We care about creating quality biologics with passion

polpharma biologics

We care

“Courageous actions come from people who dare to dream. I am immensely proud to see teams within Polpharma Biologics go beyond what has come before and lead the company to become a biotechnology leader in the region.”

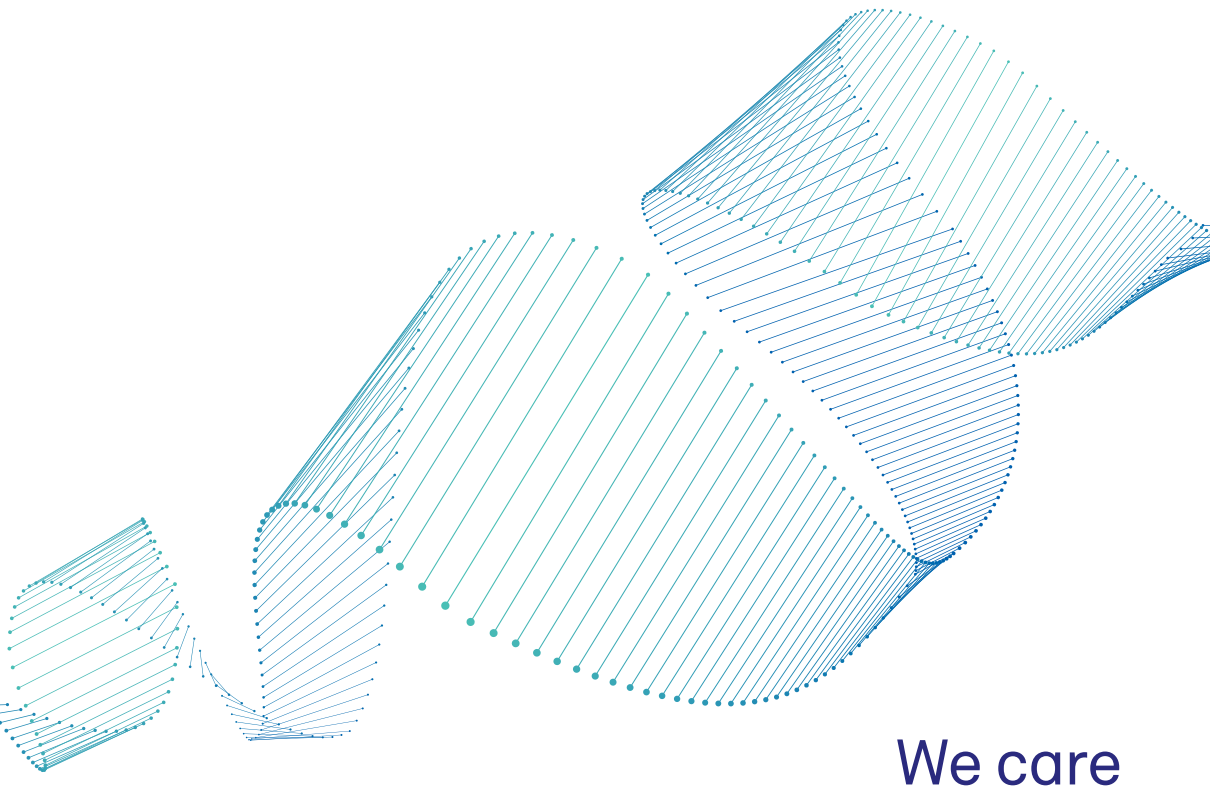
Jerzy Starak

Founder and owner of Polpharma Biologics

Biotechnology is the future
We are a part of it

Polpharma Biologics develops biosimilar medicines to broaden patients' access to life changing treatments, increase healthcare savings and fuel innovation through competition in the markets. We achieve this through developing high quality medicines and licensing them with world-leading commercialization partners.

