

Interview: Leonardo Vingiani
â?? Director, ASSOBIOTEC, Italy



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Leonardo Vingiani, Director of Assobiotec, discusses how the country's biotech industry has evolved since 2009, what areas still need improving and the enormous progress which has been made in unlocking the sector's potential in Italy.

Leonardo, to start off, what are some of the major milestones which the industry, and Assobiotec, have experienced since we were last here in 2009?

I think that in the last six years, we have had an important shift in the image of innovation as a driver of our country's competitiveness. This is something new for Italy, and it has a lot of implications, in the attitude towards research, towards innovation and innovative products and in the public's perception of patents. To give an example, until 2011 Italy was not part of the European patent legislation, which we have now joined. So there is a big change in the attitude towards innovation.

The magnitude of this shift can be seen through the number of companies which have joined our association, which thrives on innovation. In 2009 we had roughly 70 members, today we stand at more than 140. This has propelled our significance in the eyes of institutions, which now actively seek out our advice. They know that we know what is important for innovative companies.

The association operates in three main areas: healthcare biotechnology (red biotech), industrial biotechnology (white biotech) and agricultural biotechnology (green biotech). In Italy, which sector do you think holds the most promise, and which is the most significant right now?

Traditionally the weight of the biotech industry has been in red biotech, and the number and prominence of those companies is still growing today. However, since 2009 white biotech has also seen a sharp rise in both new technologies and interesting companies. I believe that this is the most promising sector for the immediate future. What we saw in the 1980's in red biotech appears to be happening today for white biotech, and we foresee a boom in this sector over the next few years.

Does that imply that for red biotech, you see the spectacular growth this sector has experienced over the last 25 years tapering off, with the new growth drivers being the white and green sectors?

I think that red biotech, and especially pharmaceutical and diagnostic biotech will continue to create a lot of new opportunities. We are rapidly moving towards precision medicines, and red biotech will have a huge role to play here. This technology will let us make the healthcare system far more efficient, by targeting individual patients with medicines which will work for them specifically while minimizing the side-effects so common in traditional one-size-fits-all drugs. This is already happening, it's not just in the distant future anymore, we already have some of these precision medicines on the market and the promise they have shown is very encouraging. I think this will be a huge factor in the future of the industry. The time of pharmaceutical blockbusters is over, the future will lie in having three or four products for the same symptoms, with each one targeting a different

type of person.

Alessandro Sidoli, the president of Assobiotec, used his introduction in the 2014 Bio in Italy report to characterize the industry as dynamic and promising, in spite of severe economic-financial difficulties companies were facing. What are some of the difficulties he was talking about?

In that introduction, he was speaking specifically about pure biotech companies in Italy. The problems stem from a financial market that is not as mature as these companies might deserve. You cannot imagine the difficulties these entrepreneurs have in just contacting a venture capitalist who is educated in the characteristics of a biotech company and who is at least passingly familiar with the industry. The financial markets in the US, the UK and Germany are more mature and more experienced in these types of cutting-edge industries. Here in Italy we are still lacking venture capitalists specialized in biotech.

Since the beginning of this year, a number of new venture capitalists have emerged who are specialized in Life Sciences. Naturally they are starting off with less risky projects such as the diagnostic sector, which is understandable. If you know that you have a project which will only be marketable in 12 years, you will need to present your business plan to somebody who understands the risks involved and who accepts the uncertainties inherent to projects of this length. In Italy we are lacking such highly specialized venture capitalists, but we are hopeful they are on the way. In the past, Italian scientists have had to go to Switzerland, France and Germany to find the funding they need. Even that is far from easy however, we have been told by outside investors that they are ready to invest in Italian companies, but that they need a leading local investor to oversee the daily status of the projects in-country. I understand that, so we are pushing hard for access to such, "educated", local venture capitalists to lead the projects we are trying to set up.

In terms of foreign versus local companies, what is the composition of the Italian pharma and biotech industries?

If you look at the so-called pure biotech companies, we have all the most relevant international companies present here in Italy. However, none of them have research centers or production sites here. They are creating links with Italian researchers, such as GSK acquiring an Italian pure biotech company named Okairos for example, and some international pharma companies which are also active in biotech have invested a lot in Italy, both upgrading existing facilities and setting up large production sites. However, it is the large investments in new research centers and production sites from international pure biotech companies we are currently lacking. Of course it is another matter for pure biotech companies set up with Italian capital. Those companies do have production and research centers here of course, and are heavily invested in the country, as one would expect.

If we don't create the capability to produce sophisticated biotech products on a large scale in Italy, I fear that in 5 to 10 years, our exports of pharmaceutical and medical products, which are currently at record levels, will disappear as emerging markets such as India and China catch up in the quality of their own production. Biotech products are much more difficult to produce, and this is where our future on the international export stage will be found. Now is the time to invest in the development of this capability. Now is when we have the buffer we need to make the shift. If we wait too long, we will be in trouble, so it is vital that we act on this soon. The government also realizes this, and is starting to pro-actively attract foreign investment to the country. At the JP Morgan convention in San Francisco for example there will be a dedicated team to explain to the international life sciences community why Italy, with its new patent agreements, tax credits and support for hiring PhD's, this is a good time to invest in the country. The atmosphere is very good here, and the government is very supportive, so we are excited about the future.

