Vincent Stephenne â?? Managing Director, BePharBel Manufacturing

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Vincent Stephenne, managing director of Belgian CDMO BePharBel Manufacturing, highlights the companyâ??s innovative approach to developing new galenic forms for existing molecules, its growth trajectory thus far, and his future plans for partnership strategies and expansion.

Could you begin by outlining your career trajectory?

I am a civil engineer with a PhD in material science. After completing my studies, I worked for Total Petrochemicals for five years, first in a team which had to develop new products in new applications.

Then I moved to a technical-commercial function before joining Baxterâ??s R&D centre focusing on the development of non-PVC products. Following that, I took on an MBA prior to helping found BePharBel in 2012.

As a managing director of a pharma company, even a small one like BePharBel Manufacturing, it is important to have a good technical background and interpersonal skills.

Why did you decide to go into a challenging low-margin industry like manufacturing and how has BePharBelâ??s footprint evolved since the companyâ??s formation?

The initial objective was to put in place a long-term industrial project, making use of the pharmaceutical expertise available in Belgium and for which it was possible to create durable value.

We positioned the company not as a CMO, but as a CDMO, meaning with strong expertise in Development, in order to propose a full service to our partners. For example, we can provide analytical support, perform stability studies and develop new formulations or update old formulations. For this, we have a highly skilled and experienced team of around 80 people with engineers, biologists, chemists and pharmacists managing our projects.

When we started the project, our main challenge was to put in place and qualify a brand new GMP plant in Courcelles, Charleroi. We invested EUR 20 million in this plant which became fully operational at the end of 2018.

Previously, we had a plant in Brussels, which we acquired from EFRA in 2014, and the Courcelles plant at limited capacity. However, in 2014 we decided to move all our manufacturing and development activity from Brussels to the new Courcelles plant.

From the manufacturing point of view, we are not yet at full capacity. The objective is to continue significant growth in our CDMO activities. Last years, we grew 25-30 percent. The objective is to take a maximum of four new projects per year, no more, to make sure that we are able to manage them with our highest quality standards.

How did you and your team initially choose the galenic forms on which to focus?

BePharBel can manufacture various kinds of galenic forms. We produce around 40 different products which means that each week our employees are manufacturing something different. Our products range from classical forms like capsules and tablets to nasal sprays and creams. The company can produce both sterile and non-sterile products at the same plant.

Working on so many different products and so many different galenics is also a way to accelerate our collective learning curve and to accumulate the knowledge needed to later develop new drugs and innovative formulations.

This diversity in our product portfolio was initially driven by our partners and our intention to be active in the sterile business. Sterile manufacturing remains a difficult exercise. This is one of the ways we can offer added value to our final partner. Belgium has several large aseptic plants so that we have been able to draw upon a good concentration of aseptic expertise and share our knowledge in the Belgian pharma hub.

When we started with the project, in the view of developing our expertise in galenics, we also decided to invest in R&D. Our focus is not on discovering new molecules, but rather on developing new galenic forms for well-known molecules. For example, recently we have patented the new MMCR technology (for multi-layer microparticle controlled-release system) enabling us to convert a well-established API from tablets to syrup, with the benefit of facilitating intake for elderly people and children and with the possibility to have a controlled release (delayed or sustained). A first proof of concept has been done on Pramipexol, for which there is a clear need in the elderly population in connection with Parkinsonâ??s Disease. We are now looking for a global partner able to support the worldwide development of this innovative Pramipexol syrup.

What are the pros and cons of being based in Belgium in terms of talent?

When we started discussions with new partners for our new plant, I insisted on adding a product development functionality in order to have a full-service offering as a factor of differentiation from CMO competitors.

Starting such a project only makes sense if you can benefit from a strong network of expertise, with many plants active in sterile and non-sterile manufacturing as well as very good academics. We have all of this in Belgium as the pharma industry employs 35,700 professionals in (bio)pharma (sixth position in EU) and invests heavily in the health sector every year.

To attract the best talents at BePharBel, the project and its human dimension is the main motivation for people to join us. Our employees can participate in projects in a way that they would not be able to in a big company.

As one of the most expensive countries in Europe for labour, it is of crucial importance to supply added-value jobs. Manufacturing alone in Belgium does not make sense: you need to add value to a project by proposing additional global services, which in our case means the development and redevelopment of galenic forms.

What types of partners were you seeking initially and how difficult was this, considering you were starting from scratch?

We bought ERFA to get a portfolio of partners. Without this acquisition, it would have been difficult to build a turnover, especially in the pharma world. Each transfer to a new plant takes time, is labour intensive and costly.

