

Overview of Life Sciences in Brazil

November 2012

Nicolas Peyret

Life Sciences Industry Team

FOREWORD

The following report is the first in a series focusing on life sciences in Brazil and areas of market opportunity for Scottish businesses and research institutions.

Brazil is the sixth largest economy in the world, the largest life-science market in Latin America and a platform used by foreign companies to penetrate the Latin America market.

Brazil has a \$26bn pharmaceutical market and a \$4.6bn medical device market both showing strong annual growth of 12 and 16%, respectively.

As such, Brazil offers tremendous opportunities for imports, corporate partnerships, and research collaborations not only in the above mentioned life-science markets but also in a range of others including animal health and agribusiness where Brazil is a world leader.

In 2013 Scottish Enterprise will produce a series of short specialist business reports on life sciences in Brazil. These are intended to offer practical assistance for companies or organisations seeking to trade or partner with organisations in Brazil. Topics being considered include:

- Cases studies of Scottish life-science companies trading in Brazil,
- Essential legislation, regulations and import taxes in specific life science markets.

We are keen to hear your suggestions for other report topics focusing on specific aspects of life sciences in Brazil. To provide feedback, please contact Nicolas Peyret at nicolas.peyret@scotent.co.uk.

EXECUTIVE SUMMARY

Assets and trends: Brazil is the fifth most populous country in the world and has the sixth largest GDP. Brazil has a number of assets and socio-economic trends that should support the development of the life science sector. The country has a strong scientific base, has abundant natural resources, is a global leader in agribusiness and biofuel and is open to new technologies including genetically modified organisms. Other trends such as population aging and growth, growth of the middle class, improvement of the public healthcare system, and development of health insurance, are also fuelling the expansion of the life-science sector.

However, there are still a number of factors that hamper the growth of this sector. These include bureaucratic processes (tax collection, export/import...), restrictions and delays in terms of patentability, inefficiencies in business law, limited access to capital for entrepreneurs and companies and unsatisfied demand for technical and commercial industry workforce.

Key life science markets: Brazil's pharmaceutical market (inclusive of biologics) was \$26bn in 2011 and is expected to have a 12% year-on-year growth until 2015. Brazil is the largest market in Latin America accounting for up to 40% of the demand. Further, Brazil is part of regional trade agreements allowing Brazilian based exporters to sell drugs tariff free or at highly preferential conditions within Latin America. Other Brazilian healthcare markets are also expected to show a healthy growth through 2015: 9.6% for the \$659M clinical diagnostic market, 11.5% for the \$616M imaging market and 16% for the \$4.6bn medical device market.

The Biotechnology sector has over 230 companies serving a \$6-7bn market. Brazil is the world second grower of genetically modified crops and a leader in biofuel use.

Research in Brazil has significantly expanded over the past few years in the areas of genomics, stem cells and regenerative medicine, and neurosciences. Brazil is also one of the leaders in tropical medicine, parasitology and agro-biotechnology. However, the research activities are still disproportionally performed in universities.

Opportunities: Brazil is a platform used by foreign companies to penetrate the Latin America market. Brazil is the largest market in South America (40%) and is part of regional trade agreements allowing Brazilian based exporters to sell drugs tariff free or at highly preferential conditions within Latin America. In addition, regulations are such that most drugs and medical devices made in Brazil can be directly sold in most Brazilian export markets.

Corporate partnerships are of interest to Brazilian companies as means to access further funding, know how, regulatory and market knowledge and routes to foreign markets, while sharing risk.

There are opportunities for contract research organisations especially in the biologics area as the number of clinical trials is expected to grow year on year by 6% leading to a CRO market size of \$182M by 2015.

Further opportunities exist in the area of e-health/telehealth which is a high growth market in Brazil and a field in which Scotland has been an early player and has ambitious plans.

There are also opportunities for Scottish institutes, universities and companies to develop partnerships to expand their expertise, test genetically modified crops, and potentially commercialise them. Brazil's open attitude about genetically modified organisms might be an opportunity to test specific applications in the country.

Brazil is also a world leader in biofuel production and use. There maybe opportunities for partnerships in this area which is linked to Scottish initiatives in industrial biotechnology and possibly synthetic biology.

Furthermore, significant collaboration and business opportunities exist in animal health and aquaculture where Scotland is a world research leader. Brazil is already a world leading cattle and poultry producer and aspires to become one of the foremost aquaculture producers.

TABLE OF CONTENTS

1.	Key Indicators	7
1.1.	Demographic and macroeconomic indicators	7
1.2.	Health indicators ¹	8
2.	General trends	8
3.	Business environment.....	12
4.	Analysis of Brazilian pharmaceutical industry.....	16
4.1.	Market and demand	16
4.2.	Regulations	18
4.3.	Trade	20
4.4.	Pharmaceutical companies in Brazil	21
4.5.	Contract Manufacturing Organisations	25
4.6.	Special segments: herbal medicines, homeopathy and vaccines	26
4.7.	Supply chain to pharmaceutical industry.....	26
5.	Biologics	27
6.	Medical devices	28
7.	Healthcare IT	31
8.	Medical imaging	31
9.	Clinical diagnostics	32
10.	Analysis of Brazilian biotechnology industry.....	32
11.	Animal Health.....	35
12.	Analysis of academic and public research in life sciences	36
13.	Opportunities for Scottish companies.....	39
	APPENDIX 1: Number of university level professors per life science discipline	41
	APPENDIX 2: Leading public research centers	43
	APPENDIX 3: Brazilian venture capital.....	44
	REFERENCES.....	45

LIST OF TABLES

Table 1: Health Indicators for Brazil	8
Table 2: Estimated cancer incidence by type (2012)	9
Table 3: Breakdown of Brazilian Pharmaceutical market (2009)	17
Table 4: Retail market leaders (2008)	22
Table 5: Market leaders per segment (2009)	23
Table 6: Biologics Market Segments and Market Shares (2010)	27
Table 7: Repartition by sector and implantation of companies	33
Table 8: Share of world paper per research field	37

LIST OF FIGURES

Figure 1: Map of Brazil	7
Figure 2: Generics, similars and biosimilars	20
Figure 3: Origin of licensed patents	38

ABBREVIATIONS

ANVISA: Agência Nacional de Vigilância Sanitária – National Health Surveillance Agency

BNDES: Banco Nacional de Desenvolvimento Econômico e Social - National Social and Economic Development Bank

CAGR: Compounded Annual Growth Rate

Embrapa: Empresa Brasileira de Pesquisa Agropecuária - Brazilian Agricultural Research Corporation

FINEP: Financiadora de Estudos e Projetos – Brazilian Innovation Agency

GM / GMO: Genetically Modified / Genetically Modified Organism

INPI: Instituto Nacional da Propriedade Industrial – National Institute of Industrial Property

LS: Life Sciences

PFS: Programa Saúde da Família - Family Health Programme

SNVS: Sistema Nacional de Vigilância Sanitária – National Health Surveillance System

SUS: Sistema Único de Saúde - Unified Health System

VC: Venture Capital

PE: Private Equity

M: Million

bn: billion

1. Key Indicators

1.1. Demographic and macroeconomic indicators¹

Figure 1 shows the various states constituting the federal republic of Brazil.

Figure 1: Map of Brazil



Source: <http://www.south-america-travel.info/maps/brazil-regions.png>

The population of Brazil is estimated to be 205.7 million making it the fifth most populous country in the world. Population growth is around 1.1%. The country is also the 5th largest in the world covering 8,459,417 sq km. 87% of the population live in urban areas with major conurbations being Sao Paulo, Rio de Janeiro, Belo Horizonte, Porto Alegre and Brasilia.

Brazil nominal GDP (current US\$) was \$2.476 trillion in 2011 ranking 6th worldwide². However GDP per capita was only \$12,594. GDP growth for 2011 is estimated to have been 2.7% from 7.5% in 2010. Growth for 2012 is expected to be slightly below 2% and should rebound to 4.1% in 2013^{3,4}. Public debt reaches 54.4% of GDP. 26% of the population is below poverty line. Brazil's currency is the real (R\$ or BRL). In 2012, the exchange rate is approximately R\$1 for \$0.49.

Growth in the Brazilian economy results mostly from domestic demand. Brazil is lagging behind in terms of foreign direct investment (2.69% of GDP in 2011) compared to other Latin America countries such as Chile, Columbia and Peru or other BRIC counties such as China and Russia.

The labour force of 104.7 million is the 6th largest in the world and is divided between sectors in the following proportions: agriculture: 20%, industry: 14% and services: 66% (2003 est.).

Unemployment rate is around 6%.

1.2. Health indicators¹

Table 1: Health Indicators for Brazil

Indicator	Value	Rank worldwide or comparison
Maternal mortality rate	58 deaths/100,000 live births (2008)	93 (Compared to 12 in the UK)
Infant mortality rate	20.5 deaths/1,000 live births	94 (Compared to 4.56 in the UK)
Life expectancy at birth	72.79 years (male: 69.24 years; female: 76.53 years)	123
Health expenditures	9% of GDP	Compared to 9.3% in the UK
Physician density	1.72 physicians/1,000 population (2007)	Compared to 2.74 in the UK
Hospital bed density	2.4 beds/1,000 population (2009)	Compared to 3.4 in the UK

2. General trends

Brazil has a number of assets and socio-economic trends that should facilitate the development of the life-science (LS) sector. The country has a strong scientific base, is a global leader in agribusiness and biofuel and has significant natural resources. The Brazilian population is growing and aging while the middle class represents an ever increasing portion of the population, driving demand for healthcare services. Healthcare has been improving and health insurance coverage expanding.

Population growth, age and socioeconomic distribution

Brazil's population is expected to reach 207M by 2015. In 2011, population growth rate was 0.9% in Brazil compared to 0.7% in the UK. By 2015, the population aged over 60 will reach 28M, 12% of the total population (compared to 23% in the UK⁵). The Brazilian middle class (monthly household income between \$970 and \$4,160) has increased from 66M (38%) in 2003 to 105M people (55%) in 2011 and is expected to reach 118M (60%) in 2014⁶.

Disease and condition prevalence

Infectious diseases are still serious issues in Brazil with seasonal epidemics of Dengue fever and increasing rates of visceral leishmaniasis. Non-infectious conditions with high prevalence include psychiatric diseases, asthma, obesity, diabetes, hypertension and cancer. The latter four conditions are showing trends of increasing prevalence. It is estimated that by 2015 67% of men and 74% of women in the Brazilian population will be overweight⁶. In 2011, there were 12.4M people suffering from Diabetes in Brazil. By 2030, this number is expected to reach 19.6M⁶. In 2012, cancer incidence was around 422,000 and more than 2M cases are expected by 2015⁶. The table below shows estimated incidence by cancer type in 2012. The fastest growing incidence rates are observed for breast, lung, colon and prostate cancers.

