Building an integrated biosimilars business

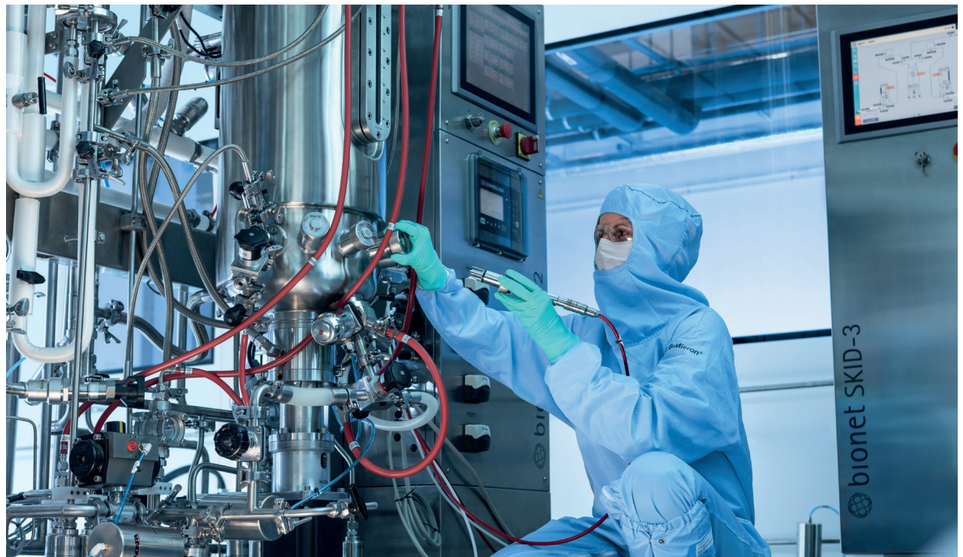
Polpharma Biologics is a fast-growing business that develops and manufactures biopharmaceuticals as new molecular entities (NMEs) or biosimilars, and also delivers biopharmaceutical CDMO services. Established in 2013 by parent company Polpharma, and spun off as a separate legal entity in January 2019, the company is already constructing its second manufacturing facility in Poland to provide customers with integrated support from cell-line development to the commercial-scale drug substance and drug product supply. Hannes Teissl, who acts as a Supervisory Board Member of Polpharma Biologics, highlights their recently inked global commercialisation agreement with Sandoz for a natalizumab biosimilar; he describes the deal as a significant milestone for the company.

Mr. Teissl joined Polpharma Group in August 2012 from pharma giant Sandoz. He has served as Vice President, Group Strategy Officer, and Head of its newly formed BU Head Biologics. He explains that he was hired specifically to build Polpharma Biologics as a premium biologics service provider with global reach and was subsequently instrumental in establishing the biosimilars joint venture Bioeq in 2014, for which he now also serves as Supervisory Board Member. "The company's owner strongly believes that as the global market for biopharmaceuticals is significant and growing at a healthy rate, there is clear and international demand for both biosimilars and integrated biopharmaceutical contract development and manufacturing services," says Mr. Teissl.

The company is moving fast: it all started with the construction of an 8,000-m2 Biotechnology Center for the development and optimisation of both upstream and downstream bioprocesses in support of projects from conception through R&D, and on to production of clinical trial as well as commercial materials — in accordance with cGMP guidelines. The Center is outfitted with state-of-the-art equipment and staffed with a diverse team of world-class veterans with years of experience at big pharma and biotech companies and highly talented local scientists.

Another important move in Polpharma Biologics' coherent strategy was the acquisition of Dutch-based Bioceros and their proprietary high-yield cell line development platform CHOBC® as well as their comprehensive process development and analytical capabilities in 2016. Since this acquisition Bioceros has further developed its novel technologies into specific cell line productivity increase (SPOTTM) and improved efficiency (SLIMTM).

Polpharma Biologics today operates across centers of excellence in Poland, the Netherlands and Switzerland providing fully integrated solutions along the biopharmaceutical value chain, covering cell line development, product and process development and



formulation, clinical and commercial scale manufacturing. With all relevant technologies, the company has truly become a one-stop-shop to support a variety of programs, high quality contract development and manufacturing services to industry partners around the globe.

The recently signed agreement with Sandoz is Polpharma Biologics' first deal with a major pharmaceutical company, and as such a significant milestone. "The agreement is particularly satisfying as Sandoz is a global leader in biosimilars," Mr. Teissl comments. He denies that his own background at Sandoz was crucial for the deal, but is convinced that the cooperation testifies to business confidence by one of the world's largest global pharmaceutical companies in Polpharma Biologics' capabilities.

The commercialisation agreement is for a natalizumab biosimilar, currently in Phase III clinical development for the treatment of relapsing-remitting multiple sclerosis (RRMS, affecting 85% of MS patients). Under this agreement, Polpharma Biologics will be responsible for the development, manufacturing and supply of the collaboration biosimilar. The potential market value is significant: the product is a biosimilar to the Tysabri drug (natalizumab) produced by Biogen. Tysabri was launched in 2004 and is used to treat RRMS (affecting 85% of MS patients). In 2018, its global sales amounted to nearly $1.9bn, which accounted for 17% of the Group's revenues.

Natalizumab is the first of a number of late-stage pipeline developments: Polpharma Biologics expects to be announcing in the near future. Mr. Teissl explains that their strategy is to develop these biosimilars in-house and then commercialise them with the best partners in specific markets. In addition, the company offers contract development and manufacturing services as it has established significant capacity to support external client projects from development through clinical and small-scale commercial manufacturing and, starting in 2020, also large-scale manufacturing of drug substance and drug product. The building has been completed, and the first drug substance manufacturing lines are currently under construction. Cleanrooms and utilities are also being installed for additional production trains, allowing rapid expansion of capacity when needed.

With all this going on the company's greatest challenge is to manage growth, Mr. Teissl admits. "When we first started out we were a small team, now we have hundreds of people working for us. Such a transition requires a lot of management attention and we're proud of having put in place an industry leading management team." While he acknowledges that there have been some high-profile failures in the biosimilars industry, he is not at all worried about market risk. "Polpharma Biologics is fully committed to provide more affordable quality biologics, which healthcare systems are in need of so much. Our specific dedication to deliver on quality, cost and supply is at the core of our strategy and is precisely why we have built a fully integrated biologics value chain. And we're clearly in a growth market."

The Business Research Company estimates there are currently more than 1000 biologic drugs in development. The number of biotech patents applied for every year has been growing at approximately 23% annually, and more than 1,500 biomolecules are currently undergoing clinical trials. To date, the success rate for biologics in clinical trials has been over twice that of small molecule drug products. By 2022, biopharmaceuticals are expected to make up about half of the top-selling 100 products and about 30% of the prescription drug market. The global biosimilars market is expected to expand at a CAGR of 31.7% from $5.95 billion in 2018 to $23.63 billion by 2023. Currently, there are over 800 biosimilars in the global pharmaceutical pipeline.

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