

The Biotechnology Market in Brazil

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Summary

The biotechnology sector in Brazil continues to experience an episode of significant expansion. Accordingly, it presents US companies involved in the biotechnology sector with significant export opportunities.

Brazil is currently a leader in agribusiness and in the production of biofuels, areas which could benefit from biotechnology It has also other aspects processes. related to structure and current economic which could conditions leverage biotechnology industry development: а 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.



The Government of Brazil (GOB) has increased significantly its support of researchers in the biotechnology sector over the past few years. The number of project grants provided to help researchers transform their discoveries into businesses is also increasing every year and so is the amount of money invested by the government to help finance start-up and small companies.

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. There has also been an increase in Brazilian tax incentives.

This market report is mostly based on a study, The Brazilian Life Science Industry - Pathways for Growth, launched in 2011 by PwC and BIOMINAS Brasil, a private institution dedicated to

promoting business in the life sciences sector. In addition to providing statistics about the industry, this report analyses four pillars of the innovation ecosystem: intellectual property and technology transfer, capital, public policies and qualified human resources.

According to the BIOMINAS study, there are 271 local Brazilian biosciences enterprises, of which 143 are biotech enterprises. Twenty-nine percent or 79 companies generate an annual gross revenue of over USD 600,000, 146 or 54% of the companies generate up to USD 600,000 gross revenue, and 17% or 46 companies generate no revenue at all. According to the sector specialists, approximately 90% of the Brazilian biotech companies are highly dependent on foreign imports, especially reagents and equipment for the production and development of technology.

Most of the Brazilian biotechnology companies are based on the Southeastern states of São Paulo, Minas Gerais and Rio de Janeiro, with 75% or 202 companies. Second, the South states of Rio Grande do Sul and Paraná, with 15% or 33 companies.

Market Overview

The purpose of this report is to provide an overview of the biotechnology market in Brazil, which is now considered to include a large variety of applications including the following:

- Human Health: Thirty-three percent or 89 companies are dedicated to the development of new medications (small molecules and biological), diagnostics, vaccines, cell therapy, regenerative medicine and tissue engineering, advanced method for assisted reproduction, genetic and molecular testing, etc.
- Agribusiness: Thirty-one percent or 84 companies develop 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 (ethanol and/or biodiesel).
- Raw Materials / Reagents: Eighteen percent or 49 companies develop reagents and/or enzymes for industrial use, methods for isolating, identifying and classifying microorganisms, culture media, biopolymers, biomaterials, etc.
- Environmental: Six percent or 16 companies develop and supply products and services for bioremediation, biological treatment of wastes and recovery of degraded areas, analysis of environmental samples using biological systems.
- Mixed: Twelve percent or 33 companies are involved in more than one of the above categories; e.g., development of kits to diagnose human and animal diseases, bio-informatics companies, CRO, CMOs, etc.

The Brazilian life science companies have basically the following business model: 179 (66%): Sale of internally-developed products. 168 (62%): Services. 49 (18%): Sale of products developed by third parties. 22 (8%): Out-licensing of technologies. 114 Brazilian biotech companies or 42% provide exports and services to foreign customers.

Domestic Production

According to BIOMINAS, 90% of the Brazilian biotechnology companies are located in the South and Southeast of the country. The Southeastern states of São Paulo, Minas Gerais and Rio de Janeiro concentrate 75% of the biotechnology activities. Fifteen percent of the companies are in the South, 5% in the North and Northeast, and 6% in the Midwest area.

The following chart provides a breakdown revenues generated by biotechnology manufacturers in Brazil. Brazil's most populous state, São Paulo, accounts for approximately 38% of all biotech production while the state of Minas Gerais accounts for another 31%. While São Paulo's production is spread throughout a number of cities and regions, Minas Gerais' production is focused mainly on the Metropolitan Region of its capital city, Belo Horizonte, making it the largest biotech cluster in South America, according to an Inter-American Development Bank study.

State	Percentage	Number of Companies
São Paulo	38%	103
Minas Gerais	31%	83
Rio Grande do Sul	7%	19
Rio de Janeiro	6%	16
Paraná	5%	14
Other States	13%	13

As it can be seen in the following chart, more than one quarter of biotech production in Brazil focuses on the Human Health sector. Agribusiness sector (Animal Health, Agriculture, and Bio-Energy) has followed the prediction and this sub sector has increased dramatically from 16% in 2006 to 31% in 2011. This is due to Brazil's focus on Agricultural innovation and the fact that Brazil is one of a handful of true agricultural powerhouses, being the second biggest country in cultivation areas dedicated to genetically modified plants, detaining expertise in new variety generation based in molecular methods.

Sector	Percentage	Number of Companies
Human Health	33%	89
Agribusiness and Animal Health	31%	84
Reagents	18%	49
Mixed	12%	33
Others	6%	16

Intellectual Property (IP)

An important instrument in creating a proper environment is the Intellectual Property system. For biotechnology companies especially, IP rights are a fundamental mechanism in fostering technological innovation, as patents represent an important element of added value.

