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Finn Søndergaard, CEO of Intsel Chimos, shares the motivation behind the company's two recent acquisitions of Diverchim and Centre Lab, and the new strategic opportunities to expand as a full-service hospital partner in the French healthcare system. Additionally, Søndergaard offers his assessments of the conditions of market access in France today.

What have been the main developments in the operations of Intsel Chimos over the last three years?

The most notable would be the organic growth and our investment in two French companies, Diverchim and Centre Lab, formerly known as Terali. In terms of performance in Intsel Chimos, over this period we have doubled our turnover and the number of employees and external consultants. Today we have 75 employees in the group and a turnover of EUR 22 (USD 25) million.

To achieve this growth, we have added new elements to our range of products and services, distinguishing Intsel Chimos as a full-service provider. Speaking about our ATU side, we have the capability to manage the entire process as long as the market authorization (MA) holder is willing to work with us. We offer an A to Z solution for our clients which is particularly important in a market like France which is perceived to be very difficult to enter. Of the approximately 250 products per year in France benefiting from ATU status, Intsel Chimos manages about 25 to 30 percent; this arm of the business is still our main driver.

Let’s talk about these two recent acquisitions in greater detail. What was the rationale behind the acquisition of Centre Lab in February 2018?

At the time, the company known as Terali was not performing well financially and the opportunity was brought to our attention. After a quick analysis, we concluded the time was right to move in the direction of increasing our capabilities into a new area. We hence took over Terali laboratories in February 2018 and created Centre Lab, which develops and manufactures hospital preparations (known as Specials in f.ex. the UK), medical devices, well-being products and cosmetics in small to medium batches. The manufacturing site, which is based in Guéret France, is certified as to GMP and it has class C and D white room facilities for liquid (oral and topics), semi-solid (pastes and creams) and solid (capsules and tablets) forms. We have already injected several million euros to revive the activity of Centre Lab and the number of employees has grown from 13 people during the recovery to 20 people; a number we hope to continue increasing in the coming months.

How has taking over Diverchim boosted the R&D capacity of Intsel Chimos to produce its own portfolio?

In July 2017, Intsel Chimos became the majority shareholder of Diverchim CDMO, a French leader in organic synthesis of original molecules. The company was founded in 2000 and is able to manufacture Active Ingredients in small quantities from a few grams to hundreds of kilograms and is dedicated to Pharmaceutical and Cosmetic Industries.

Thanks to its R&D historical know-how, Diverchim offers the combined services of a CRO and CMO and is able to switch from medical chemistry to recurrent productions based on robust and validated processes.

The rationale for acquiring Diverchim is related to the fact that Intsel Chimos is working on developing its own molecule, for the treatment of glioblastoma. It is a slow and costly process, but we are doing it as efficiently as possible. So far the greatest difficulty in the development of this product has been the production of the active ingredient – an ingredient not yet in the pharmacopoeia. At this point, we had contracted Diverchim to carry out the task. When the company fell on difficult financial times, we identified this as an opportunity to turn the situation into a positive one. Furthermore, we realized through our experiences with other laboratories, that larger batch contracts were being prioritized over the small batches necessary for the development

of our molecule. We realized this is a challenge also faced by other companies in their search for the same experience and capacities. Therefore, we took the opportunity to not only increase our own capabilities in R&D but also create the potential to expand our business activities in the future.

How have you developed Diverchim since the acquisition?

To supplement the expert know-how in fine chemistry and pharmacy we have been carrying out a strategic review mission to find new sources of growth for the company. Initially, Diverchim was doing most of its business as a CRO, but it marketed its services on the basis of “objectives of results” rather than “objectives of means”, as is practised by typical players who offer R&D services. Therefore, we decided to increase the share of custom production that offers more recurring revenues than research alone.

Diverchim has gone from a company dedicating 80 percent to research projects and 20 percent to production projects, to a company that devotes more than 70 percent of its operations to GMP production. As mentioned, Diverchim has thus moved from being a pure CRO to a CDMO but focusing on the synthesis of small quantities of active ingredients for the manufacture of commercial products and drugs in the process of preclinical and clinical development.

How do these acquisitions fit into the strategy of Intsel Chimos?

