Interview: Paolo Marcucci – President & CEO, Kedrion Biopharma, Italy

We have doubled in size, increased our international reach, and completely turned around our international presence.

20.05.2016

Tags: Pharma, Pharmaceuticals, Kedrion, Biopharma, Growth, US, ecport, Paolo Marcucci, fractionation, Healthcare, Fractionation, Interview, Insight, Exclusive, Executive, Free

Paolo Marcucci, President and CEO of Kedrion Biopharma, talks about the factors behind the company's incredible growth and its commitment to doubling exports to the US. Furthermore, he talks about the challenges and opportunities the company encountered while supporting the national health system to become self-sufficient in plasma-collection and fractionation.

We saw Kedrion Biopharma double in capacity between 2008 and 2014 in terms of market share, turnover, and employees. How was 2015 in comparison?

Revenues from sales and services were EUR 570 million, and we are growing at approximately 15%. Our market expansion is consistent with past periods, and we have strengthened our position in the US, South America, the Middle and Far East, Russia and Central Europe.

What are the factors behind this growth?

We have been consistent in our dedication to patients and have steadily invested both in product innovation and in the development of relationships with new countries. This has allowed us to maintain and develop our leadership in the countries where we are active.

You have four production sites in Italy, one of which is dedicated to doubling growth in the US market. How much progress has been made in terms of production, and how do

you see Kedrion expanding in the US?

Kedrion is expanding in the US in two ways. The first is through organic growth: we are investing in a new plant dedicated to the production of a 10% immunoglobulin that will be launched in 2020. The plant's capacity is in excess of the equivalent of two million liters of plasma, or close to ten tons of immunoglobulin. These will cover the US needs first, then the rest of the world.

[related_story]

Whilst we are waiting to launch this new product, the second way in which we are expanding in the US is through strategic partnerships. Last January, we took over from Biotest the distribution of their immunoglobulin product that is already registered and produced in the US. We will be in charge of its distribution for the next seven years. This will reinforce our global leadership and increase our share in the US market.

Is the US the main growth driver for Kedrion?

The US is the largest, most profitable market worldwide, and also the most accessible. It will definitely drive our growth for the next 5-10 years. As, right now, our market share is relatively small, it can be easily grown in terms of volume.

For the time being, we are using our fractionation capacity to develop high potential markets in Middle East, South America and Asia. Once other products are ready, we can shift some production to the US to increase turnover and profitability. We want our US activities to represent 50-60% of our turnover, but that will come with time.

After shelving plans to go public in 2008 due to market conditions, two years ago you joined the Stock Exchange Elite Program, with the aim to IPO in the medium term. What are your concrete plans in this regard?

Our plan to grow the company is the same that we had in 2008. After having missed out on market access at that time, we decided to launch a growth strategy independent of the stock exchange. Further to FSI, Fondo Strategico Italiano, becoming a shareholder in 2012, Kedrion acquired RhoGAM®, an anti-D immunoglobulin, used to prevent Hemolytic Diseases of the Fetus and the Newborn (HDFN), from Johnson and Johnson. Our growth is driven by hyperimmune globulins, for which we are leaders in the US and worldwide, as well as by standard immunoglobulins.

We have a 5-7 year plan that includes an IPO at such a time when the conditions are right from both a market and a company perspective. A good moment for us to go public could be the launch

of the 10% immunoglobulin in the US, which is planned for 2019. We have no pressure to go public, having access to capital and being in a comfortable position.

Can you share some of the most exciting projects on your agenda?

We have had access to the US market since 2011 through an agreement with Grifols. At that time, Grifols was taking over Talecris and needed to divest a number of its assets and products. This deal has resulted in great commercial reach. We have developed a very good distribution method and excellent relationships with patient associations. Sales of factor VIII have more than doubled in the last three years. As part of the deal, we became the owners of this product's original technology, meaning that purification and lyophilizing steps will be carried out in the Bolognana production site. This process will be completed by 2019-20, when we will be able to supply the US market.

