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Jorge Alderete, president of ALK Americas, outlines the Danish mid-cap's strategy in the challenging US market, including innovative market access initiatives, and how future models of patient-doctor interaction and medical distribution will look.

Jorge, you have spent over 20 years with ALK Americas but while you have always been in the biotech sector, ALK is the first pharma company you worked for and you have chosen to stay for two decades! What motivated that initial transition and what has kept you with ALK?

Immediately prior to joining ALK in 1999, I was with IDEXX Laboratories, a biotech company developing a rapid detection test for *Escherichia coli* for the pharmaceutical, food and water industries. A former colleague of mine at IDEXX had gone over to join ALK and he told me that the Danish company had amazing innovation and technology but had taken the wrong approach for the US market. When I looked into the company, I became very interested because as a research-driven global pharmaceutical company focusing on the prevention, diagnosis and treatment of allergy, ALK had developed products that actually addressed the underlying cause of allergy rather than simply treating the symptoms.

The products interacted with the immune system to either strengthen it or reduce the impact of allergens. They were not simply putting a Band-Aid on the solution. However, despite the technical strengths of the portfolio, the company was selling its products more as a commodity, competing on price. Their US organization was focused mainly on salespeople instead of business development people with the technical backgrounds to explain the medical benefits of the portfolio to healthcare professionals.

I saw the opportunity for me to change that paradigm for the organization in the US. What was important was helping physicians realize the innovation behind our portfolio and the genuine value it could bring to patients. I have stayed with ALK ever since and the organization has had a good run over the past two decades, with phenomenal double-digit growth in recent years

The Danish take a longer-term view to managing a company than the Americans, which I prefer. I do not think businesses should be run on a quarterly basis. This is why I like working for ALK: their business culture and their long-term perspective in business.

The US market is the largest in the world, which is what attracts European midcaps like ALK to the country, but it is also possibly the most complex pharma market to navigate. What have you found difficult to explain to HQ in Denmark?

Market access is the most complex part of the puzzle. When I speak to my colleagues in Europe, I love to show a slide summarizing all the actors in the US healthcare system, including pharma benefit managers (PBMs), private insurance players, wholesalers and so on. Invariably the Europeans are shocked at the complexity. The system is very convoluted and difficult to explain, and all these actors take a cut, which is why drug prices in the US are so high compared to other developed countries. However, while most drugs are more expensive in the US, it is these profits that fund the innovation for new medications through research and development. Without the higher prices in the US, innovation would be reduced significantly. Many, if not most Americans, do not understand their own healthcare system.

At the same time, Americans are very reluctant to pay out-of-pocket for drugs. Even a monthly co-pay of around USD 50 is seen as far too high, which is why pharma companies also offer coupons for most of their drugs to reduce the co-pay to USD 25 or sometimes even nothing at all.

In this context, it is also sometimes challenging to explain the commercial environment to our European colleagues. The US is the biggest market in the world with many opportunities, but the

environment is also a little more difficult than before. Gone are the days that you can launch a new product and it becomes a blockbuster with USD one billion sales almost immediately. These days, even for the Big Pharma players, it is starting to take around five to seven years to gain the sort of traction you want for key brands. You have to invest heavily in consumer education, disease awareness, sales calls to doctors and so on. The prices in the US are a lot higher than in Europe so it is a lucrative market, but some patience is needed as well for our investments to generate the kind of returns expected.

In particular, with our tablet-based sublingual allergy immunotherapy portfolio (SLIT-tablets), the challenge is with the incentives that doctors in the US face to use subcutaneous allergy immunotherapy – injectables – instead of tablets. In the US, doctors buy these biologic drugs and mix them in their own offices before billing insurance, as a Medical Benefit, for the final treatment set and subsequent injections, whereas they simply administer the tablets as a pharmacy benefit. Therefore, the margins for these injectables are higher, because they get marked up as a procedural code and medical benefit. This is in contrast to the tablets, which are a prescription drug, so there is an economic incentive for doctors to continue prescribing allergy shots instead of tablets.

This is despite the fact that the tablets are better for most patients, home administration makes it convenient, safer, and clinically more efficacious. Currently, patients have to receive the shot weekly for up to 28 weeks, and then it is one shot every four to six weeks during maintenance for 3-5 years. For the tablet, the patient only needs to take the first tablet at the doctor’s office. Subsequently, they can take the tablet at home every day. In addition, after around three to five years, the patient’s immune system becomes desensitized to the allergen.

