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SPECIAL PUBLICATION OF BRAZILIAN PHARMA SOLUTIONS

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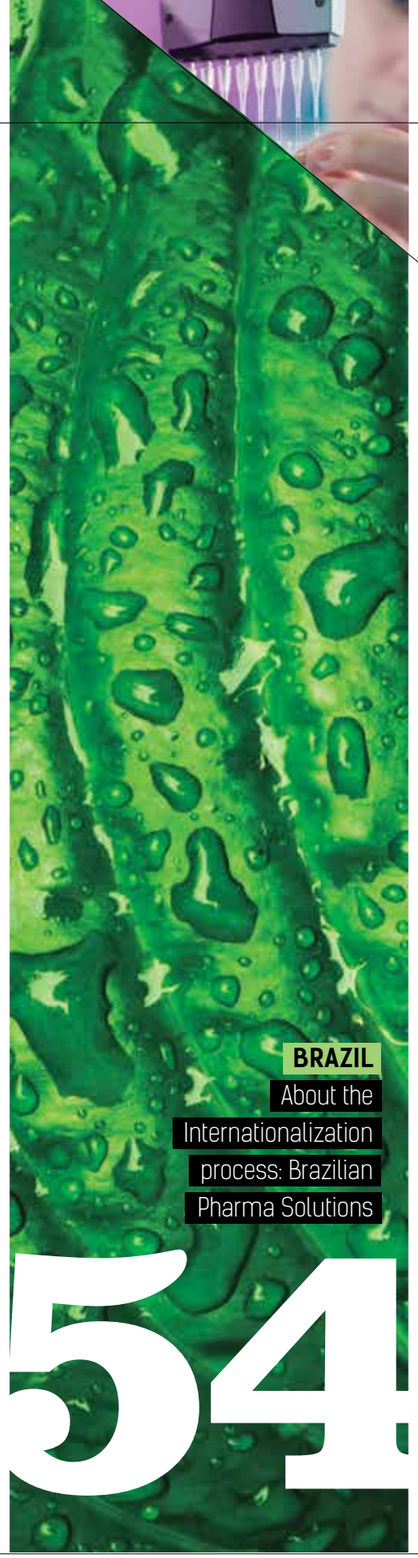

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There is an ingenious spirit in the core of Minas Gerais' culture. It is something that leads the state towards its own development, and shows Minas Gerais as a great pole for R&D.

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INDI, the Minas Gerais Investment and Trade Promotion Agency, and Fiemg, the Federation of industries of Minas Gerais, work together to turn your business feasible in this land of preciosities.

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Brazilian Government Fostering Innovation

The scientific development of any economic sector depends on the articulation and cooperation of agents representing industry, research institutions and government. In Brazil, the innovation dynamics is highlighted by the interdependency of these agents. The scientific research is concentrated within public research institutions, which are mainly financed by the State; however, it focuses on partnerships with the industry for further product and services development.

In this scenario, in 2004 was approved in Brazil the Law of Innovation (nº 10.973) which ensures incentives for innovation and scientific and technological research in the productive environment. Its main objective is to stimulate: the creation of specialized and cooperative innovation environments; the participation of Scientific and Technological Institutions (ICTs) in the innovation process; innovation in companies; the independent inventor; and the creation of investment funds for innovation.

In this environment of innovation and cooperation between ICTs, was created in 2008 the program "National Institutes of Science and Technology" (in Portuguese: Institutos Nacionais de Ciência e Tecnologia) with the main goal of mobilizing and gathering research groups of excellence in strategic areas for the country's sustainable development. The program, which counted with 126 universities and research centers, received investments of approximately BRL 850 MI in in eight different scientific areas for fostering basic research and its articulation with private institutions. This important initiative is coordinated by the Ministry of Science, Technology, Innovations and Communications (in Portuguese: *Ministério da Ciência, Tecnologia, Inovações e Comunicações – MCTIC*) with the support of other national entities. The Biotech sector is included in this initiative, as biotechnology projects are an important part of several supported areas such as the agroindustry, energy, ecology, nanotechnology and health.

The Biotech development is also supported by other initiatives, such as the PIPE (Innovative Research in Small Companies - in portuguese, Pesquisa Inovativa em Pequenas Empresas) which supports financially the execution of scientific research within micro, small and medium-sized ›

companies in the State of São Paulo. The São Paulo Research Foundation is responsible for the PIPE's execution. Other programs, such as the "Inova Saúde" and "Legal Amazon", promoted by the Brazilian Innovation Agency (FINEP), also aims to foster the Biotech sector by financing projects in several companies, small or big, from lab to market.

The MCTIC considers biotechnology as an important part of the current National Science and Technology Strategy. In an interview with Dr. Luiz Henrique Canto Pereira, National Coordinator for Heath and Biotechnology at the MCTIC, it was highlighted that it is a priority theme in the Ministry Policies and actions for the future. These actions, not only made by financial support for research projects, are represented by the formation of structured technology networks, such as several Biotech Research Networks and Technology Service Providers, that were launched in the last decade towards the creation of specialized human resources and training in PhD programs. A more recent initiative was the structuring of SulBiotec network, which aims to solve current industry technology issues through innovative biotech solutions.

According to Dr. Canto, the creation of the Brazilian Network of Alternative Methods (RENAMA) is likewise an important initiative of the Ministry for the healthcare and Biotech sectors. This network's purpose is the adoption, development and validation of methods to animal testing according to the 3Rs Principle (replacement, reduction and refinement), including technology catching-up and supplying toxicological services for both public and private sectors. Considering the outstanding results of RENAMA, Brazil is leading the structuring of a Regional Platform for Alternatives Methods in MERCOSUL which started its activities in 2016.

Another MCTIC important endeavor is the Brazil-Argentina Biotechnology Center-CBAB/CABBIO, an integrative program with regional reach that has been supported for the last 30 years training and collaborative joint projects in the region. Brazil is also contributing with Latin America's biotechnology development through several cooperation agreements with other Latin countries and European Union with the common goal for a harmonic growth and alignment with regulatory issues.

According to MCTIC, international collaboration is an essential part for the development of Biotech in Brazil. Briefly, some ongoing cooperation includes India, through the Department of Biotechnology-DBT, BRICS countries, through the Working Group for Biotechnology and Biomedicine which counts with Brazil and Russia co-lead; Canada within the Working Group on Life Sciences; the International Center for Genetic Engineering and Biotechnology-ICGEB, in this Center Brazil is playing a central and important role; the European Union Joint Research Centre, more specifically with the JRC's European Union Reference Laboratory for Alternative Methods to Animal Testing – EURL/ECVAM with close collaboration with RENAMA.

As already mentioned above, one of the most important Brazilian entities that fosters innovation in the country is FINEP. The Agency's Superintendent of Health, Agribusiness and Chemistry, Mr. Igor Bueno, numbered Biotech investments since 2003. In general, 101 biotechnology projects were financed by non-refundable resources of over BRL ›

The MCTIC considers biotechnology as an important part of the current **National Science and Technology Strategy**

173 MI in 12 open calls. A specific funding line, the "INOVA Saúde" of 2013, financed eight biotech projects for biopharmaceutical products with $ 15 MI Brazilian reais of a total of $ 50 MI non-refundable economic subsidy yet to be invested.

The Agency also has a credit line for healthcare projects and has lent, in the last years, BRL 260 MI to 5 projects with more $ 500 MI Brazilian reais still available for lending.

According to Mr. Bueno, the project selection criteria for biotechnology and health projects funding includes evaluation of the consistency of the innovation strategy; the technical, managerial and entrepreneurial capacity of the team; and the technological and productive content. Substantial results in the Biotech sector are expected for the next years by the Agency, which selects competent companies and follows these projects execution to success.

FINEP has a series of firmed collaborations with other countries financing agencies, such as Canada, Spain, France, Netherlands and others, for the development of joint open calls for technology support, including biotechnology projects financing and international technological partnerships.

Dr. Luiz Henrique Canto Pereira, National Coordinator for Heath and Biotechnology at the MCTIC

Mr. Igor Bueno, Agency's Superintendent of Health, Agribusiness and Chemistry

Also aiming the development of the Biotech industry in the country, the Ministry of Industry, Foreign Trade and Services (in Portuguese, Ministério da Indústria, Comércio Exterior e Serviços – MDIC) sees great potential, in terms of innovation, in the biotechnology applications, such as food, biofuels, cosmetic and pharmaceutical products.

MDIC participates in several fronts of support for innovation. In the Biotech sector, for instance, an important incentive for development is the regulatory support related to biosafety and genetic heritage access. The Ministry is engaged in making regulatory processes more efficient in order to facilitate companies' operations and investments in these segments. The Ministry is also dedicated to the sector's promotion, such as forming delegations for international events, or supporting national conferences with the main objective of approximating the companies to the academy and its researches and projects.

The next industrial revolution is underway from the fusion of several new technologies that have emerged recently, such as new materials, advanced robotics, 3D printing, big data, cloud computing, artificial in- ›

telligence, new materials and new processes. The convergence and connection of this myriad of technologies has changed the way production is structured, the form of demand for products and services, new profitability and monetization models, as well as the training of new talent and the generation of jobs.

This production revolution has been commonly called "Industry 4.0," or the 4th Industrial Revolution, which is the use of digital technologies associated with other technologies in the recent industrial structure, allowing gains in scale, greater efficiency, mass customization, and New manufacturing processes. It is interesting to note that this combination of technologies has a transversal character, impacting all economic sectors, such as automobile, oil and gas, machinery and equipment, mining, agro-industry, biotechnology, just to mention a few, also having a strong change in labor relations, demand for talents, forms of production, value chains, distribution, market access, marketing, etc.

