Interview with Alexander Willemse, CEO, BioConnection

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Tags: BioConnection

In addition to highlighting company strategies and strengths in our reports, we also like to get a feel for the leaders within the local markets that we cover. We noticed that you have worked for several of the Netherlands' flagship companies, namely Organon and Octoplus. What was the trajectory that led you from flagships to a small but growing company such as BioConnection?

I studied chemical engineering at Delft University of Technology where I received my Ph.D. in chemical engineering, concentrating on particle technology. After spending four years of my Ph.D. working in coatings, I got the offer to work with Organon – the pharmaceutical division of AkzoNobel – to officially begin my career in pharma.

After five years with Organon I had the opportunity to move to Leiden with Octoplus – a service provider which at the time had about 40 people in its staff – to run its external service department and all of the operations for its lab, warehouse, and pharmaceutical plant. It was a tremendous opportunity and I ultimately stayed for six years. I learned a great deal about in the inner workings of pharmaceutical services and I especially liked working with customers. While we also dealt with small molecules, the majority of our work was centered on biotech. When I left Octoplus the company had grown sizably to about 200 people.

The opportunity then came my way to join BioConnection, a very small company with a very large partner in, then Organon, now MSD. While BioConnection is an independent company, we have respectable shareholders, namely MSD on one side and Dutch government and Mibiton on the other side. At the time, Organon was in the process of being taken over by Schering Plough which

was eventually taken over by MSD (Merck&Co.) last year. With BioConnection I have been able to apply my experience in building a company in the service field.

What was the change in your managerial mindset that accompanied the transition from large companies to smaller ones?

I cannot speak in general but in my experience larger companies tend to drive internally more on politics than I generally do. Furthermore the advantage of a small company is that you can better see the results, both positive and negative, of your day-to-day work than at a large company. The ‘we’ factor is more present. A major advantage of working with a large company, in case MSD, is that everything is well arranged, especially on quality level. The challenge that I set for myself was to build a company and seeing its actual progression. On the other hand, there are also some discomforts with working for a small company as you tend to have the feeling of safety when working with larger companies. But I prefer the thrill of working with a smaller company and have the freedom to be more entrepreneurial.

Founded in 2005, BioConnection was just getting off the ground when you started as CEO in 2008. What was the strategic agenda that you came in with in order to push the company into new stages of growth?

In 2005 the shareholders raised a certain amount of money and invested it in Organon, the manufacturer. Organon, both a shareholder of and a manufacturer for BioConnection, was building two production facilities – one for Clinical Phases I-III for liquid end freeze-dried vials and prefilled syringes and a separate brand new commercial plant which can run 250,000 vials per day. The aim was to get Organon a view to the outside while giving biotech companies the opportunity to make use of the experience and know-how of a well established pharmaceutical company. Achieving both would create ideal win-win situations. The advantage that BioConnection offered was that we can bring customers from preclinical phase into Phase I and all the way to the market.

BioConnection was established early on as an independent company. While we were initially seen as a ‘service part of Organon’, that is not the case. We are an independent company with a binding contract with MSD. The facilities that we use are owned by MSD, but we own part of the capacity. In this way we offer the facilities to our customers as if they are ours. We can guarantee capacity instead of having to ask for it, it is simply ours. Outside customers looking for production services typically wonder what will happen if MSD needs to utilize full capacity and if it will interfere with how much we can produce. If such an event happens, then MSD simply has to ask our permission since we own the capacity. Up to now we have build an excellent relation with MSD, so in real-life it

also works like it was designed.

This relationship of proprietary capacity within another party's facility gives us a unique opportunity. We can operate independent of MSD while we have the advantage of a "big brother" pharma company and its state of the art facility. We do not have to worry about validation of 'our' plant or the training validation of 'our' operators since that has all been taken care of by MSD. Our main focus is helping our customers transform their compounds into a final product. We can accomplish that in the MSD labs which we have access to, but many customers want to have their processes developed externally. Therefore we work closely with the German company Coriolis Pharma who develops stable formulations for the compounds using the exact vials and syringes as packaging material that we have in our facilities in Oss. Coriolis Pharma develops the stable formulations for the drugs and the production processes; we manufacture the materials accordingly for the customers. We also work closely with PROXY Laboratories based in the Leiden Bio Science Park for all analytical QC work. Furthermore they have the capability for hand fills and also use our materials. In this way seamless transfers are possible. By working with three companies together, we can provide formulation, manufacturing, and warehouse distribution. For the customers it feels like they are working with one company only as we perform the total management.

