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## Building a Biologics Business from the Ground Up

**B**uilding a biologics business from the ground up provides tremendous flexibility but requires the right business strategy. Polpharma has attracted world-recognized leaders to build and manage all key biologics functions at its new, state-of-the-art facilities, which are located in Poland and in the Netherlands, ideally situated to serve the global markets. Backed by a strong branded small-molecule business, Polpharma has silently established a fully integrated in-house value chain for biologics and is now reaching out to potential clients that can benefit from its end-to-end contract development and manufacturing services.

### Startup Benefits with Deep Resources

Polpharma, a privately owned regional leader, employs more than 7,500 people and generates revenues of \$1 billion annually from the sale of small-molecule pharmaceuticals and APIs, largely in Central and Eastern Europe.

Polpharma entered the biologics space in 2012 and has since grown through the establishment of technical capabilities and global assets. We have brought together a diverse team of world-class veterans with local talent from the Polish biopharmaceutical industry to work in one of the most modern biotechnology centers in Europe. The success of the branded generics business of Polpharma has enabled the funding of our activities in the biologics space. As a result, Polpharma Biologics has the nimbleness and flexibility of a start-up paired with



the access to resources of an established company.

### Technical Control

Polpharma Biologics retains full control of all technical elements of the business and has built competencies in all aspects of biologics development and manufacturing from cell-line development to clinical and commercial production.

For our in-house biosimilar candidates, we bring molecules to the approval stage and then find the best commercialization partners. This approach allows us to work on biosimilars that fit our capabilities without the need to focus on a single therapeutic area or justify sales in particular markets. In addition, we have developed a strategic offering for contract development and manufacturing services to global industry partners based on our established competencies.

### Covering the Entire Spectrum

Our modern biotechnology center in Gdansk consists of a comprehensive R&D platform and GMP production capabilities, including 2 X 1000L single-

use systems with cell culture capacity for clinical and smaller commercial volumes. Our microbial fermentation capability will be fully operational in May 2018 and will be used to produce our first biosimilar candidate. It will also be available for client projects. By Q1 of 2019, a flexible fill/finish line to produce vials, prefilled syringes and lyophilized products will be operational. As a result, at this facility, Polpharma will have all of the technologies needed to support projects from development through clinical and small-scale commercial manufacturing.

With our acquisition of Bioceros in 2016, Polpharma brought in-house a well-established cell-line development platform technology, making us a truly integrated one-stop shop. Access to this proprietary technology allows us to generate and optimize cell lines in terms of yield and productivity plus apply our comprehensive modulation toolbox for the development of processes that require fingerprint-like biosimilarity – a unique combination of capabilities.

Our large-scale commercial production site near Warsaw will come onstream in 2020. This facility will mainly serve as a contract development and manufacturing site with mammalian and fill/finish technologies. We believe that this Polpharma Biologics plant will serve as an attractive option for clients that want top-of-the-line quality, on-time delivery and access to state-of-the-art technologies combined with a maximum of attention and focus, and we can meet that need.

Polpharma Biologics has immediately available capacity intended to support external clients at any stage of the development process. We are very flexible in terms of work packages and scope and are happy to work on integrated, end-to-end solutions or just on one aspect of the development cycle. Customers looking for a strategic manufacturing alliance are invited to join us as partner for the Warsaw facility so that our modular expansion is in alignment with their needs. **P**