The National Industrial Property Institute (INPI) is the Brazilian institution responsible to regulate, and for analyzing and judging patent applications. Even though Brazil has signed the principal agreements that deal with IP rights, there are three obstacles often mentioned by entrepreneurs:

- Long patent approval period: according to INPI, there is a backlog of approximately nine years to analyze biotechnology patents, by the Biotechnology Patent Division (Dibiotec). This is a reflection of an insufficient number of examiners for an increasing demand on patent requests. Aware of this matter, INPI has hired more biotechnology examiners, and also made improvements on internal processes, like cooperative agreements with other patent offices. INPI has taken planned actions to reduce patent analysis time to four years by the end of 2014.
- Restrictive patentability criteria: According to the Brazilian Industrial Property Law (LPI), the following items are not patentable: nucleotide and peptide sequences isolated from natural living organisms, such as; extracts and all molecules, substances and mixtures 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). However, there is a bill under analysis by Congress which would change the terms of the LPI, allowing for patenting of the abovementioned materials.
- Access to biodiversity: Access to biodiversity remains restricted due to a Congress Provisional Measure which stipulates that the concession of IP rights depends on approval

to access the genetic heritage and associated tradition knowledge, granted by the Genetic Heritage Management Council (CGEN), which is seen as a slow and bureaucratic process.

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

Brazil's participation in the international repository of biotechnological patents is small, only (0.45%), despite the fact that it is growing rapidly. Seventy-three percent of all licensed patents in Brazil have been originated by Brazilian Universities and Research Centers, 13% by Foreign Companies, 7% by Foreign Universities and Research Centers, and another 7% by Brazilian Companies.

Capital

Funds availability is one of the key elements required to develop the life science industry. The main sources available for funding Brazil life science companies are the following:

- Reimbursable funds: loans and financing. These include public funds, e.g. (BNDES) National Social and Economic Development Bank, a federal public company, and at present the main instrument of long-term financing for investments in all segments of the economy. e.g. (FINEP) Brazilian Innovation Agency, a public company linked to the Ministry of Science, Technology and Innovation (MCTI). FINEP has the ability to finance the entire Science, Technology and Innovation system, with both reimbursable and non-reimbursable funds, which gives this Agency a strong power to induce innovative activities. And private funds such as Commercial Banks.
- Non-reimbursable funds: grants and donations, usually from public requests or calls for grant proposals. It includes public sources like FINEP, State Research Support Foundations, CNPq Scientific and Technological Development Council which is also linked to MCTI, as well as private non-profit organizations, like the Bill and Melinda Gates Foundation.
- Internally-generated funds: capital from shareholders and retained earnings on the company's activities.
- Investors: angels, seed capital, venture capital and private equity. They acquire equity interest and look for a substantial return for when they exit the venture. They include public sources like BNDESPar, CRIATEC, a seed capital fund, as well as private investors, like FIR Capital and Burrill & Company, a global leader and pioneer in investments in the life science sector.

• Corporate partnerships: funds from cooperative agreements between companies. It can take on different formats, including R&D partnerships and joint ventures.

Investments and Partnerships

The main 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 Northeast Bank of Brazil. The objective of the fund is to invest in and develop new born technology-based companies with high growth potential. Up to August 2011, CRIATEC had invested in 28 companies and there are five more on final phases of investments.

Another venture capital fund focused on life science companies is Burril Brasil I Fund, the American capital management firm Burrill&Company, whose investors are BNDES, FINEP, the Multilateral Investment Fund (Fumin/BID), Pfizer USA, and others.

INOVA Biotecnologia, a joint venture between Eurofarma Group and Hertape Calier, focused on animal health, invested USD 120 million to produce up to 120 million doses of aftomune vaccine to control and eradicate foot-and-mouth disease.

Braskem, the largest petrochemical company in the Americas, with 26 industrial plants in Brazil, invests close to USD 30 million a year in Research and Development. "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".

Natura is the largest manufacturer of cosmetics and hygiene and beauty products in Brazil and a leader in the direct sales segment. Natura invests roughly 3% of its net revenues in innovation. Natura works with different cooperation models, including co-development, licensing, technology transfer and supply. The formats are flexible and may include investment of funds, joint fund raising, offering infrastructure, exchange of experience and know how, among others.

Grupo Suzano, one of the 10 largest pulp producers in the market, incorporated the concept of open innovation in its R&D strategy and has a long history of domestic and international cooperation agreements. Such as the interaction with the life science company FuturaGene to establish strong know how in the development of life science techniques applicable to eucalyptus tree species.

Biological Product Registration

The National Health Surveillance Agency (ANVISA), counterpart of Food and Drug Administration, regulates biological product registration. Recent regulatory framework was improved by the current normative landmark, RDC 55/2010, a Resolution that establishes Route of Development by Comparability. The regulatory route that can be used by a biological product to obtain registration from the regulatory authority, in which the exercise of comparability in terms of quality, efficacy and safety was used, between the developed product to be comparable and the comparer biological product.

RDC 55/2010 was based on different international agencies such as Health Canada, EMA Europe, CECMED Cuba, KFDA Korea, as well as on guidelines from WHO SBP World Health Organization which are specific for registration of bio therapeutics similar products.

