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We as a flexible medium-sized company have the capacity to come up with novel and effective therapies for underserved patients

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Martine Claret of Horus Pharma – a family-owned ophthalmology pharmaceutical company established in 2003 and based in Nice – discusses the highly regulated and competitive ophthalmology market, the company’s remarkable recent growth, and the state of play for SMEs in France today.

Ophthalmology is a highly regulated and competitive space dominated by giants such as Allergan and Alcon/ Novartis. Why did you decide to enter this market?

My husband and I were interested in starting our own business in order to be able to make independent decisions regarding research projects, human resources management, business and

marketing strategy. Small structures allow for this independence and give employees more freedom to think outside of the box. We are looking for the kind of talented and free-thinking individuals who originate with novel ideas. Fortunately, my husband and I had complementary backgrounds. My specialty is in R&D and pharmacology in the ophthalmology industry, with some experience as well in control and manufacturing. My husband, on the other hand, had more of a commercial background. He started his studies at a pharmacy school but then entered the EM Lyon business school to learn about marketing and sales. During his industry career, he proved to be an excellent business developer, negotiating licensing agreements. In 2003, by chance, we both found ourselves in need of a new opportunity. The small-sized pharma company I worked for was sold off and my husband, who had worked for ThÃ©a, a successful family-owned ophthalmology company, for many years, wanted to turn the page. We both had experience in multinational and small-sized pharma businesses.

Horus Pharma was not the first entrepreneurial venture we launched together as we previously opened a consulting firm in pharmaceutical business development and market access. We developed market approval dossiers that we then licensed to pharmaceutical companies. So, we thought we had the required experience to launch a pharma business. Of course, it was not an easy task, especially for financial reasons. What allowed us to launch the company was the fact that we successfully developed a generic version of Teva's Spasfon[®]. Previous attempts at creating a generic were faced with issues regarding raw material. We solved this issue by using a new raw material and filed a dossier for market approval. We then sold the dossier to about 20 generics manufacturers which provided us with the necessary funds to start our ophthalmology company. The other fortunate event was that we managed to gain licensing rights for a medical device designed to treat dry eyes called Vismed[®], a market-leading product in its category. TRB, the Swiss-German company that initially developed this product was specialized in rheumatology and did not find a market for this product. Vismed[®] is an innovative and effective device and the first to utilize hyaluronic acid for eye treatment. Since we proved the efficacy and safety of this product through multiple clinical trials, we decided to claim reimbursement by the French Social Security. Thanks to our expertise in market access, we were the first to be granted medical reimbursement for a medical device in ophthalmology.

Thanks to this initial success, Horus Pharma has managed to grow rapidly, tripling in size in the space of 8 years. The company generated EUR 43 million in sales in 2018 compared to EUR 15 million in 2010. What drove such a remarkable growth?

The product categories that have driven our growth are first of all the pharmaceuticals and medical devices for dry eyes. In this category, Vismed[®] is our flagship product, generating 45 percent of overall revenues. Incidentally, we would like to reduce this number in order to decrease our dependence on this product. In ophthalmology, except for retina treatments, pharmaceuticals are less profitable because of price pressures. As a result, we decided to develop our own products. We reinvested every penny we made in R&D and human capital. Annual R&D spending today represents 10 percent of revenues. These investments have borne fruit and we now have a number of patented ophthalmologic products that we are planning to launch soon. For instance, we have products for amniotic membranes for corneal healing, a novel emulsion for dry eyes without tensioactive materials and preservatives - an innovation that does not exist on the market yet. We also have devices to produce plasma rich in growth factors (PRGF) and a corneal cross-linking device for keratoconus treatment. Physicians are now aware that our company is developing and launching innovative products. We have differentiated ourselves from MNCs by focusing on specific niches, dry eyes and corneal healing, where we could bring something new to physicians and patients.

On the other hand, in ophthalmology, MNCs have been entirely centred around retina products and gave up on other less profitable categories. However, people still need the products we are offering. Moreover, individuals afflicted by orphan diseases such as keratoconus, which affects 35,000 patients in France alone, should not be abandoned. MNCs are not interested in such a small market. However, we as a flexible medium-sized company have the capacity to come up with novel and effective therapies for underserved patients. For instance, we have developed our amniotic membranes for corneal healing in collaboration with another small French lab. These membranes are an interesting technique that facilitates the work of eye doctors. We are able to bring all these innovations because we cultivate a culture of creativity and look outside for inspiration. More importantly, we work for the sake of physicians and patients. We educate healthcare professionals about how our products can help them and their patients and over the years we have gained their trust.

