

Gianfranco Nazzi CEO, Almirall



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Almirall CEO Gianfranco Nazzi dives into the new strategic focus of the global biopharmaceutical company with HQ in Barcelona as it seeks to serve the European medical dermatology market. The Italian executive reflects on his first few months at the helm, the cumulative experience of Almirall's management board, the global dermatology market, and reveals why expansion of the company's European footprint is crucial in order to be the in-licensing partner of choice in medical dermatology.

Gianfranco, you joined Almirall as CEO in 2021 after working with Teva for almost eight years, most recently as Executive VP for International Markets. Could you explain that transition to our audience and what attracted you to Almirall?

When working for big multinational companies, you are always part of a mechanism, but you will rarely have the chance to make as big of an impact as you can have with a company the size of Almirall.

I decided to take on the CEO role for Almirall not only due to the opportunity of the role itself, but also because of the chance to be part of the ambitious growth plans of the company. Furthermore, I share the same values as the Gallardo family, and that was also important to me. Finally, there was as well the appealing nature of the city of Barcelona.

I did, as you can imagine, a robust due diligence, getting a deeper understanding of Almirall's roots. What I found on the ground was absolutely in line with what I had read and studied about the organisation; the company is very well managed and the people, which are Almirall's most important assets, are very resilient and knowledgeable. I encountered an organisation in very good shape.

You just stated that the organisation is in very good shape, something confirmed by its latest financial disclosures which revealed growth of 7.2 percent in 2021 and pointed to dermatology as the fastest-growing segment. Can you walk our audience through the current position of Almirall?

Almirall is growing well and fast, especially on the dermatological side, where we recently launched Ilumetri in Europe, a biological product to treat moderate to severe psoriasis that closed 2021 with EUR 82 million in sales, doubling the previous year's figures.

At the end of 2021 we also launched Klisyri, a product for actinic keratosis, in Germany and the United Kingdom with very good early results. However, we are not only growing on the dermatological side, particularly in Spain, where we have a unique historic portfolio that is performing at a high level.

The situation in the United States is different because 65 percent of our product portfolio in the country has lost its patent, and only 35 percent is made up of new product launches, which, while growing fast, are not yet fully compensating for the loss of the patents.

The main interest of the company, according to the strategy we revisited last year, is to focus on Medical Dermatology, including all our research and development. However, we should not forget that our current portfolio composition is about 60 percent non-derma and we will continue to work hard in this part of the business as well. The non-derma portfolio is relevant mainly in Spain and Germany due to historical investments, and in those two markets, we will continue opportunistically to look also outside of medical dermatology.

According to the company's statements for 2021, you have an interesting late-stage pipeline that includes an asset for atopic dermatitis that appears to have shown positive phase III results and will soon move to the marketing phase. In that space, Sanofi leads with Dupixent, and LEO Pharma recently launched its own alternative. Can you elaborate on Almirall's pipeline and the strategy to succeed in atopic dermatitis?

The product you just mentioned is called lebrikizumab, a monoclonal antibody for atopic dermatitis for which we presented 16 week positive results from two phase III clinical trials, meeting all first and secondary endpoints. We are very pleased with the results so far but we need to wait for the 52 weeks results later this year.

The market for atopic dermatitis is growing double digits, at a 22 percent compound annual growth rate, and indeed the market leader today is Dupixent from Sanofi. LEO Pharma also launched its own product at the beginning of the year, called Tralokinumab, in Germany and the UK and are waiting for price approval in France. Nevertheless, the atopic dermatitis market remains unsatisfied in terms of unmet medical needs and we truly believe that lebrikizumab will play a very important role; Almirall will submit its application to the regulatory agency by the end of 2022 and the goal is to have the first launches by the end of 2023.

To what extent are you concerned about the saturation of the atopic dermatitis market considering that Sanofi has high expectations for Dupixent, a larger salesforce and is employing a multi-indication approach?

Dupixent is a good product, is performing very well and covers multiple indications, yes, and the company has done well with lifecycle management. The product has two types of targets, IL-4 and IL-13, while lebrikizumab is very selective and focuses on IL-13, which is a central mediator for atopic dermatitis. In a phase IIb trial we demonstrated rapid, dose dependent efficacy and a favourable safety profile.

While the market will be very crowded, if the 52 weeks final data of the two phase III studies confirms what we saw in phase II, Almirall is set to compete with a strong product. We will do so solely in the European market because we acquired the rights for that territory from Dermira. Eli Lilly, having bought Dermira, will commercialise the product in the rest of the world.

Almirall has revealed its interest in non-melanoma cancer products as well rare diseases and inflammatory diseases. Can you comment on that part of the strategy?

Our complete R&D focus is on Medical Dermatology and will rely on three pillars. First, immuno-inflammation, where we have products in atopic dermatitis and psoriasis. The second pillar is non-melanoma skin cancer, also known as dermato-oncology, where we currently have Klisyri for actinic keratosis, a precancerous disease. The third pillar is rare diseases due to the high unmet medical needs in this area of Medical Dermatology. We truly believe that our R&D expertise, partnership appeal and focused go-to-market model make a recipe for success.

