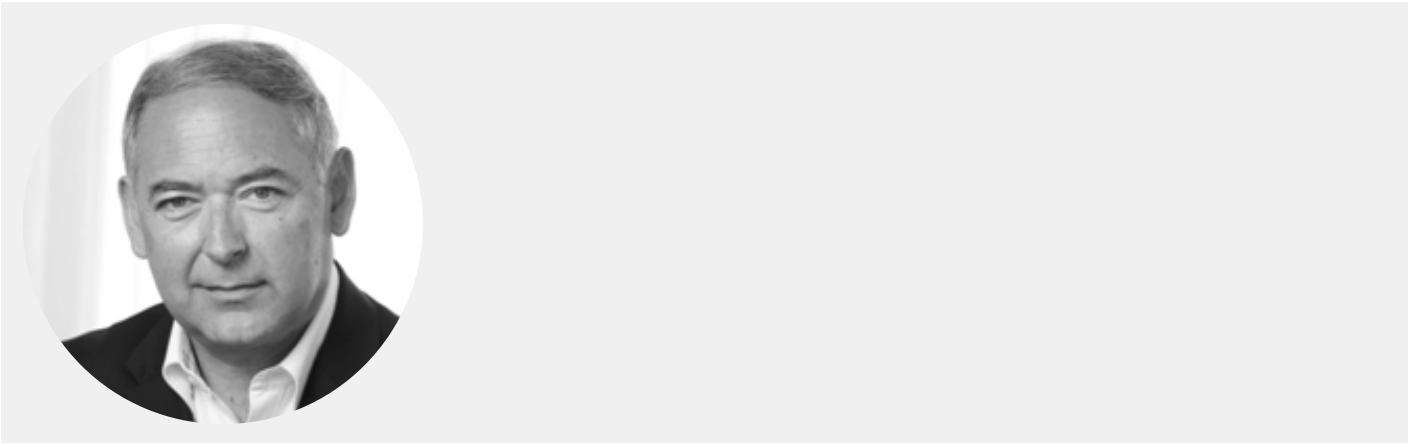
Interview: Michel Finance – CEO, Theradiag, France



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Mr. Michel Finance, CEO of Theradiag, a leading French player in in vitro diagnostics and the novel field of theranostics (a combination of treatment and diagnosis), discusses the major restructuring at Theradiag he oversaw, the crucial role that diagnostics play in the provision of efficient as well as cost-effective healthcare and the challenges and opportunities of the French research and biotech environment.

In 2013, Theradiag reorganized around two business units: in vitro diagnostics and theranostics, and earlier this year, you moved into new headquarters. Can you discuss Theradiag's current business model?

The story of Theradiag since my arrival in 2010 has been reorganization and revitalization. We used to be called Biomedical Diagnostics and in 2012, we took on the new name, Theradiag, to reflect our new strategic direction.

Firstly, we formed two business units, in vitro diagnostics (IVD), which was our traditional area of expertise, and a newer field of personalized medicine we call 'theranostics'. Theranostics was developed based on the expertise we already had in sales and marketing in the IVD field and in the therapeutic area of autoimmune diseases.

Secondly, we are developing the company from an old-fashioned distributor to a true biotech start-up by creating an innovative and proprietary portfolio of products. Five years ago, 75 percent of our activity was in distribution with the remaining 25 percent in our own products. Last year, distribution accounted for only 40 percent. Our objective is to have 75 percent of turnover coming from our own portfolio. We would like to maintain a small proportion of our sales coming from distribution because we are a small company and our distribution business can complement our own portfolio very nicely by helping us break into markets.

The objective of our IPO in 2012 was to finance this reorganization and to develop the new area of theranostics. While IVD still represents 70 to 75 percent of our business, theranostics is our main growth driver at the moment. From no sales three years ago to EUR 1.4 million (USD 1.6 million) last year, this is a very promising area, and independent analyst reports have estimated that our current portfolio alone could reach EUR 10 to 20 million (USD 11 million to 22 million) in just a few years, depending on the number of markets penetrated and the level of reimbursement.