Table 2: Estimated cancer incidence by type (2012)⁶

Cancer type	Incidence in 2012
Skin	134,170
Prostate	60,180
Breast	52,680
Colon	30,140
Lung	27,320
Uterus	21,060
Stomach	20,090

Healthcare system in Brazil

The Unified Health System (Sistema Único de Saúde or SUS), which was instituted by the 1988 constitution, is based on health being a citizen's right and the state's duty. The SUS is responsible for health promotion, surveillance, education, for vector control and for ensuring Brazilians receive care at all levels (primary, specialist outpatient and hospital).

The Brazilian health system consists of three sectors:

- The public sector (SUS) in which health services are financed and provided by the federal, state and municipal governments;
- The private (for-profit and non-for-profit) sector in which services are financed by a mix of private and public funds as the private sector provides some services contracted out by SUS.

- The private health insurance sector.

People can use services in the three sectors depending on ease of access or ability to afford the services. The system is financed through taxes, out-of-pocket spending and employer spending.

Primary care is supported by the Family Health Program (Programa Saúde da Família or PSF) which assigns a family health care team composed of a physician, a nurse, an auxiliary nurse and 4 to 6 health workers to provide free health care to all families in a given area. These teams are based at PSF clinics and provide primary care to populations of 600 to 1,000 families. In 2010 there were around 33,000 health care teams providing care for 98 million people in 85% of municipalities in Brazil⁷. Parallel to PSF clinics, there are a number of traditional primary care facilities.

Secondary care is often subcontracted by the SUS to the private sector especially for diagnostics (only 24.1% of CT scanners and 13.4% of MRI are public⁷) and therapeutic services. However, public specialised centres for dental care and sexually transmitted diseases have been developed as well as emergency clinics. Emergency clinics work alongside hospital emergency departments and work with the emergency mobile care service assisting people in need where needed with ambulances and other emergency vehicles. In 2010, 50% of Brazil's population was covered by the emergency mobile care service.

Tertiary care, which includes high-cost procedures, is mainly performed by contracted private-sector providers and public teaching hospitals and is paid for by SUS at market value. There are clear issues in terms of coordination with primary care as referral mechanism are inexistent. Integration between the three levels of care is still a challenge.

Primary care clinics and emergency units are mainly public while hospitals, outpatient clinics and diagnostic and therapeutic services are mainly private. Brazil had 6,384 hospitals in 2011, 69% of which were private. Only 35% of hospitals beds are public and 39% of private beds are available to SUS through contracts⁷.

In Brazil, there are no electronic health records maintained at national level and patients are responsible to keep paper copies of the various elements of their records. While some hospitals are moving to electronic medical records, only 10% of them have such information systems.

Health Insurance

The number of people covered by private health insurance increased from 31.8M in 2003 to 47.6M in 2011⁶. There are over 1,350 private health insurance companies in Brazil 73% of which provide medical/hospital insurance and 37% of which provide dental insurance. The revenue of

the health insurance sector was \$41.6bn in 2010 growing at a 14.6% CAGR (compounded annual growth rate) since 2003⁶. Most insurance schemes do not reimburse patients for the purchase of drugs but pay for hospital treatment and physician visits. These insurance providers are regulated by the National Health Insurance Agency. People with private health plans have better access to preventive services and a higher use of healthcare services compared to those without. However, they still use the SUS for vaccines and high-cost services (complex procedures, transplants...).

Government spending on healthcare

Health expenditures represented 9.1% of GDP in 2011 and are expected to be essentially constant until 2015. This is almost twice the percentage of GDP spent on healthcare by other BRIC countries. For Brazil this represents a \$50bn increase in healthcare expenditures from 2011 to 2015⁶. Expenditures are shared between public sector, private sector and health plans. In 2007 the public share of health expenditures was 41% (for comparison, 82% in the UK and 45.5% in the USA)⁷. 50% of public health expenditures are funded by the federal government and the other 50% shared in roughly equal proportions by states and municipalities⁷. In 2008, 67% of hospital admissions were paid for by the public sector (SUS), 20% by private health plans and 10% out of pocket⁷.

Sustainability

As a newly industrialised nation, Brazil faces a number of sustainability issues including deforestation in the Amazon basin, air and water pollution, oil spills, threats to biodiversity ... On the country environmental performance index 2012, Brazil ranked 30th ⁸. In comparison, the UK ranked 9th and the United States 49th. On the country environmental performance trend index 2012, which measures improvement trends in environmental performance, Brazil ranked 23rd compared to the UK 20th and the USA 77th.

Various surveys have shown that Brazilians consumers are keenly aware of biodiversity and environmental issues – significantly more than their peers in the UK and the USA⁹.

Brazil has been an active international proponent of sustainable development policies and has implemented national sustainability policies to limit deforestation, regulate industrial pollution and promote the use of renewable energy sources.

In particular legislation has been enacted since the 1960s to protect the 6 Brazilian biomes (Atlantic Rainforest, Amazon, Pantanal, Cerrado, Caatinga and Pampa). Brazil is home to about 13% of known species on earth. However enforcement has been difficult and illegal logging is an important issue.

Energy production in Brazil is one of the cleanest in the world. Renewables account for more than 45% of all energy supplied to society to produce goods and services. For comparison the

corresponding global figure is 13% and 8% for developed countries. More than 86% of electric energy generated in Brazil is from renewable sources (80% hydro and 6% biomass and wind). Biomass had a 31% share among energy sources in Brazil in 2010, with 17.7% sugar cane products, 9.5% wood and 3.8% other residues. The two main liquid biofuels used in Brazil are ethanol (from sugar cane) which is used in cars and light vehicles and biodiesel (from vegetable oils or animal fats) which is used in trucks and buses. Anhydrous ethanol is found in gasoline in proportions varying from 18 to 25%. Flex-fuel vehicles (currently about 90% of light vehicles in Brazil), however, use a mixture of hydrous ethanol and gasoline where proportions of gasoline can range from 0 to 100%.

Brazil is also a major actor in terms of food sustainability. It is a major crop, cattle and poultry producer and exporter and one of the world leading growers of genetically modified crops.

These areas and associated opportunities for Scotland are further developed in sections 10 and 11.

3. Business environment

Brazil ranks 126 out of 183 countries for ease of doing business in the World Bank's Doing Business 2012 report. For comparison, Japan ranks 20, Mexico 53, China 91, and India 132. Some indicators where Brazil ranks poorly include ease of trading across border, ease of enforcing contracts and ease of paying taxes¹⁰.

Innovation is a key element for most companies in the life-science (LS) sector. For companies to be successful and to assume the cost and risk associated with R&D activities, the business and legal environments need to encourage innovation. Four areas are essential to support innovation: intellectual property protection, access to capital, favourable public policies and access to a skilled workforce.

Intellectual property and business law

Brazil's share of global life science patents filed through the Patent Cooperation Treaty has increased from 0.05% in 1999 to 0.45% in 2009¹¹. In 2010, 18% of LS companies had domestic patents granted, 44% had patents filed and 33% had patent applications in preparation¹¹.

In Brazil reviewing patent applications and granting patents is the responsibility of the Instituto Nacional da Propriedad Industrial (INPI). Four issues having a negative impact on innovation in the life sciences have been identified and are being addressed by INPI:

- In 2002 it took about 9 years for a LS patent application to be analysed. INPI has taken a set of actions including hiring more life science examiners to reduce this delay to four years by 2014.

- Currently, according to industrial property law in Brazil, a range of natural products are not patentable. These include: “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 men (excluding transgenic microorganisms)”. A new bill under review by Congress would allow patentability of these products.
- Intellectual property rights related to Brazilian natural resources have to be approved by the General Heritage Management Council which significantly increases the patent granting delays.

The limited share of Brazil's international LS patents is also explained by the low R&D investment of companies (1.9% of GDP in 2009), a lack of IP culture and the concentration of researchers in universities and not industry. In 2009 only about 43% of investment by LS company was focused on R&D. In 50% of companies government funding represented more than 50% of the investment in innovation¹¹.

Access to Capital

There are essentially five funding sources for life sciences entrepreneurs and their companies¹¹.

- *Reimbursable funds* are provided either by private banks or government institutions such as the National Social and Economic Development Bank (BNDES) or Financiadora de Estudos e Projetos (FINEP), the Brazilian Innovation Agency. These funds constitute one of the main sources of R&D funding for 31% of companies.
- *Non-reimbursable funds* are essentially grants and donations from public agencies (FINEP, the various state foundations supporting research – Fundação de Amparo a Pesquisa) and private non-profit organisations. Non-reimbursable funds constitute one of the main sources of R&D funding for 69% of companies.
- *Internal Company funds* correspond to shareholders' capital or retained earnings. Such funds constitute one of the main sources of R&D funding for 31% of companies.
- *Funds from investors* who acquire company equity and expect a significant return include angels, seed capital, venture capital (VC) and private equity. Funds from investors are the principal source of R&D funding for only 19% of companies. The lack of a domestic venture capital industry and of a capital market familiar with the LS sector and its specificities explains this low number. Brazil ranks 57th on the global VCPE (Venture Capital and Private Equity) Attractiveness index 2011. For comparison on the same index

the UK ranked third and China and India ranked 25th and 26th, respectively.¹² In 2008, Brazilian portfolio companies (i.e. invested in by venture capital and private equity industry) in agribusiness, biotechnology and medicine and beauty represented respectively 4%, 4% and 3% of the 481 portfolio companies. In comparison IT and electronic represented 22%¹³. That same year in the United States, the sector where the most VC and PE money was invested was biotechnology¹⁴. The main VC fund for Brazilian LS companies has been CRIATEC, funded by BNDES and Banco do Nordeste do Brasil (BNB). By 2011 the fund had invested in about 10 LS companies and generally targeted companies focusing on areas where Brazil has competitive advantage (e.g. biomass and natural resources). Other VC investors include FIR and Rio Bravo, a Brazilian private equity firm that recently closed a \$275m fund focusing on renewable energy. Votorantim Novos Negócios Ltda, the venture capital and private equity arm of Votorantim Group, is another Brazilian VC company that invested in both Amyris biotechnology and Moksha8, a company promoting and distributing drugs produced by global pharmaceutical companies in emerging markets. The US firm Burril&Company has also set up a \$200M Brazil fund with a range of domestic investors but also some foreign LS companies such as Pfizer USA and Life Technologies.

