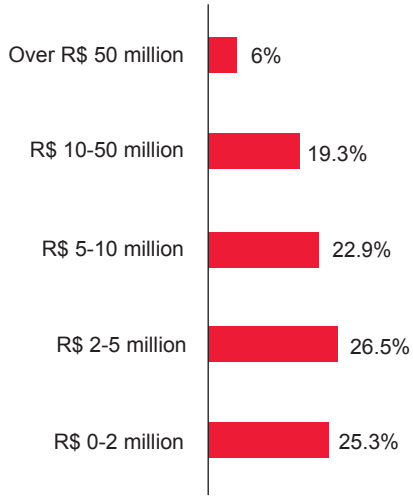
Source: Biominas/PwC Study, 2011

Regarding how these funds will be applied (Graph 16), the principal focus will be on R&D (83%) and on investing in infrastructure (58%), one of the industry's major challenges as mentioned earlier.

Graph 16 - *Where will these funds be applied? (select the three most important applications)*

Source: Biominas/PwC Study, 2011

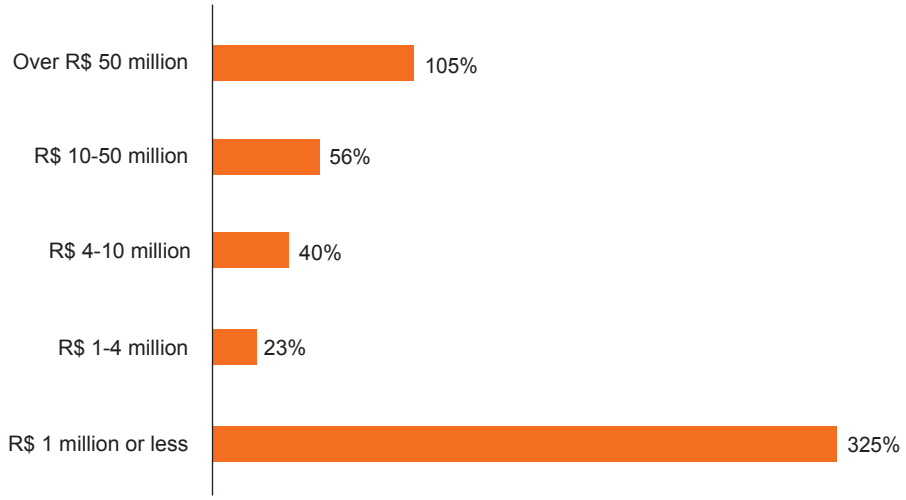
Graph 17 - *What is the approximate amount your company expects to raise over the next five years?*



Source: Biominas/PwC Study, 2011

When asked about the amount to be raised in the coming years, the sum of the 83 open answers to this question revealed that it would be in excess of R$ 500 million. The high demand for investment can be observed despite the limited availability of domestic funding, which will generate competition and selection of companies. This could also affect the ability to reach the growth objectives presented in Graph 18.

Graph 18 – *Expected growth percentage over the next two years by gross revenue category*

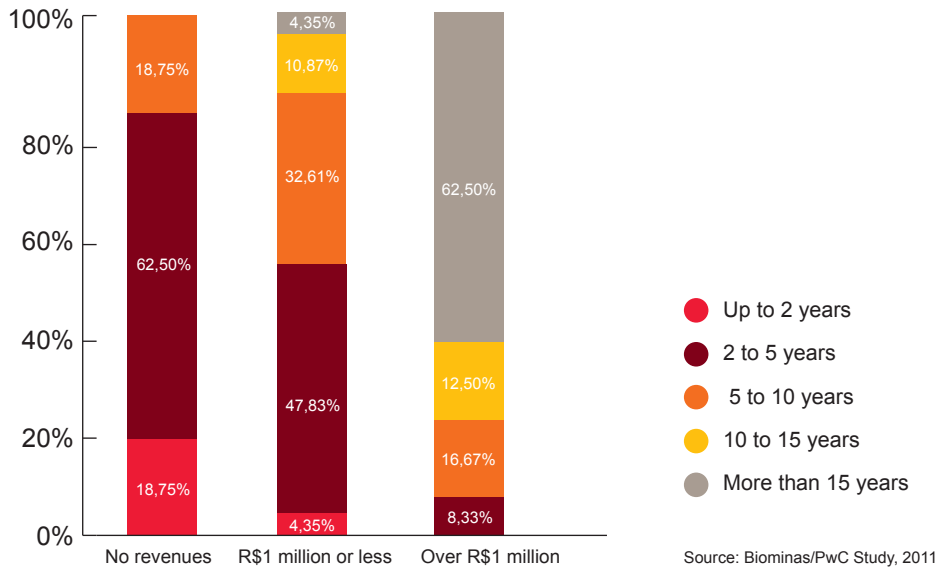


Source: Biominas/PwC Study, 2011

The low growth rates projected by the entrepreneurs in the intermediate revenue ranges could reflect their pessimism in light of the obstacles imposed by the environment in which they are inserted. Growth expectations increase as the revenue rises as those companies are better able to attract and leverage investments in addition to having had their technologies and products validated by the market, entering a phase of expanded growth. The R$1-4 million revenue range, in particular, includes several companies which are still in the process of having their technologies and business models validated.

As for the growth expectations among companies with sales of R$1 million or less, the highest projection come from companies which have been operating for 5 years or less, revealing the optimism and naivety of the new entrants, despite the industry's history of difficulties faced by life science companies in leveraging their growth (Graph 19).

