Interview: Finn SÃ¸ndergaard â?? CEO, Intsel Chimos, France

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Mr. Finn SÃ¸ndergaard, CEO of Intsel Chimos, an independent French laboratory with a long history of expertise in the import of medicines for patients in a therapeutic impasse, highlights Intsel Chimosâ?? emphasis on innovation and R&D and discusses the promising orphan drug the company is in the process of developing. He also comments on the French healthcare and pharmaceutical landscape, discussing the challenges of market access as well as highlighting Franceâ??s strength in clinical research.

Tell us about your company and its main specialty areas for our readers.

Intsel Chimos represents the merger of two companies: Chimos, a company founded in 1966, which has always been dealing with Autorisations Temporaires dâ??Utilisation (ATU; the French Temporary Use Authorization system) or ATU-like products, and Intsel, which was founded as a subsidiary of the Danish company, Marsing & Co., in 1984. Marsing & Co. primarily dealt with the supply of APIs along with a few other specialty areas.

I joined Marsing in 1989. In 1995, I came to know about Chimos and found it a very interesting company. As a result, I decided to acquire it and merged the two companies in 1996.

Since 1960s, Intsel Chimos has specialized in the import of medicines for patients in a therapeutic impasse, long before the formal establishment of the French ATU system. How important is this as a growth driver?

This remains our main growth driver for the time being, and we have been steadily taking market share, which is an achievement we are very proud of. Our decades of experience have allowed us to establish strong and effective relationships with many partners.

This is how the French ATU system works: when a healthcare specialist has exhausted all the treatment options available without the desired therapeutic results for his patient and he happens to know of a product that is only available outside of France, he is able to obtain special authorization to import this product. It does not have to be an experimental drug, just a product without market authorization in France, for whatever reason. The specialist then contacts the hospital pharmacist, who will in turn contact the Agence Nationale de SÃ©curitÃ© du MÃ©dicament et des Produits de SantÃ© (ANSM; French National Security Agency of Medicines and Health Products). ANSM decides whether to provide an ATU, which is simply an A4 piece of paper, with the name of the physician, the initials of the patient and requested product. With this document, we can then supply the hospital.

Over 90 percent of our ATU products have market authorizations from other countries and the rest are very late-stage development products, where the market authorization dossiers have already been completed and the product is simply awaiting final approval.

In 2010, Intsel Chimos obtained orphan drug status from the EMA for your molecule intended for the treatment of gliomas (brain tumours). What is the significance of this for Intsel Chimosâ?? development?

This was a hugely significant milestone for Intsel Chimos, as was the orphan drug status from FDA in 2011, and I am very proud of all that we have achieved in this regard. It was very exciting to obtain the first orphan drug designation for a product that we are developing ourselves.

We obtained the exclusive license from Centre National de la Recherche Scientifique (CNRS; French National Center for Scientific Research) in 2006, which gave us the right to take over the drugâ??s development. We have had to start almost entirely from scratch, as what CNRS did was essentially a proof of concept. The very first thing we had to do was create and synthesize the API, because it is not an existing product. It is so novel that we are defining the pharmacopeia of this API ourselves. In its finished dosage form, it would then have to be encapsulated in liposomes. Currently, those two steps have been finished.

In order to obtain market authorization, we now need to create pre-validation and validation batches. Then we will proceed to the standard pre-clinical and clinical trial stages. Drug development is never a linear process and it is both lengthy and expensive. Nonetheless, we have made very good progress and it is very exciting to watch an in-house R&D product develop. There is a very real sense of achievement.

In light of these dual areas of focus, what is Intsel Chimosâ?? current growth strategy?

We would like to continue the development of both our ATU and our in-house R&D activities. In terms of our ATU products, we are aiming to be the best and most reliable supplier to French hospitals. The increasing number of requests for products for clinical trials would seem to indicate that we are on the right track.

For our orphan drug development, the projection is that our product will be ready to go on the market in two to three years. After that, we intend to commercialize it ourselves in France and the neighbouring countries, and I have already identified a potential partner for the rest of Europe. In terms of other regions like North America and Asia, we intend to out-license it to strong regional partners.

