Interview with Alejandra Mørk, CEO, KLIFO

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After working for 18 years in Nycomed in very stable corporate positions, what drove you to invest everything that you had in this company? Where did you see the potential and what did you want to achieve back in 2008 with the company?

The situation when I made the decision (2007) and the situation today are very different. At the end of 2007 the industry was very much focused on outsourcing, there was this whole change from in-house to outsourcing, and I found it appealing to design and provide services that met these new needs. I expected it to be a growing and prosperous niche, since I recognized the new trend was heading that way.

In the last five years that I worked in Nycomed my job was to evaluate licensing opportunities, I was the gatekeeper of Nycomed's process for evaluating and licensing opportunities. Hence, I saw many companies coming in with their projects, with good ideas, promising molecules, and good visions but, lousy data. I thought that if these small companies had access to experience at the right time they would have used their initial funding to do the right studies in order to succeed in the long run.

My vision was to translate my experience from the industry into a service company that could advise biotech companies to allocate their capabilities and resources to what was really needed. I knew a lot of capable people who have left the industry and become independent consultants, therefore my idea was to organise them in way that small biotech companies could have access to their experience and in turn provide them with tailor-made services to fit their specific needs.

Based on that, and by coincidence, I was approached by KLIFO since the founder wanted to retire and sell it, so I acquired it. The company was founded in 1994 doing clinical trial services and

clinical trial supply. When I took over, we continued to do that whilst starting to build our consultancy arm. Later in 2008 and in early 2009, the financial situation changed so all those biotech companies that were going to buy our services lost their money or completely stopped their operations. The whole market changed. So we went from a building mode to a survival mode and fortunately enough we had three services (consultancy, clinical trial supply, clinical trial services), so we were not only dependent on one and we managed to develop. Our consultancy services and our clinical trial supply grew well, but, like everyone else, we struggled with our clinical trial services. However, we are still doing clinical trial services and I would bet that we are the strongest survivor among local CROs and providers of clinical trials services in Denmark.

I've worked with many CROs— big, small, international and local– and I have had both good and bad experiences, however, what I learned is that the respect that you as a service provider have towards the clients, and your ability to understand their situation and translate knowledge into good services is what generates our success.

Mr. Makin of CiToxLAB discussed with us how hard the financial crisis really hit hard, particularly for the Danish biotechs. Does the majority of your business originate from Denmark ?

We invoice at least half outside Denmark, so we couldn't survive on the Danish market alone; we are dependent on providing our services also to biotechs in other European countries and the US; fortunately the beauty about the Pharmaceutical industry is that it is so international.

Where is Denmark standing in terms of translation of research since I believe this is what you trying to do via KLIFO's drug development counselling division?

In Denmark, during the past 10 years we have had a relatively strong biotech environment, partially due to the number of financial opportunities here to support it. We have had different foundations like Novo, who have been willing to invest in biotech emerging either from universities, spinning them out from the pharmaceutical industry or other biotech companies and strengthening tech transfer.

I wouldn't dare say that the Danish experience matches that of the states, but we have had some similarities, and I think we are ahead of some of other European countries since there are many people in their 50's, like myself, who have been working in pharma for years. These seasoned professional learned the importance of having access to really good researchers in the universities, knowing how to outsource and raise money, as well as how to interact with investors.

It's not a walk in the park; it's not only about science. Many of these people started as enthusiastic and very clever scientists who understood that being a good scientist and earning money at the same time could be compatible. It is this that makes a difference.

As you said, the industry is very international and you were mentioning earlier how Eastern Europe is becoming more and more attractive. What position does Denmark hold today versus that of booming countries such as the Czech Republic or Poland; what do you still have to offer?

We cover a much broader drug development experience than biotech companies normally would in the European countries that you mentioned. As an example, we were recently asked to review an IMPD for a bio-similar product developed in one of the Eastern European countries and it was really junior work; it was obvious that they had not done that before. So it may be that their research capabilities are fine, but translating that into the documents and knowledge that you need for a drug development program is clearly lacking. We discussed the situation, and in this case they received very few inquiries from the health authorities in that country.

How could the authorities make such a misstep?