- *Funds from corporate partnerships* that are obtained from cooperative agreements with other industrial partners. Such funds are one of the main sources of R&D funding for only 11% of companies.

Skilled workforce

The Brazilian academic sector has gained significant strengths over the past decade as described in section 12 below. However, until recently the low demand for industrial researchers has led PhDs toward academic careers. Consequently there is a shortage of industrial researchers now that the industry is expanding. An especially acute shortage is felt in terms of people experienced in scale-up of biotechnological processes. There is also high demand for business development professionals with technical, commercial and negotiation expertise.

60% of LS companies indicate that they have high demand for R&D and business development professionals¹¹. 50% have high demand for management, 46% for sales professionals and 35% for production professionals¹¹.

Government support

In February 2007 President Luiz Inácio Lula da Silva signed a decree that created the National Committee for Biotechnology and outlined a national policy for the sector. The government

planned to invest R\$10 billion (£2.43 billion) in biotechnology over the next 10 years. Funding was expected from public and private investment: the government contributing 60 percent, including funds from the Brazilian Development Bank (BNDES), and the rest being provided by the private sector. The main areas to receive the investments were to be health, agriculture industry and environment. The three axes of this policy focused on innovation were¹⁵: 1) “backing action”: legislation and regulation, international agreements, human resources; 2) “Articulation”: development of technological parks, coordination of public budget, public consultation and 3) “Attack”: R&D funding, commercial promotion of the sector, enterprise finance, and set up of a mechanism to integrate industry feedback.

However, so far, according to PWC¹¹ these policies have resulted in limited creation of significant economic value for this sector. When asked in 2011 what topics represented critical success factors for the Brazilian life science industry, 47% of companies cited “clarity and greater agility in the regulatory process”, 42% “establishment of more accessible financing programs”, 30% “consolidation of public policies and increase of government incentives” and 29% “enhancement of university-company interaction processes”¹¹.

Start-up scene

In 2011 about 44% of companies in the Brazilian life science sector were less than five years old. More than half the biotech companies have either graduated from a business incubator or are still in a business incubator. There are over 400 business incubators in Brazil. Out of these the most important ones for life sciences are:

- BIO-RIO (Rio de Janeiro, RJ),
- CDT- Unersidade de Brasília (Brasília, DF)
- CENTEV - Univesidade Federal de Viçosa (Viçosa, MG)
- CIETEC (São Paulo, SP)
- HABITAT (Belo Horizonte, MG)
- IE-CBIOT – Universidade Federal de Rio Grande do Sul (Porto Alegre, RS)
- INCAMP - Universidade Estadual de Campinas (Campinas, SP)
- INOVA - Universidade Federal de Minas Gerais (Belo Horizonte, MG)
- PADETEC – Universidade Federal do Ceará (Fortaleza, CE)
- TECHNO PUC (Porto Alegre, RS)
- POSITIVA – Universidade Federal de Pernambuco (Recife, PE)
- PROSPECTA (Botucatu, SP)
- SUPERA (Ribeirão, SP)

The Brazilian biotechnology start-up scene is at a much earlier stage than in the USA. While there is very rich basic research, there is little applied research and a lack of capacity to bring

basic research to products. Brazilian researchers are not familiar with VC and have very few examples of success stories. In addition, many Brazilian universities are still not used to deal with IP despite government efforts to develop industry-academia collaborations and technology transfer offices. Further, there is a lack of people with experience to lead start-ups through growth.

The funding environment is also a challenge for life-science start-ups that by definition have no or little revenue and therefore cannot reinvest revenue for company expansion. Access to venture capital or private investors with interest in the sector is thus far very limited. Non-reimbursable government funds are restricted to specific R&D project phases and funding programs from government institutions, while having advantageous interest rates, require guarantees many of the start-ups cannot provide.

Challenges

Brazilian life-science entrepreneurs list the following three challenges for their companies¹¹:

- Raising funds (mentioned by 52%) for R&D and infrastructure expansion
- Exploring new markets (mentioned by 35%)
- Expanding the company infrastructure (mentioned by 33%)

In addition, according to PWC, market and regulatory knowledge and its integration into the company strategy is often lacking in Brazilian life-science companies.

4. Analysis of Brazilian pharmaceutical industry

4.1. Market and demand

The Brazilian pharmaceutical market exclusive of biologics was approximately \$24bn in 2011 and is expected to grow at a 12% CAGR until 2015^{6, 16}.

The following drivers explain this observed and forecasted growth:

- The Brazilian economy is expanding even though the economic crisis has recently reduced the growth rate to less than 3%.
- As the 120M strong middle class grows, the demand for drugs increases. In Brazil most insurance scheme do not reimburse patients for the purchase of drugs. Private health insurance, often offered by employers is increasing. While it pays for hospital treatment and physician visits, it rarely covers drugs, however.
- The Brazilian population is ageing as life expectancy increases: by 2020 there will be 30M people over 60 in Brazil compared to 14M in 2000¹⁷. This will lead to an explosion of chronic conditions.

- Similar drugs must be phased out by 2014. Before 1996 Brazil did not recognise patents on pharmaceutical products. Medicines with identical formulation to branded medicines but without proven bioequivalence (“similar drugs”) were therefore introduced (see Figure 2). By 2014 this \$2bn market will be open.

The non-retail segment (state, hospitals and clinic purchases) accounts approximately for 30% of the market while the retail segment (OTC + prescriptions) accounts for the remaining 70%¹⁷. The non-retail segment is divided between government purchases (21%) and purchases from hospitals and clinics (8%). 73% of government purchases are carried out by the unified healthcare system (SUS) through public tenders (for values above R\$650,000) open to Brazil established subsidiary or representative of foreign companies. A breakdown of the total market is summarised in the Table below¹⁷.

Generics first introduced in 2001 represented 15% of the retail market by 2009 and are expected to reach 18% by 2013. This growth should be even more significant after similar drugs are phased out.

Table 3: Breakdown of Brazilian Pharmaceutical market (2009)

Markets	% of total pharma market
Total pharma market	100
• Retail	70
– Generics	10.5
• Non retail	30
– Government purchases	21
– Purchases from hospital and clinics	8

Other important components of the Brazilian pharmaceutical landscape are compounding pharmacies. Pharmacy compounding allows a physician to prescribe a very specific medication, prepared by a pharmacist, for a patient’s individual needs. Prescribers might recommend compounded medications for a number of reasons including: medication being discontinued by a pharmaceutical company due to lack of profit, patient having an allergy to a particular

preservative, dye or binder in commercially available drugs, custom dosage form unavailable for paediatric use, need of combining several medications to increase compliance... Brazil has about 7,000 compounding pharmacies supplying 60M people annually, the largest such market in the world¹⁷. Compounding pharmacies are especially important in the homeopathic market. The large number of compounding pharmacies is explained by: 1) the lower price of compounded medicine compared to industrial ones, 2) physician training in compound prescription during medical school and 3) the large number of trained pharmacists in the country which is much higher than the demand from drugstores and pharmaceutical laboratories. However, this market segment has seen an increase of regulations and controls in terms of Good Compounding Practices and labelling over the past 10 years. Further, pharmacies are prohibited from making products with presentation and /or concentration equivalent to industrialized medicine. This is leading to the progressive disappearance of small compounding pharmacies and to the emergence of compounding pharmacy chains.

4.2. Regulations

Patent protection was extended to pharmaceutical products since the 1996 intellectual property law. In Brazil patents are the responsibility of the national Institute of Industrial Property (Instituto Nacional da Propriedad Industrial – INPI).

The regulatory agency that controls health related products and services is ANVISA (Agência Nacional de Vigilância Sanitária). ANVISA was established in 1999 as an autonomous agency linked to the Ministry of Health. The agency is to foster protection of the health of the population by exercising sanitary control over production and marketing of products and services subject to sanitary surveillance. The agency is also in charge of:

- Coordination of the National Sanitary Surveillance System (SNVS);
- Coordination of the National Programme of Blood and Blood Products;
- Coordination of the National Programme of Prevention and Control of Hospital Infections;
- Monitoring of drug prices and prices of medical devices;
- Regulation, control and inspection of smoking products;
- Technical support in granting of patents by the INPI.”¹⁸

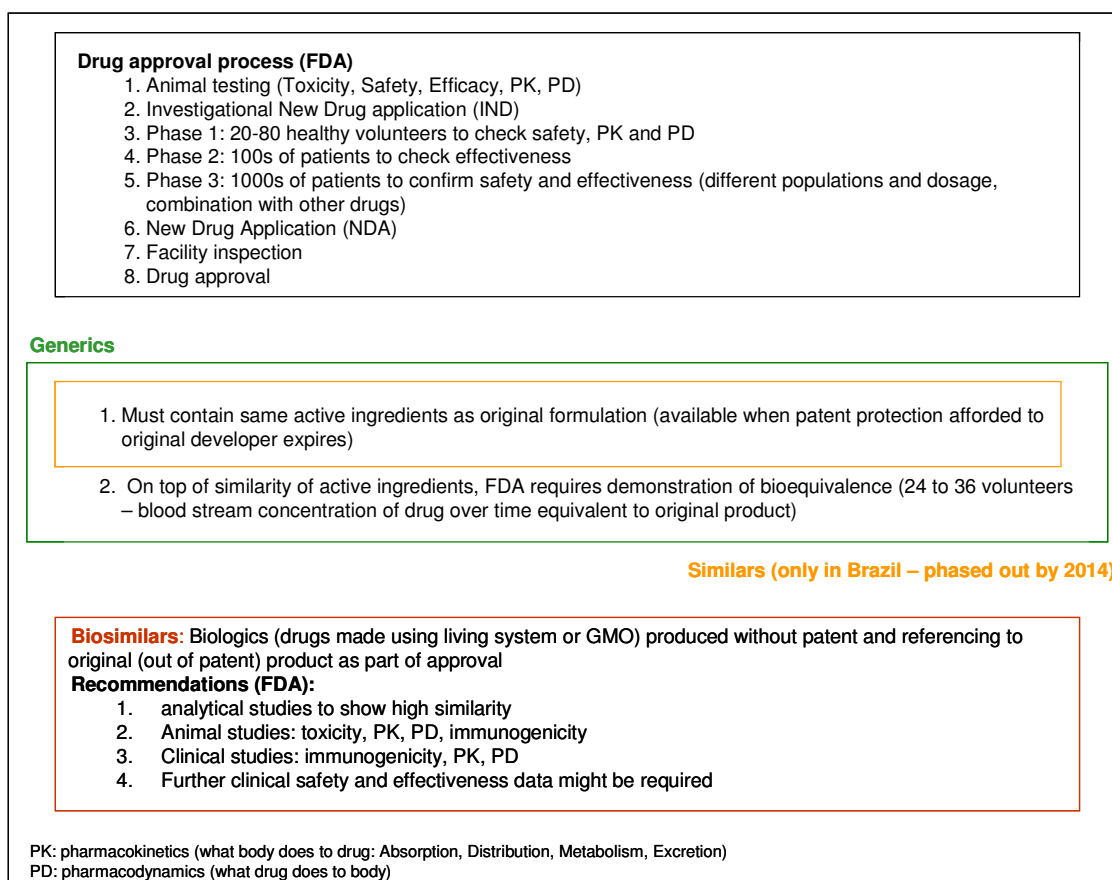
The agency imposes rules in terms of sanitary requirements, GMP and quality control that are stringent enough to ensure most drugs made in Brazil can be directly sold in most Brazilian export markets.

