Interview: Artur Chabowski â?? President of Mabion, Poland

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Artur Chabowski, president of Mabion, a pioneer Polish biotech player, discusses the historic partnership of their product, MabionCD20 with Mylan for the EU and Baltic states and the opportunities this opens up. Furthermore, he highlights the future potential of the biosimilar market and the companyÂ´s plans to design their own innovative product.

MabionÂ´s own product, MabionCD20, completed clinical trials this year and a historic partnership was set-up with Mylan for the EU and the Baltic states. How would you describe this experience thus far?

We completed the MabionCD20 clinical programme in late 2017. It lasted more than four years and was run in five countries. It is so, is far the biggest clinical trial conducted by a Polish biotech company.

To establish the partnership, we were advised by a US-based company, Plexus Ventures, and overall it was an extremely competitive process with a long list of interested parties. During this entire period our processes were analysed in depth by all interested partners, and in the end, we chose Mylan and made the deal happen.

All in all, the entire journey has been extremely rewarding, especially as MabionCD20 was positively received. This is even more exciting as we are the first Polish company to ever go through this process, and we have been successful. Nevertheless, there are plenty of challenges along the way from a product and regulatory perspective.

The upfront payment of this deal amounted to USD ten million, with an additional USD 35 million for upcoming milestones as well as a royalty package. This is the first time a partnership for the EU market has been set up between a Polish company in advanced biologics. Additionally, we are not solely a research company, but also have a production facility for all our drugs.

What opportunities does this influx of money open up?

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The funds will help cover our running expenses as we are still in the pre-revenue stage. Soon, we will file an application with the EMA and hope to launch MabionCD20 by the end of 2019.

The real door opener for us was the deal with Mylan as it gave us great visibility on the global arena among potential partners. We have been involved in smaller markets, like Ukraine, Morocco and some South American nations in the past, but the Mylan agreement is a completely different level for us. Now, we are finalising agreements across the globe, such as Australia, New Zealand, Canada, Africa, Asia and South America. It is like a jig-saw puzzle, as some agreements cover more than one country.

With regard to the US, we will be discussing MabionCD20â??s potential for entering the US market with the FDA shortly.

Many blockbuster biologic drugs are coming off patent in the near future, offering great opportunities for biosimilar companies. What exciting products do you see coming out of MabionÂ´s pipeline?

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It takes some time to develop a biosimilar treatment as companies must conduct clinical research and the regulatory pathway is strict. In turn, this creates a financial entry point. We see that many innovative companies in the market are joining the biosimilar game, as the potential is huge once a blockbuster comes off patent.

We believe Mabion can remain competitive in the long term as Poland offers a great opportunity to generate good profit margins on products. We see a future potential to not only continue creating biosimilars, but also develop more innovative drugs focused around monoclonal antibodies. Additionally, we have an opportunity to develop an exciting product, based on MabionCD20, to treat multiple sclerosis. We have just finished proof of concept research with that regard.

What is the economic impact of introducing biosimilars?

Obviously, once biosimilars enter the market, the government will be paying less for the same drug and competition will be greater, which in turn will drive down prices. For example, Mabion CD20 should be the third biosimilar drug on the market for MabtheraÂ®.

Nevertheless, I do not believe the biosimilar market will have the same aggressive conditions as the standard generics ecosystem. The development of biologic generics requires time, money and technology, and many companies do not have the necessary resources for these processes. Furthermore, we witness that compared to the US, Europe tends to be more liberal in introducing biosimilars, and this is driving the overall biologic penetration and volumes, which in the end is excellent for the patients, as they have access to better drugs.

Do you fear that the same pricing pressures which have been placed on standard generics will be placed on biosimilars, thus possibly creating an unsustainable commercial environment?

Not necessarily. There will be price pressures, though it is up to the biosimilar producers to keep the pricing point at a level which makes sense for the market. We predict a price drop of around 25 to 30 percent as compared to the originator, though really it depends on the countryÂ´s drug pricing model.

Although, as aforementioned, in the long-term, I believe the biosimilar market will have a smaller number of players than standard generics due to the required high level of financial and technological resources. And if you look at it from the global perspective, many large players, like Mylan, are expanding their biosimilar portfolios via partnerships as a way to save time and money.

What more can be done to increase penetration of biosimilars throughout Europe?

There are a few aspects to look at. From the regulatory perspective, it is up to the EMA and experts in each nation to educate the medical community and patients that biosimilars are equivalent to biologics. Moreover, producers, like Mabion, and national payers must be a part of the education process in equal parts. Additionally, from the payerâ??s perspective, biosimilars constitute a huge advantage, as a price drop leads to budget space making it possible to promote a higher uptake of new innovative drugs or fund other areas of healthcare.

Obviously, many innovative, originator-based companies are defending their position, stating biosimilars are not equal to the original, like they did many years ago for standard generics. Still, we are witnessing a split in the market, with many companies solely focusing on pure innovation, while others investing in biosimilars as they see the huge potential in the market and have the resources to be major players.

What more can be done in Poland at the governmental level to promote the next wave of local biotech companies?

We see the current governmentâ??s emphasis on promoting innovative Polish companies, and there is a growing availability to access Polish government and EU funds. Furthermore, the government wants to promote pharmaceutical development, both for originators and biosimilars, and the production of local innovative drugs, as currently the majority of them are imported. And if you look at the domestic ecosystem, there are few companies, taking that leap towards global relevance for advanced treatments like Mabion does.

For many years Poland suffered a brain drain, with excellent talent being drawn to the bright lights of innovative nations such as Germany and Switzerland. How do you attract the best talent from Poland and abroad to join Mabion?

Human capital has always been of great importance to us. If you look at the Polish pharmaceutical industry, 25 years ago after the fall of communism, we saw a large influx of foreign companies investing in local producers, mainly in the generics market. The great thing about this is that it offered Poland the ability to learn world-class manufacturing skills for generics, a great initial learning curve.

Today, venture capital companies are investing in Poland and new innovative ideas, and the country can have the capacity to be a major player in global innovation, despite not having had a strong R&D sector in the past. Currently Mabion has 160 employees, and we are looking to double this number in the next three years. We are attracting bright, excited graduates coming from all over the world

who bring different aspects and ideas with them.

Where do you want to take the company in the next four years?

We want to have MabionCD20 approved in the US and European markets. In the meantime, we will continue to expand our manufacturing site and see a three-fold increase in production capacity. Additionally, we want to launch clinical trials for our first ever innovative therapy; therefore, expanding from solely our biosimilar pillar.

Historically, your background is in the banking industry. What drew you to invest in Mabion nearly ten years ago?

In the past, I had made a number of investments, and Mabion has been the most successful by far I have been here since the beginning. The most exciting aspect of the life science sector is seeing the achievements of young Poles. Their ambition and energy are incredibly exciting, and it really allows Mabion to lead the way and be a great example of world-class R&D straight from Poland.

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