How would you characterise Almirall's financial position as it relates to M&A opportunities and its ability to compete with Big Pharma players?

Cash today is not a problem because of Almirall's strong balance sheet; our ratio of net debt to EBITDA is very good. The challenge is finding the right products. How are going to do it? We can count on three main pillars: First, with our strong internal R&D done from Barcelona -R&D represents 15 percent of Almirall's internal headcount, almost 260 people, and the company is investing about 11-12 percent of sales into R&D. Second, through collaborations with universities and biotech companies. Third, with M&A opportunities that very much depend on market availability. We are very active on this pillar, and just recently (December 2021), we in-licensed global rights for a first-in-class IL-1RAP antagonist monoclonal antibody for autoimmune diseases from Ichnos Sciences.

How will you and the management team ensure that Almirall remains an appealing potential partner for companies looking to out-license products for the European market?

Today, Almirall has a direct presence in 21 markets and sells products in more than 70 countries. One of the things we decided to do last year when rethinking our future strategy was to own the European market. Owning Europe is one of the most important parts of our strategy. For that reason, we decided to enter the Central and Eastern Europe (CEE) region, reinforcing our presence in Poland and establishing the Czech Republic and Slovakia affiliates. In addition, we are taking a

close look at the Nordic countries.

Why is this important? Because it will help the company be in a better position when looking for in-licensing opportunities. For instance, if we talk today with a Japanese company that does not have a direct presence in Europe, they will opt to partner with someone that is present and strong in all of Europe. If you can guarantee that you are the top player in the European region with a presence in most of the markets, your chances of attracting a foreign partner grow exponentially.

At the same time we need to think carefully about the geographic expansion, since being an organisation with a little less than EUR one billion in sales, we cannot spread out too thin across the globe.

How can a company with the size of Almirall succeed in the US, the largest market in the world and a very expensive one to operate in?

Doing business in the US is a completely different ballgame than in Europe. In the US, Almirall's strategy is to serve patients in niche markets where we can add value for them. Our Klisyri product, for instance, fits very well with this strategy. We are also present in the acne space, offering a clinically meaningful solution for patients.

The company is headquartered in Barcelona, Spain's most relevant healthcare hub, which provides it with access to top talent within the country. But does that appeal translate when looking for international talent?

Almirall enjoys a strong positioning and does not suffer at all when attracting big talent. If you look at our latest management board hirings, we attracted Karl Ziegelbauer (Chief Scientific Officer) from Bayer; Volker Koscielny (Chief Medical Officer) from Celgene; Paolo Cionini (Chief Commercial Officer Europe and International) from LEO Pharma, and Sandra Orta (Chief Marketing Officer) from Roche.

The same is happening in R&D; Almirall is a very attractive company for top talent. Moreover, Catalonia is quite a strong scientific hub with many research institutions and more than 1,000 clinical trials in oncology, CNS, dermatology, ophthalmology, etc. The company's geographical location is a plus. As the city and the region become more crowded from a scientific point of view, this will create a fantastic ecosystem in which to compete.

Almirall updated its ESG Strategy in 2021. Can you tell us more about it and what the company is doing in this area?

Companies cannot operate in isolation from society and from the challenges that the planet is facing. We are totally invested in facing these challenges and doing our best to adapt to and mitigate the effects of climate change. Last year we updated our ESG (Environmental, Social and Governance) strategy and defined 15 initiatives that will contribute to the achievement of the United Nations' Sustainable Development Goals (SDGs).

I am very happy to report that we have made significant progress under the main pillars of this strategy. In environmental matters, we have worked in the promotion of sustainable development

through the efficient management of natural resources and a focus on energy efficiency and carbon reduction â??achieving a 39 percent reduction in 2021 vs 2014 â??. In terms of renewable energy, we are committed not only to purchasing green energy, but also to self-generating it. We have programmed to increase and expand our current photovoltaic installations on our sites. Iâ??d also like to highlight our Sustainable Procurement Program, which is embedded in this ESG strategy, because it assesses and certifies our suppliers under the strictest sustainability criteria.

From a social perspective, we have worked in empowering our employees to grow and develop their potential, advancing on inclusion and diversity and promoting work-life balance. We also work closely with healthcare practitioners and patientsâ?? associations to understand their needs and truly do our best to provide them with solutions that will improve not only their physical symptoms but also their wellbeing. We are a people-centered company and our noble purpose â??to transform the patientsâ?? world- guides our daily activities.

Is there a final message you want to convey to our audience and your colleagues around the world?

I do want to touch on the crucial execution part. I am fortunate to lead an organisation with several product launches coming in the next few years, with a very promising late-stage pipeline and a strong balance sheet. Execution is the name of the game and, as I said before, we do not want to disappoint patients, HCPs and all the different stakeholders that are counting on us and our products.

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