Registration of products with ANVISA must be obtained before any commercial application for: pharmaceuticals and drugs, cosmetics, medical devices, sanitary products, and food & supplements. For drugs, this procedure is similar to that of the FDA. The ANVISA registration

process takes 6 to 12 months before registration comes into effect. The requesting company must be in good standing and fully authorised by ANVISA. Therefore to access the Brazilian market, there are essentially two options: create a subsidiary or finding and negotiating with a Brazilian distributor.

The Pharmaceutical Price Council (Câmara de Regulação do Mercado de Medicamentos) or CMED is responsible for negotiating and determining the price of new drugs. The council is formed by five bodies (ministries of Health, Finance, Industry and Civil House). The minister of Health is president of the council. ANVISA through the Office of Economic Evaluation of New Technologies is responsible for performing the assessment of new drugs and recommending prices which can be reviewed by the council. Once an economic dossier has been submitted by industry, the process essentially consists in classifying the drugs according to their benefits over available best-treatment comparators and performing a rapid health technology analysis (3 months) to define ceiling prices. If the new drug does not show any medical advantages, price is based on cost minimization analysis (compared cost of treatments). If the new drug is better than comparators then a premium price is allowed but it cannot be higher than the lowest price among 9 reference countries. The figure below summarizes the difference in approval processes for generics, similars and biosimilars. Similars which were a Brazilian idiosyncrasy will be phased out by 2014.

Figure 2: Generics, similars and biosimilars



4.3. Trade

Import of pharmaceutical products (including packed for retail and unpacked) represented \$2.7bn in 2009 while exports of such products represented \$768M¹⁷. Trends show that exports have been increasing faster than imports.

In 2009, out of the 100 or so countries importing drugs to Brazil, the leading importers were the USA (19% of imports), Switzerland (17%), Germany (15%), France (8%), and the UK (5%)¹⁷.

The main destinations for exports of pharmaceutical products were Latin America (61% of exports), the EU (25%) and the USA (6%)¹⁷.

In 2011 imports of pharmaceuticals to the EU from Brazil represented €436M (1.2% of Brazil exports to the EU and 0.8% of EU imports of pharmaceuticals) while exports from the EU to Brazil represented €2,589M (7.2% of EU exports to Brazil and 2.6% of EU exports of pharmaceuticals).

Similarly in the area of scientific and controlling instruments, imports from Brazil to the EU amounted to €102.6M while exports from the EU to Brazil reached €1,164M¹⁹. Pharmaceutical and medicinal products were one of the top three UK exports to Brazil in 2011.

International companies established in foreign countries have subsidiaries in Brazil responsible for the majority of imports as well as exports. International companies selected Brazil as their production platform for Latin America as Brazil accounts for up to 40% of the demand in this geographic area. Brazil is also part of regional trade agreements allowing Brazilian based exporters to sell drugs tariff free or at highly preferential conditions within Latin America.

Import taxes for importation of medicine are still high and include import duty and state tax (Federal taxes are waived). Import taxes for equipments (i.e. lab equipment) are even more significant as tax rates are higher and federal taxes apply. However, exports are encouraged through waving tax on imported components and refunding tax on domestic components.

4.4. Pharmaceutical companies in Brazil

About 300 private and 20 state-owned laboratories are operating in Brazil¹⁷. Out of these:

- 15 (including 9 international companies) have retail sales in excess of \$300M;
- 26 (including 16 international companies) have retail sales in the \$100-300M range;
- About 230 (including about 50 international companies) have retail sales lower than \$100M.

Since 2004 the Brazilian government has an active policy to support the development of the domestic pharmaceutical industry. Domestic laboratories have increased their market share over the past decade driven by government support and the rise of generics (generics offer a relatively low risk opportunity). From 2003 to 2010 the share of domestic laboratories in dollar sales of generics increased from 36% to 45%¹⁷. In Brazil, prices of generics are only 35% lower than of corresponding branded products allowing generic companies to make significant profits. Tables 4 and 5 show shares of leading companies in the retail and non-retail drug market.

Table 4: Retail market leaders (2008)¹⁷

Company	Sales (R\$ M)	Market share (%)
SANOFI-AVENTIS + MEDLEY	3,415	11.2
EMS PHARMA	2,083	6.7
ACHE	1,745	5.7
EUROFARMA	1,280	4.2
NOVARTIS	1,224	4.0
PFIZER	1,085	3.5
BAYER SCHERING	806	2.6
ASTRAZENECA	757	2.5
BOEHRINGER INGELHEIM	654	2.1
OTHERS	17,647	58%
Non-retail market leaders – 2009 (Domestic companies are identified by greyed cells)		
Company	Sales (R\$ M)	Market share (%)
ROCHE	577.6	11.8
NOVARTIS	476.4	9.7
ASTRAZENECA	367.3	7.5
CRISTÁLIA	299.7	6.1
BERGAMO (now part of Amgen)	288.1	5.9
ABBOTT	275.1	5.6
SANOFI-AVENTIS	267.2	5.5
EUROFARMA	255.8	5.2
CELLOFARM	244.1	5
PFIZER	243.4	5
OTHERS	1720	33

(Domestic companies are identified by greyed cells; average exchange rate in 2008 was R\$1~\$0.5)

Table 5: Market leaders per segment (2009)¹⁷

Prescription segment		OTC segment		Generic segment	
Company	Market share (%)	Company	Market share (%)	Company	Market share (%)
SANOFI-AVENTIS + MEDLEY	10.9	SANOFI-AVENTIS	9.0	SANOFI-AVENTIS + MEDLEY	31.2
EMS PHARMA	7.2	DM Ind FTC	6.5	EMS PHARMA	26.1
ACHE	6.9	EMS PHARMA	5.3	ACHE	8.2
NOVARTIS	5.5	J&J	4.5	EUROFARMA	8.0
EUROFARMA	5.4	NYCOMED (Takeda since 2011)	4.3	SANDOZ	5.5
PFIZER	4.8	GSK CONSUMO	4.0	GERMED PHARMA	4.1
BAYER SHERING	3.6	BOEHRINGER ING	3.4	RANBAXY	3.9
ASTRAZENECA	3.5	MANTECORP	3.1	TEUTO BRASILEIRO	2.7
SANDOZ	2.5	P&G	2.7	MERCK	1.7
OTHERS	50	ACHE		OTHERS	9
		OTHERS	54		
1% share corresponds approximately to R\$218M		1% share corresponds approximately to R\$89M		1% share corresponds approximately to R\$46M	

(Domestic companies are identified by greyed cells)

Profile of selected Brazilian laboratories

EMS Pharma (www.ems.com.br) is a family owned company founded forty years ago that has 100% Brazilian capital. EMS has two plants in SP (State of Sao Paulo) and employs more than 4,500 people. EMS has a portfolio of over 1,500 products. The company spends 6% of revenues on R&D with more than 200 professionals working in the R&D department. If compared with R&D investment of multinational companies, this number is still small: in 2011 Pfizer spent 12% of revenues on R&D and in 2010 Roche spent 19% of revenues on R&D. Breakdown per segment in 2009 was: prescription 77%, OTC 23%, and generic 59%.

Ache Laboratórios Farmacêuticos S.A. (www.ache.com.br/) is another 40-year-old company with 100% Brazilian capital. The company has over 3,000 employees and three industrial plants. In 2011 Ache revenues were R\$1,401M with EBITDA of R\$454M. R\$41M were spent on innovation. Ache has more than 260 products including 129 therapeutic classes that meet the needs of 20 medical specialties. Breakdown per segment in 2009 was: prescription 86%, OTC 14%, and generic 22%.

Eurofarma (www.eurofarma.com.br) started business in 1972 and ranks third in terms of capital among Brazilian pharmaceutical groups. In 2010 Eurofarma registered R\$1.3bn (\$765M) revenues. The company has over 4,200 employees including more than 1,700 salespeople. It has four plants in SP and one in RJ (State of Rio de Janeiro) focusing on veterinary medicine.

GERMED pharma (www.germedpharma.com.br) was founded in 2002. The company has been focusing on ophthalmology, dermatology, endometabolism, and generics.

Cristália (www.cristalia2.com.br) was founded in 1970 and currently employs 2,100 employees. The company has been focusing on the hospital segment. Cristália is the domestic laboratory with the largest number of patents. The company invested in a R\$30M R&D centre to pursue both incremental and radical research projects.

In addition to the private laboratories, Brazil has 18 state-owned pharmaceutical laboratories and several vaccine producers who altogether produce 30% of the drugs purchased by the government's unified healthcare system. However the smaller of these laboratories have been struggling to modernize their equipments and adapt to new regulations. The government has been encouraging partnerships with private laboratories to help these public institutions.

Recent Foreign investment

In the past few years, multinational companies have extended their presence and market shares in Brazil through acquisition and joint ventures with domestic laboratories. Below are recent examples:

Sanofi-aventis aquired Medley (April 2009). Sanofi-aventis acquired Medley the third largest pharmaceutical company (5.7% market share) and the number one generic company in Brazil for approximately R\$1,500M (€500M). In 2008 Medley's sales amounted to R\$458M (€153M), including two third of those sales in generics. Medley had a generic portfolio of 127 products and had a leading position to benefit from the growth of the generic market in Brazil. This acquisition not only enabled Sanofi-Aventis to reinforce its number one ranking among pharmaceutical companies in Brazil (12% market share) but also made the company the leading player in the field of generics in Brazil and in Latin America.