Graph 19 – *Company age by gross revenue category*



Source: Biominas/PwC Study, 2011

Obstacles to be overcome

In spite of the external environment, the analysis revealed internal issues which have prevented several domestic companies from fully developing themselves. The following items are worth highlighting:

1. Knowledge of the market. Often, it can be observed that life science companies begin their activities without sufficient knowledge of their market. The crucial point is not the level of sophistication or the uniqueness of the technology, which is a recurrent focus of technology entrepreneurs, but rather the utility and added value to the customer. Characterizing demand and learning the desired market buying criteria are essential items to be analyzed and also need to be inputs for the development phase. It can be observed, not infrequently, that this stage is omitted, leading to bad investments.
2. Knowledge of the regulatory environment. Developments in the life science area are highly regulated and, naturally, may represent barriers to future sale of the technology. The implications of the regulatory environment on development and sale of the product must be essential inputs in decision making by life science entrepreneurs.
3. Preparation of a strategic plan. It is unusual to find companies with well-defined short-, medium- and long-term objectives, associated with feasible growth goals. Among other things, the lack of planning leads to difficulties in estimating the amount to be invested in the coming years, the dynamics of growth and company cash generation. In this case, even in spite of the problems in funds availability, the question remains whether or not companies are optimally investing their capital.

The ability of domestic companies to strengthen these points and to navigate in the external environment, full of opportunities and threats, will dictate the prospects of the industry's development over the coming years. The following section discusses possible ways to get around the obstacles and better take advantage of the opportunities.

Biotech global trends for collaboration

This column was prepared based on "Biotech reinvented – Where do you go from here?" the White Paper published by PwC in November 2010. This article aims to provide an overview of main trends in the Biotech Industry.

The worldwide biotechnology industry (Biotech) is now about 30 years old – a good time to evaluate how it was done. Unfortunately, despite some notable successes, it has not completely fulfilled its promise.

The model based on external investment – typically, venture capital – in an innovative idea arising from an entrepreneurial source, often a group of academics, assumes that investors can realize value through one of two routes: flotation on the public markets or more frequently, a trade sale to an established company. And it carries a very high risk of failure. In one recent study of 1,606 biotech investments that were realized between 1986 and 2008, 704 investments resulted in a full or partial loss.

The business model on which Biotech has historically relied is also breaking down, as the research base moves east and raising funds gets harder.

The research base is shifting to East, as Asia's emerging economies invest more in higher education and the 'reverse brain drain' picks up pace. Between 1998 and 2006, the number of students graduating with doctorates in the physical and biological sciences soared 43% in India and a staggering 222% in China, far outstripping the rate of increase in the West. The 'returnee' trend has been equally pronounced. In the past two decades about 100,000 highly skilled Indian and Chinese expatriates have left the US for their native countries. Another 100,000 are expected to follow them in the next five years, as the opportunities at home improve.

Some of the emerging countries are also actively building domestic biotech industries. Singapore launched its Biomedical Sciences Initiative in 2000 and has already created a powerful biopharmaceutical nexus. South Korea set up a similar scheme in the late 1990s, and has earmarked $14.3 billion for its 'BioVision 2016' programme. China has invested $9.2 billion in technological R&D, including biotech, in the last 18 months alone. And India is currently exploring plans to become one of the world's top five biosimilars producers by 2020.

Also the recession has also made more difficult for biotech companies in the developed economies to raise capital. In 2008, Biotech raised just $16.3 billion in the US, Europe and Canada – 45% less than the previous year. The situation improved in 2009, but the total amount raised fell well short of historical levels, and nearly half of it went to a handful of established public companies in follow-on offerings. The majority industry observers believe the window for initial public offerings will not open again anytime soon. This has inevitably deterred many venture capitalists – particularly European venture capitalists – from investing in the sector.

In order to overcome this new environment, the Biotech companies have to adopt a very different business model in order to be more efficient – and one way of becoming more efficient is to become more collaborative.

What's more, many of the companies based in the emerging economies are not just imitating the West; they are relearning from its mistakes. They are dispensing the costly infrastructure that burdens companies in developed countries, to create new business models that are leaner and more economical, as well as pioneering innovative products and processes. So the US is gradually losing its preeminence as a centre of biomedical research.

In order to overcome this new environment, the Biotech companies have to adopt a very different business model in order to be more efficient – and one way of becoming more efficient is to become more collaborative. Sequestering intellectual property in different organisations impedes innovation, because each has access to only one part of the biochemical puzzle. This not only slows down the discovery and development process, it also increases costs, as numerous organizations replicate the same studies on the same targets. Conversely, collaboration accelerates and facilitates the process, and two new concepts – precompetitive discovery federations and competitive development consortia – lend themselves to just such an approach.

Precompetitive discovery federations - Precompetitive discovery federations are public-private partnerships in which biopharmaceutical companies swap knowledge, data and resources with one another, as well as with government agencies, universities, academic medical centres, research institutes and patient groups. They aim to overcome common bottlenecks in early-stage biomedical research by enabling the participants to piece together the scientific data on the pathophysiology of specific diseases and potential targets sitting in their separate organizations. A number of precompetitive discovery federations have already been established. Most of these collaborations have been set up fairly recently and lie towards the philanthropic end of the spectrum.

Experts from numerous organizations will assemble to solve a specific problem, regardless of whether they work in industry or academia, and whether they live in the Americas, Europe or Asia. Much of the work they do will be performed virtually, as the world becomes increasingly interconnected. And each federation will be disbanded once it is solved the problem it was set up to deal with, although the insights it generates will live on – just as filmmakers form syndicates to produce different films and the films they create outlast the syndicates themselves.

There are many advantages to this approach. It would enable each participant to save money by investing less than it would have to do to support its own internal research or exclusive external research programme. It would also reduce unnecessary duplication, help all the participants make faster, better progress by combining their insights and permit them to take more informed investment decisions. To put it another way, precompetitive discovery federations could end the "current modus operandi in which commercially driven clinical trials fall like dominos in the clinic – to the detriment of each company, to the detriment of the patients and with relatively little [shared] learning".

Competitive development consortia - The discovery process is not the only area of scientific R&D that would benefit from closer collaboration. The development process could also be improved with the introduction of competitive development consortia (as we have called them) in which rival biopharmaceutical companies join forces with each other, as well as with contract research organizations and platform technology providers. At present, four or five firms often focus on the same target at the same time, and each might develop two or three compounds to hit that target.

Greater collaboration will be required not only in R&D but in the rest of the value chain. The Biotech companies must to adopt this more collaborative model in order to become more attractive and sustainable.

