Interview: LoiÌ?c Maurel â?? CEO, Diaxonhit Group, France

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The CEO of Diaxonhit Group, a fully integrated French leader in in vitro diagnostics, discusses the companyâ??s strategic focus on specialty vitro diagnostics, his perspective on the challenge of consolidation that the diagnostics industry faces, as well as his cautiously optimistic assessment of French competitiveness in the pharmaceutical and life sciences sectors.

Ever since Diaxonhit positioned itself as a pure player in specialty *in vitro* diagnostics in 2008, it has seen exceptional growth. How has Diaxonhit evolved so successfully during your term as CEO?

Diaxonhit was founded in 1997 and we had an IPO in 2005. Initially, our company had two areas of operations. Our technology, based on alternative RNA splicing, has both therapeutic and diagnostic applications, and Exonhit Therapeutics, as we were known at the beginning, was involved in both. After I became CEO in 2008, we had a strategic review and we decided to focus on diagnostics exclusively, and specifically, specialty diagnostics. There was clearly potential in our technology and it only remained for us to invest it wisely.

At this point, in vitro diagnostics as a segment was slowly growing, except for certain niche areas like molecular biology â?? everything related to genomic research, as well as assays developed for specialists. It was thus a natural decision for us to move into speciality diagnostics. We also stopped our first program, which was related to Alzheimerâ??s. This is the most difficult disease to start with, because our technology relies on the measurement of RNA splicing events, which occurs in blood. Given that Alzheimerâ??s is a neurological condition, the blood-brain barrier created problems for research. It also became clear that eventually, our company would need to commercialize our products. Instead of starting from scratch, we decided to acquire InGen Biosciences to facilitate this aspect of our business. This was finalized at the end of 2012, and we rebranded ourselves as Diaxonhit, with a â??Dâ?? to emphasis our focus on diagnostics. We are now a fully integrated player in the field of *in vitro* diagnostics, from development to commercialisation, as well as some production.

Diaxonhit owns a diversified portfolio including proprietary diagnostic products, centred on two specialty areas: infectious diseases and cancer diagnosis. Can you tell us more about your promising pipeline in those specialty areas?

We have three main products in the pipeline. The first, Dx15, is a thyroid cancer test. Usually in presence of a cyst, physicians will perform a fine needle aspiration (FNA). FNA samples can be challenging to interpret and in 15 percent to 30 percent of cases, results are indeterminate, that is to say , the cytologist cannot say whether the cyst is benign or cancerous. Our test can be used on these indeterminate cysts, which helps to eliminate unnecessary thyroidectomies of benign cysts. In France, there are around 7200 unnecessary thyroidectomies every year. The use of this will undoubtedly have a significant impact.

The second is the BJI InoPlex, the first multiplex serological blood test to differentiate between mechanical and infection problems with hip-knee replacement surgeries. There are 3.5 million hip-knee replacement surgeries globally. 20 percent of these patients suffer from pain. In 95 percent of these cases, the pain is related to mechanical problems with the prosthesis, and in the remaining 5 percent, it is infection-related. The problem is differentiating between the two causes, and conventional methods like clinical examination, blood tests or even X-rays cannot solve this (or in the case of X-rays, when they do highlight a cause, the problem would have progressed to such a serious extent). Thus, BJI Inoplex helps physicians in a differential diagnosis between the mechanical failure of the prosthesis and a potential infection.

We are also developing companion diagnostics for two French companies: Erytech, in cancer and Innavirvax, who is developing a promising therapeutic vaccine for HIV.

In Europe, we have also licensed Allomap from CareDx Inc. (Brisbane CA). It is a non-invasive, gene-expression profiling blood test, which acts as a substitute for cardiac biopsy in heart transplant patients. It is the only molecular test to be recommended by the International Society of Heart and Lung Transplantation (ISHLT). There are 2000 new patients in both US and Europe, every year, and 20,000 cardiac heart transplant patients living in both Europe and the US. As of today, 50 percent of the US patients have already benefited from this test at least once. Diaxonhit will commercialize Allomap using a central lab in University Hospital of Strasbourg, France, where all European samples will be processed.

In addition, we manage distribution for other diagnostics companies. Transplantation accounts for 80 percent of our business, with products from Thermo Fisher and One Lambda, microbiology with Quidel, for instance, autoimmunity with Aesku and quality control products sold to both hospital and private labs.

Diagnostics is a huge industry (globally around EUR 40 billion (USD 45 billion) in 2012) but it has a very fragmented playing field. There are a few major players like Roche Diagnostics, Siemens Healthcare Global, Abbott and bioMÃ©rieux in France but the vast majority of the rest are small and medium enterprises (SMEs). Where do you see the industry heading?

The fundamental truth about the diagnostics market is that it is in dire need of consolidation. I would say it is 30 or even 40 years behind the pharmaceuticals industry in terms of development and sophistication, but evolving very rapidly. Consolidation has started, but there is still a long way to go.