Thus, we can try to materialize the impacts of this new industrial revolution citing Mckinsey's recent report, Perspectives on Manufacturing, Disruptive Technologies and Industry 4.0, which demonstrates that this new revolution will reduce plant maintenance costs by 10-40%, an increase of 45-55% in productivity, reducing the time available to market between 20-50% by 2020. In addition, such a revolution will also change the forms of production in several countries, as well as greatly impact the world of work. According to the same consultancy, there will be a greater gap between the demand for qualified professionals and the supply of professionals with low qualification, that is, many of the current professions will be extinguished and there will be new demand for new professionals, which was exposed in another document made BCG: Man and Machine in Industry 4.0.

In order to build a short- and medium-term policy to begin the preparation of

Rafael Moreira,
Special Advisor for Industry 4.0
Ministry of Industry, Trade and Services – Brazil

Brazil for this new world, the MDIC has established a Working Group for Industry 4.0 (GTI 4.0), which will include the participation of several members of the government, civil society, corporate entities, academia, among other actors, to discuss and present a list of pragmatic actions and short and medium term initiatives for a launch later this year.

The pillars of the National Strategy for Industry 4.0 are to observe and construct instruments that can serve the Brazilian industry independent of its level of technological maturity, focusing on issues related to credit and financing, exports and internationalization, expansion of competitiveness, research, development and innovation. The generation of talent, the construction of experiments and test beds, vital regulatory issues, as well as launching platforms for cross-cutting and non-resolution issues, with a view to increasing the technical density of the discussions national and internationally.

Obviously the biological engineering and advanced biomanufacturing segment will be considered as one of the economic segments in the Brazilian Strategy for Industry

MINISTRY OF INDUSTRY, FOREIGN TRADES AND SERVICES

BRASIL BRAZILIAN GOVERNMENT

4.0. In spite of the size of the sector and its economic and social impacts, Brazil will be fostering new technologies for this industry, such as DNA sequencing, high-throughput prototyping of biological systems, emerging technologies like CRISPR, as well as a suitable regulatory environment for creation of new biological products.

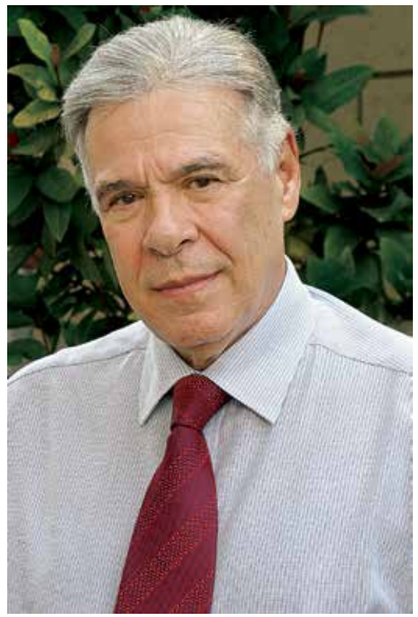
Investments in research networks in the segment, generation of test beds, critical promotion for adoption of new technologies in the public and private health sector, international cooperation, among other initiatives will be part of the Strategy for Industry 4.0 in progress. ●

CRISTÁLIA

FOUNDED in 1969, Cristália is the largest complex for Pharmaceutical, Pharmochemical and Biotechnology products in Brazil. 100% national, it is a country pioneer in the complete drug chain, from molecule conception to the finished product. As one of the most ground-breaking companies in the country, Cristália has 91 registered patents, a national record and proof of constant innovation. Regarding its capacities, it is noteworthy that Cristália produces 53% of its active pharmaceutical ingredients (APIs), while other Brazilian pharmaceutical industries import more than 90% of these APIs.

According to Mr. Ogari Pacheco, Chairman of Cristália's Board of Directors, the company has activities in the Biotech sector for the past 15 years. Cristália operates strategically in a vertical manner in order to face the hard access to some raw materials. In other words, the company develops and produces internally its finished products since cell line development to complete downstream process. The collagenase enzyme, for instance, was conceptualized and developed using a microorganism derived from the Brazilian biodiversity. The company is currently developing other biological products, such as recombinant growth hormones for both human and animal health. The company's biotech strategy also includes the production of monoclonal antibodies, such as trastuzumab and etanercept, as parts of Productive Development Partnerships (PDPs), which involves the Brazilian government support and a binational cooperation for the development process.

Mr. Pacheco pointed out that the company has invested over $ 260 MI US dollars in facilities for biological production and R&D, including clinical studies for its innovative products. Cristália exports APIs and finished products for more than 30 countries in the world and expects to distribute collagenase to the European and North American markets. ●



Mr. Ogari Pacheco, Chairman of Cristália's Board of Directors

CRISTÁLIA
Always a step ahead...

Biotech in Brazil
Current and Future Scenarios

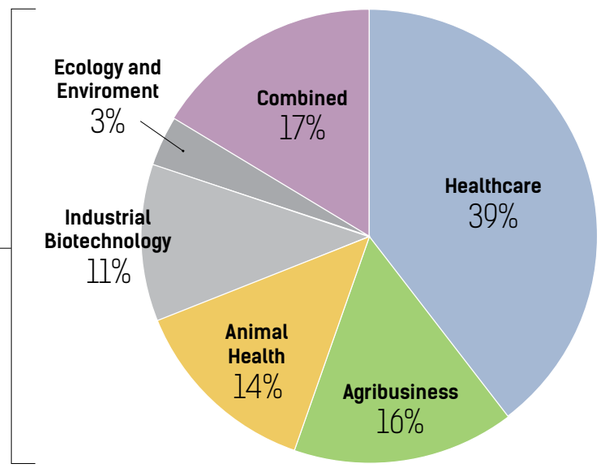
Biotechnology is currently an important driver in the world's economy and its applications have the potential for far-reaching economic, social and environmental impacts. The scenario in Brazil is no different since the country has several advantages favoring the sector's development and growth. Among these advantages, it is possible to highlight: the country's vast pharmaceutical market, the 7th largest in the world, given Brazilian population size and national policies to healthcare access; local resources, since Brazil is one of the most biodiverse countries in the world; strong government R&D incentives and public grants for research; among other factors that, combined, create a progressive environment for innovation.

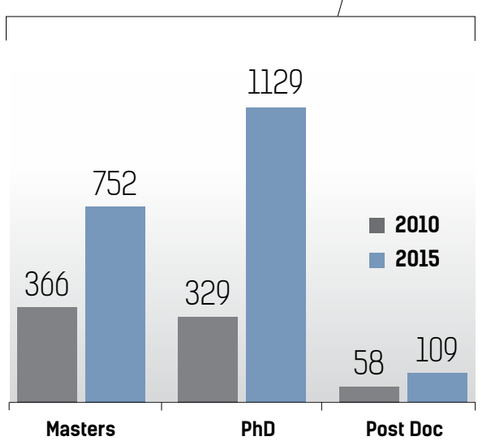
In Brazil, the use of biotechnology advanced techniques was initiated in the 70s, with the advent of genetic engineering applied to the agribusiness, focusing on the development of strains resistant to infestations, diseases and environmental stresses, as well as in the development of more productive species. Differently from the past decades, the current Biotech scenario is mainly focused on human health technologies. A report published by Biominas Brasil, in 2016, showed that 40% of the local biotech companies operate in the human health sector.

The existence of a healthcare model guided by universal access associated with demographic changes in the country, has increased public spending with medicines and, consequently, biologicals. For instance, biological products are the main responsible for the public healthcare spending. Although they represent only 5% of all distributed drugs, these items consume 43% of the Ministry of Health budget for pharmaceutical products. Aiming to revert this picture, the government has been stimulating national production, mainly through Productive Development Partnerships (in Portuguese, Parcerias para o Desenvolvimento Produtivo – PDPs). The PDPs are a process of cooperation through agreements between public and private institutions focused on the development, transfer and absorption of strategic technologies and products of interest to the country's National Health System (in Portuguese, Sistema Único de Saúde - SUS).

The Biominas'2016 Study also showed that Brazilian biotech companies are mainly concentrated in the southeast region, where 74% of all biotech companies are installed. This may be explained by the proximity to the main research institutions in the country, such as the São Paulo University (USP), which performs high quality biotech research, the Oswaldo Cruz Foundation (Fiocruz), among several others that concentrate the country's R&D. These institutions are denominated Scientific and Technological Institutions (in Portuguese, Instituições Científicas e Tecnológicas – ICTs) and, beyond generating the Brazilian technological development, the ICTs are responsible for great part of the specialized human resources formation. According to GEOCAPES (a platform with data from the Coordination for the Improvement of Higher Education Personnel – CAPES), the number of biotechnology researchers in training is increasing in all regions of the country.

Even though the country has an increasingly body of scientists (masters and PhD levels), especially in basic research, the scientific and technological development is hindered by lack of resources, given the fact that the ICTs are mainly publicly financed and because of other intrinsic characteristics of public research, which do not incentive a substantial further technological development. The Brazilian Biotech industry is the reflection of this picture since the country has approximately 300 biotech companies. A small number when compared to big economies such as ›





United States or Spain, which have respectively 11,500 and 2,700 biotech companies, according to the Organization for Economic Co-operation and Development (OECD).

However, in order to face those difficulties, the Brazilian Government is investing substantially in the sector development. The Brazilian Development Bank (BNDES) plays an important role as it is an instrument for the financial support to the government and ministries incentive actions, mostly related to R&D, innovation, and national production with the main goal of attending the sector's and population's necessities.