Amgen acquired Bergamo (April 2011). Amgen acquired Bergamo, a privately-held Brazilian pharmaceutical company for \$215M. Amgen has also agreed to reacquire rights in Brazil to

Bergamos's products that were previously granted to Mantecorp (subsequently acquired by Hypermarcas). These transactions gave Amgen an entry into the Brazilian market, one of the fastest growing pharmaceutical markets in the world. Bergamo was a leading supplier of medicines to the Brazilian hospital sector with capabilities in oncology medicines and revenues of \$80M in 2010 growing at an annual rate of 19% since 2007.

Takeda acquired Multilab (May 2012). Takeda Pharmaceutical Co acquired Brazilian drug maker Multilab Industria e Comercio de Produtos Farmaceuticos. The deal included an initial R\$500 million (\$246.5 million) in cash, plus up to R\$40 million in additional future milestone payments. Multilab which focuses on the OTC and branded generics had revenues of R\$140 million in 2011 with sales growing at over 20% over the last three years. This will make Takeda one of the top 10 pharmaceutical companies in Brazil. This is part of Takeda's strategy of investment in emerging markets started with its €9.60 billion purchase of Switzerland's Nycomed last year.

MSD takes control of Supera Farma Laboratorios SA (February 2012). Merck & Co. Inc. announced it will establish by the end of 2012 a joint venture with Supera Farma Laboratorios SA, a company that is owned by Brazilian drug makers Cristália Labs and Eurofarma Laboratorios. The joint venture, of which Merck will own a 51-percent share, will make and sell new drugs and branded generics produced by all three companies.

Research and development

In Brazil patent protection was only extended to pharmaceutical products in 1997. Therefore R&D investments from private laboratories have traditionally been limited and are still low compared to international standards (~10-15%). However the business strategy is changing and major companies invest over 6% of revenues on research projects. From 2005 to 2008, R&D investment from private companies grew at a 30% CAGR¹⁷. Brazil has the capacity to do basic research and clinical tests. However there is a lack of capacity in terms of pre-clinical research. This is especially true for biotech products.

Innovations are still disproportionately concentrated in universities (see section on academic and public research).

4.5. Contract Manufacturing Organisations

The Brazilian outsourcing market was R\$250M (\$125M) in 2008¹⁷. The demand comes from both domestic laboratories that cannot meet current demand or international companies dismantling outdated or unprofitable lines. The market is very competitive with a large number of players. Three types of companies are involved in this market:

- Companies with outsourcing as core business have a 25% share of the outsourcing market (e.g. Blisfarma, serpac, Mappel);

- Companies for which outsourcing is a non-core business they are committed to have a 30% share of the outsourcing market (e.g. Eurofarma, Nycomed now acquired by Takeda, Boehringer)
- Companies that sell idle capacity but have no focus on outsourcing have a 45% share of the outsourcing market (e.g. Mante Corp, Roche, Sanofi-Aventis)

The companies listed above as examples are the major suppliers in the Brazilian outsourcing market and together have about 60% market share.

4.6. Special segments: herbal medicines, homeopathy and vaccines

The herbal medicine segment is strong in Brazil with revenue over \$1bn in 2010¹⁷. This segment has been supported by the distribution of phytomedicine through SUS and the familiarity of GPs with phytotherapy. 200 companies are active in this segment but the following six represent together a 60% market share: Nycomed/Takeda, Herbarium, Majram, Abbott, Farmasa, and Hebron. This sector is expected to expand as Brazilian biodiversity becomes more systematically exploited.

Homeopathic drugs were a small market of about \$120M in 2010¹⁷. However this market is expected to expand significantly as similar drugs are phased out in 2014 and the number of compounding pharmacies is reduced. Market leaders are Almeida Prado (60% market share), Weleda, Laboratorio Simoes, Dr. Valdomiro Pereira and Heel do Brasil. Industrial homeopathic medicine need to be produced using GMP and registered with ANVISA.

The Human vaccine market reached \$690M in 2010¹⁷. Market leaders are: Instituto Butantan (35% market share), Biomanguinhos (30% market share), TEPCAR and Fundacao Ataulfo de Paiva (20% market share), GSK (8% market share), and Sanofi Pasteur (3% market share). Domestic laboratories essentially produce vaccines for endemic diseases covered by the National Program of Immunization.

4.7. Supply chain to pharmaceutical industry

The Brazilian market for pharmaceutical raw materials reached R\$3bn (\$1.5bn) in 2009 a 16% CAGR over the past 5 years¹⁷. Most Brazilian laboratories with the exception of Roche and Cristália do not have knowledge or infrastructure to produce their own pharmaceutical ingredients. Therefore the demand is either covered by exports (80%) or locally established foreign companies (BASF – 10% market share) or domestic companies (Globe Química, Nortec Química). Main imports come from Germany, China and the USA. There are over 650 companies operating in this market and also providing ingredients to the food and cosmetic industry. Exports are modest and represent 20% of imports.

The production equipment market is highly volatile (\$50-100M per year). As there are essentially no domestic manufacturers, the equipment is imported from Germany, the USA and the UK.

In terms of laboratory research equipment, there are only small domestic equipment manufacturers and major international equipment manufacturers have local subsidiaries.

5. Biologics

In 2010 the Brazilian biologics market reached \$1802M¹⁶. The market is expected to exceed \$6bn by 2017 with a growth rate of 19% over the period¹⁶. Growth will increase in 2014 due to several biologics going out of patent. The leading segment will be monoclonal antibodies which already represented almost half of the market in 2010. Market shares of other segments are shown in the table below.

Table 6: Biologics Market Segments and Market Shares (2010)¹⁶

Segment	Market share (%)
Monoclonal antibodies	42.6
Interferon	8.5
Blood agents	11.5
Filgrastin	3.9
Somatropin	3.6
Erythropoietin	8.2
Insulin	21.6

Expertise, technology and investment required for the production of biologics constitute barriers to entry that have limited the development of this market. Development and production of biologics can be significantly more onerous than of chemical drugs due to the longer development time and level of quality control required during manufacturing. In addition requirements for more animal and clinical studies and trials are another challenge that makes the development of biosimilars more difficult than generics (see Figure 2). Further, there is a lack of regulation and approval process for biosimilars. Finally, a number of biologics based treatments are not reimbursed by private insurances.

Market expansion has been driven by government sponsored programs aiming to make expensive medicines such as blood factors available to the public, investment from global biologics companies as well as investment from biosimilars companies from other emerging markets especially India.

There are four Brazilian companies involved in the development of biologics: Meizler, Biosintética, Blausigel, and Cristália. The market is dominated by large multinational companies (Amgen, Roche, Novo Nordisk, Eli Lilly, Sanofi-Aventis, Abbott, and Pfizer). Roche, Eli Lilly and Novo Nordisk are market leaders with respective market shares of 24%, 13% and 9% in 2010¹⁶.

Out of 26 brands of biologics only 8 are Brazilian and have lower penetration than their international competitors. Multinational companies have acquired several Brazilian laboratories (Laboratório Bergamo acquired by Amgen in 2011; Acquisition of a 40% share of Teuto by Pfizer), and developed partnerships (Joint venture of Supera with Merck). However several established Brazilian pharmaceutical companies are trying to enter the biologics market:

- EMS, the largest Brazilian generic manufacturer established a partnership with Shanghai Biomabs Pharmaceutical Co to produce biosimilars;
- Lifemed acquired FK Biotecnologia and tries to penetrate the cancer vaccine and monoclonal antibody market;
- União Química is entering the human insulin segment.

6. Medical devices

The medical device market in Brazil was estimated at \$4,680M in 2011 and expected to grow at a 16% CAGR through to 2015⁶. This is the largest medical device market in market in Latin America and the second among emerging countries after China in terms of medical equipment sales revenue.

Drivers and restrains

The market is driven by an increase in cardiologic diseases and the associated demand for monitoring and interventional devices, the penetration of low cost versions of a range of medical devices developed by Chinese and Brazilian companies, the need for radiotherapy devices for cancer treatment and for paraenteral and enteral nutrition devices. The market is also sustained by the importance placed by the Brazilian population on physical aesthetics leading to a large number of cosmetic procedures. For example, the domestic dental implant market was worth \$295 millions in 2011 and the Brazilian implant manufacturer Neodent became one of the top 10 dental implant manufacturers worldwide. However market expansion is restrained by a lack of adoption for new technologies, high dependency on importation and exchange rate, and increased requirements for quality controls. Leading growth import opportunities are expected to be in the cardiology, orthopaedic and telemedicine/mobile health segments.

High growth segments

The mortality rate from coronary heart disease is expected to triple in Latin America over the next 20 years fuelled by high obesity, cholesterol and hypertension rates among the population. The Brazilian Ministry of Health created new resolutions for the treatment of acute myocardial infarction and acute coronary syndrome including new guidelines, increased reimbursement for procedures, establishment of coronary care units and funding for 700 beds. Further, pharmacological stents might become reimbursed as soon as 2013.

The aging population, decreased device cost and increased reimbursement by private insurers will fuel the growth of the orthopaedic medical device market which is expected to reach \$700M by 2015⁶.

Telemedicine for the management of chronic diseases is also a promising area with 20% annual growth in Brazil. The Federal Government will invest \$38.9M in its telehealth programme this year.

Government support for the sector

In June the Brazilian government announced a stimulus package for the sector targeted at local medical technology companies and public hospitals. As part of the package, public hospitals will be encouraged to buy local equipment instead of imported equivalent products as long as the local products are no more than 25% more expensive than imports. BNDES will provide credit for hospital equipment tied to requirements that at least 60% of the money is spent on domestically produced equipment.

Regulations – selling in Brazil²⁰

Brazil is a member of MERCOSUR (Southern Common Market) which also includes Argentina, Paraguay and Uruguay. The registration of medical devices is harmonised between these countries making it easier to gain admission to other countries when registered in one of them.

To sell medical devices in Brazil companies need to be registered with ANVISA and only companies based in Brazil can apply for this registration. Therefore foreign companies either need a local subsidiary or an agreement with Brazilian third parties. Selection of third parties is a strategic decision. Three possible approaches are:

- Use of a local manufacturer and distributor,
- Use of a combination of a local hosting company - who will provide a registration and license holding service - and a distributor - who will import and distribute the product. A change of distributor will not require re-registering the product.
- Use of a license holding distributor, who will share registration cost as part of the distribution agreement. In this case, changing distributor requires a new registration.

