Interview: Harry Flore â?? CEO, HAL Allergy, The Netherlands

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A well-established player in the Allergy market, the Dutch company HAL Allergy recently expanded its activities with the addition of its HALIX Contract Manufacturing Outsourcing (CMO) arm. CEO Harry Flore highlights how the complete package and Good Manufacturing Practice (GMP) experience offered by HALIX, along with the companyâ??s long-standing in-house manufacturing experience makes them the partner of choice for the industry. In addition, Flore emphasizes how the company has benefited from the Netherlandsâ?? strong research and life sciences eco-system, particularly within the Leiden BioScience Park.

In 2012, HAL Allergy moved into the CMO market, with the creation of HALIX. What was the rationale for this move?

HAL Allergy decided to enter the growing CMO market, as we saw a promising business opportunity to provide specialized services based on our extensive GMP know-how to those customers, where large scale CMOâ??s would not be interested in. Factually it was not too much of a challenge to prepare our production facility accordingly for such CMO tasks. Being one of the few pharmaceutical companies in the Netherlands that possess the whole chain in house from start to finish â?? research and development, to production, marketing and sales â?? HAL Allergy decided to make our expertise and our facilities available for clients. HALIX was thus established as a stand-alone company and now makes use of HAL Allergyâ??s personnel and expertise through service level agreements.

Opening a CMO business also gives us the possibility to look at early stage product development â?? either investments, in-licensing, or joint ventures â?? that might be of interest for HAL Allergy. At

this moment, no such projects have been undertaken, as we have not yet had a client ask us to produce a product in our field of expertise, allergy, but such an opportunity could arise even tomorrow. At the same time, we have been able to foster interesting synergies between our traditional allergy business and the newer CMO business. As just one example, we have been asked by clients to perform cell culturing and to produce monoclonals and viruses. We are now using this cell culturing technology developed by HALIX for the development of certain allergy products at HAL Allergy.

What are the main assets of HALIX which make it the CMO partner of choice of the industry?

HALIX focuses on fill and finish, freeze drying and the production of proteins. We offer the whole production chain, and, in the future, we will also offer registration and medical advice, two areas of in-house expertise for HAL Allergy. Having run many phase I, II, and III trials in the past years, we can help clients understand how to optimally set up dossiers and clinical trials. As one example, we complete randomizations so that clients will have their products filled here, randomized, and sent to whoever they want. Ours is a total package embedded in the GMP experience that we complete day and day for our in-house HAL Allergy operations, a fact that sets us apart from stand-alone CMOs**.**

We are very proud that HALIX is moving fast from a no-name company to one that is well recognized. Indeed, HALIX is growing so fast that we will soon build a new building for CMO activity, especially as clients are now asking for certain clean rooms that we lack at this moment. We will build the facility on top of our current product, next to our production, or in a new facility at the Leiden Bio Science Park.

HAL Allergy started more than 50 years ago as a small and innovative local company in Haarlem, Haarlems Allergenen Laboratorium. What is the specific importance of the Netherlands to the company today?

When we decided to move the company from Haarlem in 2009, we also considered moving the company to another location altogether. However, the company possesses very good personnel with a lot of knowledge of the production and R&D side of our business, and we knew that we would lose much of this if we moved to England or Germany for example. As such, we decided to stay in the Netherlands.

As a next step, we chose to locate our new facilities in Leiden, as we need to be in an environment where a lot of things are happening intellectually. Leiden Bio Science Park is the largest science cluster in the Netherlands and one of the most successful, as it brings together Leiden University, Leiden University Medical Center (LUMC), and approximately 148 companies in close proximity. Start-ups are very important to the Park, and there is a lot of energy here thanks to the high level of interaction between start-ups and more well-established companies. Furthermore, there is a lot of expertise moving around between companies in the Park, strong links to the Technical University of Delft and Rotterdam, and more than 6000 medical doctors in this region. We thus have not been disappointed by our decision to set up our company here.

How does R&D conducted in the Netherlands move HAL Allergy forward?

At the research level, we undertake many collaborations locally. In one project with Leiden University, we are looking at needle free allergy immunotherapies. Some groups, including a key target group, children, are afraid of needles. Needle free application also has several benefits â?? it does not cause much pain, is reproducible, and targets even better the immune cells we are looking for. Although very good researchers in the field of allergy are present in the Netherlands and at the LUMC.

Could you give us an overview of HAL Allergyâ??s offering in the field?