We believe that the authorities in this case probably have as little experience as those that applied, and they would most likely get that protocol approved in that country of origin, which would result in a very weak platform for bringing that product further across Europe. They would never get it approved in Germany or in the UK, not to mention with the FDA. This is the area in which we really can offer our experience.

In regard to the information you were mentioning about the e-formats for the hospitals, isn't this also one of Denmark's really big pillars; pushing intelligent e-delivery healthcare?

That is what we hope to do but it's still a little of the same— we can see the possibility, technologically we are ready, but organizationally, it doesn't work. We have been invited and we have also prepared proposals for several studies for tele-medicine, but then the projects didn't get funding and it was not regarded as a good opportunity vs. that of developing a new medicinal product. It is disappointing, since the technology is here and after talking with the practitioners, they are more than eager to utilize it.

Having said that and taking into account the challenges, what can Denmark teach the rest of the world?

I think the fact that we have been able to maintain large pharmaceutical companies, like Novo Nordisk, Leo Pharma, Ferring and Lundbeck, compared to the size of the country is a telltale sign that we have a lot of expertise.

Furthermore, Danish industry is very open to work internationally. Novo Nordisk for example have their HQ here and employ a significant number of people, but just a few years back they moved part of their commercial organization to Switzerland, and they have huge activities in the US and in China. They have been global in their thinking; Lundbeck is trying to do the same; Ferring moved

many of their activities outside Denmark early, Leo Pharma perhaps less, but at least for their clinical development they are targeting primarily Asia and the US. This dynamic of keeping the HQ here, but at the same time being international, creates a healthy environment because companies avoid leaning back.

Furthermore, I really believe that you need the whole chain. So you need renowned universities that are highly competent; you need a healthcare system that uses a modern methodology that contributes to research; you need biotech companies that can translate some of that expertise into innovation and product development, and you need the big pharmaceutical companies to sustain it and generate the value. The reality is biotechs cannot generate enough value that is most important for Danish society is the export of medicine, so you need to combine all the aforementioned elements.

You are describing the ecosystem of the life science industry, where does KLIFO fit?

Our focus is to professionalize drug development. What we want to do is to ease the way to smart and sustainable solutions for biotech companies. Ease the way by either providing the competencies directly, saying : if this is what you want to do, this is what you need to know. Or in the case of the companies doing what has not been done before, we can find out who can do it for them. It's not that we necessarily can provide all the solutions, or want to provide all the solutions, but we certainly can contribute in helping to find them. From highly technological matters at one end of the spectrum, to advising companies on where they can find a CRO, we help them answer a myriad of questions. How can their vision can come true? What should be their target product profile? What is the competitive environment? What sort of competence do they need in order to do what they want? Etc.

We want to be part of our clients' success; therefore we work with them from a strategic, tactical, and operational level. We can provide all this expertise because the people we have in our consultancy have been involved at all levels, they have been at the top of R&D, heading the department, they have been project leaders and they have been writing the clinical overviews. Multidisciplinary profiles are what we seek in KLIFO's team because only that way we can cover the whole chain.

Let's say I'm a biotech company based out of Lyon, in France. Why would I choose to work with you rather than with an international CRO, like Quintiles for example?

It depends on what you are looking for. If you are planning a huge phase 3 program in 20 countries and 300 centers across the world, you should go for Quintiles. But, if you are a 20-person biotech company outsourcing here, that is looking to do a proof of concept study, you should look for a

company that understands your situation and what you are working with, that has good communication and enough experience—this will lead you to choose KLIFO.

At KLIFO you will get the expertise and the attention that you need. Indeed, several of our clients choose us instead of Quintiles because they have tried Quintiles and they have seen how hard it is to be the small client at the end of their list of priorities.

On a more personal note, given your move from a huge corporation to starting you own company— would you recommend it? If so, what would be that one thing you would tell an executive in a similar dilemma?

I would recommend it because it is professionally very enjoyable and satisfying. I have the opportunity to work with so many different projects and solutions, which allows me to learn something new every day. It is rewarding to have the opportunity to ask the right questions in a scientific advice meeting or discuss with a CEO what sort of organization he needs.

My piece of advice for those who want to start their own company will be to work very hard. When you buy consultancy services sometimes you think that it is easy, but it is on the contrary a very competitive environment and you are never better than the last assignment you had, so you have to outperform every time.

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