Ms. Carla Reis, responsible for Industrial Analysis in the BNDES' Health Department, mentioned the Bank's policies for financial support to the sector in an interview. According to Ms. Reis, a series of coordinated public policies of incentive and financing were established after 2010 with important investments being made in the healthcare and biofuels sectors. These policies included: "BNDES Profarma - Biotecnologia" which had the goal of supporting the development and production of biopharmaceutical products. That program was part of a bigger initiative, the BNDES Profarma, dedicated to foster investments and innovation in the Brazilian health industry. On the same page, the "Inova Saúde Biofármacos, Farmoquímicos e Medicamentos" was a program created to support activities of Research, Development and Innovation in public or private institutions that operate under the Brazilian Economic and Industrial Health Complex. The program was part of the "Plano Inova Empresa", a plan that allocated R$ 3.6 billion into innovation activities of the Health Complex, promoted jointly with the Brazilian Innovation Agency (FINEP) and the Ministry of Science, Technology, Innovation and Communications (MCTIC).

In the Biofuels sector, there was also a remarkable coordinated effort joining BNDES and FINEP, known as the PAISS (Plan of Innovation Support to the Sugar and Alcohol Sector).

Ms. Reis believes that the Brazilian Biotech sector presents a substantial growing potential in the diverse segments of applications, highlighting the healthcare, the agribusiness and the biofuels.

The robust cycle of investments made in the last 5 years is now expected to mature, as the installed capacity is progressively occupied with biopharmaceuticals and biofuels production. For this reason, the next years will probably concentrate investments on R&D activities rather than on new facilities.

This complete innovative scenario ›

Ms. Carla Reis, responsible for Industrial Analysis in the BNDES' Health Department

also brings positive perspectives for private investors. For instance, the "Fundo Pitanga", a 100 MI Brazilian reais investment fund, is actively seeking early-stage startups with new technologies and innovative business models, including in the Biotech sector. According to Mr. Gabriel Perez, a partner at Pitanga, investing in biotechnology in Brazil is still a challenge: "The country has great potential, given the quality of the research performed and the market size, particularly in health and in agribusiness. However, finding innovative projects with commercial potential is hard, for a combination of reasons. For instance, the lack of market vision in local academia, the lack of appetite for technological innovation in the local industry and the fact that the country hasn't yet developed a substantial mass of professionals qualified to drive Biotech innovation. Still, there are great private and public initiatives in place looking to address these issues". •

Mr. Gabriel Perez,
a partner at Pitanga

fundopitanga

LIBBS

LIBBS is a 100% Brazilian pharmaceutical industry. Founded in 1958, Libbs has a portfolio with over 80 brands in specialties such as cardiology, gynecology, oncology, dermatology, pulmonology, transplantation, and central nervous system. The company also produces active pharmaceutical ingredients (APIs) for its own production lines and for others, in Brazil and abroad.

Biotechnology is part of the company's recent expansion. Libbs launched in November 2016 the first Brazilian industrial scale facility for the development and production of biologicals based on monoclonal antibodies for the treatment of cancer and autoimmune diseases. Mr. Marco Dacal, Libbs' B2B Business Unity Director, highlighted in an interview that the biotechnology facility counts with a single-use system, which guarantees quality, provides economy and prevents contamination in the production process. This modern technology, that allows a more flexible and optimized process, is expected to produce over 400 Kg in biologicals a year. The national production of rituximab, trastuzumab, bevacizumab, adalimumab and etanercept may decrease the country's technological dependence on high-cost drug importation.

Libbs invested $ 477 MI Brazilian reais in this expansion, being $ 227 MI in the biotech facility and $ 250 MI in clinical studies.

When fully functional, this facility will be able to meet the most rigorous international regulatory requirements, what makes Libbs a future biotech development, production and exportation industry. •

Mr. Marco Dacal,
Libbs' B2B Business Unity Director

Libbs

Operational Efficiency - A critical factor of Pharma companies' competitiveness in Brazil for the coming years

Fabio Bussinger is Managing Partner of the "Instituto Farma de Governança Operacional – IFGO", and BCO Farma Operational Benchmarking panel coordinator
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The Brazilian pharmaceutical sector has undergone a major structural and economic transformation in the last 3 years, where operational efficiency and production cost control have played a crucial role in the competitiveness of companies with local operations.

In the last 20 years in Brazil, product cost was a secondary factor of financial results for the sector companies, since market growth was always higher than two digits year after year. For example, higher than Chinese growth in the same period. The commercial execution combined with the increase in Market share were the main drivers of financial results, even at the expense of low operational productivity. In addition, between 2000 and 2012, demand has always exceeded the total installed capacity of the sector, contributing to margin maintenance and sales growth. However, this scenario has changed radically in the last 3 years, with a brutal competition increase in the generics and branded generics market, moreover, the total installed production capacity have exceeded the aggregate demand between 2011 and 2012, pushing the margins accordingly.

In this new setting, companies with local operations are redirecting their strategies focused on increasing efficiency and productivity, aiming at reducing operations' costs and wastes. An innovative Operational Governance management tool was released in Brazil in 2015 – the BCO Farma - Operational Competitiveness Benchmarking (in Portuguese: *Benchmarking de Competitividade Operacional Farma*). The tool measures and compares 24 indicators of operational performance among companies, being used as reference for the establishment of operational optimization goals with market parameters, not only historical internal parameters of each company. BCO Farma is a pioneering initiative worldwide, and has already contributed to an average 15% increase in operating productivity between 2015 and 2016 of the panel companies.

In the long term, the project aims to ensure an environment of high productivity and efficiency for Research & Development products with future commercial operations, increasing the local and international competitiveness of companies in the sector.

In this context, the country will have a strong pressure of fiscal control over the next few years, which affects the spending in health of all government spheres. In parallel, it leads to a demographic stabilization, probably associated with a socio-economic mobility, that is inverse to the phenomenon that occurred in the last decade in Brazil, where approximately 40 million have entered the middle class. Compared to this background, consumers will increasingly have the final price decision, where companies that have the highest efficiency and operational productivity will be able to offer medicines with more competitive prices with margin maintenance.

This new dynamic of constant search for increased operational efficiency in the pharmaceutical sector as a strategic factor, will have as a direct consequence the increase of international competitiveness of companies with local operations. It will increase space and opportunities for pharmaceutical commodities export, being one of the alternatives using the Brazilian industrial park idle capacity. This will be an inevitable move for companies that want to continue to grow sustainably at competitive costs, since domestic demand tends to be stable or even to retract in long term, no longer experiencing the 2-digit growth in the past. •

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TISMOO is the first laboratory in the world exclusively dedicated to genetic analysis focusing on personalized therapeutic perspectives for Autism Spectrum Disorder (ASD) and other neurological disorders of genetic origin, such as Rett Syndrome, Timothy Syndrome, Fragile X Syndrome, Angelman Syndrome, Phelan-McDermid Syndrome, among others.

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- **Precision genomic medicine;**
- **Big data, Artificial Intelligence and Deep Learning;**
- **Stem cell technology.**

To know more about us access

tismoo.us

Recent Regulatory Framework for the Brazilian Pharmaceutical Sector

The pharmaceutical sector in Brazil is mainly regulated by the Brazilian Health Regulatory Agency (ANVISA). The Agency, created in 1999 and linked to the Ministry of Health (MoH), is responsible for the health control of all products and services under health surveillance, such as medicines, food, cosmetics, sanitizers, medical devices and others, including health services control. The Agency's goal is to promote and protect the population's health with coordinated actions jointly with the States' governments by establishing rules through resolutions, guides, ordinances and others. ANVISA inspects, follows and executes policies, guidelines and actions of health surveillance in the country as well in the Brazilian borders, being considered one of the most rigorous regulatory agencies in the world.

Since the Agency's creation, health surveillance in Brazil has always followed the main international references for the establishment of the Brazilian regulatory framework. However, ANVISA elaborates a national version, with local regulation procedures adapted to the local reality, what sometimes impacted on import or export efforts, international product registration, among other foreign trade processes given differences in some procedures and requirements. This fact, allied to the Brazilian legislative framework, local procedures of border cargo release, or even the amount of professional human resources available to the Agency leaded to some problems such as: costly importation processes of unregistered pharmaceutical products for judicial requirements; long waiting lists for product registration with no expected date grant; or even unavailability of specialty pharmaceutical products in Brazil given the lack of interest of multinational industries in facing a long and onerous registration and importation process.

Pursuing a better alignment with international regulators, at the end of 2016 ANVISA was accepted as member of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The ICH gathers regulating authorities and pharma industry associations to discuss technical and scientific issues regarding pharmaceutical products approval. From now on, ANVISA has automatic rights to nominate specialists to be part of working groups, and to contribute actively in the development and approval of ICH guidelines.

The membership decision, made in Osaka/Japan, came after a positive recommendation of the management committee, which recognized that the Brazilian Agency met satisfactorily the requirements for being an ICH member.

ANVISA has being putting efforts towards this membership since 2012, when an internal evaluation was made for the analysis of potential impacts and benefits to the country's regulation. In addition, the Agency also considered the local industry's opinion regarding the possible harmonization benefits and challenges. Knowing that the ICH is the main reference in the elaboration of international technical guidelines, and that ANVISA always accounted the ICH's regulatory framework as basis for its own decisions, the Agency decided to enter with the membership request.

In an interview with Ms. Patricia Tagliari, ANVISA's Head of International Affairs Office, it was highlighted that the reformulation process that the ICH has passed over the last two years allowed a larger inclusion of additional country regulators, considering new relevant consumer markets and important industries recent performances. These newly included agents are allowed to participate in ICH discussion process for the elaboration of the international references. This reformulation permitted a reengagement with the international initiative, what will possibly favor the local industry and lead to a maturing of the current Brazilian regulation procedures.