HAL Allergy looks at all the major allergens. Birch pollen, for example, is a major concern for Northern countries, while olive allergies are more prevalent in the Southern geographies. Grass and dust mite allergies are common in almost all geographies, mites being the most common cause of allergy in the Far East, Middle East, USA, and Europe. We also have immunotherapy products for bee and wasp venom, representing very effective treatments for patients who are at great danger of undergoing anaphylactic shock if they have an allergy and are stung. Furthermore, we started to look into food allergies, a field very much in demand today. Other companies are also working in this field, but our science shows that our product is superior. This will put HAL Allergy ahead in that area of the market.

What developments have substantially impacted the company in recent years?

In Europe, the Therapieallergene-Verordnung or *therapy allergens* ordinance (TAV) specifies that certain immunotherapy products need to be registered according to current EMA standards, and this ongoing procedure will change the whole landscape in Europe for allergy immunotherapy. All companies will have to comply with this ordinance, within certain relatively flexible timelines. I can say that HAL Allergy is one of the few companies safely meeting these deadlines, and we are completing clinical trials, with many more scheduled in the years to come, to continue our forward progress. We have just finished a phase III trial for a product to treat birch pollen allergy, and it will probably be the first product registered under this new TAV, first in Germany and then in the rest of Europe. We are ahead of the game in this aspect and are very proud of this.

What is your assessment of the awareness surrounding allergy immunotherapy here in the Netherlands?

We feel that the awareness of this kind of therapy is much larger in Germany, both for authorities and patients. Allergology is not a separate profession or study in the Netherlands, which also contributes to awareness being much lower than we would like it to be. Allergy immunotherapy offers a real relief for patients. Furthermore, it cuts down on hospitalization costs, days lost for work, and time lost at work. If someone is on steroids and antihistamines their attention level is much lower, and, so even if they do go to work, they lose valuable work time. All of these are economical factors to take into consideration when looking at allergy immunotherapy. The Dutch authorities and insurance companies are not as aware of this possibility of saving money as they could be.

How do you raise awareness of these allergy immunotherapy treatments?

We cannot do this alone and have to work in a concerted effort. At the EU level, interested actors participated in a symposium at the end of October with the EU Commissioner of Health for Food and Health Safety. Following the meeting, he was convinced of the benefits of and need for allergy immunotherapy, especially coupled with better diagnostics. Without proper diagnostics, allergy immunotherapy cannot be as effective. For example, if you have a birch pollen allergy have but receive an allergy immunotherapy treatment for grass pollen, you will not be cured. Furthermore, if you are an allergic person, you can develop asthma, which is an even more costly disease for the community, and immunotherapy in principle helps to prevent asthma.

HAL Allergy has evolved into an international player. What is the current companyâ??s internationalization strategy and its main targets in this respect for the upcoming years?

Our clientele is international, but we are very much focused in Europe. Germany is our largest and base market, and we are expanding and gaining market share locally, while at the same time building up our presence in Poland, Spain, Austria, and Italy. We are now looking to the US, a large

market where the allergy immunotherapy field is not yet well developed. There are some large players, but it is currently a very diffuse market, and we feel that we can make major inroads given our expertise. As a first step, we are looking at FDA approval for our products, although this will take several years given that the US does not accept European registrations and vice versa.

Looking forward, where would you like to see HAL Allergy in five years, in 2020? What are your main objectives for yourself and your team?

I would certainly like to have finished the registration for the rest of the TAV products, completed a solid entry into the US market â?? not simply in terms of registration but in terms of product marketing- and undertaken a consolidation within the European markets. The TAV forces companies to register all of their products, representing a substantial cost. As such, smaller and less focused companies will not survive. Overall, the market will grow, and the market share for the companies that will survive will grow. Within this context, we are convinced that HAL Allergy will survive and thrive.

You have been leading the company for almost a decade. What keeps you motivated?

Backed by a very supportive major shareholder, HAL Allergy stands today as a very profitable company that invests a large portion of its revenues back into R&D. We want to make sure that in five yearsâ?? time, we will have a pipeline that serves us for the next ten years. On a personal level, I want to make sure that upon my retirement, I leave behind a company that is flexible enough and capable of accepting and working with changes. The industry is changing, and the requirements of the governmental authorities are increasing every year. I have seen this trend both in the GMP environment and the registration/marketing/authorization environment, and a company needs to be flexible to react and accommodate. Thus far during my tenure, HAL Allergy has well managed these challenges with flexibility, moving from being a very good pharmacy company to a full-fledged pharma company in a process of growth and dynamism that will continue.

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