Polpharma's Innovative Child is ready to harvest

Jerzy Starak’s billions invested in Polpharma Biologics are going to soon bear fruit in the form of new biosimilar drugs

The company in which Jerzy Starak has invested billions will soon launch its first drugs and is announcing research for new ones

“The situation in our industry is that old basic drugs are cheap. Pharmaceutical companies in developed markets are seeking value in innovative therapies," says Maciej Wieczorek, an owner of pharmaceutical stocks worth billions, who produces generic drugs at Celon Pharma, but is also looking for innovative molecules, recently explained in an interview with "PB."

DRUG WAITING ROOM:
The first biosimilar drug that Polpharma Biologics, headed by Jan Krzewiński, is working on, may hit the market as early as next year, and the distribution rights to another were transferred to the Sandoz concern last year. The company, which has so far produced drugs on a small-scale for clinical trials, will soon open a large facility near Warsaw to service commercial demand. Photo: ARC

Jerzy Starak also understands that simple truth; he is one of the wealthiest Poles and the man behind the success of the Polpharma group, which bases its business on generic drugs. A large chunk of the profits from those sales over the years has gone to develop innovative molecules that require and a lot of money, but have the potential to bring very high returns. In Jerzy Starak's group, Polpharma Biologics is responsible for innovation, which may soon begin to reap the fruits of many years of investment.

"Since the beginning of last year, we have been operating as a separate group - Polpharma Biologics. However, we grew out of Polpharma, we were originally its biotechnology division. We are still very much supported by the owner, who, in less than a decade, invested huge funds in research, building an international team and infrastructure. We are approaching the turning point - in the fourth quarter, Polpharma Biologics will launch a modern plant in Duchnice near Warsaw, where drugs developed by the group will be produced on a commercial scale; the market launch of those drugs is approaching," says Jan Krzewiński, president of Polpharma Biologics.

Biosimilar development

The company currently employs 450 people in a research and development center in Gdańsk, where batches of drugs for clinical trials are also produced. It employs specialists from all over the world, drawn from leading global pharmaceutical companies, including over 50 Polish biotechnologists.

"By the end of the year, employment in the Gdańsk facility will increase by another 50 people, and 200 people will work in Duchnice. Our business model assumes that, in addition

to the production of drugs we developed, we will provide services for other pharmaceutical companies in the field of research, development and production of innovative molecules," says Jan Krzewiński.

In addition to Gdańsk and Duchnice, the group also has a location in Utrecht, the Netherlands, where 50 people from the company purchased by Jerzy Starak in 2016, work on cell lines, i.e. the first stage of creating new, innovative drugs. Initially, the exploratory arm of Polpharma was supposed to work on innovative molecules, but it was quickly decided that biosimilar molecules, i.e. molecules imitating the mechanism of advanced drugs, the patent protection of which is close to expiry, will be of equal importance. For Polish stock exchange investors, the best-known company dealing with biosimilars is Mabion, which - with problems - is working on introducing a drug biosimilar to rituximab from Roche, used, among others, in the treatment of lymphomas and rheumatoid arthritis.

"Currently, there is no company on the Polish market with scale comparable to ours and with a similar business model. We are able to handle new drugs from the cell line stage to large-scale production. We are working on two innovative drugs, and there are currently seven molecules in our portfolio of biosimilar drugs. These are long-term and costly processes: work on a single project lasts 8-9 years on average and requires investments in excess of $150 million to reach the commercialization phase," says Jan Krzewiński.

The company benefits mainly from the owner's funding, as well as from NCBR subsidies. He is not thinking of listing on the Warsaw Stock Exchange at the moment, but is looking for other financing options.

"In the next 6-12 months we want to build a broad consortium of banks and obtain debt financing for development," claims Jan Krzewiński.

Drug premiere

The most advanced drug in the Polpharma Biologics portfolio is a product biosimilar to ranibizumab, known under the trade name Lucentis, developed in a joint-venture with a German partner, a subsidiary of Bioeq. It is a drug used in treating various eye diseases, developed by the American company Genentech, whose annual sales in the USA alone exceed $2 billion. Polpharma Biologics holds half of the shares in a joint-venture, which is close to launching the product. How close?

"We do not want to discuss specific dates. As part of the joint venture, Polpharma Biologics will be responsible for the production of the drug in commercial quantities, among other things," says Jan Krzewiński.