In general lines, the regulatory framework of both agencies has important similarities. However, differences in compositions and classifications of these guidelines were observed. Therefore, these differences must be revised, in addition to guidelines implementation, aiming at a better alignment between the organizations requirements. This effort of international best practices adequacy is already being performed, especially regarding Pharmacovigilance, Clinical Research, Common Technical Document (CTD) and Medical Dictionary for Regulatory Activities (MedDRA), and shall be completed in 5 years. ›

CRISTÁLIA. BIOTECHNOLOGY FROM BRAZIL TO THE WORLD

International reference in innovation and technology with 91 patens in Brazil and abroad, Cristália is a genuine Brazilian laboratory manufacturing 53% of its own APIs (facing the Brazilian average of 10%), exporting for over 30 countries, leads the anesthetic market in Latin America.

Pioneering in biotechnology

Cristália invested more than US$90 millions the last 15 years in order to build and equip the first GMP biotechnology private plants: one dedicated to biosimilars and other to biotechnological products. Due to these initiatives, for the first time ever, Brazil becomes independent on imported raw material in order to export biotechnology.

CRISTÁLIA

Always a step ahead...

45 Years

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Cristália's colagenase

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■ Trastuzumabe

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■ Somatropin

Recombinant human growth hormone

- Produced using DNA recombinant technology in a 100% national prokaryotic expression platform, already on Phase III Clinical Trial
- Primary used both on children and adults with deficiency in hGH

■ Etanercept

A fusion protein used for autoimmune diseases treatment

- Recombinant protein used on autoimmune diseases such as rheumatoid arthritis, psoriasis, and psoriatic arthritis.

According to Ms. Tagliari, the potential benefits of this membership is the possible increased access to pharmaceutical products by the population, even in less time. The harmonization with the international guidelines makes the registration process easier for national and foreign companies to submit and have their products approved in different ICH countries members. After all, when a regulation is more aligned with international standards, it is possible to predict more easily in medium to long term the entrance of Brazilian products in foreign markets also guided by ICH. Ms Tagliari even pointed that the more aligned regulations are in different parts of the world, the more facilitated it is the decision-making of companies on how and where to invest, especially regarding the safety and efficacy of drugs.

Following the same line of reasoning of Ms. Tagliari, Mr. Anderson Ribeiro, Partner at Kasznar Leonardos Law firm, mentioned that ANVISA's engagement with ICH is the recognition of an excellent work developed in the last 18 years by the Agency. Mr. Ribeiro pointed that the regulated sector has always stressed the relevance and potential benefits from this international alignment. The opportunity arose with the ICH's reformulation in 2015 which allowed the organization expansion and gave ANVISA, as well as other countries regulators, the possibility of membership. One of the most expected benefits, according to Mr. Ribeiro, is the improvement of the regulatory deadlines given the harmony among the regulations and rules. In addition, another important change expected is the dossier submission in the country, which should be less laborious and more adapted to local reality. The harmonization process should improve the current mismatch regarding approval deadlines and mitigate the likelihood of judicial orders against Government to supply pharmaceutical products. These orders lead to substantial use of public resources, for instance, with several single demands for innovative therapies, without approval in the country, resulting from the current regulatory gap.

Ms. Patricia Tagliari, ANVISA's Head of International Affairs Office

Another recent and important change in the Brazilian regulatory framework for pharmaceutical products is the concept for "Previous Consent" related to industrial property in the country.

In Brazil, patents are regulated by the National Institute of Industrial Property (in Portuguese, Instituto Nacional de Propriedade Industrial – INPI). INPI was established in 1970 and is responsible for the improvement, dissemination and management of the Brazilian system of granting and guaranteeing intellectual property rights for the industry. However, once the patent application in the country relates to pharmaceutical applications, since 2001, ANVISA is also involved in the granting process along with INPI. Thus, this jointly analysis, dependent on ANVISA's "Previous Consent", generated a substantial backlog in the analysis process for the pharmaceutical and biopharmaceutical applications. Patent documents were taking over 12 years or more to have a final conclusion. This important delay was mainly due to disagreements and divergences on the analysis criteria between the two organizations. Besides the delay in the analysis, this scenario was generating an uncertain and insecure environment for intellectual property in the country, which was very negative especially in terms of foreign investments.

Aiming to solve these uncertainties, the two agencies published in the beginning of 2017 a joint ordinance, that better allocates the responsibilities of each of these agencies in the patenting process. ANVISA may no longer evaluate patentability criteria, limiting its analysis to product or process risks to human health.

According to Ms. Claudia Magioli, INPI's General Patent Coordinator, the INPI's body of patent examiners is currently much more structured and prepared, compared to 2001 when the Previous Consent was stablished for the analysis of pharmaceutical and biopharmaceutical applications. One of the main problems generated by the Previous Consent, beyond the delays in the applications analysis, was the impact of the 10 year guarantee of market exclusivity after patent grant. Since the analysis was taking over 12 years from deposit to final decision, market exclusivity was often extended for 2 or more years. This exclusivity affected the population directly since the access to med- ›

Ms. Claudia Magioli, INPI's General Patent Coordinator

Mr. Anderson Ribeiro, Partner at Kasznar Leonardos Law firm

Phytobios

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A platform to screen, discover and optimize bioactive substances from the Brazilian Biodiversity

Drug Discovery

Prospecting of new molecules in Brazilian Biomes

Drug Development

Regulatory pre-clinical and clinical trials for registration in Brazil

Innovation

Out licensing of proprietary projects

Commercial office

Natural Products Innovation Laboratory (Lipron)

Agricultural experimental field

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Parcerias para um mundo melhor

60 ANOS

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icines was being hindered when reference products were the only option in the country for a prolonged time. In this sense, the recent joint ordinance between ANVISA and INPI may optimize this system since ANVISA's recommendations will be made in the form of subside to the INPI, which will have autonomy to fulfill or not accordingly to its internal procedures. Ms. Magioli highlighted that one of the Institute's goals is to deliver high quality exams, which may generate strong patent titles followed by legal certainty to patent owners. This chain, allied to a more systematized patenting process and following specific guidelines developed jointly with the pharma and biopharma industry, has a considerable potential to attract more investments to the country and lead to further development of the sector.

Ms. Ana Paula Santos Celidonio, partner at the Gusmão & Labrunie Intellectual Property law firm and the head of the Patent Team, also sees the joint ordinance publication positively. The agreement between the agencies may facilitate the patent granting system workflow in a scenario of years of delay and in a sector of fast technological growth such as Biotech. According to Ms. Celidonio, the ordinance may bring more certainties regarding rules and guidelines used to patent applications analysis and decisions in the pharmaceutical field.

Ms. Ana Paula Santos Celidonio, partner at the Gusmão & Labrunie Intellectual Property law firm and the head of the Patent Team

GUSMÃO & LABRUNIE
INTELLECTUAL PROPERTY
Customized excelence.

In conclusion, the results for this recent regulatory framework may only appear in the following years. However, the perspectives are mainly positive and suggest a possible evolution in important policies for the Biopharmaceutical sector such as sanitary surveillance and industrial property. •

MERCK SHARP & DOHME (MSD)

OPERATING in Brazil since 1952, MSD is a world leader in healthcare. MSD has worldwide strategic partnerships for production in order to increase patient access to its products, bringing medicines and vaccines - for human and animal health clients in over 140 countries and expanding its productive capacity. MSD has a strong Biotech operation in Brazil mainly concerned to vaccine distribution. Its core initiative in this sense is the Productive Development Partnership (PDP) with the Butantan Institute. This partnership relates to the national production of the HPV and Hepatitis A vaccines.

Since Brazil has one of the best immunization programs in the world, the country is an important part of the MSD's biotech strategy. In an interview with Mr. Guilherme Leser, MSD's Government Affairs & Access Executive Director, 10% to 15% of the global MSD's HPV and Hepatitis A production is allocated to Brazil. This significant share is important to MSD commercially and visionary, since MSD's main goal is to reach alternatives to increase patient access to healthcare.

According to Mr. Leser, the purposed plan is to produce these vaccines in Brazil having the Butantan Institute as a manufacturing ally. Additionally, it is expected that this productive partnership attends, not only the Brazilian demand, but also of other Latin America countries or even of other continents.

The company invests in partnerships, consulting and training with Brazilian institutions. MSD aims at the development of local production lines with international standards of quality, seeking line expansion and possible future product exportation, especially for other Latin American countries. Another line of investments includes clinical and epidemiological studies in Brazil together with local reference institutions focusing on clinical development and patient database construction in the country. •

Mr. Guilherme Leser, MSD's Government Affairs & Access Executive Director

MSD
INVENÇÕES PARA A VIDA

In 2017, Blau Farmacêutica S/A. is celebrating its 30th anniversary. The company, founded in 1987, now completes 30 years of success and growth, in which it developed more than 100 pharmaceutical products meeting a large number of therapeutic specialties.

Blau's core business focuses on biotechnological and biological products like filgrastim, epoetin alpha, interferon beta, growth hormone and others, which may be used in many different therapeuticc áreas, such as oncology, nephrology, transplant and others.

The company holds subsidiaries in six LATAM countries, including Brazil, Uruguay, Colombia, Argentina, Chile and Peru, with Mexico about to enter the list.

Blau's growth strategy combined with the acceptance of its products by the new markets is resulting in the growing demand of their product line not only in LATAM countries, but also in many other countries around the world, where the company already exports its products to, due to the company's technical competence which ensures the quality, efficacy and safety of its products.

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Brazilian States Contributing to Innovation

In the past years, Brazil has become one of the most entrepreneurial countries in the world. Startup accelerators and fostering programs have emerged all over the country and, along with this increase, it has been noticed a larger availability of investments funds, from angel and seed capital, to venture capital and private equity. This innovative environment was influenced by several factors, such as the economic picture in the beginning of this decade, the existence of financial resources for innovation, as well as the international entrepreneur movement. Even though this environment was created nationwide, some Brazilian states have stood out. Among other reasons, local government support is a critical factor for the emergence and maintenance of innovation clusters in some Brazilian regions.