We would also like to continue our in-house R&D development and hopefully develop a few more products over the next few years. To finance and support this goal, we are considering the IPO of a minority share in the next couple of years as well.

Ultimately, our growth strategy is centred on innovation. Innovation is at the core of our company, for two reasons. Firstly, there are synergies that can be tapped between our activities in the supply of ATU to hospitals and our in-house R&D. We would like to take advantage of this. Secondly, to really develop a product to its full potential, we need to have its intellectual property and truly own the product. Hence, R&D and innovation are crucial to Intsel Chimosâ?? further development.

France has always been an attractive research environment but there has recently been fears that it is losing its competitiveness. How conducive has Intsel Chimos found the French research environment?

Generally speaking, France has a very high standard of academic and research excellence, and this is a prerequisite for private companies looking for a base. In addition, France has a nice system when it comes to making public research available to private companies. Whenever a public researcher works in R&D, the CNRS takes ownership of the results and in theory, they manage the commercialisation process, part of which also includes ensuring that the researcher gets appropriately remunerated should the product get to market successfully.

The worry with public-private collaboration is that public researchers are afraid they might be shortchanged when it comes to remuneration. This system theoretically addresses this, though I am not sure how well-implemented it is in practice. In France but also more broadly in Europe, there is an innate suspicion of having too much money flow from private companies to public researchers, due to a fear of conflicts of interest. This is understandable and the entire issue is very delicate. But in terms of the quality of research, France is an excellent country.

France has a notorious reputation for being an extremely challenging country for market access. What has Intsel Chimosâ?? experience been with regard to the issue of market access?

When it comes to the ATU, France undoubtedly has an excellent system. It was the first country to formally structure it into a working system and other European countries have taken France as a model.

In terms of general products, obtaining market access in France requires the usual procedures of obtaining market authorization, negotiating prices and joining the reimbursement list. In France, there are a number of authorities involved in the process and it is not a fast process, to say the least. Despite the major restructuring of ANSM in 2012, the situation has not really improved.

It would be in the interest of all parties â?? pharma companies, patients, government agencies â?? if this process was expedited. It is an issue that decreases Franceâ??s competitiveness.

This may not be a popular idea, but I would like to question why different European countries still require their own regulatory agencies, given that the European Medicines Agency exists? It is difficult to understand why EMA would approve a product that would then be rejected in France or other European countries, so there is some repetition in the regional and domestic market approval processes. France is definitely doing a very thorough job in terms of market authorization but the process needs to be expedited.

Within the context of increasing healthcare costs and the need to maintain a sustainable healthcare budget, some stakeholders like FranÃ§ois Sarkozy has suggested that the consolidation of hospitals in France need to be part of the solution. What is your opinion on this?

To some extent, consolidation and centralization has already begun, with the Centre Hospitalier Universitaire (CHU; French network of teaching hospitals). From a research and treatment perspective, these centralizations work beautifully because they concentrate speciality areas and generate more synergies. It is evident that you cannot offer all hospital services and specialties in a small, remote hospital.

However, such consolidations inevitably involve investments, relocation and restructuring costs. Whether it is always a cost-effective solution and would generate the cost savings to justify it is unclear. There is a similar process happening in Denmark and it remains to be seen how successful it would be.

In view of these increasing healthcare costs, it has always been a surprise to me that France, unlike many other European countries, is still so slow in the uptake of generics.

You are one of the few non-French CEOs of a French laboratory. What has been the main challenge for you?

One obstacle I faced initially was in my search for public funding, as an SME. I perceived some element of distrust from institutions like the Banque Publique dâ??Investissement (BPI; French Bank of Public Investment) because I was a foreigner; there may have been doubt of my commitment to developing a French SME.

However, in general I have loved working in France â?? and still do. I have been involved with Intsel Chimos in various capacities since 1989, most notably as CEO and owner since 2009, and as long as you keep an open mind, there are not many challenges to working as a foreigner in France. At Intsel Chimos, I would say there is a very nice mix of cultures and we take the best from both the Danish and the French cultures. It does help immensely if you speak French, but regardless, the important thing is to be open-minded and flexible.

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