Another shorter-term insourcing project is that of the ex-Johnson & Johnson anti-D product for the manufacturing of which we have completed investments at our Melville plant in the US. This new production line is expected to be approved by the end of 2017. As a result we will be more competitive, and we will further expand our outreach to further countries.

Will partnerships like those with Johnson & Johnson, Grifols, and Biotest be crucial for Kedrion's future growth?

Different deals have different meanings. Johnson & Johnson was a consolidation deal that we did directly. This is a general industry trend.

The deal with Grifols was also due to consolidation, but indirectly: Grifols was taking over Talecris and, as there were only three players in the US, the FTC suggested that we should become the fourth.

Biotest is the result of the credibility that we developed in pursuing the US market and our leadership. We demonstrated that we could do better than them in that market, and it was a very satisfying deal.

Kedrion has really helped the Italian national health system become self-sufficient in plasma collection and fractionation. Have you received appreciation for this effort at regional or national level?

It has been a mutually rewarding cooperation. The Italian self-sufficiency programme was launched in 1990 when many international companies were invited to invest in Italy. In reality, we were the only one who really believed in the programme. We invested a lot and improved access to plasma;

in doing so we benefitted the Italian system in general, as well as donors, physicians and patients.

It has been rewarding because we had the opportunity to use our plant at 80-90% of its production capacity, and to invest continuously to grow that capacity. The system, however, was due for a change. We supported that change, which was 10 years in the making. The market has been opened and the first tender of the new era was won by CSL Behring.

There were no plans to thank each other but the partnership was beneficial both for us and for the government.

Have you looked at other countries to replicate this effort?

While supporting the opening of the Italian market, we have asked to be able to import self-sufficiency plasma from different countries to Italy and do the same kind of contract manufacturing for them. This state of things is quite difficult for us, and we are at a competitive disadvantage today as other Western European countries are in the position to import plasma from countries like Iran to be contract manufactured whereas we cannot.

This is for two reasons. Firstly, the authorities believe that Italy should be a totally protected country, even more than Europe. Secondly, up to a year ago, the authorities did not have the means to inspect transfusion centers in foreign countries. There now are inspectors, but the ways to import this plasma have to be developed, or we will run into difficulties competing with the rest of the world.

Have you seen any willingness on the part of the authorities to improve the situation?

We made the very brave move to invest in Italy to increase our purification capacity. So what happens is that our production sites in Hungary and in the US carry out the relatively easy first part of the fractionation process, whereas the complex, high-value purification step takes place in Italy.

The problem is that AIFA, the Italian Medicines Agency, and the Ministry of Health are not really taking into account the need to speed up intermediates import procedures. To get an import permit to Italy for an intermediate from plasma manufactured in an FDA, Food and Drugs Administration, approved plant, takes between 12 and 15 months. This is not conducive to managing an industrial business, especially in comparison to companies in other countries that are doing the same in a matter of days.

[Featured_in]

Another issue that we have is that our regulations are different to the rest of Europe. There are peculiarities that make Italy very complicated and businesses more expensive to run. However, we are investing in Italy because there is a pharmaceutical culture here. Despite the bureaucracy, restrictions and import delays and external competition, there is a lot of knowledge in Italian suppliers, technicians, and R&D. In a relatively small space in Tuscany, we have three high-ranking universities that are focused on medicine, pharmacy and biotechnology, which are attracting a lot of students from all over Italy. There are plenty of highly-skilled people who are willing to dedicate their professional lives to the pharmaceutical industry. We are also close to Bologna, where many world-leading mechanical manufacturing companies are based. We are part of the Toscana Life Science Foundation (TLS), where we have based our orphan drugs production and development site. It is decidedly appealing to be part of such an environment. It would be so much easier if bureaucracy were in line with the industry.

In the next 3-5 years, what is your vision for Italy and globally?

My vision for the future is to repeat what we have achieved in the past. We have doubled in size, increased our international reach, and completely turned around our international presence. We want to continue our double-digit growth for the next five years, more than doubling our size and ensuring that at least 50% of our turnover comes from the US. In Italy, we want to maintain our presence in terms of volume and improve our market share. Our aim is to keep investing in our Italian facilities in order to become more and more competitive.

See more interviews