Introducing a drug biosimilar to Lucentis to the market may be a matter of just several months. Bioeq has already completed clinical trials, signed a distribution agreement with the Coherus BioSciences group and is waiting for a registration application to be filed with the US FDA. Patent protection for Lucentis in the US expired in June of this year (two years before the expiry of the protection in the European Union), and Coherus has publicly announced that sale of the drug may begin next year. If this happens, the product to which Polpharma Biologics holds half the rights will be the first Lucentis biosimilar available on the market.

"In the case of biosimilars it is of course best to be first; after the release of the equivalent to the reference product, prices of course drop, but their level will, we hope, allow for a good return on investment. When you are the third or fourth producer of a biosimilar drug, in order to gain any market position, the only option that remains is to very aggressively lower the price, even down to 10-20% of the original," says Jan Krzewiński.

Pharmaceutical partnerships

Work on a drug biosimilar to natalizumab, known under the trade name of Tysabri and used primarily in the treatment of multiple sclerosis, is also very advanced.

"We have completed the recruitment of patients for the third and final phase of clinical trials," says Jan Krzewiński.

Last year, Polpharma Biologics signed an agreement with Sandoz, which is part of the Swiss concern Novartis. As part of the agreement, Sandoz will handle the drug's global commercialization, while production will take place in Poland. The value of the transaction and the detailed contract terms were not disclosed, but when it was signed in September 2019, representatives of other Polish biotechnology companies had no doubts in discussions with "PB" that this was the largest transaction of its kind in the history of the Polish market, and the payment itself in advance from Sandoz "should be in the tens of millions of dollars."

"When signing this type of agreement, we want the partner to provide not just money. First of all, we look for know-how in the field of clinical development and regulation, as well as a global structure that allows for effective commercialization of the drug. Natalizumab, like ranibizumab, will also be produced in Poland," says Jan Krzewiński.

Other biosimilars in the Polpharma Biologics portfolio are less advanced - none of the molecules have yet been introduced into clinical trials. There are also two innovative molecules developed by the company in the preclinical phase; Polpharma Biologics does not yet specify what therapeutic targets they involve.

"We are not a public company, so we do not need to provide detailed information. We plan for one new drug to appear in our portfolio every other year," says Jan Krzewiński.

THE EXPERT'S VIEW

An innovative sector almost from scratch

JERZY STARAK, Chairman of the Supervisory Board of Polpharma Group and Polpharma Biologics

If anyone doubted the strategic nature of the pharmaceutical sector, I hope the pandemic dispelled that. A strong pharmaceutical industry is fundamental to state security. The industry and drug development rest on two pillars. One has been known for a long time, i.e. proven patents used to treat most of the key common diseases - and this is what we do at the Polpharma Group. The second pillar is development and the need to constantly invest in innovation, because all medicine is based on science and constantly finding new solutions. I see the future in biological medicines - that's why I invested in Polpharma Biologics. It is important to know that one of the largest such centers in Europe is located in Poland - it is

here that new molecules, active substances and drugs for the largest companies in the world are created. We created an extremely innovative biotechnology sector almost from scratch, consistently investing not only in laboratories and production lines, but also in know-how, driving growth of highly-qualified jobs, as well as developing cooperation between science and business. It was Polpharma Biologics that established a team with best-in-class specialists leading operations and sharing knowledge gained in the best biotechnology companies in the world.

A growing group of innovators

So far, no Polish company has managed to introduce an innovative drug to the market - no one was even close, which should come as no surprise, because, according to estimates, only one in a thousand tested molecules passes from the preclinical to the clinical phase, and ultimately only one in five drugs tested in human clinical trials is used to treat patients. The pioneer was Adamed, which took a potential diabetes drug into human clinical trials a decade ago, but the project was ultimately not successful. Currently, innovative drugs from three Polish companies are at the stage of clinical trials, all of which are listed on the Warsaw Stock Exchange - Ryvu (former Selvita) has two oncological molecules, and OncoArendi and Celon Pharma have one each. In the biosimilar segment, apart from Polpharma Biologics, the stock market-listed Mabion is doing advanced work: its drug has undergone clinical trials, but currently has problems obtaining approval from the European Medicines Agency to be allowed on the market. Stock market investors expected approval in 2020, but the company recently announced that registration may not take place until 2022.

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