Essentially you are benefitting from the synergies of two circles: the infrastructural synergies afforded by your organizational set-up and the operational synergies with partner companies.

Yes, and that makes us a pretty unique company. When people ask us what we have as a company, we say that we have the production quality and experience of MSD, the knowhow of an experienced biotech service company and the flexibility of a small company. We can assist customers from early stage development up until commercial scale manufacturing.

The idea behind the cooperation is that Coriolis is experienced in the development of formulations, analytics and production processes for biopharmaceutical drugs, but needs a manufacturing partner since they do not have GMP production capacity. PROXY Laboratories benefits from the partnership because they are specialized in analytical QC work and can run batches up to a certain scale and then transfer them over to us. We combine the forces of formulation, manufacturing, and analytics. Each company can conceivably expand into each others' fields, but it would require significant new investments and facility upgrades. So far we have serviced several customers through this very simple, but very experienced and dedicated, network. The CEOs of these companies know each other well and there is a very positive chemistry between the three companies. We are three individual companies who each focus on our own strengths thereby minimizing transfers.

BioConnection describes itself as one of the first European companies to provide both production and expertise for small biopharmaceutical companies. Given that the Netherlands is squeezed in between three of Europe's five largest pharmaceutical markets, you would think that this market need would have been fulfilled prior to BioConnection's establishment in 2005. How and why has BioConnection been able to achieve an industry first?

When I first started, part of my strategic vision was the philosophy that it would not be sufficient to just provide fill and finish services. Of course it is a unique and expensive ballgame to have EMA and FDA approved sterile fill and finish offerings; but it is not sufficient. If you want to help young biotech companies you have to provide the whole service package. Where we are unique is that even before Phase I we can provide young biotechs with toxicology materials as well as GMP grade material for global use from 10,000 – 250,000 vials which is full market scale. For this we have access to an over €100 million euro site to bring our customers from Phase III into full commercial development. We have the whole operational range within one company.

Other companies are in the market for development and clinical trials, but not many have the focus or the facilities for commercial scale. We have access to this commercial side which makes BioConnection a company to whom you can go to for toxicology batches up until full commercialization. Not many companies in the Netherlands or in all of Europe can offer what we do.

Very few biotech companies actually have a product on the market. Has the market evolved to the way that you expected it to in order to utilize the potential of your commercialization capacities?

We have mainly focused on Phases I-III especially since the commercial plant just opened up in 2009. There was no use for BioConnection to already acquire customers prior to 2009 because it simply was not there. Now we are aiming more at customers who are running Phase II-III trials who are looking forward to the market. By working with BioConnection, their products become more easily sellable to large pharmaceutical companies since they already have a scaled process. A biotech company can run their first years of production from our plant and then if they happened to get acquired by larger pharmaceutical companies, they can then transfer production. We welcome, but do not necessarily need 20 year contracts. Instead, the value that we offer is that we can be the stepping stone for small biotechs to show to large companies that they can run at full scale. We have about five customers who are now entering into Phase III and are looking to transfer production to us for early launch.

The idea when starting the company was to provide customers with the whole package and that companies would grow alongside BioConnection from Phase I-III and then to market commercialization. Admittedly that was a bit of an optimistic view since a lot, maybe even the majority, of companies fail somewhere between Phases I-III. And not even all companies that survive phase III reach full commercial scale and some of those that do reach that stage are eventually taken over. You need a huge amount of early customers to fill commercial capacity 10 years later. Because that business model won't survive we are now looking more at customers who are at the end of their clinical trials and are preparing to enter the market on their own.

Dutch companies naturally look abroad for customers and partners given the small market size of the Netherlands. Which geographic areas are you particularly keen to look to for customers?

For the commercial side, we tend to have mainly Western European customers. American companies tend to have commercial production in the US and European companies tend to have commercial production in Europe. On the other hand, if you look at Phases I-III, we have a global customer focus because it does not matter where your product development takes place.