We interviewed 3 State organizations focused on innovation and entrepreneurship regarding their initiatives to support the Brazilian startup scene.

The State of São Paulo is the primary innovation pole in Brazil. The most mature startups in the country are concentrated in the State's capital, also named São Paulo, which is the Brazilian financial, commercial and industrial center. The city is filled with co-working spaces, such as the CUBO, several startup accelerators and investment funds.

One of the most important supporters of technological development in the State is the São Paulo Research Foundation (FAPESP). FAPESP is a public foundation, funded by the taxpayers in the State of São Paulo, which has the mission to support research projects in all fields of knowledge. FAPESP's central initiative is the PIPE Program (Innovative Research in Small Business Program). Operational since 1997, the program aims to support the development of innovative research, to be carried out in small businesses that have their headquarters in the State of São Paulo, centered on significant science and technology problems that have a high potential for commercial or social return. According to Mr. Américo Craveiro, one of FAPESP's research coordinators, there are 248 ongoing projects in the program, of which about 10% are Biotechnology projects. FAPESP has other initiatives focused on biotech, such as the BIOTA (FAPESP Research Program on Biodiversity Characterization, Conservation, Restoration and Sustainable Use), aimed at the sustainable exploitation of the State's biodiversity; and the BIOEN (FAPESP Bioenergy Research Program), a Program that aims to integrate comprehensive research on sugarcane and other plants that can be used as biofuel sources.

Mr. Craveiro pointed out that, in addition to supporting scientific and technological research, FAPESP also promotes the business development and competitiveness of the supported programs. Aiming at the increase of private investments in research, the foundation promotes the PIPE High-Tech Entrepreneurial Training Program, an event where participant startups join a seven-week entrepreneurship training, offered in partnership with the George Washington University. The training was based on the Costumer Discovery methodology, which helps companies to adapt their solutions to real market demands, in order to become competitive businesses in the country. According to Mr. Craveiro, given the success of the first edition, four rounds will be offered every year.

In the State of Minas Gerais, the State Secretariat of Economic Development, Science, Technology and Higher Education of Minas Gerais (SEDECTES) is responsible for formulating and implementing public policies that ensure scientific and technological development. According to Mr. Roberto ›

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for Latin America

In house Sequencing >

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Our laboratory is equipped with multiple Illumina HiSeqs...

...and a fully automated wet lab, including robots for extraction and library prep.

Mendelics has the largest sequencing capacity in Latin America, including Illumina HiSeq2500 and HiSeq4000 platforms.

With an extensive track record working with Pharma, we have shown scalability and flexibility to provide customized service from dozens to thousands of tests.

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Proven track record
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Our integrated solution has served for the systematic sequencing of Cystic Fibrosis, Retinitis Pigmentosa, Duchenne Muscular Dystrophy among other rare diseases. The company has been recognized with the **MIT Technology Review Innovators Under 35-Award** in 2014. All Brazilian melanoma genomes for the International Cancer Genome Consortium were processed at our facility. Mendelics is clearly at the forefront of genomic diagnostics in LatAm.

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Mendelics

Rosenbaum, SEDECTES' Superintendent of Technological Innovation, the Secretariat has been focusing its efforts on the startup environment in order to make Minas Gerais the best State to innovate.

This environment can be illustrated by the "San Pedro Valley", a reference between the Silicon Valley in California and a neighborhood in the city of Belo Horizonte, Minas Gerais' capital, where several successful tech startups were born. In the same city is installed one of the most important universities of the country, the Federal University of Minas Gerais (UFMG), a large source of IT talents and the country leader in patent deposits, half of them in biotech applications. Beyond the academic biotechnological development, the city is considered the largest biotech cluster in the country hosting several companies focused mainly on human health and agribusiness. The State has other two clusters, one in the city of Viçosa and another in the region called "Triângulo Mineiro", both strong agribusiness biotech clusters.

Mr. Américo Craveiro, one of FAPESP's research coordinators

Mr. Roberto Rosenbaum, SEDECTES' Superintendent of Technological Innovation

SEDECTES supports this robust environment through the promotion of national and international fairs, business missions and other events; professional training; exhibits; sector studies among other forms of incentive. According to Mr. Rosenbaum, the Secretariat strategic planning for the next years intends to foster innovation in the sense of taking the knowledge out of the academy for the development of products, services and businesses. It is important to highlight the Biominas Brasil pre-accelerating program, BioStartup Lab is supported by SEDECTES and by the SEBRAE Minas (Brazilian Micro and Small Business Support Service), the initiative aims to foster the emergence of life sciences and biotech startups by selecting impact projects and helping researchers to build a logical and strong business model.

Another important Brazilian State in the Biotech Innovation scene is the Paraná State. According to Mr. Jean Alberini, Economic Development Manager of the Paraná Development Agency (APD), Biotech is one of the current government's strategic and priority areas. The APD is an autonomous social service specialized in promotion and attraction of investments and economic development. APD has the objective of attracting new enterprises to the State of Paraná. The Agency works by structuring tax incentives aiming at companies and industries settlement in the State, and also with support in investments to improve infrastructure, foreign trade, reduction of bureaucracy and professional training, in order to make Paraná the most attractive State for new productive enterprises that ›

Mr. Jean Alberini, Economic Development Manager of the Paraná Development Agency (APD)

RISING INNOVATION

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Aché offers health companies and professionals innovative products that improve patients' quality of life

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Leader in Prescription Generation

306 Products in portfolio: Prescription, OTC, Generics and Dermocosmetics

2.600 sales reps

18 medical specialties

132 therapeutic classes

FINANCIAL SOUNDNESS

US$ 800 million

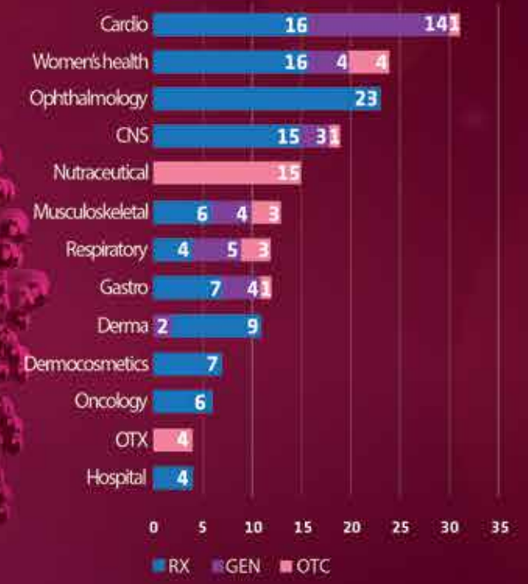
Net income in 2016 (R$ 2.7 billion)

30,6%

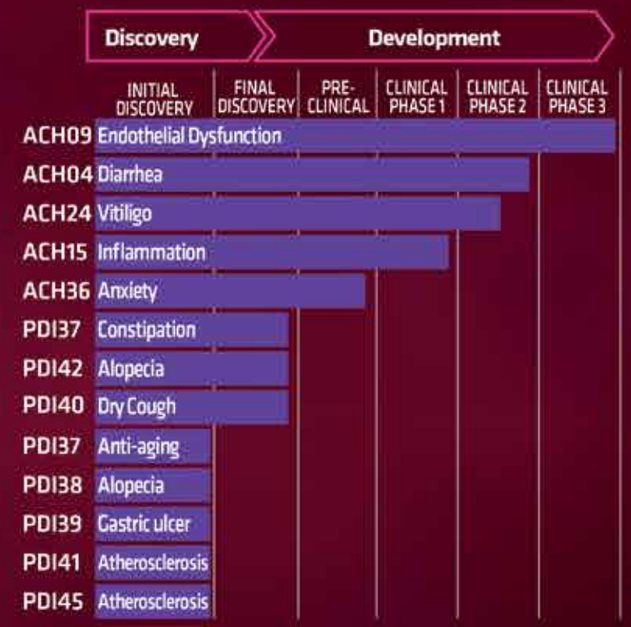
EBITDA

181 projects in pipeline

50% OF INNOVATION



RADICAL INNOVATION



13 thousand Patients in clinical trials

Development of the first 100% Brazilian drug

40 International partners

20 countries Covered by out-licensing agreements

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generate employment, income, prosperity and sustainable development.

According to Mr. Alberini, the local government has attracted over $ 40 BI Brazilian reais in investments in a three year period through its incentive program. The APD supported the North American company Alltech, a leading global biotechnology enterprise focused on animal health and crop science, to establish operations in the country. This successful attraction is mainly due to the government's incentives operationalized by the APD. •

ORYGEN BIOTECNOLOGIA

ORYGEN is a Brazilian joint venture established between Biolab Sanus Farmacêutica Ltda and Eurofarma Laboratórios S.A with support from the Brazilian Government in order to produce biological and biosimilar products. The opportunity of PDPs in Brazil monoclonal antibodies for cancer and inflammatory diseases was the initial reason for establishing the joint venture. Subsequently Orygen has also initiated the development of vaccines for cancer and infectious diseases.

The first of Orygen's products is expected to be on the market in 2019. The company is actively seeking portfolio expansion through both national and international agreements. In conversation with Dr. Andrew Simpson, Orygen's Scientific Director, the company's initial focus is to supply Latin America countries, however, as Orygen's innovative products address worldwide issues, the company will also have the global market as a possible target.