In Brazil, medical devices are classified in four categories (I to IV) based on increasing risk to patients or users. While the process is broadly similar to those of other countries, it can be lengthy and range from three months to two years depending on the type of submission. In addition to the selection of a Brazilian third party or creation of a subsidiary, the following are required for the registration process:

- A Certificate of Free Sale notarized by the Brazilian consulate showing that product is approved in home market (can sometimes be replaced by INMETRO certificate, see below).
- A certification from the National Institute of Metrology Normalisation and Industrial Quality (Instituto Nacional de Metrologia, Normalização e Qualidade Industrial or INMETRO) for some devices including electrically powered ones.
- A GMP certification, valid for 2 years, based on an inspection by ANVISA, is also required for all class III and IV devices as well as some class I and II.
- An Economic Information Report, which includes pricing comparison and patient information, is required for some devices (e.g. implantable medical devices, cardiovascular products, dialysis equipments and personal hearing aids).
- Some clinical trial data that meet ANVISA requirements might be necessary for high risk devices.
- A technical file which is somewhat similar to FDA 510(K) or CE marking

The above documents then need to be submitted to ANVISA as part of the registration package. Reviews take 6 to 12 months for most devices of class I to III. ANVISA registration and INMETRO Certificates need to be renewed every five years. ANVISA conducts on-site GMP audits every two years and requires report of self inspection the other years.

While importing to Brazil might be involving in terms of regulatory compliance and identification of a partner or set up of a subsidiary, there are several examples of Scottish SMEs that have successfully engaged in this process. For instance, Touch Bionics has partnered with a Brazilian company to distribute its product and train Brazilian patients and practitioners interested in Touch Bionics' products. Trade missions often facilitate the partner finding process.

Recent foreign investment

In 2008, Philips acquired Brazilian-based Dixtal Biomédica e Tecnologia, a leading Brazilian manufacturer of in-hospital patient monitoring, anesthesia, ventilation equipment, and ECG (electrocardiogram) as well as other sensors for vital sign measurements. Dixtal will become part of Philips' Healthcare division.

Acquisition of Dixtal extended Philips' product portfolio to include Dixtal's mid- to economy-range patient monitoring products, and gave Philips access to Dixtal's anesthesia machines and its invasive ventilation products.

7. Healthcare IT

The Brazilian healthcare IT market was estimated to be \$411M in 2011 and expected to reach \$714M in 2015⁶. Key drivers include the need to improve productivity in hospitals and the growth of mobile health apps related to the expanding tablet and smartphone market. Private hospitals have been trying to increase efficiency and this should increase the need for electronic medical record systems and hospital information systems. However, the market expansion is limited by a lack of awareness of the benefits of such systems and by a lack of basic infrastructure (internet links, phone links...) in rural areas.

Recent foreign investment

Agfa HealthCare, a healthcare company and member of Agfa-Gevaert Group, acquired WPD Informatica Ltda (WPD), last year. Through this acquisition, Agfa HealthCare entered the Brazilian market for Hospital Information Systems. The combination of the technology from both companies will create a state-of-the-art clinical information management system. This acquisition enabled Agfa HealthCare to enter Brazilian market for both Imaging and IT systems for radiology.

In 2010, Philips acquired Tecso Informatica, one of Brazil's leading radiology information systems, and Wheb Sistemas, a leading Brazilian provider of clinical information systems. Clinical informatics systems integrate information among various hospital departments (e.g., radiology, cardiology) and help to streamline workflow and manage costs, while providing high-quality care. These acquisitions made Philips one of Brazil's leading clinical informatics companies.

8. Medical imaging

The Brazilian medical imaging market was estimated to be \$616M in 2011 and is expected to reach \$952M in 2015 representing a year-on-year annual growth of 11.5%⁶.

The market expansion is driven by:

- Inclusion of PET scans in the list of procedures covered by private insurance plans for people suspected of having lymphoma or lung cancer;
- Significant amount and means of funding for companies wanting to further their technologic capabilities;
- Increased use of portable ultrasound systems.

However the market expansion will be limited by several factors including:

- Limited share of new imaging technologies such as MRI and CT (4.1%) among the currently installed base mainly composed of X-ray machines;

- Concentration of the imaging machine park in private hospitals (only 29.7% in public health institutions);
- Lack of trained professionals to operate advanced imaging equipment.

Recent foreign investment

Philips Medical Systems acquired VMI-Sistemas Medicos in 2007. VMI, was a Brazilian imaging diagnostic company based in Minas Gerais. Through this acquisition, Philips became a leader in general x-ray in Brazil and gained the ability to produce both analogical and digital x-ray equipment in Brazil offering more affordable solutions to the local market.

9. Clinical diagnostics

The clinical diagnostics market was estimated to be \$659M in 2011 and is expected to reach \$949M in 2015 after a year-on-year annual growth of 9.6%⁶. The market growth is driven by an increase of people with private insurance, a trend toward the modernisation of infrastructure across the country, the creation of 12 additional public health laboratories performing molecular biology test and the development of point of care testing. The two major private clinical diagnostic laboratories in the country are Dasa and Fleury. However market expansion is still limited by the lack of awareness and accessibility for testing in rural areas and Brazil dependence on imports (97%) for diagnostics kits.

10. Analysis of Brazilian biotechnology industry²¹

The Brazilian biotech market is estimated to be \$6-7bn. In this section biotechnology companies are defined as companies that apply biological organisms, biological systems or biological processes, for important projects either in internal R&D or in manufacturing or provision of specialist services. Also included are companies that are important for the sector such as bioinformatics, specialised consultancy companies and CROs.

Brazil's approximately 240 biotechnology companies focus on the following key sectors as shown in the table below with their geographical implantation: agriculture, animal health, bioenergy, human health, and reagents.

Table 7: Repartition by sector and implantation of companies

Sector	Definition	% of biotech companies	Areas of implantation
Human health	Drug development, vaccines, cell therapy, stem cell research, development of new vectors and formulations, diagnostic, recombinant proteins.	39.7	São Paulo (50%), Minas Gerais (20%), Rio de Janeiro (16%)
Animal health	Genetic improvement and cloning, drugs and vaccines, development of new technologies in animal reproduction	14.3	São Paulo (41%), Minas Gerais (32%)
Reagents	Enzymes, reagents for diagnostic kits, bioactive molecules, antibodies	13.3	São Paulo, Minas Gerais (70%)
Agriculture	Biological pest control and biofertilizers, transgenic seeds and plants, genetic improvement and cloning	9.7	São Paulo, Minas Gerais (70%)
Environment	Bioremediation, waste management and recovery of degraded areas	9.7	Rio de Janeiro (44%), São Paulo, Minas Gerais
Bioenergy	New technologies for biofuels	5.1	São Paulo
Other	Development of molecular diagnostic tests, bioinformatics companies, specialized consultancies and CROs	8.4	

The Brazilian landscape for biotech companies has several key interesting characteristics:

- The majority of companies are micro or small sized: 56% have revenues of \$1.5M or less. Only 10% have revenues in excess of \$7.5M.
- 80% of companies have less than 50 employees; 9% of companies have more than 100 employees;
- 50% of companies have plans to export but 86% of them import reagent, equipment and services;
- 30% of companies are incubated and 20% have graduated from a business incubator;
- 95% of companies have some kind of relationships with Universities or research centres and in 77% of the cases the aim of this relationship is co-development of products or processes;
- 78% of companies use some kind of public funding for R&D;
- 14% of companies use venture capital funding;
- 40% of companies have patents issued or applied for;
- 40% of companies are located in the state of São Paulo, 25% in the state of Minas Gerais and 13% in the state of Rio de Janeiro. In other words, 78% of companies are concentrated in a circle with a 600km diameter.

Most Brazilian biotechnology companies are oriented toward innovation: 66% of them sell internally developed products.

Overall companies are young with 73% of companies having been established for less than 10 years.

Sugarcane and biofuels

Brazil is the world's largest sugarcane producer. In Brazil sugarcane is used to produce both sugar and alcohol. Sugarcane has the best energy balance ratio of all four crops used to make ethanol (sugarcane, corn, beet and wheat). Ethanol became a major product following a government programme to reduce dependence on foreign oil launched in response to the two oil crises of the seventies. Nowadays, nearly all cars sold in the country are designed to run on a mixture conventional fuel / ethanol and work with a proportion of up to 100% ethanol. Brazil has key assets for ethanol production: know how, favourable climate, and available land suitable for growing cane without requiring deforestation or competition with food production. Brazil and the United States are the world leading producers of ethanol. However the USA produce ethanol mainly from corn. Brazil is now importing ethanol from the US to satisfy local demand and its ethanol imports might balance its exports as crop yields are expected to decrease in 2012.

A number of research initiatives are ongoing to improve cultivation and exploitation of sugarcane: ethanol production processes from cane sucrose are being optimised, ways to produce ethanol from cane cellulosic and hemicellulosic parts (bagasse, leaf litter and stalk tips) are being researched and sugarcanes are being genetically modified to become more drought tolerant. This year the National Development Bank (BNDES) and the Science and Technology Finance Agency (FINEP) will spend \$600M in financing for projects focusing on cellulosic ethanol production. This process could potentially increase ethanol production from existing crops by 50%. BNDES has also allocated \$1.1bn to produce new biochemical products from sugarcane and bagasse.

Genetically modified (GM) crops

33.3M hectares were cultivated with GM crops in 2011, making Brazil the second producer after the USA (69M hectares). GM crops cultivated in Brazil are mainly maize, soybean and cotton. However, most GM crops planted in Brazil have been imported.

The first Brazilian engineered GM crop, a transgenic bean, has been approved last year by the Brazilian National Technical Commission on Biosafety (CTNBio). Beans are highly nutritious and one of the most important legumes consumed by over 500 million people in Latin America and Africa. Beans are also the major source of protein for the economically disadvantaged. Currently Brazil is the largest producer, responsible for approximately 20% of the global production (3.8 million tons in the 2010/2011 period). 70% of the country's production is made by small farmers (less than 100 hectares) and Brazil does not produce enough to meet its own needs. The major threat to the farmer's plants, causing losses of up to a 100%, is the golden mosaic virus. In Brazil

alone, annual losses vary between 2 and 7% of the production. That would be enough to feed up to 18 Million adults in the country. The transgenic bean developed by the Brazilian Agricultural Research Corporation (Embrapa), a public research institution linked to the federal government is engineered to be resistant to the golden mosaic virus.

