Fabrizio Chines – President & CEO, SIFI

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SIFI's Fabrizio Chines outlines how the company is progressing in European ophthalmic markets, explains the added value it is bringing to the glaucoma field, and tells us about its orphan drug for acanthamoeba keratitisis.

Last time you spoke to PharmaBoardroom back in 2016, you mentioned the long-term goal of establishing SIFI as "a leader in the European ophthalmic market." What progress has been made towards this ambitious goal in the intervening six years?

Since 2016, SIFI has made a lot of progress towards that ambition, establishing direct operations in Spain, France, and Turkey; building on our strong foundations in Italy and Romania; and expanding our distribution network. Our objective has remained constant: to become a leading ophthalmology player throughout the major European countries.

There have, however, been some issues along the way. One was, of course, COVID, but back in 2019 an earthquake in the vicinity of our production facility forced us to shut down operations for around five months. These issues have delayed SIFI's ability to grow at the trajectory we would have liked – either organically or inorganically – but overall, we are still on track to reach our objectives in the next few years.

How have you gone about selecting the European markets in which to expand SIFI's operations?

Our overall objective is to be an active player in the major European markets: France, Germany, Italy, Spain and the UK. However, when it comes to market selection, we conduct a detailed analysis of the competitiveness of our portfolio against country-specific market conditions, potential competitors – whether local or multinational players –, as well as acquisition opportunities.

Through these analyses, we were able to identify a small product acquisition opportunity in Spain, and a larger one in France, bolstering our own portfolio of products that have been successful elsewhere in those markets.

Looking forward, Germany and the UK are the next strategic targets, but in those markets we will focus first on innovation. SIFI is currently in the process of registering its innovative orphan drug, which we will use to kickstart German operations in 2023, followed by the UK.

How have SIFI's legacy products been performing in recent years, especially given the relatively sluggish growth of the ophthalmology market overall?

While the international regulatory approval process needed to market our legacy products in Europe – other than Italy and Romania – took longer than expected, we have now started to successfully launch these historical products directly in Spain, followed by the UK via a commercial partner, and France and Germany are on the horizon.

With our exposure to acute conditions, whether through pharmaceuticals like antibiotics or medical devices like intraocular lenses, the pandemic years have not been easy for us. Having said that, our legacy products performed in line or better than the relative market segments.

In recent years, glaucoma has become a much larger area of focus. This is a therapeutic area of relatively more significance in pharma retail markets outside of Italy, in part due to different market access dynamics. For example, ophthalmic antibiotics are not reimbursed in Italy, whereas they are in countries like France, meaning that Italian prices are, on average, higher. Glaucoma will be crucial to SIFI's future growth story and – through internal development as well as external partnerships –we will be launching some differentiated glaucoma products in the next few months.

What added value will SIFI's products bring to the glaucoma field?

They add value as 'generic plus' products which offer improvements to patients and payers on the originator products by, for example, working for longer durations, or not containing cornea-damaging preservatives. By combining an incremental innovation with good execution in marketing and sales and taking advantage of the originators' loss of exclusivity, the launch of these products should allow SIFI to gain market share in the glaucoma segment.

This is a strategy we have already succeeded in Italy many years ago with the launch of IOPIZE, the world first generic formulation of latanoprost, which is still the second brand in the segment. It should be noted that SIFI is not a generic company, but rather a partner to ophthalmologists, striving to bring innovation, even if an incremental one, to make a difference to patients, payers, or both.

The challenge is now replicating this success beyond our domestic market, where SIFI does not possess the same brand equity. A bolstered glaucoma portfolio more generally will be crucial to competing in Western Europe and fulfilling our objective of becoming a European ophthalmology player, as glaucoma represents up to 50 percent of the ophthalmology retail market in value.

What approach to in-licensing products from other companies has SIFI adopted thus far?

Collaboration has always been important to SIFI. Whether you call it business development or open innovation, the reality is that we lack the resources to build a new molecule from scratch. This means that we must either adapt products from other therapeutic areas to ophthalmology, as we did back in the 1990s with netilmicin, an antibiotic that is now almost exclusive to SIFI in ophthalmology, or engage in collaborative agreements with third parties.

Whilst we have also embarked on more innovative earlier-stage projects, we have lately built the glaucoma assets through business development agreements, retaining control on key areas such as regulatory, pricing and reimbursement processes where we are hitting our targets to launch across the geographies we are currently present in, including France, in the next few months. This will be an important year for SIFI to deliver across all our key markets.

What impact do you hope that SIFI's move into the orphan drug field will have on rare disease patients in ophthalmology, and what changes will it necessitate in the firm's

traditional go-to-market model?

Our product AKANTIOR is on track to be approved by the EMA as an orphan drug for acanthamoeba keratitis. This is a devastating disease that can lead to blindness or enucleation of the eye and SIFI's product would be the first licensed product globally. The Phase III trial, which ended in 2021, gave a great efficacy and safety profile readout, and we plan to file in early May. This is a potentially transformational product for SIFI and will necessitate a shift away from our traditional retail model.

Coming back to the objective of building a European company, this product is where we plan to start direct operations in Germany and the UK, because it will require a more focused effort. Indeed, in the orphan space there is no need to fight against competitors but find the right way to support the patient through their journey, and indeed work with stakeholders to gain access to a currently unavailable cure

AKANTIOR also has an orphan drug designation from the US FDA for acanthamoeba keratitis as well as for fungal keratitis. Given that SIFI is developing both the API and the finished product, this is the result of 12 years of development. Liaising with the FDA is new for the company, but we are hopeful of a full approval.

We will consider options for commercialisation of AKANTIOR outside our core markets which include licensing and distribution, especially in the US.