4 Partnering for growth

The previous sections illustrate well the complex context in which life science companies are inserted and the obstacles they face. These difficulties are shared with life science companies all over the world, however, the Brazilian environment imposes additional challenges, in light of the heavy taxes, high interest rates and legal uncertainty (both in regulatory and intellectual property aspects).

In addition, the financial, manpower and infrastructure limitations contribute to make development of the industry even more challenging. In this environment, the ability to establish partnerships and alternative business models will play an important role in the growth of the life science industry.

4.1. Corporate partnerships

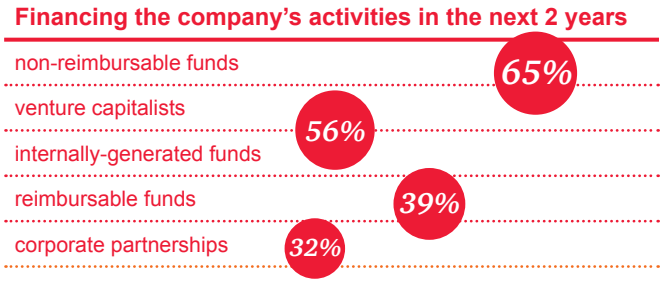
Partnership is a broad term which includes different arrangements in which those involved inject resources and competencies to reach a common objective. As examples of corporate partnerships we can mention co-development partnerships , licensing, co-marketing, distribution and sales, as well as joint ventures and mergers and acquisitions.

The types of partnership vary essentially as to the objectives and levels of complexity and involvement, as indicated below:

Table 4 - *Characterization of the different types of partnership*

Types of Partnership	Objectives	Degree of Involvement
Interaction with universities	Access to specialized infrastructure and to new technologies, solution of technological problems	+
Licensing	Access to new technologies (licensee)/ Capitalization (licensor)	++
Marketing, Distribution and Sales	Access to new products (licensee)/Access to the market (licensor)	++
Co-development	Add resources and competencies	+++
Joint Venture	Add resources and competencies	++++
Mergers and Acquisitions	Add resources and competencies	+++++

Source: Biominas Brasil, 2011



Analyzing the results of the survey, industry history and recent movements reveal that Brazilian life science companies have not used corporate partnerships widely or successfully to leverage their growth.

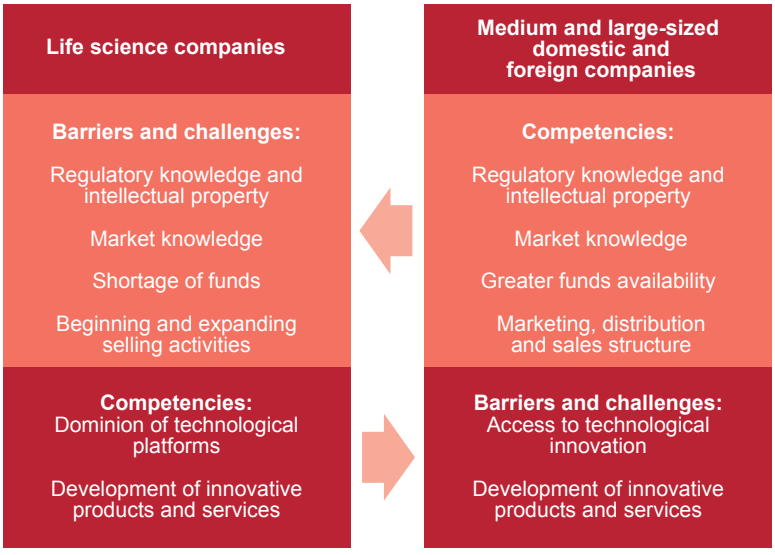
In line with this observation, among the critical factors of success for this industry listed by the companies (Graph 12, Page 26),establishing partnerships and cooperative agreement came in next-to-last (11.2%), in contrast to the two most often mentioned options: clarity and greater speed in the regulatory process (46.9%) and the establishment of more accessible financing programs (41.8%).

Regarding the greatest challenges to be faced in the next two years (Graph 14, Page 40), only 18.4% of the companies indicated attracting partners for sales and distribution, and 23.5% attraction of partners for co-development and/or licensing; well below the first options: fund raising (52%), exploring new markets (35%) and establishing or expanding company infrastructure (33%).

It is clear, therefore, that companies do not view partnerships as a way to overcome their main obstacles. The same situation repeats itself when financing the company's activities: corporate partnerships appeared in fifth place in importance among sources of funds for the next two years (Graph 15, Page 41). In first place, with 65%, were non-reimbursable funds, followed by venture capitalists (56%), internally-generated funds (56%), reimbursable funds (39%) and corporate partnerships (32%).

As discussed in Section 2.2, corporate partnerships are highly attractive as compared to other sources of funds, as they dilute the risk of the investment with third parties, add competencies and accelerate development. As can be observed in diagram 1, there is a high level of complementarity between the challenges faced by life science companies and the competencies of medium- and large-sized companies, and vice versa, contributing to stimulate this kind of cooperation. More than overcoming the obstacles, this model has the potential of leveraging the development of the companies involved, dividing costs and risks and adding competencies.

Diagram 1 - *Rationale for corporate partnerships in the life science industry*



Source: Biominas/PwC Study, 2011

In addition to the benefits mentioned, cooperation between small and large companies can represent an important tool to access government funds and tax incentives for innovation. In relation to the first point, it is known that medium- and large-sized companies are better structured to access funding agents such as the BNDES, as demonstrated by the distribution of the investments made by BNDES PROFARMA through June 2011:

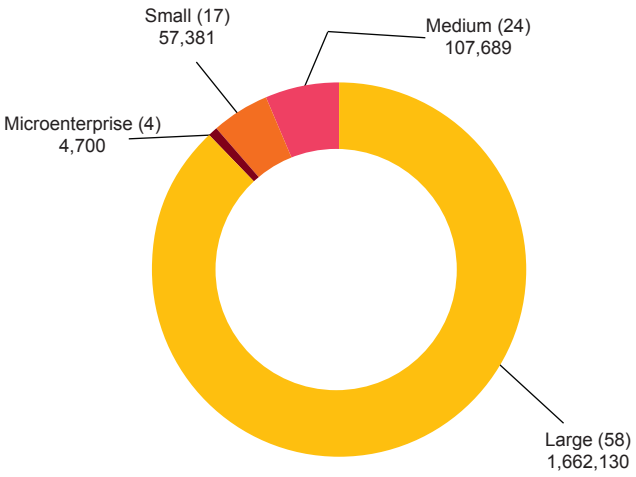
Establishment of this type of partnership with innovative domestic companies tends to strengthen proposals of medium- and large-sized companies when submitted to the BNDES or other government financing organ, while making possible the development of the small companies.

