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AseBio is the association promoting the development of the Spanish biotechnology industry. Its general manager, Ion Arocena, lays out the main priorities for the country's sector, including the need to reevaluate public funding mechanisms at a national and European level, and provides an explanation for Spain's leadership in clinical trials and their position as a scientific publication powerhouse, ranking 8th globally.

Can you briefly reintroduce AseBio, its members and agenda?

AseBio is the trade organization that represents the Spanish biotech ecosystem. We gather close to 280 members, most of them private companies but also research bodies, scientific parks, universities, professional associations and foundations. About 85 percent of our corporate members are small to medium enterprises (SMEs).

Our members carry activities in different sectors, some develop products for healthcare, others for agriculture. The association's agenda is currently focused on placing biotechnology at the heart of the economic and social development of Spain during its recovery from the pandemic and the economic downturn it has brought.

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science being produced is important both in volume and quality; we have been able to showcase the capabilities of the industry to deliver real outcomes.

How do you explain that while Spain lags on innovation, as you explained, there is no shortage of Spanish talent in important positions for multinational innovators, including the upcoming CEO for Johnson & Johnson, Joaquin Duato?

It is clear that the Spanish biotech ecosystem is world-class in terms of scientific production, talent and scientific infrastructure. What needs to be improved is the ability to transform the science we generate into industry and economic value; it is a chronic challenge that has faced us for 50 years. Luckily, we are making progress.

For example, 15 years ago, there were no biotech-focused VC investors in Spain, but today we have seen the creation of a dynamic VC ecosystem that has succeeded in channeling funds to the country's biotech industry; there is, however, room for improvement in the volume of funds available and the diversity of investment targets. There are certain types of companies with different business models and level of maturity that remain unable to attract investment, but progress has been made.

AseBio's 2020 report showed that Spanish biotechs were able to raise over €150 million in private investment, including from international investors, 50 percent more than the previous year.

What role has the association taken to help its members access funds from national and international investors?

AseBio tries to organize activities, especially platform activities such as BioSpain, which is our biannual exposition where our members interact with investors, pharma companies, government authorities and international stakeholders.

We also organize the AseBio Investor Day every two years where we showcase investment opportunities to national and international investors. One of our main objectives is to help our members and the overall Spanish ecosystem attract resources. Spain has traditionally been a country where economic players look to traditional banks, but we know that it is not the best model for biotechs. Therefore, we are trying to build bridges to create an environment that fosters trust between national and international investors, consultants and legal providers.

One of the Spanish ecosystem’s challenges in terms of public policy is that most if the traditional tools were based on soft loans which are not designed to finance high-risk projects with long timelines. There has been progress made in that field after Spain launched a public VC instrument, similar to a matching fund, for biotech startups called INNVIERTE. The instrument was frozen for a couple of years and reactivated in 2019 and 2020.

The instrument is well designed and works, but gaps remain in the ecosystem where other public instruments could help. Our industry needs grants more than soft loans.. Grants are a better match for our industry, but in the cases were soft loans are made, their structure should be reconsidered so payments are on pace with the development of the company.

With so many different opportunities at a continental level, how does European Union funding fit into the scheme you are describing?

I believe that European financing is really competitive and a tough proposition for extremely young SMEs. Biotech startups require support during initial stagesbefore they are ready to . compete for European funding.

In fact, it’s clear to us that European and national funding are not interchangeable, and one cannot substitute the other. In order to attract European funding, you need to have a level of national funding that allows you local ecosystem to be sustainable and competitive, and set the ground to compete at European level.

AseBio believes that biotech can play a critical role in supporting the economic recovery of Spain and Europe; we have earned the right to be recognized as an essential part of the knowledge-based economy. Biotechnology should be considered by the authorities as a pillar of the economic recovery plan.

One area where Spain excels internationally is clinical trials, accounting for 4.3 percent of global clinical trial activity in 2020. What are some of the reasons behind that achievement and how can the ecosystem leverage it to develop homemade innovation?

Indeed, Spain is extremely competitive in clinical trials. One reason is perhaps the good quality of our health system, hospitals and the level of our healthcare professionals and clinical researchers.

