Simão Soares – President, P-BIO

The focus on top-tier research in Portugal has the potential to drive technology transfer from the academic lab to commercial success

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P-BIO, Portugal's leading association for its biotech industry, is approaching a quarter century in existence. Its president, Simão Soares, tells PharmaBoardroom that there has been "substantial positive change" in the country's biotech environment in these years, and - while the overall industry is still relatively modest in size compared to some of its European counterparts - he is able to highlight several Portuguese biotech success stories. Moreover, he has firm hopes of Portuguese biotech emulating the country's digital sector and becoming a prime destination for international investment and start-ups.

P-BIO has existed for over two decades after first being established in 1999. How would you describe the progress of the country's science and entrepreneurial environment since P-BIO began its operations and where does the country stand today?

P-BIO originated in 1999, when several companies recognized the need to collaborate and founded the organization to address common issues within the biotechnology sector, which was relatively small at the time. Today, we've witnessed substantial positive change in Portugal's biotechnology environment. The country now has a more diverse range of biotech companies, operating in various fields. This growth reflects an expanding ecosystem, fueled by both successful and less successful projects, which have contributed with valuable experience for Portugal.

P-BIO’s scope extends beyond pharmaceutical applications and encompasses companies that utilize biotechnology to develop their products or services. Our membership includes a spectrum of firms, from small innovative companies working on new technologies, to large biopharma players. For instance, we engage with companies like Merck and Pfizer, especially in the area of rare diseases, where these companies are highly involved. We’ve established workgroups focused on rare diseases, collaborating with policymakers and organizations responsible for policy formulation, access, and regulatory issues. Furthermore, P-BIO serves as a bridge, connecting innovative small companies with limited resources and large companies, fostering the potential for collaboration.

Promoting biotechnology to the public is another facet of our mission. We strive to showcase the positive impact of biotechnology on our daily lives, from improving health through diagnostics and therapeutics to enhancing food production. We believe we’ve made considerable progress, but we must remain realistic. Portugal’s biotechnology scene is still growing, and it’s still small compared to more mature ecosystems. Nevertheless, several factors make Portugal an attractive hub for biotechnology. We possess a pool of highly talented human resources, thanks to substantial investment in training and education. Moreover, the country is well-connected globally. This presents a favorable environment to foster innovation and knowledge transfer, driving the growth of new companies. If you examine patenting trends, you’ll find that biotechnology, alongside fields such as medical technologies and organic chemistry, rank highly. This proves a strong motivation for innovation in these areas. Furthermore, the focus on top-tier research in Portugal has the potential to drive technology transfer from the academic lab to commercial success.

Across Europe many countries are also aiming to build their competencies in this space, with mixed results. How do you define and measure what success looks like for Portuguese biotech?

Measuring success can be challenging, but we have some promising indicators. For instance, our active involvement in Horizon 2020 and our recent attainment of an additional €36 million for new projects demonstrate that Portugal is gaining recognition and trust in the arena. Furthermore, the establishment of the new NOVA Institute for Medical Systems Biology (NIMSB) is a prime example of our progress. This institute’s inception is a testament to Portugal’s ability to capture competitive funding.

Furthermore, success can be observed in the stories of both researchers and companies that have flourished in Portugal. A prime example is Lymphact, a startup founded at the Instituto de Medicina

Molecular in Lisbon and was acquired by a larger entity, eventually becoming part of a prominent biopharmaceutical organization. These successes highlight the potential and possibilities within Portugal. Celebrating such achievements and using them as inspiring examples is crucial to motivating further progress and innovation. While measuring success in the Portuguese biotech sector can be difficult, these examples show that we are on the right path and have the potential to thrive even further.

In your experience do you feel that initiatives like Horizon 2020 have helped to address some of the barriers in translational innovation or can they create additional complications in terms of following rigid guidelines to access funding?

The impact of such initiatives largely depends on the funding agency involved. When dealing with European agencies directly, such as Horizon 2020, now Horizon Europe, the process can be challenging to secure funding, but the management is relatively straightforward. These programs are often designed to support and advance scientific endeavors by focusing on tangible outcomes. This encourages participants to work on developing technology while demonstrating results.

However, when it comes to national funding agencies, particularly in Southern European countries like Portugal, the process can be complex. National funding tends to be bureaucratic, involving significant administrative requirements that may pose challenges, especially for smaller companies. Simplification of these procedures is crucial to facilitate the application process.

On a global scale, if we look at countries like the US or the UK, they have established simple funding mechanisms that are well-suited for small companies in particular. These mechanisms prioritize assessing the actual results achieved rather than getting bogged down in administrative details, like scrutinizing every invoice and contract procedure. This approach allows small companies to focus on their core work rather than dealing with tedious administrative issues.

Many innovations in this field are led by small companies. Simplifying the funding application process, especially at the national level, would further support the growth and success of these small enterprises, contributing to innovation.

How have the impacts of COVID shifted the priority for building capabilities around Portugal’s biotech ecosystem?

Many countries worldwide including Portugal realized the need for a resilient healthcare sector and the acceleration of digitalization. As a result, there has been an increase in funding to support digital transformation particularly in healthcare.

However, the response isn't limited to just these digital health firms. The impact can be seen in various areas. For example, Portugal has initiated a significant program known as "industrial agendas." This is a consortium of Portuguese companies collaborating with academia and other entities to develop and industrialize technology across different areas, including biotechnology. One of these agendas is focused on the utilization of insects as a tool for different applications, particularly for new feed and food production, environmental bioremediation and soil fertilizer. Moreover, there are several other agendas addressing areas like health and blue biotechnology.