This is crucial because there needs to be a critical mass for the industry to be successful. For instance, we have an annual turnover of EUR 30 million (USD 34 million), and this puts us in the position of the fourth largest French company in the industry. The unavoidable fact is that diagnostics is what we call a â??Nespressoâ?? business. Successful companies already provide both instruments and reagents; the consolidation of private labs creates a need for larger automates. The point of care is also developing rapidly. The place of genomics will increase. In addition, companion diagnostics are developing very rapidly. Having a critical mass in terms of product offerings (both reagents and instruments) and accordingly, firm size, is crucial in generating efficiencies, leading to better outcomes for patients and the more cost-effective provision of healthcare. The benefits of the diagnostics industry are still largely untapped in terms of reducing healthcare costs. European healthcare stakeholders need to understand the potential in this market.

There is great potential in the industry. Personalized healthcare is the most important current trend and the digitalization of healthcare is a major topic of interest nowadays. eHealth is knocking at the door and much more rapidly than expected. My radical idea is that artificial intelligence could eventually replace pathologists. Increasingly, society wants to take charge of its own health and

welfare. For instance, in France, there is a wait of several months for a consultation with a cardiologist. I believe personal diagnostics is a currently unmet need, and it will continue to grow in the future.

What is your ambition for Diaxonhit and how do you plan to differentiate Diaxonhit from other players in this crowded market?

We have a two-pronged strategy: internal and external growth. Internal growth means increasing our distribution channels and finding new distribution partners, as well as developing and launching our proprietary products successfully. Distribution is one important component of our market operations. This is one area in which we have a competitive advantage, because American or Asian firms find the European market very segmented and confusing and thus, it is difficult for them to enter European markets. What we do is work with these firms as a distribution partner, and this creates opportunities for us to obtain licensing deals for Europe. We are progressing proactively on this front.

External growth means making more acquisitions and expanding the company. We have plans to expand geographically as well, through acquisitions and subsequently affiliates, in a few years, beginning with a couple of major European economies such as Germany, Italy and Spain, and later on in the US.

We have great experience in acquiring companies, but more importantly, we are also good at integration, because acquisition is just the first step; integration is key to successful partnerships.

Ultimately, I would like Diaxonhit to be a significant participant in the consolidation of the diagnostics industry. More concretely, the five-year plan is to reach EUR 100 million (USD 113 million) in sales. It is ambitious, but not unrealistic.

In recent years, there has been increased debate surrounding a perceived decline in French competitiveness in the pharmaceutical and life sciences sector. How do you assess the French pharmaceutical and life sciences environment?

The perennial question for France is: why, despite having all of the necessary raw ingredients, does France still lag behind in terms of competitiveness and attractiveness when it comes to pharmaceutical and life sciences development? I can provide a never-ending list about Franceâ??s strengths. We have strong government support in terms of financial schemes, with tax credit policies. We also have a dynamic stock market. We have a strong tradition of medical and research excellence, and we have brilliant doctors, researchers, CEOs and employees. We have venture capital and we have entrepreneurs in France. There is always room for improvement but we are quite well-equipped with the ingredients for success.

What more do we need? Ultimately, there are two main barriers to success. Firstly, very paradoxically, the government undermines its own attempts to promote innovation. It goes beyond the problem of inefficiency or too much administration â?? sometimes, the policies they implement are not conducive to their aim of promoting innovation. To take an example, the Hollande administration recently implemented a tax policy penalizing companies for offering employees stock options or shares. Diaxonhit used to offer 25-30 percent of our employees stock options as performance bonuses, because we like our employees to be fully involved and invested in the company. But there was some negative perception regarding CEOs of huge companies getting paid millions in stock options each year, so the government decided to limit it across the board. They implemented a policy mandating companies to pay a tax equivalent to 30 percent of the stock options they offer their employees. This severely penalizes small and medium enterprises like us. Specifically for Diaxonhit, this tax amounted to another 1.5-2.5 percent pay raise for the entire company, which was financially impossible. Therefore, we had to eliminate this initiative.

Another example of this is that on one hand, the government encourages academic and industry partnerships. In the diagnostics industry, we frequently obtain samples from public hospitals, which we use for our research and validation studies. On the other hand, it looks like samples from academic centres can no longer be included under the tax credit scheme. This immediately and clearly disincentivizes companies from working with French academic institutions. Diagnostics companies may now source samples from private bio banks and also from the US, where they are cheaper. I fail to see the benefit of this policy.

The second factor comes down to mentality. In France, there is a peculiar suspicion of success that discourages people from aiming for the best. This is problematic, because France already discourages professionals through its high tax rates and its high living costs. Given the current level of international mobility, France is vulnerable to brain drain. It is already facing intense competition from other European cities like London for talent.

What would be your final message to our audience?

France is still a great country to live and work in. But there needs to be an honest revaluation of the existing situation, and there are many areas for improvement. Market access is the most important challenge that needs to be addressed. Particularly for the government, if they genuinely want to support innovation and the pharmaceutical and life sciences as an industry, they need to implement a more coherent set of policies.

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