With regard to tax incentives, the Lei do Bem in Article 7 establishes that amounts transferred to microenterprises and small companies to perform technological research and develop technological innovation may be deducted as operating expenses and, therefore, qualify for tax incentives. Therefore, this mechanism could foster partnerships of medium- and large-sized companies with microenterprises and small domestic life science companies.

Despite the favorable rationale, the lack of an innovation tradition in the domestic industry as well as a cooperative culture, together with the low propensity of entrepreneurs in assuming risks and lack of experience in negotiating contracts of this kind still inhibit a wider use of corporate partnership mechanisms in Brazil. This scenario is expected to improve in the coming years. The case of Inova Biotecnologia, a joint-venture between Grupo Eurofarma and Hertape Calier, is an example of a successful partnership (Box 3). Illustrative Boxes 4, 5 e 6 report the perception and receptivity of companies like Braskem, Natura and Suzano to the concept of corporate partnerships.

Regardless of the favorable prospects in Brazil, life science companies must not limit themselves to the domestic market, but expand their network of relationships and interactions internationally so as to access the competencies and resources necessary for their full development wherever these resources may be located.

Figure 10 - *Distribution of funding by the BNDES PROFARMA[18] by company size*



Source: Department of Intermediate Chemical and Pharmaceutical Products of the National Economic and Social Development Bank (BNDES), 2011

[18] The objective of the BNDES PROFARMA program is to finance investments of companies headquartered in Brazil, which are part of the Health Industry Complex (*Complexo Industrial da Saúde*), through sub-programs: *BNDES Profarma - Produção, BNDES Profarma - Exportação, BNDES Profarma - Inovação and BNDES Profarma - Reestruturação*.

4.2. Virtual business model

The economic crisis of 2008 and closing of the IPO window in the Unites States for a long period of time catalyzed discussions on the sustainability of the life science industry business models. In 2009, an article by Bruce Booth published in Nature Biotechnology magazine traced this discouraging scenario and proposed the establishment of more streamlined and efficient models. In the same year, the article *Pharma 2020: Challenging business models by* PwC challenged the current life science industry model and presented alternative structures which could emerge. Among these structures, the virtual model can be highlighted.

In the virtual model, company operations are outsourced or performed by a network of collaborators, with the administrative structure focusing on the strategic vision and management of the different service providers and alliances as demonstrated by Figure 11.

Figure 11 – *Dynamics of the virtual business model*

Source: PwC, Pharma 2020: Challenging business models, 2009
Available at: *http://www.pwc.com/pharma2020*

An article by Justin Chakma, also in 2009 in Nature Biotechnology, evaluated the virtual model from the point of view of venture capital investors and compiled a list of pros and cons summarized below:

Table 5 - *Pros and cons of the virtual business model*

Pros	Cons
Reduction of fixed costs and expenses	Loss of direct control on the part of the contracting party (especially in large organizations)
Increased efficacy in the use of capital and reduction in the negative cash flow	Greater chance for delays and less sense of urgency
Increased efficiency and flexibility in the company	Delays due to geographic and climactic factors
Reduction in employee turnover	Need for qualified project managers
Simplified management and eliminated red tape	Less diversification of the portfolio

Source: Source: Chakma, J. Is it virtuous to be virtual? The VC viewpoint. Nature Biotechnology, Vol. 27 (10), 886-888, 2009

International pharmaceutical companies have been implementing the virtual model to develop new products, expanding their network of partners and collaborators around the world. This movement has not been limited to developed countries, as exemplified by recent initiatives of technology scouting and co-development partnerships implemented by multinational pharmaceutical laboratories in the country. Supported by Biominas Brasil, companies such as Roche, Sanofi, GSK and Ferring Pharmaceuticals advanced in the common goal of including Brazil in their global R&D network.

In Brazil, the virtual model has been used especially by small companies in the life science industry. One example is *Recepta Biopharma*, a company dedicated to the research and development of monoclonal antibodies for treatment of cancer. Recepta has a network of researchers distributed in several research institutions and hospitals in Brazil and has domestic and international service providers to conduct development of its products. This network not only allows for greater access to know how but also makes the company's fixed infrastructure leaner.

Another company that used this model was Alvos. The company licensed technology from the Oswaldo Cruz Foundation (FIOCRUZ) based on the SM-14 molecule, with the potential of developing vaccines against schistosomiasis and fasciolosis. Using funds from partners *Biominas Brasil* and *Fundotec*, a fund managed by FIR Capital, and non-reimbursable funds from a FINEP university-company interaction program, Alvos advanced in the development of the vaccines using a network of collaborators and service providers until it attracted the attention of *Ourofino*, one of the market leaders in the area of animal health. At the end of 2010, *Ourofino* completed its acquisition of *Alvos*.

Thus, adoption of a virtual model, both by new companies as well as by already existing companies, can be an interesting way to accelerate product development. The main advantage of the model is a more flexible business format with less investment and lower fixed costs due to the use of infrastructure belonging to third parties, such as universities, research institutions and specialized service providers. On the other hand, although foreign partners may be used, the best option to keep costs low and facilitate management of operations is to have infrastructure available in the country. However, the development chain in several areas is still incomplete in Brazil and may impact on the success of this model.