This complete strategic overhaul of Theradiag is evident in not just our new name and new headquarters, but in all aspects of our operations, from product portfolio to management style and from our personnel composition and the spirit of the company.

What is Theradiag’s internationalization strategy?

Another important aspect of our restructuring is our internationalization plan. While an excellent market for innovation and R&D, in terms of sheer size alone, France cannot compare to the US or China, for instance. This issue is further exacerbated by the challenges surrounding pricing and market access. For the diagnostics market, with its low margins and volume dependence, and particularly for a small company like us, we cannot only stay in France, and we need partners to establish ourselves in other countries.

Currently, our sales are 59 percent in France and 41 percent export-oriented. We aim to reach 75 percent exports in two or three years. This will happen organically as we readjust our activities towards our own innovative portfolio and also through external partnerships. Two markets we are very interested in breaking into at the moment are the US and Asia. For instance, recently we signed a licensing agreement with Miraca Life Sciences for therapeutic drug monitoring tests in the US, which could be a game changer for Theradiag. We have also signed a strategic partnership with HOB Biotech, China’s market leader in allergy and autoimmunity *in vitro* diagnostics, which will not only allow us to commercialize our products in Asia but also gain access to the innovative tests being developed by HOB, thereby expanding our portfolio.

We look forward to developing more partnerships along these lines in order to further drive Theradiag's growth.

Diagnostics is a huge industry dominated by key players like Roche Diagnostics, Abbott, Siemens and bioMérieux, but with 90 percent of the players in France still being SMEs, how is Theradiag differentiating itself within this fragmented playing field?

What is unique for Theradiag is that we are fully vertically integrated. Most diagnostics players either focus on R&D or distribution. We are able to do the entire development line, from R&D to innovation to development, production, commercializaton, certification and then to distribution. There are not many companies like us.

This is our strategy to differentiate ourselves: by moving up the value chain. Fifteen years ago, we were only a pure distributor in IVD. Gradually, we have moved into R&D in IVD, and now we are looking theranostics, and in particularly, molecular biology and the development of our own biomarkers. For us, this is the best – and only – way of surviving in the diagnostics business.

We are also continuously developing and innovating. The key is to plan ahead and have a portfolio of products at every stage of development. We have developed signature microRNAs to increase the predictive power of diagnostic tools. This is a very ambitious project and we have no direct competitors in Europe.

One of the successes of Theradiag has been your ability to create partnerships with established Big Pharma companies such as UCB and Hospira. How do these partnerships fit into your development strategy?

Partnerships are a crucial component of our business model. Diagnostics is a natural component for specialty areas like autoimmune and inflammatory diseases, our traditional expertise, and oncology, which is a new area we are entering. This is because these conditions require consistent treatment and monitoring over a significant time frame.

Our two major partnerships have been with UCB and Hospira. We are looking at newcomers in the fields because they have the incentive to work with us as diagnostics providers, as they want to showcase the competitiveness of their novel biotherapies or biosimilars compared to the existing blockbusters on the market. It is a mutually beneficial arrangement: pharma companies can offer regulatory authorities the added 'bonus' service of diagnostic tools to track how efficient and cost-effective their biotherapies are, while diagnostic companies benefit from not having to market their products themselves. There is huge potential here, because biotherapies and biosimilars will

continue to increase in market share.

This is what we have done with Hospira for the launch of Inflectra, their biosimilar for Infliximab, in conjunction with our monitoring kits in France, and Europe more generally, as well as Canada and Australia. Hospira won the first two big tenders for biosimilars in Europe, in part through the offering of our diagnostic monitoring services for free.

Our next step is to convince a pharma company to involve us in their drug development from the very beginning, including using the diagnostic tool during clinical trials as a way of measuring efficacy. The pharma company can then use these results to demonstrate their efficiency to regulatory authorities during pricing and reimbursement negotiations.

