Interview with Robert D. Lefebvre, Vice President Commercial Operations Europe, Middle East, Asia, Kedrion International GmbH

01.02.2013

Tags: Kedrion International GmbH

Prior to joining Kedrion you worked for CSL Behring for a number of years. What opportunities did you see for yourself in moving from there to Kedrion?

The biggest opportunity was to join a younger, smaller company that was at an earlier stage of development compared to a larger, more established organization. This would allow me to help the company establish a strong presence in a large part of the world. Kedrion is an Italian-based company with a strong family ownership tradition. It has a long history of success in the Italian market. For strategic reasons the company decided that continued success and growth would come from expanding outside of Italy. While some export business had already been done, Kedrion needed to establish a beachhead outside of Italy to expand and establish a presence in the rest of the European market, which they did not have at this point. This led to the creation of Ked Pharmaceuticals AG in 2005, in order to first establish a sales presence in Austriaand then to expand into a number of other countries, and beyond that a number of other regions. Vienna has become the center of Kedrion’s European, Middle East and Asian commercial businesses.

What sort of risk do you feel was involved in making this transition?

The whole idea of moving from a career that had been centered in North America to Europe where I had never lived before presented a certain personal challenge. From the business side, I was

continuing a transition from pharmaceuticals to a specific segment of the biopharmaceutical industry. Kedrion has to be able to effectively balance the expansion required in terms of manufacturing capacitywhile ensuring that the market is able to take in products that the business produces. Over the past 18 months Kedrion has shown some very interesting successes. At the group level, Kedrion has been able to establish a solid presence in the United States. The company adroitly managed the purchase of assets from the proposed merger of Grifols with Talecris, which required an asset divestiture for the US FTC (US Federal Trade Commission) to allow that merger to occur. Kedrion managed to buy some of those assets, which accelerated the company's presence in the United States by a number of years ahead of their previously planned entry into the US. The international expansion strategy involved establishing a beachhead in Europe, which was done in 2005 and then launching a third leg in the US, which occurred about 18 months ago with the creation of Kedrion Biopharmceuticals Incorporated in Fort Lee, New Jersey. If you look at Kedrion's financial structure the company now has a somewhat broader capital shareholder group because a major Italian funding agency (Fondo Strategico Italiano last year became a shareholder in Kedrion. By attracting more capital to the company they were able to acquire a fairly important brand from J&J called RhoGAM. They have now acquired worldwide rights to this brand which gives them a strong position in the US, where it was already strong, but now allows Kedrion to leverage that brand equity and use it to expand its presence in other markets of the world. Some of the business risks that one can see in joining a smaller company are now starting to be balanced against some of the success that Kedrion has had in terms of expansion. Looking at our annual report you will see that Kedrion have strong presence throughout Latin America, with one of those presences being in Mexico with the establishment of a joint venture that we created a number of years ago. We have legal entities in Portugal as well as in Switzerland. Kedrion International GmbH is a full legal entity in Austria, and it is from Austria that we direct the commercial activities of our businesses in Europe, the Middle East and Asia. In 2007, Kedrion bought a wholly owned subsidiary of Teva Pharmaceuticals based in Hungary called Human Bioplazma Pharmaceuticals (HBP). Fundamentally, what was then a division of Teva acted as the Hungarian version of Kedrion. It was a Hungarian company with 30-40 years of history in the Hungarian business, a close working relationship with the Hungarian government's blood collection services, and the primary partner able to take that plasma from the Hungarian government, convert it into plasma proteins and then service the Hungarian domestic market with finished products. HBP had also established an export business, particularly in Asia and Latin America, which is run out of Vienna as well. We have really brought Hungary into the fold of Europe and it is one of our largest markets. Kedrion is basically the number one plasma protein competitor in the Hungarian market.

Dr. Schrot of Biotest noted that Eastern Europe was becoming the target region for the company as a whole. Besides from just Hungary, do you see Eastern Europe as a real emerging market for Kedrion in general?

Absolutely. As the markets of countries like Poland, Romania, Bulgaria and the Czech Republic continue to evolve and their healthcare systems strengthen and mature, their ability to start accessing rare disease products that we make is growing. They need to be able to access them in a way that allows for stable and consistent supply. The Balkan states, which for Kedrion are run out of Italy, are also growing at a rapid pace and export relationships have been solidly established. For the Far East and CIS states, I think there is opportunity, but it needs to be managed carefully. Kedrion is taking its time to evaluate what can be done; there is huge demand and it is just a matter of finding the right way to penetrate those markets, be it through a joint venture, wholly owned subsidiary, distributorship or a combination of the three.

Many of the companies we have met have cited Vienna as being a hub between the East and West. Mr. Kwizda from Kwizda Holdings said that has become less relevant compared to ten years ago. Vienna for you is an extremely important city in terms of being the next place outside of Italy. Does that give you a competitive edge against other companies that are moving their subsidiaries farther east in Europe?

I am not sure if competitive edge is the right term. Kedrion is committed to its headquarters here in Vienna. The employees are primarily Austrian, and the expertise we have built up in dealing with multiple markets from Vienna could very well be one of the competitive edges that we have. We are basically handling all of the commercial aspects of the business across those regions – Europe, Middle East, Asia – from Vienna. Is that going to continue being a competitive edge in terms of what it takes to be successful in the expansion of Eastern Europe? I think it could be, but it is people-based as opposed to having a structural or industrial edge. Compared to other places in which businesses are headquartered, such as Switzerland or Germany, there are strengths and weaknesses based upon every individual company decision. Kedrion has a long history of being in Vienna, and from here it has expanded and developed firm relationships in all those three key regions.