According to RDC 55/2010, in Brazil, there are two categories of biological and biotechnological products. Innovative products are denominated new biological product and copies are denominated biological products.

This Resolution applies to new biological products and biological products to be subjected to analysis for grant of registration. The following are biological products for purposes of this Resolution:

- I vaccines
- II hyper immune serum
- III blood products
- IV biomedicines classified as:
- a) drugs obtained from biological fluids or tissues of animal origin, and
- b) drugs obtained by biotechnological procedures.
- V monoclonal antibodies
- VI medicines containing live microorganisms, attenuated or dead

This Resolution does not apply to antibiotics and semi-synthetic conjugated estrogens (anovulatory), probiotics and allergens, which have their own regulation.

Only new organic products and organic products registered with the ANVISA, manufactured or imported by establishments duly authorized by the federal government and licensed by the state government may be marketed and distributed in Brazil.

ANVISA has detected additional regulatory requirements and in order to improve the technical and regulatory frameworks, ANVISA has issued specific technical guides on biological products registration. The complete text for RDC 55/2010 and above mentioned guides can be found at ANVISA's website, under a link on biological products or *produtos biológicos*.

Equipment and Consumables Suppliers

Biotech equipment and consumables are essential for every Brazilian laboratory and public institution to develop its Biotechnology projects, products and services. The Brazilian market offers particularly attractive sales opportunities for the following products:

- Biotech instrumentation.
- Instruments for the life sciences and medical research.
- In vitro diagnostic kits.
- Laboratory equipment.
- Laboratory testing services for agricultural diagnostics.
- Molecular biology reagents.
- Reagents for life sciences research.
- Scientific instruments.
- Tests for early detection of cancer, heart disease, fertility, infectious diseases and drugs.

Best Sales Prospects

According to a study launched by the Brazilian Association of Biotechnology (BRBIOTEC), 86% of the Brazilian biotech companies are highly dependent on imports of products and services. Seventy-seven percent of the companies import especially reagents, and 65% import equipment. "These numbers clearly demonstrate that imports are not only important for the development of the sector, but crucial for its existence".

The top prospects for US exporters seeking to sell to Brazilian buyers in the Biotechnology sector include the following:

- Animal diagnostic kits.
- Ecotoxicity and mutagenicity tests.
- ELISA.
- Diagnostics of micotoxins, endotoxins, biocorrosion of microprocessors.
- Identification of transgenics.
- Immunological tests.
- Instruments for the life sciences and medical research.
- Laboratory equipment.
- Molecular biology reagents.
- Molecular diagnostics.
- Rapid tests for a variety of diseases including HIV, Bird Flu, etc.
- Rapid tests of animal health and reproduction.
- Reagents for life sciences research.
- Selective ions.
- Self-tests for home care sector.
- Tests for the evaluation of food quality.
- Turbidimetry used for quantitative analyses.
- Pollution bio-indicators.

Biotech Events

BioPartnering Latin American 2012 (BPL) - Rio de Janeiro, September 11 - 13, 2012

BPL is an event of the biotechnology and life sciences industry, organized by BIOMINAS Brasil and Technology Vision Group (TVG). It is focused on establishing strategic contacts, generating business through meetings and promoting networking. In 2012, BPL reaches its third edition and is part of the BioPartnering[™] events, held in many countries. BPL brings the virtual platform *biopartnering.com[™]* which is an unique on line system for scheduling meetings through the identification and contacting of potential partners before, during and after the event. The target audience is the following: Pharmaceutical senior executives, Managers of life science companies, Investors, Government Representatives, Service providers, Research centers, and Universities. The three BPL 2012 discussing topics will be: Human and Animal Health; Industrial; and Agribusiness and Environment.

Date: September 11 - 13, 2012

Location: Rio de Janeiro, Brazil

Information contact: Arthur Nigri - Email.: <u>bpl@biominas.org.br</u> - Phone: 55 31 3303-0012

Resources

ANVISA - National Health Surveillance Agency - <u>http://www.anvisa.gov.br/eng/index.htm</u> ANVISA is designated as an autonomous agency operating under a special regime. This means that ANVISA is an independently administered, financially-autonomous regulatory agency, with security of tenure for its directors during the period of their mandates. The Agency is managed by a Collegiate Board of Directors, comprised of five members. ANVISA is linked to the Ministry of Health under a management contract.

BIOMINAS Brasil - www.biominas.org.br

A private institution dedicated to promoting life science business activities in Brazil. BIOMINAS assists on the development of biotech companies through specialized consulting, business development, company incubation, and investment. A complete report on the Brazilian Life Science Industry can be found at BIOMINAS website.

BRBIOTEC - Brazilian Association of Biotechnology - <u>http://www.brbiotec.org.br/</u> A private organization, whose objective is to develop the biotechnology sector in Brazil.

For More Information

The U.S. Commercial Service in Belo Horizonte / Brazil can be contacted via e-mail at: <u>vania.resende@trade.gov;</u> Phone: 55 31 3213-1583; or visit our website: <u>www.focusbrazil.org.br</u> or <u>www.buyusa.gov/brazil</u>.

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