Box 3. INOVA Biotecnologia: the first fruits of a successful partnership

INOVA Biotecnologia is a joint venture between *Eurofarma Group* and *Hertape Calier*, focusing on activities in the area of animal health. *Eurofarma* is one of Brazil's principal pharmaceutical companies, acting on the human and animal health segments, while *Hertape Calier* is an originally Brazilian company with notable expertise in the development and sales of innovations in the veterinary area.

Stemming from a R$200 million investment, the joint venture produces the Aftomune vaccine to control and eradicate hoof-and-mouth disease and has capacity to produce between 100 and 120 million doses per year.

INOVA Biotecnologia enters into a competitive market with annual sales of R$ 500 million with strong competitors such as *Ourofino Agronegócios* and the Argentine company Biogénesis-Bagó.

The partnership was designed to add competencies and divide risks. In this case, *Eurofarma* contributed with strong commercial expertise and financial support, while *Hertape Calier* brought experience in recombinant vaccines and biotechnological processes. In addition to having worked together on development, the companies will join forces to sell and distribute the vaccine.

Box 4. Braskem and the Prospect of Partnerships with Brazilian Life Science Companies

Formed in August 2002, *Braskem* is the largest petrochemical company in the Americas and the third largest producer of polypropylene in the world. It currently produces more than 15 million tons/year of thermoplastic resins and other petrochemical products, has 29 industrial plants, 26 of which in Brazil and three in the Unites States and invests close to R$50 million a year in research and development.

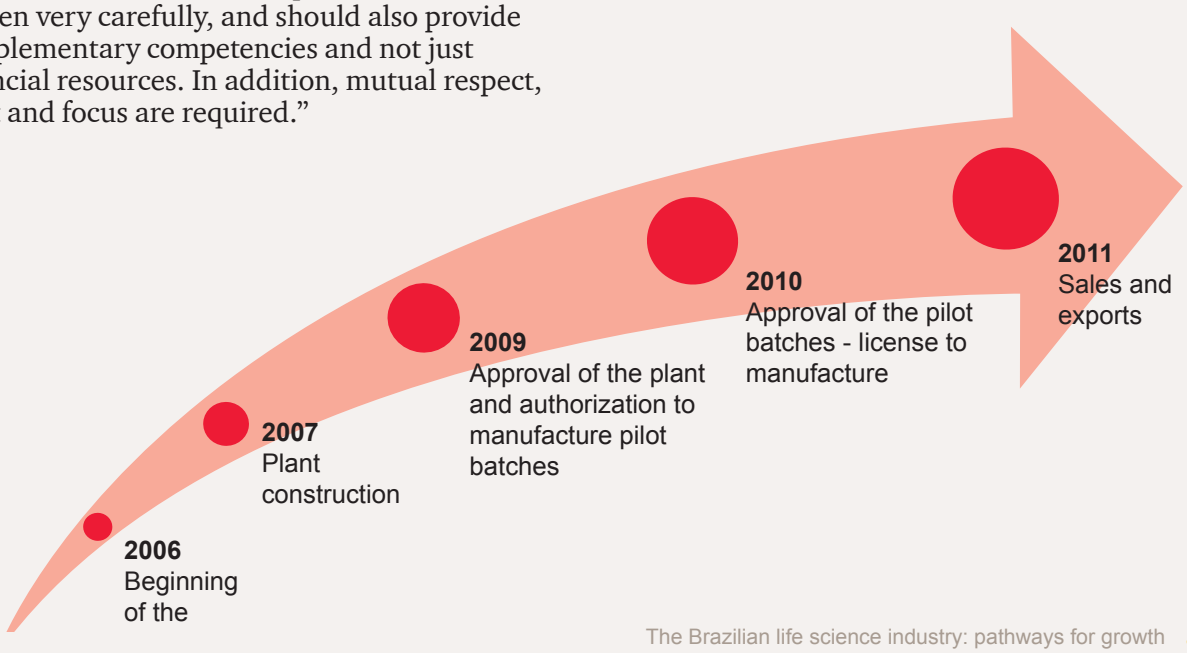
Braskem has several open innovation initiatives currently in progress in Brazil, which shows its trust in the potential of science and technology developed in the country. According to Paulo Coutinho, the company's Open Innovation Manager, " *Braskem* looks to establish open and flexible partnerships with domestic and multinational companies, with the objective of incorporating cutting edge technologies and acquiring competencies in areas like biotechnology".

With regard to the obstacles to establishing partnerships with Brazilian life science companies, Paulo believes that there are still no well-established communication channels between large companies and innovative start-ups and that this interaction needs to be expanded so that high value partnership can emerge.

"The companies may be in an initial stage of development, as long as they are aligned with the company's strategy."

Paulo Coutinho, Open Innovation Manager, Braskem

With the objective of fostering the establishment of partnerships in Brazil, Hugo Zanocchi, president of INOVA, emphasizes the principal points to be observed: "The partner needs to be chosen very carefully, and should also provide complementary competencies and not just financial resources. In addition, mutual respect, trust and focus are required."



Box 5. Natura and the Prospect of Partnerships with Brazilian Life Science Companies

Natura is the largest manufacturer of cosmetics and hygiene and beauty products in Brazil and leader in the direct sales segment. The company is recognized for its constant efforts to permeate sustainability in all aspects of everyday business, harmoniously aligning economic, social and environmental aspects.

Natura invests roughly 3% of its net revenues in innovation. One of the company's strategic areas is life science and establishment of partnerships will be one of the ways it plans to acquire knowledge, access technological innovations and develop new products, services and businesses in this segment.

Among the criteria used to evaluate potential partners are highlighted technical competence in the area of interest, flexibility in exchanging informationand the possibility of co-development. According to Paulo Benevides, Natura's Scientific Manager, "the stage of development is not the key factor, but knowing the technology potential and value added is critical in evaluating the format of the partnership and indicate to which research and development platform the proposal will be directed."

Different cooperation models may be established with the company, including co-development, licensing, technology transfer and supply. The formats are flexible and discussed on a case-by-case basis, but may include investment of funds, joint fund raising, offering infrastructure, exchange of experience and know how, among others.