Genetically modified mosquitoes

Earlier this year, Brazil has opened its first large-scale genetically modified mosquito farm in an effort to reduce the incidence of dengue fever. The GM mosquitoes, engineered by the UK firm Oxitec, can only grow and reach maturity if provided the antibiotics tetracycline. When the GM mosquitoes grown with the help of tetracycline are released in the wild, their offspring, lacking the needed tetracycline, dies reducing drastically the mosquito population. Previous experimental release of the GM mosquitoes in selected areas of Brazil led to 90% decrease of mosquito populations.

Recent foreign investment

Amyris, the US synthetic biology company, has set up a Brazilian subsidiary with a pilot plant employing more than 100 people in Campinas, SP. The company is using its proprietary engineered yeast to produce Biofene[®], Amyris's brand of farnesene, from sugarcane. Biofene can be transformed for a wide variety of chemical applications including: lubricants, base oils, cosmetics ingredients, polymers and plastics additives, flavors, fragrances and surfactants. Amyris has also completed an industrial scale facility for the production of Biofene[™], in Piracicaba, SP at a facility owned by Biomin do Brasil Nutrição.

In 2008, Monsanto acquired the sugarcane breeding and technology companies, CanaVialis S.A. and Alellyx S.A. for \$290M. CanaVialis was the world's largest private sugarcane breeding company, developing and commercialising proprietary plant's genetic raw material, to bring significant yield increases to sugarcane production over publicly available varieties. Alellyx was an applied genomics company focusing on developing biotech traits for sugarcane.

11. Animal Health

Cattle and poultry

Brazil has the world's largest number of beef heads (205M) that are almost exclusively grass fed, making it in 2011 first among producers and exporters worldwide. In 2011 Brazil was also the 4th largest producer and exporter of pork and the 4th largest producer and 2nd largest exporter of turkey meat. Brazil is also the third largest producer of chicken meat²².

Brazil's strengths in these areas are supported by its self sufficiency in terms of crop production for animal feed.

The 50 top Brazilian food companies are responsible for 80% of the slaughter²³. In 2011, Brasil Food (BRF) with revenues in excess of \$20bn and over 115,000 employees was the largest Brazilian meat exporter, the 5th Brazilian exporter and the world's largest chicken exporter. Scotland strengths in animal health (including improved breeding) are world leading: the Scottish animal health research cluster is the largest in Europe and there is a small but growing cluster of dynamic SMEs in this field. Collaborating with Brazil in this area could clearly benefit Scottish businesses and research institutes.

Aquaculture

Brazil has 8,500 km of coastline, and 12% of the world's freshwater reserves including 10M hectares of freshwater reservoirs (many of which are associated with hydroelectric production). With production of 500,000 tons estimated for 2011, Brazil currently ranks at position 17 worldwide for aquaculture production. However, the government has ambitious plans to develop the sector and intends to make Brazil the 10th largest producer by 2015 (1 million tons) and double this production level by 2020²⁴. Three years ago a new Ministry was created for the Fishery and Aquaculture Sector. This has led to several National Aquaculture Plans which have increased investment in the field (infrastructure, logistics, credit facilities, education and training, new cooperatives, and promotion of healthier and safer fisheries and aquaculture products in the domestic market). Further, the Ministry has reduced bureaucracy and promoted sustainable and regulated use of Brazil's resources.

Collaborations have been initiated between Embrapa and Stirling Institute of Aquaculture. Based on Scotland's expertise in aquaculture and Brazil's ambitions and potential in the field, developing such collaborations might represent a significant opportunity for Scottish businesses and research institutes. The Scottish company FishVet Group has already an operational site in Brazil and offers an example of how Scottish companies can seize opportunities in this emerging market.

12. Analysis of academic and public research in life sciences

In 2011, out of 65,882 university professors, 25,889 (~39%) were working in life sciences and related areas including medical sciences. A breakdown of the numbers of professors in life-science or related disciplines is shown in Appendix 1.

The number of doctorate has tripled over the past 10 years from 3,797 in 1998 to 10,705 in 2008. 42% of the doctorates were awarded in the life sciences segment (18% in the health area, 12% in

agro sciences, and 12% in biological sciences)²⁵. Simultaneously scientific production has increased from 1% of global share in 1992 to over 2.7% in 2008²⁵ while Brazil has increased its research output from about 8,000 papers in 1998 to over 17,500 in 2007²⁵.

Brazil's research has significantly expanded over the past few years in the areas of genomics, stem cells and regenerative medicine, and neurosciences. Brazil was the first Latin American country to allow embryonic stem cells to be used in May 2008 and the fifth nation in the world to produce induced pluripotent stem cells. In 2009, the National Cellular Therapy Network (RNTC) invested R\$ 22 million in building eight Mobile Technology Centers that will produce stem cells, and R\$ 10 million in 49 stem-cell research projects with long-term objective to provide SUS with new therapies. Brazil has also been hosting a number of stem-cell clinical trials. Further, Brazil is one of the leaders in tropical medicine, parasitology and agro-biotechnology (second position worldwide in cultivation of genetically modified plants) as shown in the table below.

Table 8: Share of world paper per research field

Field	Share of world papers % (2003-2007)
Tropical medicine	18
Parasitology	12
Multidisciplinary agriculture	9
Oral surgery and medicine	8
Entomology	7
Dairy and animal sciences	6
Biology	6
Soil sciences	6
Veterinarian sciences	6
Zoology	6

Based on Thomson Reuters Web of Science data²⁵

The most well know universities are:

- Universidade de Sao Paulo (USP)
- Universidade de campinas (UNICAMP)
- Universidade Federal de Rio de Janeiro (UFRJ)
- Universidade Federal de Minas Gerais

Several key public centers are leading research in life sciences (see Appendix 2 for details):

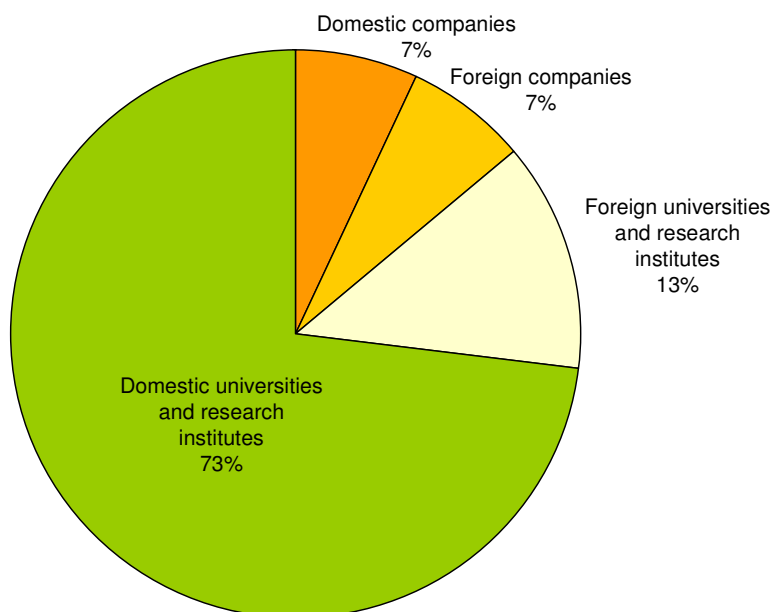
- Centro de Biotecnologia da Amazônia

- Centro de Biotecnologia da Universidade Federal do Rio Grande do Sul
- Centro de Referência em Farmacologia
- Empresa Brasileira de Pesquisa Agropecuária
- Escola Superior de Agricultura "LuizQueiroz" da Universidade de São Paulo
- Fundação Osvaldo Cruz
- Instituto Agrônômico de Campinas
- Instituto Butantan
- Instituto de Ciências Biológicas da Universidade Federal de Minas Gerais

Only Fundação Osvaldo Cruz and Instituto Butantan have a performance comparable to the above cited universities.

The importance of Brazilian universities for the technological and economic development of the country is illustrated by the figure below showing the predominant share of Brazilian universities in patent licensing to companies. This shows the crucial role of Brazilian universities in maintaining the dynamism of the sector and explains the government efforts to develop industry-academia partnerships and collaborations.

Figure 3: Origin of licensed patents¹¹



Several partnerships and collaboration agreements have recently been signed between UK and Brazilian universities. A new scheme from the Universities of Nottingham and Birmingham started in 2011 to attract and support Brazilian postgraduate students (3 year PhD scholarship) and

researchers (3 month research support) who wish to receive training or carry out research in the UK focusing on several priority areas including food security, global infection and healthcare²⁶.

In 2011 as well, the National Environment Research Council (NERC), under an agreement with the Research Council for the State of Sao Paulo (PAPESP) to streamline application processes for joint projects, awarded a grant to support a joint research project focusing on the study of the Amazonian atmosphere and its potential influence on the regional and global climate²⁷.

In September 2012, the University of Aberdeen signed a £4.5 million partnership with the University of Rio Grande de Sul and the UK Energy company BG group, which is active in Brazil, to develop new technology focusing on the Brazilian oil and Gas industry. Another agreement involves research collaboration between eight UK and Brazilian universities and British Petroleum²⁸. Similar agreements could be envisioned in the life science sector.

13. Opportunities for Scottish companies

Brazil is a platform used by foreign companies to penetrate the Latin America market: Brazil is the largest market in South America (40%) and is part of regional trade agreements allowing Brazilian based exporters to sell drugs tariff free or at highly preferential conditions within Latin America. In addition, regulations in terms of sanitary requirements, GMP and quality control are such that most drugs and medical devices made in Brazil can be directly sold in most Brazilian export markets. However strict and sometimes idiosyncratic business regulations often require the help of local experts.

Corporate partnerships are of interest to Brazilian companies as means to access further funding, know how, regulatory and market knowledge and routes to foreign markets, while sharing risk. They could also help Brazilian companies deal with shortages of skilled business development professionals with technical, commercial and negotiation expertise.

There is also an acute shortage of people experienced in scale-up of biotechnological processes and therefore opportunities for consultancies and partnerships.

There are clear opportunities for CROs especially in the biologics area. The number of clinical trials is expected to grow year on year by 6% to reach ~740 by 2015, leading to a CRO market size of \$182M.

E-health/telehealth is another high growth market partly due to Brazil's geography and population implantation. As Scotland is very active in this area (DALLAS project), there might be opportunities for Scottish enterprises and academic groups working in this field. Scotland has been an early supporter/adopter of some of these technologies (telehealth programme).

In terms of laboratory research equipment, there are only small domestic equipment manufacturers and major international equipment manufacturers have local subsidiaries.