2011 saw an increase in the number of plasma derivative products. How do you evaluate 2012? What are the main growth drivers going into 2013?

Based on the different therapeutic categories, the basic plasma protein market for Kedrion International is in a very good position in terms of external demand. The immunoglobulin market

continues to show growth globally based on reports published by the Plasma Proteins Therapeutic Association (PPTA), so I expect demand growth in that area to continue strongly. Likewise for albumin, on a worldwide basis it has been showing strong growth trends, and those will continue. Some of Kedrion's growth for 2013 is based on meeting that increased demand. Even if Kedrion maintains its market share, by definition the company will be growing because the markets themselves are growing. In terms of market share expansion, our strategy will be based on entering new territories, regions and markets that have been previously unexplored. Within Kedrion's well established markets, the company will continue to strengthen its presence and market share.

What are the new markets you are moving into here? Is retail a potential option for you?

Kedrion's products do not lend themselves to a retail market environment because every one of the company's products is indicated for either hospital-based or rare diseases. There is an element of retail depending on how it is defined in the treatment of primary immune deficiencies. This allows patients to take care of themselves under their own control at home using new products subcutaneously rather than intravenously. A lot of development in the primary immune deficiency market is in the Nordic region, where a large proportion of prescribed immunoglobulin is subcutaneous. There will be some shift of this particular sector into half retail, half hospital-based business. Apart from that we do not see much change in the Austrian market beyond what has been for now our classic penetration which is hospital-based and to some degree an immunoglobulin-based therapy used by physicians in the oncology space. New products are coming down the pipe, and in my case bringing into the portfolio of products that we have had in other countries and then bringing those into my portfolio of products that we would register in the countries for which I am responsible. That would expand the portfolio I have on offer in those countries. While I am not increasing my market share by brand, I am by footprint.

In terms of decision-making with the hospital business, it used to be much more based on individual doctors, now decisions are made by a committee. How do you tackle that challenge with Kedrion?

In our business it is a combination of the right product, time, place, with consistency, as well as having established relationships. This business has had time periods of instability of supply. It is a fairly long manufacturing process which sometimes leads to unpredictable stoppages or issues around production. It is a matter of getting to know your customer so well that you can understand what his needs will be and he can understand what your capabilities are, which in general need to be above the competition. The decision making has become more committee-based or buying

group-based so that as hospitals come together to say that as a larger bargaining entity they can negotiate more effectively for the supply of products for which we can predict the demand, then you are dealing with a buying group as opposed to an individual hospital. Again, I think the same competitive levers are going to be put into play – right product, at the right time, consistently, and dealing with issues rapidly.

Buying groups have much more negotiation power and they will want the same provider to provide more products. Do you see that as having a direct positive impact on having more?

Absolutely. If, as a supplier, I can supply more of your needs as a hospital and you have grown accustomed to or have trust in my ability to supply you with your needs, then I am in a better position to negotiate and probably have less issues surrounding line item discussions around price only. I should also have a better range of products to offer the customer. That is part of what is driving us to ensure that our portfolio is as wide as possible.

You have had an extensive career with a number of companies, including CSL Behring, Novartis, and Bristol Myers Squibb – what have been the most significant differences in moving from a pharmaceutical background into the plasma proteins business?

The main difference is the tremendous amount of closeness between end user and the very beginnings of supply. The supply chain and plasma proteins and its connection to the end user's needs is that much tighter, more intimate, and any interruption along that chain can have an impact that will lead to a customer not being able to access life-saving therapy. That brings it completely together – much closer than anything I have seen in pharmaceuticals. In pharma, you end up learning a lot about customer orientation and insight. Additionally, being able to differentiate what you have against anything the customer can choose is a huge commercial driver for success. This business has historically been primarily production and manufacturing driven. Because of the complexity, length of time, and the costs involved in these products, the mindset used to be focused on making products the best in class, and as quality driven as possible, with the entire supply chain knowing that if a product can be made, it will be sold. As the industry has settled down, and as the players have become more mature, the business is becoming more about having a customer choose you versus the three or four competitors that are out there. This brings you back to a more classic pharmaceutical mindset; unless you have invented something completely new, you will be faced with convincing the customer that you are the best choice at that time. Bringing that mindset over to this business has been my biggest learning experience.

How would you say that the face-to-face relationships in Europe and specifically Austria compare to those of North America?

You are dealing with people to people, and therefore the face-to-face relationships have not changed much. If you are able to establish a relationship whereby there is some trust in terms of what you can bring, the relationship ends up being very similar to anything I have seen anywhere in the world. Decision-making is clear, quick, and there is a higher degree of pragmatism with business management using the “good enough, go” mentality, something which big pharma companies need to improve. This happens much more in smaller companies, particularly when the hierarchy to decision-making is so short. As the capital requirements of the company require more investment, there will be an evolution of Kedrion into a larger company, and I am sure things will change as they get larger. At this stage, there is a long-term vision that is clearly communicated, and if the external world changes, Kedrion makes the necessary corrections . The decision making is that much faster and more efficient, and puts an onus of accountability not just on myself but anyone involved in the decision.

If we were to return to Austria in three or four years, what would you like to have achieved by that point and where will we find you?

Fundamentally, this business should be contributing 40 percent of the volume of what Kedrion will be at in those days. The company is not quite there yet but should be in three to four years. We should have firmly established solid positions in all of the European markets in which we operate. We are at different stages now, with decent footprints in Austria and Portugal, starting a decent footprint in Germany, and all of them should be at a solid level in three or four years. For me, I should be continuing with Kedrion in whatever role they desire for me.

See more interviews