In his experience in scouting technologies and partnerships in Brazil, Paulo commented that he has observed that entrepreneurs are not in tune with demand, and often perform all the development independently, without obtaining inputs from the market. "All parties could benefit from greater interaction, even in initial development stages", concluded Paulo.

Box 6. Grupo Suzano, growing with international partnerships

With a history of more than 85 years in the paper and pulp industry, Suzano is one of the 10 largest pulp producers in the market, and the second largest eucalyptus pulp producer in the world. Present in close to eighty countries, its principal products are eucalyptus pulp, printing and writing paper and cardboard. The company incorporated the concept of open innovation in its R&D strategy and has a long history of domestic and international cooperation agreements. An illustrative case is the interaction with the life science company FuturaGene.

In 2001, Suzano began an R&D partnership with CBD, a spin off from the University of Jerusalem, Israel, with the purpose of developing genetically-modified eucalyptus varities. In 2006, CBD was incorporated by FuturaGene, the latter a spin off from Purdue University in the United States. Together, the companies established strong know how in the development of life science techniques applicable to tree species. The partnership between Suzano and FuturaGene was maintained over the years and culminated, in 2010, with the acquisition of the company. With this movement, Suzano became one of the largest developers of agricultural biotechnology in the world.

FuturaGene has several similarities with Brazilian life science companies, such as the academic origin and history of incubation, and represents an example of how corporate partnerships can leverage the growth of technology-based companies. According to Eduardo Mello, FuturaGene Vice President of Operations, despite the lack of interaction channels between large companies and domestic life science companies, "Brazil has vast areas of farm land, an extensive genetic base and centers of reference in plant life science, which are significant advantages for local development of innovations."

"Brazil has vast areas of farm land, an extensive genetic base and centers of reference in plant life science, which are significant attractions for local development of innovations."

Eduardo Mello, FuturaGene Vice-President of Operations

Antônio Britto

Executive President
Interfarma – Association of the Pharmaceutical Research Industry

Innovation, Yoga and the Elevator

Imagine a checklist of conditions and attributes a country needs to have to become active and victorious in innovation: human capital, available financing, laws which assure respect for intellectual property, a consensus between society and the Government that the ability to generate technology will define the success and the future of nations.

Brazil knows this list and has it. Thanks to a continued effort over the past few years, we have increased our number of master's degree and PhD recipients, became more present in scientific publications, defined many and good financing systems, assured a favorable climate for innovation (from a legal standpoint) and not a day goes by without important sectors of our economy clamoring for or defending innovation.

I like to joke by comparing innovation with yoga in Brazil. I have never seen nor heard of anyone who criticizes yoga. But few people actually practice it.

Why is there such a distance in Brazil between what it could do and what it does do in innovation?

One attempt to explain that should start with a question which is at the same time economic and cultural: Brazil's dimensions have, for the last 500 years, permitted the illusion that we could be big by reaping what nature gave us, planting, or more recently, producing here, given the dimension of our domestic market, what was developed far away.

Our companies do not link survival with innovation. It is still curious that, when mentioning the exceptions, the same names always come up, all deserving but few in numbers. These are companies which took on as part of their reason to exist, to look for and produce what is really new and not a copy, adapt or expand something which already exists. It is not without reason that over 70% of our PhD's remain inside universities with strictly academic lives. If they depended solely on companies to employ them, we would have the highest unemployment rate among PhD's and authors of scientific articles on the planet.

The second reason comes from Brazilian government. Our authorities, practically mirroring the attitude of companies, have made innovation neither a priority nor easy to execute. If you want to innovate, go to the Science and Technology Ministry, which now also has the word "Innovation" in its name, stop by the FINEP, arrive armed with lots of patience to ANVISA and the INPI, depending on the Development, Industry and Commerce Ministry (MDIC)'s industrial policy, money from the BNDES or some approval from the Finance Ministry and many more things... If you do not tire in the process or are not strong enough and have the proper connections to ask someone of authority in Government to give a firm order to ten or fifteen public organs, the process will wind up taking so much time that you will miss your opportunity.

Global reality does not allow Brazil to just talk about innovation. Now, either it acts in a concrete way or it will squander the excellent moment we are experiencing.

Because, in the world, things are not like that. Smaller countries, perhaps for that very reason, like Korea, Ireland and Singapore, organize government activities, creating central offices where all involved organs sit down together. In other words: there, you knock on a door and the problem is solved. Here, you need to give a map to the innovator so that he or she doesn't get lost in the Government...

A third, and no less important reason, arises out of a Brazilian paradox. If we look at the legal macro-structure, the Constitution, the principal laws, we have a country with excellent and secure rules which favor innovation. From the Industrial Property Law (Lei de Propriedade Industrial) and the Lei do Bem, over the last 20 years we have elaborated a modern set of laws, able to generate legal stability to anyone willing to take the risk to innovate. But just get down to the regulations and regulators and you will start to experience the nightmare of all the outrageous deadlines and requirements.

This is not the problem of any particular Government. Historically, innovators have suffered through ten-year waits at the INPI to get a patent or approval periods three or four times greater than the world average in public health. A few days ago, I heard one of these authorities say something which epitomizes the spirit of this kind of regulator. He said he was shocked to have heard someone who analyzes applications say that "a quick decision is a suspicious decision". In other word, the dominant sentiment indicates that taking time, delaying, wasting time and losing opportunities are proof of professional integrity...

Together, these three reasons paint a worrisome picture. The private sector, for the most part, inattentive or impotent in the face of the current world economy where the planet's most valued company achieved its success with strokes of innovation and creativity. And where globalization "commoditizes" everything that is not new, producing in large scale and demolishing value in seconds. Brazilian government, which suffers the effects of the lack of innovation, has accommodated itself in the midst of its current favorable export scenario and has not defined focused policies, with a clear definition of what we want. And finally, there is the insular character of innovation in Brazil: many of us try innovation but we do not communicate with each other nor do we connect in cooperative projects.

In another conversation in Brasília, I received an appeal and a well-intentioned invitation to establish a pharmaceutical and chemical complex in a friendly and distant State of Brazil. I left there thinking: is this a dream or a project? If it were a project, we would have started to define specific areas where we have or could have human capital, working out ways that this human capital could participate in the initiative, seeking partnerships around the world and finally choosing a location based on what had been defined previously.