We develop our biosimilars in our own fully integrated European operations. The process covers the entire drug development value chain: from a unique and insightful approach to portfolio selection – starting with development of the cell line to technical proof of similarity, to clinical development with regulatory and intellectual property (IP) throughout, to commercial-scale manufacturing. Our facilities are amongst the most modern in the industry and our talent is second-to-none.



We care

Developing & manufacturing biosimilars

We have built comprehensive and outstanding biosimilar capabilities.

All our work is ultimately designed to provide patients worldwide with access to the most advanced medicines. We develop biosimilars that match their reference product in terms of safety, efficacy and quality, but which are also more affordable than the originator drug. Based on our platform approach and extensive expertise in cell line development, product quality attribute (PQA) modulation and process development, our teams are able to reduce the overall cost of goods and shorten development timelines.

→ Ranibizumab
Ophthalmology

→ Natalizumab
Neurology

→ Vedolizumab
Autoimmune

→ Ocrelizumab
Neurology

→ Undisclosed PB019
Immunology

→ Undisclosed PB020
Blood Disorders

→ Undisclosed PB021
Various

→ Undisclosed PB022
Asthma

→ Undisclosed PB023
Blood Disorders

We select multiple biosimilar candidates each year, based upon solid market analysis and clinical evaluation, as well as an extensive development and manufacturing assessment.

We care about global sustainability, speed to market and scientific rigour - in compliance with the highest quality requirements.

Development & manufacturing solutions

From idea to global supply

We have extensive experience in development including clinical, regulatory and IP, all with a strong underlying focus on quality

We start our biosimilar development with the creation of a cell line in our Utrecht facilities in the Netherlands. Process and formulation development continues in our Gdańsk and Warsaw-Duchnice sites in Poland, followed by the generation of drug substance and drug product for our PK/PD, safety and efficacy clinical trials. Our in-house regulatory and IP team are with us along the way advising and guiding the organization to the ultimate target of health authority submissions.

Mammalian solutions

We have all the components in-house to take biosimilars from cell line development to a final commercial medicine, that is available to patients worldwide and has passed the rigorous, regulated health authority requirements.

Microbial solutions

We have established dedicated laboratories with specialized staff who hold extensive experience in microbial development and manufacturing.

Our sites

With state-of-the-art facilities across Europe, Polpharma Biologics is at the forefront of the next wave in biosimilars; leveraging our knowledge, capabilities and footprint to develop innovative solutions for patients around the world.

1

Utrecht (the Netherlands)

Our Utrecht site is home to our industry-leading proprietary cell line development platform.