There is a strong ecosystem of consultants, clinical research organizations (CROs), and a comprehensive regulatory framework which is recognized as world-class; Spain was one of the first countries to develop a national clinical trials regulation based on the European regulation.

At the same time, the ecosystem's challenge is to leverage those capacities to help local biotech companies to develop Made in Spain innovation. We believe that Next Generation EU – the European Union economic recovery package to support member states adversely impacted by the COVID-19 pandemic – is a unique opportunity to connect Spain's strengths in clinical development with the needs of local biotech companies. We need to strengthen the financial ability of our companies to develop the Made in Spain innovations until later stages of development, to capture as much value as we can.

Next Generation EU is a chance to develop locally, produce locally and to consolidate our position as a global powerhouse. As a country, we must put in place the right instruments to help them.

Have you detected a particular therapeutic area of expertise that you would like to highlight?

After asking our members to periodically report on the clinical assets they are developing, we have detected that oncology is the clear hotspot. Also, there is great expertise in degenerative diseases and advanced therapy medicinal products (ATMPs), where many companies have been able to develop clinical assets up to commercialization. For example, TiGenix developed Alofisel, the first allogeneic stem cell therapy to be approved by the EMA. We should continue building on that expertise to help more companies succeed in ATMPs.

Since it is a key element for success in the biotech startup journey, how strong is the Spanish ecosystem as it relates to service providers for clinical development such as CDMOs?

Spain's local ecosystem of CDMOs has grown significantly over the last decade. We have CDMOs that produce recombinant proteins in bacterial systems and mammalian cells, viral vectors and clinical grade cell therapies. The country possesses an infrastructure that can be leveraged to foster the development of the local biotech ecosystem.

Moving on to the Covid-19 pandemic, Italy and Spain were the two first European countries to be severely hit by the virus. What were the repercussions for the Spanish biotechnology industry?

The industry was able to respond really fast. Beyond drug development companies, AseBio represents companies working in the diagnostics field, which managed to develop and launch real solutions to the market, including PCR tests, antibody and antigen testing kits. Spanish society really appreciated the rapid response from the industry, understanding that the national ecosystem was capable of successfully developing those products in record time while scaling up manufacturing capacity to supply the country and even export markets.

In May 2020, we highlighted that Spanish biotech companies were producing 750,000 test kits per week at a time when international markets were closed. This situation helped the association showcase the value of the industry. Since our industry is not so dependent on regular economic cycles, 90 percent of our associates maintained or increased their activity during the Covid-19 crisis.

In a such a competitive sector, one that requires long-term high-risk investment, how do you evaluate the entrepreneurial spirit in Spain when it comes to taking risks?

The situation has been progressing but there is plenty of room to improve. We need to train people in both the private and public sectors in order to develop collaborative projects that demand a different mindset than the one from people that have only worked in academia or big companies.

The level of entrepreneurial spirit varies from region to region since some of them, due to historical reasons, were able to develop the full value chain and have people with expertise in the settings that allow biotechs to succeed; that is the case of Catalonia.

In terms of human resources, our CDMOs are having a difficult time finding highly skilled people inside the country for their GMP manufacturing sites, quality assurance or regulatory affairs; they are going abroad or having to develop training programs to develop the skills internally.

AseBio has put an emphasis on how certain European regulations regarding state aid are preventing innovative biotechnology companies from developing. Can you explain the association’s position?

Companies in Spain and across the continent are struggling with European and national regulations, particularly with those regulating state aid. We have been working at both levels to improve the biotech framework conditions because, while R&D financing is key, regulations must be comprehensive, going beyond to adapt to the particularities of biotechnology companies that are developing disruptive technology.

AseBio is working to put the spotlight on how European regulations around state aid are damaging innovative ecosystems, particularly the definition of “undertaking in difficulty” which is included in the General Block Exemption Regulation that is making highly innovative companies ineligible for aid in R&D. The sector’s R&D model takes several years and is costly, making companies fall into the undertaking in difficulty category which excludes them from receiving state aid. This is extremely damaging for biotech companies and all R&D intensive organizations.

We believe that Europe should rethink its position and make it one of the learnings from the Covid-19 pandemic.

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