Here, we still start with the opposite. And for this reason it does not amount to much. On a recent trip to Germany, when we were arriving at a human health research center, the tour guide on the bus we were travelling in described the place we were going to visit. "Here", she said, "medications have been researched for 120 years. More than 10 Nobel Prizes have come out of here. There are 19 companies installed in 600 buildings. And one of these companies, just to research insulin has 8500 employees, 1500 of which are PhD's".

The girl described a project: focus, consistency over time, integration between the State and private enterprise, academia and companies. Instead of a disconnected archipelago, it is a solid continent of permanent initiatives always in the same direction.

I am optimistic. Global reality does not allow Brazil to just talk about innovation. Now, either it acts in a concrete way or it will squander the excellent moment we are experiencing. The Federal Government, by personal conviction of the President and several State governments (for example, São Paulo) are giving clear signs of restlessness on the subject, which, in itself, is an important step.

I like to use the following image with authorities: we have been very capable of solving problems on the ground floor of our social and economic reality: getting children into school, magnificently expanding coverage of basic diseases, among other things. The problem is that our success keeps on building new and more challenging "floors", where problems are more difficult; the quality of education and no longer just access to it; more complex diseases and so on.

The important question for future generations is the following: which elevator are we going to use to reach the upper and more difficult floors? The rhetoric that we will execute the next stage using the strategies of the one behind us is nostalgic and suicidal.

The elevator we need, and deserve, passes by a new direction in our relationship with education and innovation. Or, if you like, practicing a lot of yoga. And getting the elevator to move...

Halla Thorsteinsdóttir

McLaughlin-Rotman Centre for Global Health, University of Toronto

Brazil's Southern Internationalization

It is well known to biotech observers that to form alliances is the mainstay of biotech firms, mainly to access knowledge, markets and funds. In a global world these alliances are often international and Brazilian health biotech firms are increasingly looking outside their national borders for biotech alliances. Our recent study on international collaboration of low/middle income countries' health biotech firms (firms in Brazil, China, Cuba, Egypt, India and South Africa), published in the journal Nature Biotechnology, shows that 64% of the Brazilian firms are engaged in international collaboration. It is a higher collaboration percentage than firms in China have, where 40% of the health biotech firms are collaborating internationally. Then again Brazil's collaboration is at lower levels than India's and South Africa's which have over 70% of their firms engaged in international collaboration.

While international alliances are of key importance to Brazilian firms it can be a challenge to decide which linkages will be most fruitful. Most roads lead to the North with 60% of the Brazilian firms collaborating with Northern firms. Still, in terms of total numbers of collaborations, Brazilian firms have more South-South collaborations than firms in any other country surveyed. As most Northern countries have been going through economic turmoil in the last few years Brazil's relatively strong emphasis on South-South collaboration may prove to be a prudent strategy.

Brazilian firms and their Southern collaborators are therefore not leveraging on each other's product development strengths and developing cost effective health products adjusted to their shared health problems.

A big attraction for biotech firms is to reach foreign markets through South-South collaboration. Our survey showed that most of the South-South collaboration of the firms we contacted involved end-stage commercialization activities. That was true for all the countries in the study and certainly for Brazilian firms, with 66% of their South-South collaborations involving distribution. This is not surprising and reflects an astute strategy as marketing opportunities are flourishing in the South. This applies particularly to the emerging markets, China and India, where economic growth and growing middle-class populations create a hefty demand for biotech products. Our survey showed that Brazil had the most frequent ties to Argentina, China, and Cuba but also had commercialization ties to other Latin American countries. As some low/middle income countries have a track record in producing relatively affordable health products, an increased South-South collaboration in health biotech may lead to enhanced availability of relatively inexpensive health products in these countries.

South-South collaborations involving research and developmental (R&D) activities were few and far between, as only 13% of Brazilian collaborations involved R&D. Brazil did not stand out in terms of limited R&D activities as the other countries surveyed also collaborated rarely in these types of activities. Brazilian firms and their Southern collaborators are therefore not leveraging on each other's product development strengths and developing cost effective health products adjusted to their shared health problems. It would be of interest to do a comparable study on Brazil's collaborations with Northern countries to see if they work more frequently together in R&D.

When we looked at which countries Brazilian firms collaborated with in R&D we noted that Cuba was their main collaborator. Further when we looked at which Brazilian firms were involved we observed that Brazilian and Cuban public research organization were the ones that were mostly collaborating in R&D. They were included in the study because of their heavy emphasis on entrepreneurial activities and thus have arms that focus specifically on manufacturing and commercialization.

The limited South-South collaboration in R&D may reflect that there is only a handful of Brazilian health biotech firms active in R&D. We sent the survey to all firms in Brazil that define themselves to work in health biotech. Most of them may license their products from innovators in the field, or focus on generics production and distribution. Many of the firms are thus not likely to be involved in R&D activities at all and hence not be involved in South-South R&D collaborations. With stronger focus on R&D by more Brazilian firms the future, we may observe an increase in South-South R&D collaboration. There seems to be a connection between collaboration in end-stage commercialization and R&D and 'joint product on market' was the most frequently cited output for R&D collaborations. Brazilian firms may thus start their collaboration by limiting themselves to commercialization activities but as trust of their collaborators builds they can start to jointly develop new and improved health products for their populations. When that happens South-South health biotech collaboration will not only reflect trade ties but also Southern brain-power being used to deal with shared health problems.

5 Methodology

Definitions and inclusion criteria

This study focused on private life science companies, which have a majority of their capital owned by Brazilians, and which perform research and development activities. In addition to understanding the current situation, the study is forward-looking in nature, bringing analyses about the future prospects and critical factors of success.

The life science company definition was the same as in the 2009 study, that is: a group of ventures which develop advanced products and services based on knowledge of biological processes and systems. Thus, it was possible to include in this study segments which have become increasingly important in Brazil, such as, for example, services to validate new medication (pre-clinical testing) and the development of state-of-the-art medical devices, which would not fit within the strict concept of biotechnology, as defined by the OECD: companies whose main commercial activity involves the application of advanced life science techniques to produce goods and services and/or to perform research and development (R&D) activities.