It's evident that biotechnology is a prominent topic within these agendas. As P-BIO, we hope to see an increase in investments in this field, recognizing the substantial opportunities within Portugal's ecosystem.

How would you describe Portugal's competencies around conducting clinical trials?

A widespread understanding of clinical trials was direct result of COVID, making it a well-recognized topic even by the general public. An important development in this context is the launch of a new chapter by the European Medicines Agency in 2022. This chapter introduces a common database for clinical trial data, providing transparency to the process. This initiative is significant because it levels the playing field among countries involved in clinical trials.

Countries like Belgium that have traditionally been leaders in clinical trials now find themselves in competition with other geographies, being this an opportunity for countries like Portugal and some Eastern European nations, where costs are lower. Portugal has already been engaging in clinical trials and there is certainly a substantial opportunity to expand these efforts further. Although the scale has been relatively small, Portugal has notable examples of clinical trial initiatives. For instance, in Braga, the Clinical Academic Center of Braga (2CA-Braga) focuses on clinical trials.

Still, some regulatory issues and the creation of a common entry point needs to be addressed to further bolster our competitiveness. Instead of reinventing the wheel, Portugal can learn from the experiences of countries like Belgium and adapt them to the local context. This process would involve aligning regulatory frameworks, streamlining bureaucracy, and creating a unified entry point. Such a common entry point would be particularly valuable for entities coming from outside

Portugal. It would provide them with access to the relevant communities and patients without having to navigate the specificities of the country on their own.

Portugal's experience in diagnostics is another advantage in the realm of clinical trials. The country has various companies capable of supporting the pipeline for developing in vitro systems. Moreover, at P-BIO we have been promoting Bio-Health 2030 plan, a roadmap to support the positioning of Portugal as an R&D hub for biotech.

Can you please expand on the details of the P-BIO Bio-Health 2030 plan and its underlying strategy?

The P-BIO Bio-Health 2030 plan is a significant strategy developed to enhance and further develop Portugal's biotechnology footing. This strategy was built during COVID which underscored the crucial role of biotechnology in addressing health crises, as I have mentioned. The pandemic served as a turning point in making the importance of biotechnology more widely recognized, not just in terms of scientific research but also in practical, real-world applications. The rapid development of vaccines is a prominent example of biotechnology's impact on daily life.

We used this opportunity to communicate the relevance of biotechnology across various sectors and the pivotal role it played in the global response to the pandemic. The plan highlights that the substantial investments in R&D over the past two decades paid off in enabling the swift development of vaccines and other solutions during the pandemic. By emphasizing prior investments, we hoped to reinforce the importance of supporting R&D even during non-pandemic times.

The Bio-Health 2030 plan is divided into three primary verticals. The first vertical focuses on basic research, emphasizing the necessity for consistent policies and public resources that foster science in a long-term way. The aim is to create a program, referred to as "trusts," that can operate independently of political and governmental cycles, ensuring that science and biotechnology enjoy stability in terms of funding and support.

The second vertical centers on tech transfer and applied research. This area presents significant potential for growth and development. By establishing a supranational tech transfer office, we hope to help streamline agreements and promote efficient tech transfer activities. Additionally, fostering an ecosystem where venture capital investors can offer not only financial support but also their knowledge and experience to entrepreneurs is a priority. The plan also includes the creation of a

service provider network, spanning clinical trials, regulatory affairs, formulations, and other relevant fields.

The third vertical concentrates on nurturing companies that focus on deep tech and R&D. Many of these small companies are pre-revenue and rely heavily on IP. These companies often require specialized financial incentives tailored to their specific needs. Implementing a special tax system for such companies is one of the strategies under consideration. Similar initiatives have been successful in other countries and can serve as models for nurturing and supporting startups.

Our plan further highlights the importance of making Portugal's national health system a center for clinical trials. This approach is a win-win solution, as it provides essential funding for the national health system and offers access to innovative therapeutics.

Finally, the plan considers Portugal's role as a potential "factory of Europe," particularly in sectors that rely on qualified talent and cutting-edge technology. By fostering a pipeline that starts with fundamental research, progresses to technology development, and culminates in industrialization within Portugal, the country can capture more value from its investments in human resources, technology, and innovation. The plan outlines a roadmap that focuses on key areas, such as medical devices, new drug development, and production, where Portugal already has strengths or potential for growth.

What are some policy changes you hope to see happen withing Portugal's biotechnology environment and how do you hope for the country to perceived globally in this area?

I believe we have already laid a strong foundation. We've developed a comprehensive strategy backed by solid data and a clear understanding of Portugal's unique strengths. What we hope for on the government's part is for them to take a deeper look at the measures we've outlined as part of the Bio-Health 2030 strategy. We've set out these measures with specific, quantifiable goals. We'd like to see a continued commitment to aligning policies and actions with our overarching strategy.

Globally, our aspiration is for Portugal to be recognized as a prime destination for companies in the biotechnology and life sciences sectors, similar to what has occurred in the digital sector. Portugal has already become a magnet for digital companies seeking access to talent, a place with an excellent work-life balance, and strong infrastructure. We aim to replicate this success in biotechnology and life sciences. With a bubbling ecosystem that includes organizations like P-BIO,

along with numerous associations focused on various aspects of the sector, we offer entry points for companies looking to expand into Portugal. We hope to continue welcoming international companies and fostering a reputation as a hub for innovation, scientific research, and biotechnology advancements on a global scale.

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