As part of our diversification activities, we are increasing our footprint in the distribution of generics in hospitals, and at the same time, developing our drug involved in the treatment of glioblastoma with the launch of pre-clinical and clinical trials for this future product. Centre Lab has as its main activity the manufacture of hospital preparations and distribution to hospitals and clinics; a very complimentary function to Intsel Chimos. Besides hospital preparations, Centre Lab offers a specialized formulation tool for small series production, complementary to Diverchim’s activity. Therefore, the group is creating a global offer for the hospital sector to produce APIs with Diverchim (in small quantities), formulate and manufacture final products at Centre Lab (in small series), and finally distribute to hospitals through Intsel Chimos. The same chain – in total or in parts – is available to third-parties.

This venture is still quite new and we are currently adding capacity to Diverchim, this we believe will be important to the group and what we can contribute to the French healthcare system. There will be a need for small batch APIs moving forward. France is facing a recurring challenge of

medication shortages due to the increased outsourcing to countries like China and India. The manufacturers are very consolidated which cause issues if for one reason or another there is a sudden halt in production from raw materials over intermediates and advanced intermediates to the finished API.

In this context, I would expect local authorities to establish precautionary measures to ensure that the patients most in need of certain products will not suffer in the instance of shortages. Here, Diverchim is well positioned to produce from a few grams to 300 kilograms per batch. Complimentary to this, Centre Lab has the capability to produce the finished dosage forms of such products.

Who are the primary customers of Intsel Chimos?

Our focus, both before and after the acquisitions, is the common denominator we have between the patients receiving “our” medications, the doctors treating them and their hospitals. As regards products with larger indications for more generalized patient populations, we see a mix of pharmaceutical players from niche laboratories to larger pharma. Bigger and large pharmaceutical companies rarely outsource their MA-products. If they do so this is mainly because their product does not fall within their core competencies. This could for example be a niche drug that would require a specialized access team and/or where the handling of the product falls outside their standard operating procedures. Additionally, if a company is unable to obtain a favourable price in the market for a certain product, they may pass on the production or exploitation/distribution to a company like Intsel Chimos.

What is your assessment of the current French market access scheme?

In the context of the ATU system, the Macron administration has decided to manage ATU’s on a per-indication basis. Additionally, the National Agency for the Safety of Medicines and Health Products (ANSM) has eased the process for doctors, pharmacists, and hospitals to submit an ATU application. So far, for our company, this has not had much impact other than a rise in multiple indications being granted ATU status. The reason behind this seems to be a strategy to help curb public healthcare costs.

Before the current administration, a law was put in place which stated that if an ATU reached sales of EUR 30 (USD 34) million while the cost per patient per year exceeded EUR 10,000 (USD 11,300),

the manufacturer should pay reimbursement to the state. Therefore, with the admission of multiple indications, this regulation is applied to all indications on an individual level.

Some pharmaceutical stakeholders have voiced that while the ATU system works well to deliver drugs to patients in need, the system must be adjusted to also act as a driver of market access. What are your thoughts on this statement?

It is evident that to doctors and patients that find themselves in critical situations, the ATU system always allows for access to essential medicines. However, it is true, that when the time comes to apply for an MA in France, the process time remains high – slightly less than three times the European standard of 180 days. The safety and efficacy of a drug are reviewed by the ANSM, but even after, the dossier must pass by the High Authority of Health (HAS), the Economic Committee for Health Products (CEPS), and a number of other instances.

Moreover, France is known to negotiate the lowest possible prices in all of Europe. In addition to the aforementioned ATU sales penalty, when the product eventually receives its MA the manufacturer must pay the difference between the market price and the price during ATU. With all this taken into consideration, the ATU scheme does not necessarily help pharma players reach multiple-indication MA sooner but to a large extent does secure the access for patients to a medicine/treatment they would not otherwise have.

Looking forward, what are your strategic priorities for Intsel Chimos moving forward?

In our ATU business, we aim to be a one-stop shop for our existing and future partners in bringing their products to the French market. They agree to make their drugs available to us and we take care of everything thereafter. I would like to see Intsel Chimos become a full-service provider to the French healthcare system, more precisely the hospital network. We have the potential to be a partner of choice to the hospital pharmacies that manufacture products in house by collecting several small quantity orders and producing larger batches at a single time. This way we can deliver a more standardized product with, for example, stability studies and shelf life – a more complete offer.

France is perceived as a difficult market to enter – and rightly so – but it is by no means impossible if you know how to navigate in it. Being the second largest pharmaceutical market in Europe and with its highly skilled medical community, it deserves full attention and the best possible treatment

of its patients.

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