To expand our vision to the fast evolving markets, we cooperate with four other Dutch companies in a partnership called "Gateway-2-Europe." We have been to India and China because of large market opportunities that we see there – particularly for Indian companies who want to bring their products to European markets. There are many (biotech) products present in India that already supply their home market. But apart from the large companies who tend to buy facilities in Europe, it is difficult for them to bring products to European markets. We are aiming for companies who have the product and the money but neither the facilities nor the experience in how to register products into the EU. The US has its FDA meaning only one institute and one language countrywide. However, the European Union is not synonymous with the "United States of Europe", since we have 27 member states with many different languages. It is essential that a company knows how to register its product on the European market. Indian and Chinese companies need to retest their products. Furthermore they lack EMA validated, registered, and approved production facilities for injectables. Our offer is to produce their product in our facility and support them with the dossier in order to bring their product onto European markets. Since they already have the (biotech) products in their local markets, we can help them with our analytical and manufacturing facilities and assist in converting their medicines from an "Indian product" into a "European product." With that strategy in mind, we opened Gateway-2-Europe and we are now focusing on the Indian market to bring products from medium sized companies here.

As we head into the final weeks of 2010, how has the year-to-date been so far for BioConnection?

BioConnection is doing well, although there are some caveats with MSD's announcement of their proposed closure of part of its Oss R&D unit. There is currently an investigation for a new life science park here in Oss. Since this announcement past summer there was a lot of media attention devoted to this Oss area. Although nothing has changed for us, the happenings here in Oss have had an effect on the perception for the outside world. We are very much linked with MSD. Not only are they our shareholder and manufacturer, but being located just across the street, the first question that we received at that time from future customers is no longer about the quality of our systems, our track-record or our experience. Instead, it is, "what is happening with MSD?" It is a disturbing effect which we hope will be settled soon.

Do you find yourself in a continuous education process to separate yourself from MSD and disabuse the perceptions that you are operationally one in the same?

While we do definitely value the healthy cooperation with MSD being one of the pillars of this company, the vision of the outside world is often blurred by what is being discussed in the media. There is a lot swirling around in the media that is not based on solid facts which gives a very chaotic view to the outside world.

Going back to our performance, yes, we are doing well, but we also suffer from the economic crisis because we essentially spend money from other companies. If young biotechs do not have money, then they do not have money for us. What we have seen in 2008 and 2009 were fewer IPOs and scarcer venture capital. Young biotechs are currently in very tight cash positions and do not have the money to spend with us.

We typically run about one year behind what is happening in the market. Young biotech companies have money for 1-3 years when they hit waves of financing. They then have to spend it as fast as possible because they want to enter Phase 1-2 quickly, which is good for us. However, that also means that when the market collapses, they still spend money. We have noticed this cycle going on for the past two years. We currently need new investments in biotech companies which will take about a year; but it is happening – markets are opening up again.

Turning our attention to the topic that we first started on – corporate culture – now that you do run a small company, what are the core values that try to instill amongst your staff in order to successfully manage the organization?

It is quite simple: we work for customers. We have to understand the ups and downs in the demands of small biotechs and help them in their creative process. Understanding those demands can avoid frustration over ever-changing needs and it helps us to run a stable business. Naturally,

our customers are not always stable since they are in ongoing processes in their business. We look for people who enjoy working in such a dynamic business geared towards understanding customer needs.

Our manufacturing partner, MSD, is a large company who usually does not meet the hectic nature of a young biotech company. We therefore have to build the bridge between our very driven and enthusiastic, but sometimes hectic, customers and the more traditional large scale operations of pharmaceutical companies. We have the ideal mix between entrepreneurial development partners and a world-class manufacturing company.

There is no shortage of young biotech companies here in the Netherlands given the country’s strength in innovation and research sciences. As BioConnection grows in conjunction with them, where do you see this company being positioned in 5-7 years?

Some of it depends on what happens here at MSD in Oss. We see many opportunities to get involved in a potential life science park being that our business model lends itself very well to it. If that opportunity arises, I see a bright future for BioConnection growing in our staff and facilities. If that does not happen then we will do it on our own, so without Life Science Park, and growth will come from not only BioConnection, but also from our partners and their organic growth. If the life science park turns out to be a success then perhaps we can run our own operation here with our partners under a new name and in one location but under the same principle – three separate companies working in conjunction with each other. That would be an ideal future outlook.

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