We now have international pharma companies as partners, as well as several medium-sized family-owned or private companies. Most of our partners are in Europe, but we are also represented in Canada. As we are not FDA approved, we are not present in the USA.

Manufacturing is not the most glamorous part of the pharma pipeline, representing only seven percent of expenditures. With COVID-19 and an increased focus on supply chain reliability, do you see the conversation around manufacturing changing?

This crisis has shown that the global pharma supply chain is not robust enough. We are all too dependent on Asia for many materials, and it is important that we change this. There are many SMEs active in manufacturing drugs in Europe, and this crisis is an opportunity to rethink the European model. Could Europe decide to give more financial support to these SMEs? There could be a simplification of the quality and regulatory roles to keep a strong and active network of manufacturing sites in Europe.

A difficulty we are facing in Europe is that 80 percent of APIs are manufactured in Asia. It is important that EU authorities find a solution. To give an example, one of the recommendations we give to our partners is to put in place self-mitigation methods to minimise risks from fluctuations in API stocks. It is key for the future of the European pharma industry to establish a safer supply of APIs.

What is your value proposition to your customers?

I prefer the term â??partnerâ?? to â??customerâ??. When you decide to sign a manufacturing contract it is for a period of between five and ten years. In such conditions it is important to have a good relationship in terms of transparency and trust as, over such a long period of time, you will face issues in terms of flexibility and communication.

Our partners join us because we manage the whole process, from the supply of raw material to the release of the final product. It is important for them to find a reliable partner able to manage the manufacturing of the product, but also supply and release, as well as stability studies. They also recognize our flexibility and capacity to adapt to changing rules.

What do you see as the major challenges and opportunities of the COVID-19 crisis for BePharBel?

Obviously, the first half of this year has been more challenging than expected, having had to keep operations running despite the crisis. We have faced this down quite easily and as managing director, I was proud to achieve this together with all our employees who really wanted to keep the operations running.

Of course, we target a turnover growth of about 25 to 30 percent each year which means that we need to find new projects and new partners. Due to the crisis, we have observed that there is less contact with potential partners and decisions on new projects have been postponed. I, therefore, believe that the impact of the crisis will be higher in the medium term.

The key opportunity of the crisis is to revamp the industry model at the European level in order to keep a good level of manufacturing in E.U.

It is also a good period for companies to speed up development and new R&D projects.

What are the next steps for BePharBel and how will they be financed?

To continue our CDMO activities and take on more and more development projects, we want to strengthen and build relationships, helping partners to manufacture their products on a daily basis.

The second step is to propose more services, such as the manufacturing of clinical lots for biotech companies. Up to now, we have not yet had the authorisation for this, but we hope to get it next year. We are also preparing to export our products; currently, we have a small portfolio in Belgium that we are manufacturing ourselves, but we would like to launch these products outside of Belgium with the help of European partners.

Up to now, we have a few investors in the company, all of whom are very experienced people able to financially support our development. These people are also important in terms of knowledge transfer and training. Getting experienced people on our board is also helpful in terms of employee motivation. The core value of all our investors is that they are looking for long term profitability and develop a strong SME.

The objective is not to put in place a project and sell it five years later. In ten years, I would like BePharBel to be recognised at the European level as a key CDMO with a very good identity in terms of galenics and product development. It is important, as we put in place a long-term project, to go step by step and make sure each step is very well handled.

For our MMCR technology, which is now mature, we need to benefit from the work already done by finding a global industrial partner for our Pramipexol project or supply the generic MMCR technology to any other API which could benefit from it and broadly develop our pipeline with several new leads every year. This will be key to change BePharBelâ??s dimension and create more value and jobs.

What is your message to executives around the world about Belgium as a pharma investment destination?

Belgium is probably one of the best countries in the world to invest in pharma.

Firstly, there are many investors with a strong pharma background in Belgium, and for any new project, you will find funding.

Secondly, Belgium has very highly qualified people able to conduct such projects. We, generally speaking, have a good reputation in the world for the quality of our work. Launching new scientific projects is not difficult in Belgium. For example, we are located a few kilometres away from Bone Therapeutics, which is a successful part of a biotechnology park (Brussels South Charleroi BioPark) containing many spinoffs from universities developing new drugs and methodologies.

Finally, there is good support from regional governments as well as local investment agencies (in our case, Sambrinvest) for innovative projects in terms of financing and ingraining companies within local innovative ecosystems. It is important, especially for SMEs, to have innovation.

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