You mentioned GSK's acquisition of Okairos, what other activity are you seeing in terms of mergers and acquisitions?

In the last couple of years, we have estimated the amount of money generated by Italian companies in the biotech sector at about 5 billion, and these were companies which started with capital of maybe a few million, so the value created has been massive. On the mergers and acquisition side, I think the owners of Okairos were quite happy, but from the point of view of the country, there has been a loss of know-how and economic value. This is absolutely not positive. That said, the M&A are physiological in biotechnology. The deal of Okairos isn't the first and certainly will not be the last, even if I am not able to make predictions about M&A activities at this time. We must, however, on the one hand give more support to the development of start-ups and SMEs, on the other hand strengthen the innovative vocation of our pharmaceutical industry.

Back in 2009, an important theme in our report was the government's drive for generics. What has been the industry's response to this push by the government since then?

I know this is unconventional, but I thank generics. If we want to maintain the healthcare system as it is today, it is vital that we save money through generics, in order to finance innovation. Without these savings, we will not be able to innovate sufficiently to effectively maintain our standard of healthcare. Therefore, the relationship between the generics industry and Assobiotec is quite good, we see them as a partner. As I emphasized earlier we believe that the country's future lies in investing in patented medicines, and the most intelligent road to finance that is, again, by generating savings through the use of generics.

The general budget for the country cannot realistically extend further resources towards innovation in the current environment, as a result we need to be pragmatic and embrace the opportunities generics represent, and not just the perceived dangers. People must have the honesty to recognize our situation. We need innovation, and generics are the most intelligent path to get there. It is a misconception to believe that innovation and cost-containment cannot coexist. They can, in the form of generics.

With R&D being crucial to the industry, how much of the current research in the country is being funded by EU programs, by the government, and by the companies themselves?

I must add another actor: the regions. I will start though by elaborating on the resources provided by the private sector. In the entire economy, no private sector understands the importance of investing in research as well as the biotech sector. They are investing far more than most industries, with the average research to earnings ratio standing at just over 20% of revenues, and pure biotech companies averaging more than 30% with a few outliers edging towards 50%. On the public side we have the EU resources, which, at this time of limited national resources, are absolutely crucial to us. At a national level, there is almost nothing, but regionally, we are seeing several regions in the North and South allocating a healthy amount of resources to the biotech sector, which is extremely encouraging, though it is understandably still much less than the EU funding.

I know that there is a will, in the national government, to change the situation on their end, but I don't know that they have the capability right now. We need to look at the situation as it is, not as we would like it to be. This government has proven very supportive and capable, however I believe that there are other areas in the healthcare industry where their efforts could prove more effective.

When we spoke to Regina Revilla, the president of ASEBIO in Spain, she emphasized the difficulty which young, capable entrepreneurs were having in first accessing capital, and then in navigating the bureaucracy there. How is the situation in Italy in this regard?

The bureaucracy is still one of the major problems at a national level, luckily it is improving, largely due to a lack of resources. At regional level however, the problem is far less present. So the bureaucracy is a big problem nationally, and it represents an opportunity for the government to make a large improvement to the business environment without spending any money, on the contrary improving this would save them both time and money. We really think that today, at a time with less national resources, we can still do more to make improvements.

Continuing on the concept of doing more with less, Italian scientists, despite receiving less funding than many of their European counterparts, appear to be keeping pace in terms of research output. How is it possible that they, in the words of Alessandro Sidoli, “continue to do more and more with less and less, and with increasing success”?

I think that here in Italy, we truly have amazingly talented scientists. They have consistently proven that they are able to do as well as others, with less resources. It also has to do with the fact that the cost of a researcher in Italy is 30% less than in Germany, France or the UK, and a full 50% less than in the USA. I think that these two factors, the high productivity and the lower cost, can be very attractive at an international level especially when combined with the tax incentives offered by the government. This is a real advantage to us. This Italian spirit of finding a path through the difficulties, to reach the goal no matter what, is inherent to the country, and it gives us a step up on the international stage.

Are you also seeing more cooperation between universities and private companies on research?

This was a very big problem for us up until the turn of the millennium. It used to be that companies and universities walked on separate paths, and did not cooperate. Since then both universities and companies have realized that neither can afford to waste resources in this manner, and cooperation has improved. We are improving quickly, and I believe this was one of the most important drivers behind the growth in the biotech sector over the last 15 years. There is more which needs to be learned in the area of technology transfer, we can still be more efficient here.

Given that you have witnessed the rise of the biotech sector in Italy, and with the atmosphere in Italy clearly more optimistic than it has been in a while, what are your expectations for the industry over the next five years?

I expect that in five years we will gain a real champion in the biotech sector in Italy. We will gain a company which can show clear value to the country, and which can act as an example to the public of the promise this industry holds. That will act as a catalyst for new enthusiasm in the industry as a creator of jobs, investment and competitiveness for the country. My message to the international business community would be that Italy is truly excelling in its ability to translate knowledge into value, a fact which is supported by scientific indicators but which is still not well known internationally. This is a very good time for Italy, there is a lot of value to be created in this country. I would tell the international community to come take advantage of it, to invest in Italy.

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