Beyond the joint venture companies financing, Orygen's establishment also counted on funding from the Brazilian Innovation Agency (FINEP) and from the World Health Organization (WHO) specifically for the development of a schistosomiasis vaccine. It will be the first parasitic vaccine developed in Brazil, in partnership with a Brazilian research institute, the Oswaldo Cruz Foundation (Fiocruz) and has just reached phase II studies in Africa. •

Dr. Andrew Simpson, Orygen's Scientific Director

About the Internationalization process: Brazilian Pharma Solutions

www.brazilianpharmasolutions.com.br

With more than 207 million inhabitants, besides being one of the biggest pharmaceutical markets in the world, Brazil is also notable for its ability to produce reliable and high quality products. The numbers confirm: in 2016 alone, US$ 546 million were exported in pharmochemicals, US$ 121.5 million in other pharmaceutical inputs (excipients) and, thanks to the internationalization of the chain, US$ 952.5 million in medicines.

However, the scenario was not always positive. Within the context of globalization, the 1990s were marked by major transformations in Brazilian society. The opening of the country to imports led to the devaluation of domestic production and intense competition. In this way, the pharmaceutical sector was severely impacted.

Facing this situation, the Brazilian Association of the Pharmaceutical and Pharmaceutical Industries, Abiquifi, was obliged to choose to give up or find new operational possibilities to guarantee the continuity of the sector. The choice was the second alternative.

The search for greater visibility was the option to guarantee the sector's sustainability in face of the current situation. The strategy of stimulating exports was aimed at generating resources for the growth of Brazilian industry, without causing a shortage in the domestic market. At the same time, making the country an attractive destination for investments in research, development, new technologies and partnerships.

Therefore, since 1995 Abiquifi and its partners have been leading businesspersons and representatives of Brazilian funding and health surveillance agencies to participate in the CPhI Worldwide, the Conference on Active Pharmaceutical Ingredients, a great showcase for Brazilian production to show its quality to the world. And since 2011, Brazilian Pharma Solutions has been formalized, an action carried out in partnership with The Brazilian Trade and Investment Promotion Agency (Apex-Brasil), with the objective of enhancing the participation of Brazilian companies in the international scenario, increasing not only exports, but also the exchange of technology, attraction of investments and the internationalization of the sector.

Márcia Nejaim, Business Director at Apex-Brasil, said: "We know that the size of our market is attractive for investors, but we think that the country's potential in the industry is even broader. Brazil has an advanced medical infrastructure and a growing community of local researchers. We have become a global player in this industry, currently exporting 140 biotech products and services to 89 different countries. For Apex-Brasil, the Brazilian Pharma Solutions Project is a way to leverage the results of Brazilian operations in this sector, which fosters innovation in the industry as a whole."

Norberto Prestes, Abiquifi's International Affairs Manager

One of the project partners is PluriCell. Biologist Marcos Valadares, partner of the Research and Development company, reinforces the importance of the contact with players of great importance and the institutional support offered by the initiative. "It demonstrates the commitment to the development of high-tech companies in the national territory," he says and mention: "We have three distributors abroad in advanced stages of negotiation, one partnership in progress and one under discussion".

In this context, attesting the quality and competitiveness of Brazilian companies, several of them have already started the internationalization process, says Abiquifi's International Affairs Manager, Norberto Prestes: "Acquisitions of laboratories throughout Latin America, establishing partnerships with R&D companies from the USA and Canada, among others, are some examples".

Given the importance of Brazilian Pharma Solutions for the sector, the work only tends to intensify. The next biennium aims at opening up new world markets for the Brazilian product, as well as consolidating trade with Latin America. "In addition, the project will focus on the convergence of health strategies between countries in this region, development of regulatory agencies with international standards and establishment of partnerships for biotechnology and clinical trials," adds José Correia da Silva, Chairman of Abiquifi's Board. •

About the country

Denise Golgher, Ph.D.
New technologies/
Human health Consultant

Brazil is a country of more than 207 million[1], which has undergone a fast demographic and epidemiological transition. According to the United Nations projections, the number of people older than 60 will jump from 11.7% (2015) to 29.3% in 2050, almost 10% higher than the world's average. By then, 6.7% of the population will have 80 years or more, and the average life expectancy will be 82.2 years[2].

The main cause of death among Brazilians is cardiovascular diseases, followed by cancer and other non-communicable diseases. More than half of the population is overweight (53%)[3] and, in general, a sedentary life style as a norm. Brazilians fulfill all the check marks for the development of multiple chronic diseases. In fact, research has shown that 81% of the elderly has reported 1-4 chronic diseases and 15% to five and more. IMS Health estimated that the country would soon rise to the fourth position in pharmaceutical spending, behind only the US, China, and Japan.

The country is, by far, the biggest market in Latin America and its health industry became attractive for foreign investment ›

1. http://www.ibge.gov.br/, access on 19.04.2017 // 2. United Nations, Department of Economic and Social Affairs, Population Division (2015).
3. http://www.valor.com.br/brasil/4940026/em-dez-anos-obesidade-passa-de-12-para-19-da-populacao-no-brasil, access on 19.04.2017.

and new businesses related to health care. However, Brazil is not just a big market for sales of services or medication, it is also a country with a very sophisticated medical and scientific community, and a plethora of initiatives that aim to stimulate entrepreneurship and innovation.

HUMAN HEALTH INNOVATION

Genomics and digital health are fuelling an engine that was inexistent 5-7 years ago. The opportunity seized, the possibility to generate innovation applied to human health that is not as risky, expensive and time consuming as the development of new drugs, has been embraced by local venture capitalists, entrepreneurs and different sorts of public and private institutions devoted to the promotion and support of innovation. This entrepreneurial environment, hand in hand with the establishment of innovation centers at teaching hospitals and big diagnostic companies are creating new business opportunities.

Two of the biggest private hospitals in the country, Albert Einstein and Sírio-Libanês, both located in São Paulo, are taking action. The former has a technological innovation center to support projects and startups; the latter, in partnership with the Consulting Company Everis, promotes an annual prize *"Empreenda Saúde"*, to stimulate the development of new entrepreneurs/startups in health.

Foundations connected to Universities have programs that foment the creation of new enterprises. A good example is Fundepar, a venture fund created by Fundep (UFMG). The success of an original program to support the writing of business plans for projects from UFMG, facilitated the foundation of the venture capital fund, Fundepar. So far, it invests in startups located at the State of Minas Gerais, but there are plans to expand to the rest of the country. The Certi Foundation, located at the campus of the Universidade Federal de Santa Catarina (Florianópolis), active since 1984, has also spun off a venture capital company, CVentures.

Biominas Brasil, a foundation that is not specifically connected to any University (but works closely with several), in partnership with Sebrae Minas, created Bio Startup Lab.

These are just some of the entrepreneurial initiatives taking place, impossible to quote all of them in this short space. Needless to say, the more startups, the better. There is an urgent need to generate recent new cases that can replace our previous (now old) successful ones: Biobras (recombinant insulin), bought by Novo Nordisk; Ferrara ophthalmics (Ferrara rings, which are exported to several countries for the treatment of patients with keratoconus); Biocor (porcine cardiac valve), bought by St Jude Medical (now Abbott).

Precision medicine in cancer care has been a big driver for innovative projects and the growth of molecular diagnostic tests has been quite impressive in the past 5 years, in particular, tests based on next generation sequencing (NGS). According to the company Illumina, progress in oncology has been particularly impressive, and Brazil is leading the business in Latin America.

Although oncology takes the lead, genomics in general has raised the interest of the local investors.

Mendelics, a specialized laboratory, which pioneered clinical exome analysis in the country, is the leader in the diagnostic of rare diseases. It is in its second round of venture capital investment backed by BBI Financial VC investment fund. SP Ventures has invested in the company Genotyping, which offers genetic tests for cardiology, oncology and genetic diseases in general. Both are located in São Paulo.

CVentures Primus, invested in a new enterprise, Neoprospecta, dedicated to molecular analysis/diagnostic of microorganisms in several different areas (human and animal health, food industry and others). Very recently, the company Myleus, from Belo Horizonte (Southeast region), which is also dedicated to the DNA sequencing and analysis of microorganisms, has received investment from the Primatec fund.

More than half of the population is overweight **[53%]** and, in general, a sedentary life style as a norm

THE BIGGER CHALLENGE: DRUG DEVELOPMENT

Research institutions, hospitals, pharmaceutical industry, diagnostic companies are all eager to innovate and have been increasing their partnerships with foreign institutions. This is good for the country, nevertheless, not enough is being done for drug development.

The Brazilian government will have to face the challenge of investing a lot more resources at the riskier business of innovative drugs and therapies. While this does not happen, some small biotechnology companies are paving the way.

Recepta Pharma, located in the city of São Paulo, is dedicated to the development of antibodies for the treatment of cancer. It was founded in 2006 with technology licensed from the Ludwig Cancer Institute in New York, and has been rather successful in advancing the development of its products. Interestingly enough, it was the first biotechnology company in Brazil to obtain royalties from out licensing proprietary technology related to a monoclonal antibody to a foreign country.

Working with a different business model, the Rio de Janeiro-based Biozeus, is screening research projects from Universities and Research Institutes from the entire country in search for new molecules. The goal is to establish an attractive pipeline of new drug candidates in different therapeutic areas. Independent of the success that its drug-candidates might achieve, the company is already playing a very important role. The establishment of partnerships, licensing deals and co-development contracts with several governmental research institutions is not a trivial endeavor.

Although both of these companies have benefitted, directly and/or indirectly, from governmental resources, the choice of investment was the result of private investors that decided to take the long-term risky investment, this is rare in Brazil.

After 14 years of consultancy in human health technologies in this country, I am comfortable to state that the ecosystem has changed a lot, for the better. The government is making an effort, especially to stimulate venture capital. Criatec, the early venture fund from BNDES (Brazilian Development Bank), is its third edition, but an analysis of its portfolio companies indicates that none of the companies are in novel drug development. Our pipeline is clearly not enough and it is past time to do more. •

EVOLUTION IS VITAL

Biolab is one of the 10 largest pharmaceutical companies in Brazil, a reference in the global market with a solid commitment to the development of science and the pharmaceutical industry within our country. We research, develop, produce and commercialize medicinal products with the purpose of taking part in these achievements and promote other people's accomplishments.