Given the issue of unsustainable healthcare expenditures in France and also in Europe, what role can Theradiag play in addressing this issue?

Diagnostics and especially theranostics in the field of personalized healthcare must be an important element of any effective and comprehensive solution to this problem. Personalized healthcare and theranostics can generate significant healthcare savings. We have commissioned a pharmacoeconomic study with a group of scientists, experts, KOLs and French hospitals, showing that we can save 25 percent of total drug costs for Crohn's disease treatment in five years if we start monitoring patients using IVD. This study was published on October 30th in the journal Market Access and Health Policy..

The problem is that we simply have not raised sufficient awareness of the benefits of diagnostics. 70 percent of all therapeutic decisions made by doctors are based on biological tests. We are a crucial part of the healthcare system. But we have yet to convince the authorities that we are not just an additional cost to be minimized but an indispensable and cost-effectiveness component.

In France, the problem is that the cost of a disease is not calculated holistically, from diagnosis to pharmacological treatment to hospitalization, unlike in the UK. In France, each area has a separate 'pocket' and health authorities only wish to cut budgets from individual pockets, usually the pharmaceutical pocket. But this is insufficient and we need to start looking at more innovative ways to reduce costs.

Given the importance of R&D to Theradiag's restructured business model, how has Theradiag found the clinical research environment in France?

France has the advantages of a brilliant ecosystem of both public and private R&D innovation, with many excellent ideas with huge potential. The problem with France is related to the translation of

these ideas into viable business ventures. We have the best academic institutions and innovation but we struggle with commercializing them.

A major cause of this problem is the French mentality surrounding commercialization. For academic researchers with institutions like CNRS, L'Institut national de la santé et de la recherche médicale (INSERM; French institute of health and medical research) and Institut Pasteur, there is a stigma attached to having the desire to start your own company. In the US, it is completely the opposite. For instance, our microRNA project begun with patents which we obtained from CNRS. It was not easy to create this partnership and as soon as we began to talk about commercial applications, CNRS lost interest. They gave us a great scientific base but we had to do the full development on our own.

Mr. François Sarkozy has said that France is not a very good incubator for biotech companies. With your decade's experience in the French biotech industry, what is your perspective on this?

France is definitely not a mature biotech market yet, but we have improved significantly in the past decade. In the mid-2000s, we only had eight biotech companies listed on the stock exchange. Now, we have 72.

We have decent financing options. There is some public financing, like the BPI and Sofinnova, and there are some venture capital funds. There is undoubtedly not nearly as much funding as there is in the US, but there is enough for a biotech company to start developing itself. After that, it depends on your own work to continue developing the company. For Theradiag, after a few rounds of raising capital, we decided to IPO.

Ultimately, a start-up is very self-directed. We cannot simply criticize the system for not being good enough, we must find the solutions ourselves or we will fail. For instance, if getting favourable pricing and reimbursement decisions in France is difficult, then look at other European markets as alternatives.

How has your experience in both Big Pharma and biotech contributed to your current position at Theradiag?

With my international finance and M&A background, nearly two decades of experience in Big Pharma and then a few years overseeing IPOs and general managementt for biotech companies, I have a wealth of experience to offer Theradiag. In particularly, I know the way partnerships work for Big Pharma and how to facilitate partnerships discussions between Theradiag and pharma

companies.

What is your five year plan for Theradiag?

Theradiag currently has an annual turnover of EUR 7 million (USD 7.7 million). Our concrete target is to grow into a mid-sized diagnostics company, with around EUR 25 to 50 million (USD 28 to 55 million) turnover.

For diagnostics in particular, Big Pharma should see us as partners and not competitors. The patient should be the main focus of the industry and it is crucial that we know for sure how effective our therapies are! Big Pharma and diagnostics need to work together.

There are undeniably many challenges for a company in France, but there are also huge opportunities. You can be successful as a French company, but not only in France – you need to innovate and internationalize.

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