Leveraging our expertise ophthalmology, we are expanding our portfolio with dermatologic products used around the eye. Developing such products is not easy since the eye is such a sensitive organ. They need to be preservative-free and well-tolerated by patients. There are a lot of products on the market that are not tolerated well for a few reasons. The first is due to changes in the environment such as air pollution. Another is older people have a modified immunological system which makes them more sensitive to certain chemicals. We realized that the existing dermatologic formulations consist of a long list of ingredients. The sheer number of ingredients makes it more likely that these formulations contain irritating substances or even endocrine disruptors. As a result, we decided to differentiate ourselves by developing products with few, well-identified ingredients. Moreover, each ingredient has a reason to be there. Finally, we were able to develop a preservative-free product thanks to our patented packaging process whereby we produce a sterile formulation that is then poured into a special package that keeps it sterile during its entire life span. That is how our Ilast[®] product range was born. Because of their superior benefits to the majority of existing products, they are marketed as premium products with a higher-than-average price tag. Their main benefit is that they are well-tolerated by the skin. We plan to further expand the Ilast[®] brand with new product launches.

Over the years, France has introduced a number of initiatives to promote local innovation, especially by SMEs. How has Horus Pharma benefited from them?

In terms of R&D, we employ young researchers under a special type of contract (CIFRE contract) subsidized by the state. These contracts are a big help for both small pharma companies and PhD students. Social benefits charges are paid by the state and researchers are able to carry out their thesis while being paid a salary and being hosted by a research institute such as the Vision Institute, universities and hospitals. The contract lasts for three years, the duration of the thesis, which gives companies the opportunity to detect talented people, and for them to start their career. In my opinion, this contract type is a successful government initiative and should be developed further to promote made in France research and innovation. In this regard, France has been leading the way with other initiatives such as the research tax credit (crédit d'impôt recherche) that some say have turned France into a research tax haven. Public funding programs through Bpifrance are also a big help. Over recent years, the capabilities, resources and geographical presence of Bpifrance have been bolstered and the organization now plays an important role in supporting the local innovative ecosystem. I have personally found the people working there to be highly competent. They understood what we were trying to achieve. These programs should be protected and enhanced. Without them, Horus Pharma would not have been able to bring innovations to the market.

The Macron government is perceived as business-friendly and reformative. For instance, the Minister of Economy and Finances Bruno Le Maire has recently announced the introduction of the "PACTE law" designed to help SMEs grow. Do you perceive a change in mentality since Macron took power?

As I said, there is already a good supporting structure in place to help innovative SMEs. That said, I do think the new administration is more business-oriented and is heeding the concerns of SMEs. However, we will have to wait and see. Until now, not much has changed since President Macron took the reins of the country. Nonetheless, I am optimistic since he has only been in power for a year and a half. Realistically, it is going to take more time to change structures that have been in place for decades. And trying to transform things too quickly leads to unrest as we see today.

I think the current government would like to remove a lot of administrative and regulatory burdens put on SMEs. However, inertia is a strong force. Existing institutions do not want to change.

A good example of over-regulation is the serialization law, which in this case is mandated by the European Union. Serialization is not adapted to the French system. Compared to other EU members states, the French pharmaceutical distribution system is a closed system which means that, in French pharmacies, there is not one single falsified product. Products are controlled and tracked across the value chain and pharmacies have a personal responsibility to make sure their products are safe. As a result, there is absolutely no urgent need to apply this European directive in France. However, France has rushed to implement it. Italians have been more careful. They have their own system that works for them and is a lot cheaper than France's. They are going to put it in place bit by bit in the next three years. I think Germany will do the same as the administration will be reluctant to put constraints on SMEs in a country where the Mittelstand plays such an important role for the economy.

In contrast, France was initially overzealous in rolling out the directive, applying it to companies that were not targeted by it. Fortunately, the current administration seems to have changed course and adopted a more reasonable approach. Nonetheless, it remains true that, for Horus Pharma, serialization is an additional burden that does not bring us any value. In its original form, the law was biased against small companies: we would have to pay the tax based on the output of the production line of the manufacturer, shared with big pharma companies, and not the number of units produced. Together with other SMEs, we have asked that the rights we must pay be proportional to the number of units produced and managed to have the law tweaked. Moreover, companies that do not export in the EU have no reason to implement it. For companies that want to export, serialization makes a lot of sense. However, they should be able to do it at their own pace.