A specialized company, focused on innovative medicinal products, responsible for over 50% of its revenue, Biolab adds up knowledge and vigor. Furthermore, it employs dynamic and enterprising professionals that foresee the market needs, and fully dedicate themselves to evolution. We are a pulsating company, committed to the future and, thus, we invest 10% of our revenue in Research, Development and Innovation (RDI).

With one of the most modern RDI Centers in Brazil and a team with over 100 professionals – masters, doctors and specialists – completely dedicated to this area, Biolab has applied 261 patents, 53 of them already granted.

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THERMO FISHER SCIENTIFIC

THERMO Fisher is the world leader in innovative technologies for life sciences research, development, diagnostics, and other laboratory applications. The company helps their customers accelerate research, solve complex analytical challenges, improve patient diagnostics and increase laboratory productivity. Thermo Fisher has distribution activities in Brazil and one local facility focused on production of Taq DNA Polymerase and oligopeptides. Additionally, according to Ms. Daniela Queiroz, Thermo Fisher's Senior Vertical Market Manager, one of the main goals of the company's operation in Brazil is to provide customer support, from research to development and logistics, within their scientific tools.

Another important Thermo Fisher activity in Brazil is the establishment of partnerships for the development of customized scientific solutions. Ms. Queiroz highlighted that the company has been the equipment supplier of important biotech companies in the country; has developed multiplex kits for diseases together with a renowned Brazilian research institution; and has provided culture media for the national dengue vaccine that is being developed by the Butantan Institute.

Thermo Fisher is a strong supporter of the Brazilian Biotech R&D sector with activities in both academic and industrial areas and, additionally, helps startups and SMEs companies with scientific solutions. Leader in allergy and transplant diagnostics, the Brazilian subsidiary aims to help Asia Pacific and Emerging Markets region reach 25% of the company's global sales by 2020. Thermo Fisher's operation in Brazil counts on 400 local employees and receives continuous investments from the headquarters. Recently were invested about 5 MI US dollars in a local laboratory for customer support and applications development. •

Ms. Daniela Queiroz, Thermo Fisher's Senior Vertical Market Manager

ThermoFisher SCIENTIFIC

The world leader in serving science

Brazilian biodiversity:

New frontiers in Drug Discovery

Cristina Dislich Ropke, PhD
CEO at Phytobios, Biodiversity Director at ABIFINA (Brazilian Association of Fine Chemistry Industries, Biotechnology and its Specialties)

The environment for drug discovery and development has been facing some major challenges, such as pharmaceutical industry pipelines that are insufficient to replace revenues from drugs that are becoming generic, increasing criticism of university technology licensing practices and high attrition rates in early stage research. To overcome these challenges, there is a reconfiguration of the pharmaceutical value change coming in place, mainly creating novel business models for Drug Discovery. This will provide an opportunity for biotech startups and research-based pharma companies to develop full-scale discover molecules powerhouses. This kind of companies will be more efficient, since they suffer less from strategic attrition and the new drug candidates can be systematically tested across different therapeutic areas.

Recently, natural products have re-emerged as one of the solutions to fill the innovation gap in early drug discovery, which has proven challenging for previous organizational models. Looking ahead, ›

recent technological advances could be sufficient to revitalize the value of natural products as starting points for drug discovery, particularly with the recent growing interest in phenotypic screening.

A multidisciplinary approach to drug discovery, involving the generation of truly novel molecular diversity from natural product sources, combined with total and combinatorial synthetic methodologies, and including the manipulation of biosynthetic pathways provides a new solution to the current global productivity crisis regarding new chemical entities for several diseases. Brazil is home to one of the richest biodiversities in the world, and in the last 10 years, massive governmental investments have been made to provide state-of-the-art research capabilities for Drug Discovery in the country.

Another very positive aspect, is that the legal framework in Brazil, for access to genetic resources and benefit sharing has been strengthened. As disclosed by the Brazilian Ministry of Environment, the Law No. 13,123/2015 refers to a new model for the development of research carried out using Brazilian biodiversity. The law brings innovations that intend to simplify and accelerate all procedures related to access to genetic resources or associated traditional knowledge. From a global perspective, it is important to create an open discussion that takes into consideration diverse points of view. In different countries industries, researchers, local groups with knowledge of natural resources and government actors, struggle to develop a balancing act that benefits each of these parts. Brazil is taking important steps towards the creation of an open discussion environment in a legal certainty scenario. The legal access to genetic resources can address health needs and domestic economic development simultaneously.

> The legal access to genetic resources can address health needs and **domestic economic development** simultaneously

Therefore, all these aspects turn Brazil into an important player in modern drug discovery based on biodiversity. •

Formerly, the Biotech sector was funded mainly by public resources. Now, it is heated by **angel investors, private funds, venture capitalists, corporate ventures** and others

Brazilian startups bring biotech innovation to the world

Biotech Startups are a reality in Brazil. The entrepreneur movement, relatively new in the country, has successful cases of projects coming out of the university and becoming biotech products or services. Also, investors are discovering this promising market. Formerly, the Biotech sector was funded mainly by public resources. Now, it is heated by angel investors, private funds, venture capitalists, corporate ventures and others.

Moreover, different forms of support have emerged in the last years, such as specialty accelerating programs and challenges for impact biotech and healthcare projects. An excellent environment for entrepreneurship is being created in the country and several entities, public or private, are responsible for it.

We interviewed the founders of 5 biotech startups that stood out with innovative products, services and business models in the last years. Their cases are presented in the following boxes:

Dr. Alysson R. Muotri, Professor at the Medicine School at the University of California

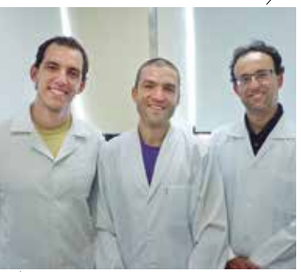
TISMOO

TISMOO is the first laboratory exclusively dedicated to genetic analysis and focused on personalized medicine for Autism Spectrum Disorder and other neurological disorders. The concept started at the University of California and has challenged neurosciences paradigms that claimed that such disorders were untreatable and irreversible. Recent research revealed that it is possible to design the best treatment to help specific individuals through genomic evaluation and in vitro cell modeling.

The company, founded by a group of Brazilian researchers, is headed by the molecular biologist Dr. Alysson R. Muotri, who is currently a Professor at the Medicine School at the University of California. Dr. Muotri's project drew the pharmaceutical industry's attention, since the technology could help to design personalized potential novel therapies for several neurological disorders. The company's services are, beyond panels and whole genome sequencing, mutations analysis, genetic interpretation of clinical conditions and functional analysis of genetic alterations through cell reprogramming for drug tests and design of personalized therapies. The cell reprogramming technology enables the creation of a cloned human "mini-brain" organoid, or an in vitro avatar of a specific patient, which is a perfect safe model for drug tests. It also provides data for causality studies of relevant genetic variants.

According to Dr. Muotri, the high incidence of autism spectrum disorders and the laborious and slow diagnostic closure were some of the reasons for the company's creation. Parents with children with suspected disorders were often frustrated since there was no specialized tests or companies for such conditions. Early disease suspicion allied to genetic analysis may lead to early diagnosis, specific therapy choice and to better patient prognosis.

Tismoo's revenue started within the first six months of operations. The startup is already international, with operations in Brazil and in the US, gathering the best of neurosciences research of both countries. Future projects include expansion of the operations to Europe and Asia. ●



Dr. Marcos Valadares, Dr. Diogo Biagi e Dr. Alexandre Pereira

PLURICELL BIOTECH

PURICELL BIOTECH is a Research and Development company for production and distribution of human cells from induced pluripotent stem cells (iPS). The company was founded by the São Paulo University researchers Dr. Diogo Biagi, Dr. Alexandre Pereira and Dr. Marcos Valadares. During Dr. Biagi's doctorate, he observed that the concept of its research, the use iPS for hypertrophic heart disease, could be used in preclinical testing as in vitro human cells model for drug testing and development.

Today, the company works with human cardiomyocytes derived from iPS aiming at the industry's unmet need for more efficient preclinical testing. Currently, toxicity tests are performed using animal or human immortalized cells, which do not have enough similarity to real conditions and toxicity may only be detected posteriorly, in the clinical setting. According to Dr. Marcos Valadares, the company has as competitive advantage its innovative business model, besides its expertise in pluripotency induction and cell line maintenance. They offer subscription plans, where the client pays for an annual plan and receives periodically an amount of cells for its studies.

Pluricell was mainly funded by the São Paulo Research Foundation - FAPESP (in portuguese, Fundação de Amparo à Pesquisa do Estado de São Paulo), which financed the development project with over 2 million reais (approximately US$ 600 thousand). The company also raised funds through crowdfunding, in 2016, for leveraging the commercialization, with revenues starting in the same year. The company has other R&D projects, such as keratinocytes for skin studies, in final stages of development. Pluricell is aiming the international market and is currently looking for distribution partners outside Brazil for its cell lines. •

Dr. Cristina Ropke,
CEO of Phytobios

PHYTOBIOS

THE ORIGINAL project of Phytobios was created in 2004 when a group of companies decided to invest in the Brazilian biodiversity in a joint venture model for cosmetic and pharmaceutical product development. In 2012, the company went through a business remodeling, and the joint venture was dismantled when one of the investor companies, the Centroflora Group, acquired all of the company's shares. Then, the company re-emerged with a new concept and with the pharmaceutical market as its main target.