Nevertheless, ALK’s Americas business is performing well and the region is a strategic one for the group. What are the challenges and opportunities here?

ALK had previously out-licensed its tablet franchise to Merck & Co. (MSD outside the US and Canada) beginning in 2007 but in 2016, this agreement was terminated and by 2017, the rights to our grass, ragweed and then-investigational house dust mite SLIT-tablets returned to us. At that point, we also transitioned the organization from a B2B biologics company to a pharmaceutical one with market access, medical sales and marketing functions to better address the needs of the market. We moved our US operations to New Jersey to take advantage of the pharma ecosystem there since most of the pharma companies in the US are based in the New Jersey area. We

launched our house dust mite SLIT-tablet in the US in 2018 – 50 percent of the US population is allergic to house dust mites. Between 2018 and 2019, we actually doubled our workforce.

Our big push – and we are continuing to do this – is to reach out to consumers. As I mentioned, physicians do not have the direct economic incentives to prescribe tablets, even though it would be beneficial to them in the longer run because right now around 60 to 70 percent of patients do not want to get allergy shots. Doctors are therefore effectively losing the majority of patients with allergy. These patients could be prescribed tablets.

However, as TV ads are very expensive in the US, we are focusing on targeted digital and mobile advertising. For instance, we can target consumers that go online to Google symptoms like 'itchy eyes' or that share negative experiences with allergy shots on online forums. This ensures that our ads are viewed by the right target audience. We want to raise consumer awareness as well as direct consumers to doctors that are familiar with our portfolio. Last year, we were able to drive 66,000 patients to talk about these tablets with their allergists, which is great.

As telemedicine becomes more prevalent these days, especially with the current COVID-19 situation, patients are also getting used to the convenience of not having to visit their doctors, which will make our tablets even more appealing.

This is in line with the global direction of the company. In 2017, ALK decided to create a consumer care division to develop closer relationships with our consumers. It was first launched in Germany and then the UK, and it will arrive in the US in Q3 2020.

You have highlighted some of the challenges patients face in accessing affordable and innovative therapies as a result of the presence of all these different stakeholders with divergent interests. How can such obstacles to access and affordability be addressed?

Affordability is key. We recently launched a specialty pharmacy network for our portfolio. This allows us to bypass wholesalers and retail pharmacies, reducing our costs. Specialty pharmacies work with pharma companies to help patients understand and access the product. For instance, for a patient to access the tablets for allergy immunotherapy in the US, their doctor needs to apply for prior authorizations demonstrating that other drugs have been tried unsuccessfully, like antihistamines and corticosteroids. Specialty pharmacists work with doctor offices to ensure that these prior authorization forms are done so patients can access their drugs. They also have CRM systems to let patients know about any relevant coupons that exist to reduce their co-pays.

Personally, I believe that companies like Amazon are going to change healthcare distribution in the US. I envision the future of healthcare being, a patient goes to the doctor and receives a prescription. By the time he is home, Amazon has already delivered the drugs. This will severely affect wholesalers and retail pharmacies, as well as reduce drug prices significantly and increasing patient access

On another note, as a European midcap in the US, how does ALK attract the kind of talent you need to compete against the larger players?

What attracts talents to our company is the ability to become part of the decision-making process. As a mid-sized European biopharma, we have a very dynamic and flat structure that empowers people to strategize and lead, not just execute the business plan. What I have heard is that decision-making at Big Pharma is top-down. Here at ALK, it is bottom-up and inclusive, which is very attractive to many experienced industry executives.

On a final note, how has the COVID-19 situation impacted your operations in the US and what do you envision for the company moving forward?

In the short term, we can definitely see a negative impact because of the quarantine and other COVID-19 measures. Patients are afraid to see their doctors. We need time for that fear to dissipate. However, in the longer-term, more patients will prefer to take their medication at home instead of having to visit the doctor weekly, which is positive for our tablet portfolio.

In addition, after COVID-19, people will take respiratory conditions more seriously. In particular, left untreated, allergies can lead to more serious respiratory diseases, like asthma. Hopefully, this situation will encourage people with allergies to seek proper medical treatment instead of self-medicating with OTC medications like antihistamines and corticosteroids, which only treat the symptoms.

Finally, I believe remote working will become much more popular. Now that most of the world has been forced into social distance and/or quarantine, I think people are starting to realize that people can work more efficiently remotely. Many intercontinental business trips and meetings will be replaced by teleconference and videoconference. Even patients might realize that virtual meetings with their doctors are better and more convenient than having to go to the doctor’s office and sit in a waiting room with other sick people.

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