Ophthalmology is a market that has historically been characterized by incremental more than disruptive or radical innovation, but SIFI seems determined to achieve breakthroughs in the field, with Well Fusion, an innovative technology for intraocular lenses (IOLs) and Synfo, a novel formulation of artificial tears, released in 2021. What impact are you hoping for from these technologies?

Ophthalmology is quite an interesting niche, not only in terms of growth dynamics but also because the anatomical condition of the eye makes it a perfect testbed for new technologies like artificial intelligence (AI), cell and gene therapies, and new surgical techniques.

Leveraging on close relationship with cataract surgeons we diversified into R&D and manufacturing of innovative IOLs, where we have expanded our commercial reach from Italy to Romania, Spain, and later this year into Turkey. Additionally, SIFI has been able to secure access to China – the market with the greatest opportunities for growth in cataract surgery – forming a joint venture

company, AffaMed Technologies, based on SIFI's products and IP.

SIFI pioneered the extended depth of focus IOL technology back in 2015, a category lately joined by the majors, including J&J, Alcon, and Bausch & Lomb. Now we have further pushed the envelope with Well Fusion, a unique binocular implants' system that corrects presbyopia, providing a high quality of vision across all distances. This is something that we are very proud of and we have clinical evidence of great satisfaction from patients.

SIFI is a small company with some significant innovations. Our growth will be based on launching innovative products in the most competitive markets and working with partners in the regions that are beyond our current capabilities, such as China and the US.

How digitalised was SIFI pre-pandemic, and how will digital tools come to augment the company's operations?

Ophthalmology is a great place to be for AI-based therapies. Indeed, the first AI-based diagnostic device to be approved by the FDA was in ophthalmology, using machine learning and image processing to create a diagnosis equal to that of a doctor.

We are pursuing two major investment lines in this space. One is the digital transformation of processes, whether in digital marketing, regulatory, or manufacturing. As an example, we have built a platform that enables better stakeholder interaction through a push-pull system; doctors are able to request specific content of interest to them. At the same time, our sales reps interact and direct the doctors. Of course, there are also built-in KPIs and analytics that our people across all departments can use to improve the efficiency and efficacy of their activities. While Pharma was later to the party on the importance of digitalisation than some other sectors, the pandemic has reinforced the need for new models and tools for stakeholder interaction.

In manufacturing and regulatory, where SIFI has started to invest in areas like smart manufacturing, we are looking to continuously improve the digitalisation of several processes.

In terms of digital therapeutics, we are still at an early stage. However, the company is actively working to access technologies through a model of open innovation. Given our size, this approach is key, as we do not have the resources to build an internal R&D organisation creating digital products from scratch, but instead look for early-stage partnerships. Earlier entry means certainly more risk but gives us a greater chance to secure technology that in later stages would make too hard competing with Big Pharma.

We are also developing specific digital assets in combination with our traditional therapeutics, whether drugs or devices. These are focused efforts, for example supporting patients in the orphan space for the acanthamoeba keratitis. This is an ongoing project, which will also results in an app to help patients with compliance and a number of other features.

How would you characterise the business environment for pharma companies in Italy today? Are the Italian authorities more appreciative of the work that innovative local players like SIFI are doing?

We are in a better position than in 2016 because, generally speaking, the Italian government realised that it was not sustainable to continue cutting healthcare spending. This led to more Italian companies and multinationals investing in our Country and to Italy overtaking France and Germany in terms of manufacturing output. Maintaining this edge will, however, be challenging as Germany and France have already developed their own national plans to regain the leadership.

For smaller companies like SIFI, being based in Italy comes both with lost opportunities and small advantages. Overall, the environment is still favourable, but the outlook is somewhat bleaker than a few years ago. If you look into digital therapeutics, as an example, Germany has already been reimbursing these products for three years, creating a very attractive environment for R&D investments. Italy is still to do so. A domestic market that pays for innovation is closely tied to bringing in more R&D and manufacturing investments. Tax breaks and other incentives are also important, and Italy has a few, but the rules change too frequently creating uncertainty for long term planning.

In the course of SIFI’s transformational journey, what principles are you leaning on to guide the company?

Our number one value is serving patients. Unquestionably our biggest challenge is to improve patients’ quality of life and improve their vision.

Our other strong beliefs are being innovative and creating shared value. Our private equity, 21 Invest, has helped shape a more strategic approach to ESG for SIFI, which means not just to be a good corporate citizen, but to create value that goes beyond the short-term profits and result in a long term competitive advantage. This will benefit specific communities and segments of the population, for example through the development of an orphan drug for underserved patients or

increasing local R&D talent pools by partnering with local universities.

As a matter of fact, SIFI received in 2021 an award from Italy's leading business school, SDA Bocconi, as the best performing company in the mid-sized category based on financial performance, innovation, and ESG metrics.

What would you like PharmaBoardroom's readers to take away about SIFI from this interview?

We are balancing our pipeline with short term product launches in glaucoma with earlier-stage projects that could drive the long-term growth of the company. For example, this year we will complete a Phase II trial in dry eye for a very innovative drug candidate with a novel mechanism of action and novel delivery system. It is not an eyedrop but a topical gel that the patient applies to their forehead, which could represent a great improvement for patients. If the project is able to transition to Phase III, we expect it to be another inflection point in the company's value.

In conclusion, 2022 will be a key year for SIFI to build the foundations for future growth. Inflection points include the regulatory pathway for our orphan drug in Europe and the US, the results of the aforementioned Phase II trial, and the successful launch of our glaucoma portfolio and continued penetration in key European markets.

SIFI is committed to improving the lives of people living with eye disorders.
Including those that are often forgotten as they live with an extremely rare but acute and debilitating disease, like acanthamoeba keratitis.
This commitment is directly reflected in our product portfolio and pipeline.

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