Phytobios current business model has two main strands: first is providing services in radical innovation projects based in the country's biodiversity. The other is the discovery of ›

new drugs and the development of finished pharmaceutical products with complete clinical efficacy evidences. Both strands work in parallel with the company's expertise in the intellectual property and technology patent protection. The company's main goal is to transform and materialize the Brazilian biodiversity potential by associating cutting edge technology to the world's most biodiverse country. The role of Phytobios is to discover new molecules for the global market through its proprietary platform for drug discovery.

The company was primarily funded by the joint venture companies, and, later by the Brazilian Innovation Agency (FINEP, in portuguese, Financiadora de Estudos e Projetos). Phytobios revenues are mainly due to radical innovation services and intellectual property generation.

Dr. Cristina Ropke, CEO of Phytobios, believes that Brazil has everything to become a great player in the international drug development sector, since the legal frame for sustainable biodiversity research and use is evolving. It may only strengthen the Brazilian biotech sector and increase the international capillarity of national technologies from the biodiversity. •

Dr. Luis Caroli,
Biozeus' CEO

BIOZEUS

BIOZEUS is a drug development company founded in 2012 with the mandate to identify, de-risk and advance the development of promising early-stage human drug candidates discovered at leading Brazilian research institutions.

BIOZEUS works with a small team of experts in Rio de Janeiro and a worldwide network of team members, bringing in specific drug development know-how, to transform new discoveries into viable drug development candidates and investment opportunities for the worldwide pharmaceutical/ biotechnology industry.

By bridging the commercialization gap between academia and industry, Biozeus translates research discoveries into new therapies for patients around the world.

The company was created and funded by FinHealth, the only Brazilian venture capital company fully dedicated to the health care sector.

According to Dr. Luis Caroli, Biozeus' CEO, Biozeus has the broad and varied expertise and infrastructure required to source, evaluate and advance both small molecule and biologic innovative technologies through early clinical stages and then license it to a bigger partner.

The company's current pipeline includes projects in major therapeutic categories and range in development stage from discovery through late stage preclinical development. •

Dr. Carolina Reis de Oliveira,
OneSkin's Co-founder

ONESKIN

THE STARTUP OneSkin was originated from the founder´s knowledge in cellular biology applications allied with their experience in entrepreneurship. Their willingness to innovate, since their doctorate project with stem cells, tissue engineering and bioinformatics, encouraged them to outline strategies to take cell biology technologies into the market. Together with two other PhD colleagues, Dr. Carolina Reis de Oliveira co-founded a startup in Brazil for in vitro and in silico solutions that, at the time, gave her the opportunity to participate in a Business Accelerator program focused on Biotec - IndieBio, based in San Francisco, CA. This program is known as the world's largest seed biotech accelerator and offers a four-month program with 250,000 US dollars in funding, lab and co-working space, dedicated mentorship, and the opportunity of becoming part of a huge network of IndieBio alumni, investors, biotech entrepreneurs, corporate partners, and others.

The OneSkin project was idealized and built within this program, which helped the researchers to develop a sustainable short and long term business model focused on specific niches and aligned with market's expectations and demands.

According to Dr. Carolina, the startup initial business proposal was to develop human 3D skin allied to genetic testing aiming animal testing replacement. However, market analysis showed that the aging sector was, and still is, continuously growing and current models for proof of efficacy for anti-aging products were not well established in the industry sector. Therefore, their technology was remodeled into skin aging simulation models and anti-aging quantification through molecular data analysis. In this sense, the company's proposed technology comprise a more accurate and precise cosmetic efficacy testing including a quantitative analysis to measure in vitro skin age. The main goal is to identify molecules able to truly reverse skin aging and in-license them for development, co-development, and commercialization.

OneSkin has recently raised a seed investment round, which has helped the startup to perform pilot tests and technology validation. The company intends to start molecule screening later this year with expected revenues in 2018. ●

SERVIER

SERVIER, a pharmaceutical company headquartered in France, has a strong international presence, operating in 148 countries with more than 21,000 employees. The company is known for its constant search for innovation, investing 25% of its turnover in R&D activities and focusing on five major research areas: cardiovascular diseases, cancer, diabetes, immuno-inflammatory diseases and neurodegenerative diseases.

The company sees great potential for innovation in Brazil and operates in the country through a subsidiary with a manufacturing site and an International Center for Therapeutic Research (ICTR) at Rio de Janeiro. Part of local investment strategy involves the scouting of local projects and the development of partnerships, aiming the co-development of innovative pharmaceutical research projects. Regarding the biotechnology sector, the company also focus on collaborations, especially with startups, having more than 15 international agreements stablished so far.

Mr. Christophe Sabathier, Servier's General Manager in Brasil, pointed out some important partnerships in the country. "Servier's has the Oswaldo Cruz Foundation (Fiocruz) as one of its strategic partners for the development of innovation projects in Brazil. Recently, three technical cooperation projects were signed, and other collaborations involving technology transfer, research and production of new medicines are being negotiated. Among these ongoing projects is the technology transfer of modified micropellets release platform to FarManguinhos, which will allow the manufacturing of the third generation of an innovative medicine to the treatment of Cardiac Ischemia. In partnership with Fiocruz, the company promotes the International Award Fiocruz-Servier, aimed at researches in the field of neurosciences, such as neuroinflammation, neurodevelopmental disorders and zika virus infections, granting $ 120 thousand Brazilian reais to highlight projects".

Mr. Christophe Sabathier,
Servier's General Manager in Brasil

Another important Servier activity in Brazil was the development of the first edition of the event Sourcing Room Servier, which has reached its final phase with 4 selected startups for strategic analysis and due diligence. As a consequence, according to Mr. Sabathier, Servier is confident to make its first deals with Brazilian startups in a near future, and will probably develop new editions of the event in Brazil, given the quality and the amount of research projects.

In addition, over the last years Servier has been scouting projects and partnerships with several institutions, including Brazilian incubators and technology parks, and has encountered encouraging results. The company's attention was drawn to the heterogeneity and quantity of projects with an international level of technical quality. However, the company points out that to reach an agreement, not only the technical quality is taken into consideration, but also an assessment regarding each project stage of development and intellectual property. ●

Clinical Research in Brazil:
Is it really booming... or about to boom?

Douglas Valverde,
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The question above, at the title of this article, is a fair one to raise so the main objective here is to share some "cold" facts with regards to the R&D environment in Brazil that will help us build a potential answer to the question: Is the Clinical Research in Brazil really booming? It is key to disclose my direct interest in answering YES but will try to be impartial, at least while writing these lines.

The fact #1: our baseline is low whereas our potential is high. Brazil accounts for only 1,5% of the total clinical research projects running at this very moment World Wide; out of curiosity the State of Florida conducted in 2016 more trials than our whole country. If we do simple calculation based on population, Brazil should at least represent 3%. Adding to this fact, the vegetative growth (rate of births vs death rate/year) of our population is higher than the global average (1,26% vs 1,20) and such gap should increase in the upcoming years (1,17% vs 0,33%).

#2: the new regulatory environment is getting better. Taking into account the official numbers from ABRACRO (Brazilian Association of CRO), we find that during 2013-14 the average time for regulatory approval of new clinical trials in Brazil reached a sky high rate of close to 12 months which posed as major barrier for foreign investments in the area. The latest picture is significantly better, nowadays it takes around 6-7 months to Anvisa approve a new clinical trial in the country, being slight faster in the case of small molecules because the new legislation determines the deadline of 90 days for the regulator to act after submission. More recently, the new Legislation from Dec/14 and the inclusion of Anvisa as a member of the ICH regulatory group in Nov/16 pave the way for more efficient and prosperous clinical research projects in the near future.

Adding to the facts above, the #3 evidence relates to the unique ethnical diversity of our population which is a result of more than 500 years of mingling of 3 groups: Indians, Caucasians (mostly Portuguese) and Africans. Noteworthy, Brazil holds the largest Japanese colony outside Japan and because of that even the regulatory agents in Japan accept clinical research data generated in the patient pool of Japanese-Brazilians. As a side note, there is a huge pool of naïve patients in the country because of inequities from both economic and public heath standpoints. This unique canvas of ethnical backgrounds represents a micro cosmos or a proxy to the diversity found all over the Globe which essentially broadens the application of data generated in the Brazilian population.

Now the #5 fact, we can proudly be outspoken about our very distinctive scientific quality in clinical projects around different therapeutic areas. Most multinational pharmaceutical companies have used high quality clinical research centers/ hospitals in Brazil along the years. Many blockbuster pharmaceutical products available in Brazil were part of clinical programs conducted partially in the country in the therapeutic areas of: Oncology, Infectious Diseases, Cardiovascular, Metabolics, Rheumatology and Rare Diseases. Reference hospitals like Hospital das Clínicas, Escola Paulista de Medicina, Einstein, Sírio Libanês are recognized outside Brazilian borders by the quality of their investigators, the technological infrastructure, the professional multidisciplinary teams and clinical research standards.

In conclusion, if we stick to the 5 facts described earlier one tend to imagine that, despite political and social-economic turmoil or punctual risks, Brazil may be a fairly attractive investment option for international players (pharma companies, sponsors in general, service providers, CRO, public entities, investors, funds) once they open up their global maps and discuss about priority countries to further invest. ●

Being Brasil means being competitive, sustainable, creative and determined.

It means being one of the best business partners in the world.

BE BRASIL

Brazil is big: that is clear on any world map; but Brazil is much more than that. Its greatness also comes from the tenacity of its people, from the power of its creative economy, from the solutions it presents for sustainable development, from the way it innovates in many fields of knowledge. Brazil is a competitive country that ranks among the world leaders in products and services in several industries. A country that is this great in so many industries certainly has great business opportunities.

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