2

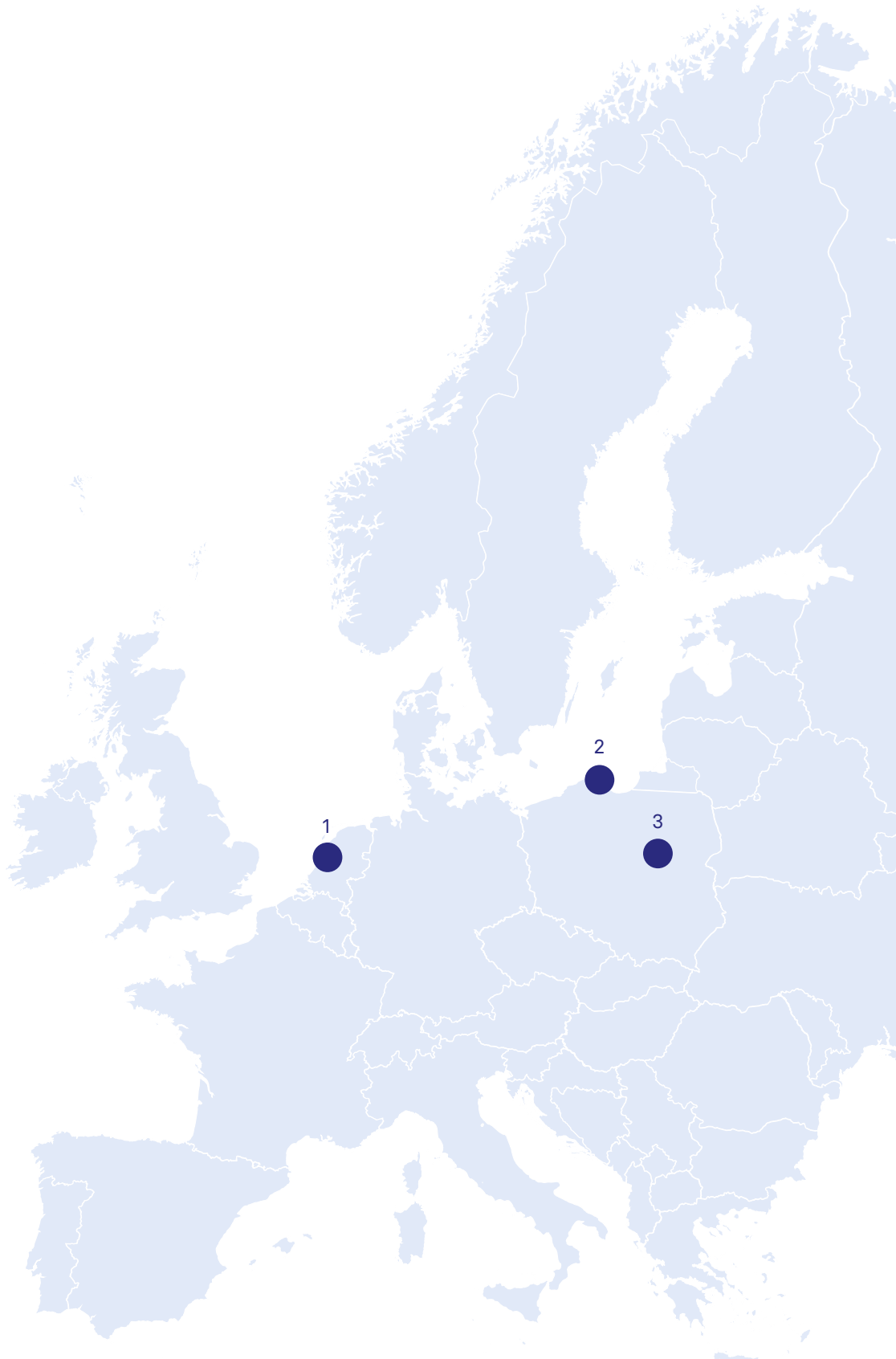
Gdańsk (Poland)

Our FDA-approved Gdańsk site includes mammalian and microbial R&D and manufacturing facilities for mid-scale production.

3

Warsaw-Duchnice (Poland)

Our Warsaw-Duchnice site is one of the largest in the region single use mammalian manufacturing sites.



Our history

2013-14

Biotechnology R&D centre established in Gdańsk, Poland.

Bioeq established - joint venture with Athos on the co-development of ranibizumab.

2016-17

GMP certification of mammalian plant in Gdańsk for IMP (EMA).

Acquisition of Bioceros, an early stage biotech development company in Utrecht, the Netherlands.

2018-19

Creation of an independent company Polpharma Biologics (spin-off from Polpharma).

Out-licensing deal for natalizumab with Sandoz.

Out-licensing deal for ranibizumab with Coherus (Bioeq).

2021

GMP certification of microbial plant (EMA) in Gdańsk for commercial API manufacturing.

Out-licensing deal for ranibizumab with Teva and MS Pharma (Bioeq).

2022

Successful FDA inspection for microbial plant and GMP inspection for commercial manufacturing of API in mammalian plant in Gdańsk.

Ranibizumab launch in the US and in Europe.

2023

GMP certification of Warsaw-Duchnice (Poland) site (EMA).

Natalizumab approval by FDA and EMA.

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