Regarding the PACTE law, it is an interesting law that addresses a lot of concerns of SMEs. For instance, the law is simplifying the so-called "social thresholds" (seuils sociaux) that impose certain obligations to employers depending on the number of employees. If the administration actually implements it, this law bodes well for SMEs. However, I have my doubts that it will be. The reason is civil servants usually lack business experience.

Horus Pharma started exporting its products in 2010 and has established two affiliates in Benelux and Spain. Why did you decide to target these markets?

First of all, I think that pharmaceutical SMEs do not have the choice between internationalization and staying home-based. Internationalization is absolutely necessary. Choosing the right time to do so is the question!

Even though we are grateful to have products reimbursed by the Social Security, we also need to go out of this system as it puts incredible pressure on margins. Incidentally, this situation puts us at a disadvantage to gather enough resources in order to internationalize our operations. For example, classic eye drops are priced between EUR 8 and 10 in French pharmacies, while in the U.S. or Japan it is retailed at up to USD 150. However, it does not cost more to produce in these countries. As a result, American manufacturers are put at a significant advantage to sell abroad once they have already amortized development costs in the U.S.

Nonetheless, we still need to internationalize ourselves to step out of the French reimbursement system. We are entering countries where either there is no reimbursement for our products or prices are not as low. For instance, in Germany, the largest pharmaceutical market in Europe, prices are higher. So, we decided to first open affiliates in Europe as we can apply for European market approvals for our pharmaceutical products. As we encountered administrative constraints in France, we had to apply for European market approvals through other countries. In the case of medical devices, the process is much easier as all one needs is the CE marking. Now, our international sales represent 10 percent of overall revenues, and our goal is to reach 50 percent in the next 5 years. We are developing our distribution network. We have an export service which registers our products in non-European countries and are now in contact with distributors in Morocco, Lebanon, Mexico and other countries. However, it takes a lot of time, money and effort to get products registered and enter the market.

As I said before, internationalization is necessary, but it is by no means an easy task. Even though international sales represent 10 percent of revenues, it causes 80 percent of problems! Employees at every level must now adopt a global mindset. Nevertheless, I think our teams have adapted well to this transformation.

To answer your original question, the reason we chose the countries you mentioned to base our affiliates in was mainly a question of human resources. There we found people with both an entrepreneurial spirit and the right managerial skills that match the Horus Pharma business philosophy.

You referred to the U.S. and Japan as very attractive markets. Have you already explored opportunities in these two countries?

We already entered the U.S. with our Ilast[®] product line but ran into issues with our distributor. The distributor neglected our products, and then copied them! Generally speaking, it is incredibly difficult for pharmaceutical companies to enter the U.S. market because of stringent regulations and protectionist measures. For instance, we often had to deal with issues at customs.

Regarding Japan, it is indeed a very attractive market, especially for our dermo-cosmetics line. In fact, one of Horus Pharma's investors, Embryolisse, a cosmetics company, has found huge success there. The company actually acquired its Japanese distributor, and its business also skyrocketed in China after a Chinese actress mentioned she uses their products. We would like to follow in their footsteps. We would like to partner with Japanese companies and are in contact with some of them. I think we could build a successful story together.

What are the advantages and challenges of being based in Nice?

It is not easy I would say. In France, everything is centralized in Paris, and this is especially the case in the pharmaceutical industry. Most pharmaceutical companies are based in the Paris region and so are all the regulatory agencies â?? which is understandable.

Allergan and Galderma used to have R&D centres near Nice but they both closed down. Monaco also used to have a burgeoning pharmaceutical industry, but all the companies were either acquired or moved. This, therefore, poses a challenge for recruiting talent. Moreover, Nice does not have a pharmacy faculty, the closest one being in Marseille. There is also a lack of top engineering and business schools in the region. Another handicap is the lack of means of transportation. There is one airport, but no high-speed train. By train, it takes three hours to go from Marseille to Paris but two and a half hours from Nice to Marseille. As a result, we are somewhat enclaved both economically and geographically.

Where would you like Horus Pharma to be in the next five years?

My first goal is to successfully complete the internationalization of our business. I would also like to launch new products every year. We are ready to launch a new retina treatment, a corticoid intravitreal injection in-licensed from U.S.-based Alimera Sciences. It is a very interesting treatment for diabetic macular edema. I would like to add more products to our portfolio in this area. In fact, there are a lot of startups working on molecules for retina treatment and Horus Pharma should develop partnerships with them. I regret the fact that a lot of these startups develop good products that never get to the market. Apart for financial constraints, I think the reason is that they do not spend enough time thinking about marketing and sales: Who benefits most from our treatment? How do I get access to these patients? Horus Pharma has strong expertise in this area and can help them successfully access the market.

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