To aid in this classification, the OECD published a list of biotechnology techniques:

List of life science techniques
DNA/RNA: genomic, pharmagenomic, gene probes, genetic engineering, sequencing/synthesis/ DNA/RNA amplification, profile of gene expression and use of antisense technology.
Proteins and other molecules: sequencing/synthesis/protein and peptide engineering (including high molecular weight hormones); methods of high molecular weight drug addressing; proteomic, isolation and pruification of proteins, signalling and identification of cell receivers.
Cell and tissue culture and engineering: cell/tissue culture, cell fusion tissue engineering, vaccines/immunomodulators, embryo manipulation.
Bio-technological processing techniques: fermentation using bioreactors, bioprocessing, bioleaching, biopulping, biobleaching,biodessulphrization, bioreemediation, biofiltration and phytoremediation.
Gene and RNA vectors: gene therapy, viral vectors.
Bioinformatics: construction of genome and protein sequence data base; complex biological process modelling, including systems biology.
Nanobiotechnology: utilization of namo/micromanufacturing tools and processes to build devices to study biological systems and applications as vehicle to administer drugs in the diagnostic area, etc.

Source: A Framework for Biotechnology Statistics, OECD Paris (2005)

Due to its characteristics and specific structure, domestic pharmaceutical companies were not considered in industry statistics, but may be the object of future studies.

Categorization

The companies were grouped into five areas of activity (with respective examples), namely:

Human health: companies dedicated to developing and selling new medications (small molecules and biological), diagnostics, vaccines, cell therapy, regenerative medicine and tissue engineering, implants and medical equipment which have a positive effect on the biological micro-environment, advanced method for assisted reproduction, genetic and molecular testing etc.

Agribusiness: companies dedicated to developing and selling technologies in the area of animal health (diagnostics, vaccines, therapeutic products, embryo transfers, artificial insemination, genetic engineering, cloning), agriculture (seeds and plants modified by genetic or transgenic engineering, new method for pest control or food conservation, plant cloning, biochemical, immunological or molecular diagnostics, production of fertilizers and/or inoculants from microorganisms) and bio-energy (companies developing technologies to produce ethanol and/or biodiesel).

Raw materials: development and sale of reagents and/or enzymes for industrial use, methods for isolating, identifying and classifying microorganisms, culture media, biopolymers, biomaterials, etc.

Environment: development and supply of products and services for bioremediation, biological treatment of wastes and recovery of degraded areas, analysis of environmental samples using biological systems.

Mixed: companies involved in more than one of the above categories; for example, development of kits to diagnose human and animal diseases, bio-informatic companies, CRO, CMOs, etc.

Obtaining data and analysis

Biominas Brasil mantains a rich and updated database of Brazilian life science companies. The data base currently has information on 271 companies distributed in 18 states.

To obtain data, an online questionnaire was sent to companies in the data base between the months of May and July 2011. 103 answers were obtained, which represents a sample error of 6.5% and a 90% confidence level. The questionnaire was constructed in a hierarchic format and had both open and closed questions.

In addition, interviews were held with some companies and important players to obtain additional information and better understand the environment and viewpoint of Brazilian entrepreneurs. The companies were chosen to represent the different segments and profiles.

As an incentive to participate in the survey, a Directory of Life Science Companies was developed, which lists and gives profiles of the companies that answered the questionnaire, in addition to providing contact information and short descriptions. The Directory is available for access at the Biominas Brasil (*www.biominas.org.br*) and PwC (*www.pwc.com/br*) websites.

6 Acknowledgements

This study could not have been developed without the valuable contribution of the 103 companies that answered the questionnaire. We give our sincere thanks and attach the Directory of Brazilian Life Science Companies, which compiles a brief description of the responding companies and provides contact information.

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Credits

Biominas Brasil

Eduardo Emrich Soares, Chief Executive Officer
Isabela Drummond, Consulting Manager
Agda Martins, Business Analyst
Fábio Munakata, Business Analyst
Thales Figueiredo, Business Analyst

PwC

Eliane Kihara, Partner - Pharma Leader
Rodrigo Viñau, Manager
Marco Conejero, Manager of the Agribusiness Research & Knowledge Center

7 Institutional and contact information

Biominas Brasil

Private institution dedicated to promoting life science business activities in Brazil, Biominas Brasil has been on the market for over 21 years, and has contributed to the creation of numerous companies.

A national reference in the industry, Biominas Brasil assists the development of companies from the initial stages to maturity through:

- Specialized Consulting
- Business Development
- Company Incubation
- Investment

The exclusive focus on life science, deep knowledge of the industry and its broad and vast network of contacts make Biominas Brasil your ideal partner in developing successful life science business activities.

Contacts:

Eduardo Emrich Soares, Chief Executive Officer (eduardo@biominas.org.br)
Isabela Drummond, Consulting Manager (isabela@biominas.org.br)

PwC

PwC refers to the network of member firms, totally separated and independent, present in 154 countries worldwide. More than 161,000 professionals around the globe work connected, ensuring the quality and excellence of the delivered services. Between the customers that compose our network are some of the biggest organizations worldwide, acting in diverse sectors. The Brazilian company has around 4,700 professionals and 17 offices, which compose an expressive network of geographical reach for auditing and assessment services in the country.

We provide auditing services, tributary and corporation assessment, business management consulting and business outsourcing for administrative process focusing economic activities for big and medium enterprises, considering four main areas:

- Business sustainability.
- Corporative risks management.
- Organizational restructuring, merging, acquisitions and business recovery.
- Performance and process improvement, including outsourcing of fiscal and accounting functions, and others.

Contacts:

Eliane Kihara, **Partner (eliane.kihara@br.pwc.com)**
Rodrigo Viñau, **Manager (rodrigo.vinau@br.pwc.com)**
Marco Conejero, **Manager (marco.conejero@br.pwc.com)**