Brazil is poised to expand its GM crop production and to overtake the US as the world leader in cultivation of genetically modified plants. Brazil has also significant research expertise in this area. There are opportunities for Scottish institutes, universities and companies to develop partnerships to expand their expertise in GM crops and potentially test and commercialise them. In Europe and Scotland, regulations partly fuelled by the anti-GM lobby have limited the research and commercialisation of such crops with the risk for local research in this field to lose its cutting edge. Further, Brazil's open attitude about GMOs might be an opportunity to test specific applications in the country. Of course there is some sensitivity about the release of GMOs in Brazil and the applications will likely need to present clear potential benefits for the country.

Brazil is also a world leader in biofuel production and use. There may be opportunities for partnerships in this area which is linked to Scottish initiatives in industrial biotechnology and synthetic biology.

Brazil's enormous cattle and poultry industry and ambitions in aquaculture are potential opportunities for Scotland's businesses and world-leading research organisations in these areas.

APPENDIX 1: Number of university level professors per life science discipline

Discipline	Number of professors	Percent of total number of professors across all disciplines
Agronomy	1990	3.0%
Environment and agriculture	1416	2.1%
Agricultural engineering	248	0.4%
Fishing and Forest resources and engineering	529	0.8%
Plant health and pathology	124	0.2%
Plant technology	251	0.4%
Plant improvement	126	0.2%
Cellulose and paper science	11	0.0%
Zootechnics	772	1.2%
Animal production	87	0.1%
Nutrition and animal feeding	14	0.0%
Veterinary medicine	993	1.5%
Clinical veterinary medicine	51	0.1%
Animal pathologic anatomy	31	0.0%
General medicine	979	1.5%
Preventive medicine	105	0.2%
Clinical medicine	659	1.0%
Anaesthesiology	29	0.0%
Cardiology	155	0.2%
Dermatology	20	0.0%
Endocrinology	95	0.1%
Gastroenterology	43	0.1%
Haematology and histology	39	0.1%
Infectious diseases	617	0.9%
Medical radiology	97	0.1%
Nephrology	52	0.1%
Neurology	242	0.4%
Nutrition	373	0.6%
Obstetrics and gynaecology	150	0.2%
Ophthalmology	40	0.1%
Oncology	178	0.3%
Orthopaedics	37	0.1%
Pathologic anatomy and clinical pathology	405	0.6%
Paediatrics	246	0.4%
Pulmonology	46	0.1%
Surgery	504	0.8%
Nursing	1029	1.6%
Pharmacy	987	1.5%
Pharmacology	277	0.4%
Dentistry	1635	2.5%

Clinical dentistry	75	0.1%
Orthodontics	37	0.1%
Endodontics	43	0.1%
Dentistry materials	28	0.0%
Biophysics	161	0.2%
Biology	923	1.4%
Biological system modelling	10	0.0%
Biochemistry	545	0.8%
Biomedical engineering	189	0.3%
Biotechnology	989	1.5%
Botanics	549	0.8%
Ecology	1094	1.7%
Genetics	598	0.9%
Immunology	161	0.2%
Microbiology	341	0.5%
Molecular biology	80	0.1%
Morphology	186	0.3%
Neurophysiology	38	0.1%
Parasitology	212	0.3%
Physiology	487	0.7%
Taxonomy	35	0.1%
Toxicology	46	0.1%
Zoology	694	1.1%
Collective health	934	1.4%
Health and biology	1162	1.8%
Maternal and infantile health	97	0.1%
Public health	412	0.6%
Epidemiology	81	0.1%
Total	25889	39.3%

Source: Data from CAPES, <http://geocapes.capes.gov.br/geocapesds/>, accessed on 25 July 2012

APPENDIX 2: Leading public research centers

Centro de Biotecnologia da Amazônia (CBA/AM) located in Manaus (AM) has 25 laboratories dedicated to the biodiversity of the Amazon region and focusing on microbiology, biochemistry and molecular biology, pharmacology and toxicology, natural products and extract production.

Centro de Biotecnologia da Universidade Federal do Rio Grande do Sul (CTbiot) located in Porto Alegre (RS) performs research on genetics and molecular biology of microorganisms, biological control, molecular diagnostic of diseases (humans, animals and plants), animal health and reproduction, and plant biotechnology.

Centro de Referência em Farmacologia (CRF) - Fundação CERTI located in Florianópolis (SC) conducts non-clinical studies (including pharmacodynamics, pharmacokinetics and toxicology), supports research and contributes to the development of pharmaceutical drugs and cosmetics production.

Empresa Brasileira de Pesquisa Agropecuária (Embrapa) is a company owned by the Brazilian government leading development of bio and nanotechnology for agribusiness with laboratories for cloning, molecular biology, tissue culture, bioremediation, genetic engineering, nanoparticles and development of transgenic organisms. It has implantations in several Brazilian states and also provides incubation space for new enterprises in agribusiness.

Escola Superior de Agricultura "LuizQueiroz" da Universidade de São Paulo (ESALQ-USP) located in Piracicaba (SP) offers undergraduate and graduate courses and focuses on R&D in biotechnology for agriculture.

Fundação Osvaldo Cruz (Fiocruz) located in Rio de Janeiro (RJ) is a federal research institute with many biotechnology related departments and research projects with units developing and manufacturing medicines and vaccines (Bio-Manguinhos and Far-Manguinhos).

Instituto Agrônomo de Campinas located in Campinas (SP) is an Institute of the São Paulo State Department of Agriculture with research centers dedicated to research on coffee, sugarcane and plant genetics.

Instituto Butantan located in São Paulo (SP), a state institute, is one of the biggest research centers in biomedicine, responsible for the production of 90% of the serum and vaccines made in Brazil as well as products such as anatoxins and hemoderivatives.

Instituto de Ciências Biológicas da Universidade Federal de Minas Gerais (ICB - UFMG) located in Belo Horizonte (MG) has 10 departments with several research laboratories focusing on genetics, pharmacology, biochemistry, immunology and microbiology.

APPENDIX 3: Brazilian venture capital

<http://www.fundocriatec.com.br/>

<http://www.votorantim.com.br/pt-br/negocios/novosnegocios/Paginas/novosNegocios.aspx>

http://www.fircapital.com/fircapital/web/default_pti.asp?idioma=0&conta=45

<http://www.riobravo.com.br/en/Pages/Home.aspx>

REFERENCES

- 1 When not otherwise specified, data in this section are from: Central Intelligence Agency. The World Factbook; <https://www.cia.gov/library/publications/the-world-factbook/>; accessed on 12 July 2012
- 2 World DataBank – World Development Indicators and Global development Finance; <http://databank.worldbank.org/ddp/home.do>; accessed on 5 September 2012
- 3 *Emerging Markets Weekly Economic Briefing*; 24 August 2012; Oxford Economics
- 4 *Emerging Markets Weekly Economic Briefing*; 20 July 2012; Oxford Economics
- 5 Rutherford, T.; Population Ageing: Statistics; Standard Note SN/SG/3228; 10 Feb 2012; House of Commons Library
- 6 Healthcare Landscape, Outlook, and Growth Opportunities in Brazil; June 2012; FROST & SULLIVAN
- 7 Paim J. et al; The Brazilian health system: history, advances, and challenges; 2011; *Lancet* 377; 1778-97
- 8 Emerson, J.W., Hsu A., Levy, M.A., de Sherbinin, A., Mara V., Esty, D.C., and Jaiteh, M.; 2012; 2012 Environmental Performance Index and Pilot Trend Environmental Performance Index; New Haven; Yale Center for Environmental Law and Policy
- 9 Biodiversity Barometer 2012, Union for Ethical Biotrade.
- 10 Doing Business 2012 - Economy Profile: Brazil; The International Bank for Reconstruction and Development - The World Bank
- 11 PricewaterhouseCooper Brazil Ltd; The Brazilian life science industry: pathways for growth; 2011
- 12 Groth, A., Liechtenstein, H., and Lieser, K., The Global Venture Capital and Private Equity Country Attractiveness Index; 2011
- 13 Overview of the Brazilian Venture Capital and Private Equity Industry; Research report; Dec 2008; Edition sponsored by Pinheiro Neto Advogados; Deloitte
- 14 The Money Tree™ Report by PriceWaterhouseCoopers and the National Venture capital Association based on data from Thomson Reuters; Press Release; Jan 24, 2009
- 15 Grando, F.; Brazil's Biotech Policy; <http://portal.saude.gov.br/portal/arquivos/pdf/Apresentador2FrancelinoGrando.pdf>; accessed on 28 Sep 2012
- 16 Biologics Market in Brazil; March 2012; FROST & SULLIVAN
- 17 Brazil's Pharmaceutical Industry – Opportunities for Swiss Suppliers; June 2010; OSEC
- 18 <http://www.anvisa.gov.br/eng/index.htm>; accessed on 31 July 2012
- 19 Brazil - EU Bilateral Trade and Trade with the World; DG Trade; 21 Mar 2012

-
- 20 Medical Device Approvals in Brazil: A Review and Update; 2011; White Paper, Underwriters Laboratories Inc.
- 21 Brazil Biotech Map 2011; Brazilian Center for Analysis and Planning
- 22 Rangel, M. ; The Brazilian Poultry Industry ;Global Good Agricultural Practice Tour 2011; União Brasileira de Avicultura
- 23 Nunes, F.G.; Brazil - Meat and poultry production; *Meat Trade News Daily*; 27 Apr 2012
- 24 Roderick, E.; Brazil, Potential Next Big Aquaculture Producer; World Aquaculture 2011 - Natal, Brazil ; *Panorama Acuicola Magazine* ; August 30, 2011
- 25 King A. C.; Global Research Report – Brazil; June 2009; Thomson Reuters
- 26 UK universities' partnership deepens links with Brazil; 23 Jun 2011;
<http://www.birmingham.ac.uk/news/latest/2011/06/23June-UK-universities-partnership-deepens-links-with-Brazil.aspx>; accessed on 05 Oct 2012
- 27 UK researchers to take the lead in international partnerships; 06 Jul 2011; NERC Press Office,
<http://www.manchester.ac.uk/aboutus/news/display/?id=7211>; accessed on 05 Oct 2012
- 28 Aberdeen signs pioneering research partnerships in Brazil; 2 Oct 2012;
<http://www.abdn.ac.uk/news/details-13199.php>; accessed on 05 Oct 2012

If you are interested in additional information about any of the areas covered within this document, please contact:

Dr. Nicolas Peyret
nicolas.peyret@scotent.co.uk
or
enquiries@scotent.co.uk

© Scottish Enterprise 2012