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MAMMALIAN BIOLOGICS

WE HAVE THE FLEXIBILITY TO TAKE MULTIPLE CONSTRUCTS ON, PRODUCING SMALL QUANTITIES FOR CLIENTS TO PERFORM EFFICACY STUDIES, WHILE ENSURING THAT EACH CONSTRUCT MEETS MANUFACTURABILITY CRITERIA.

There has been, and continues to be, an ongoing shift of early-stage biologics development work away from big biotech to small and mid-size private biotechnology companies, with around 50% of new phase I clinical trials now being initiated by private biotech.

These companies may be science strong, but they rarely have the internal capabilities to fully develop and manufacture a biotherapeutic themselves, so they rely heavily on contract development partners. This is very different from the commercial manufacturing outsourcing market where the client brings a huge amount of expertise in every area; small and mid-size biotechs need their contract partner to help guide their project and fill expertise gaps to maximize the chances of the project being successful.

Because of this, from the start, we have always looked to build a company that would act like a partner in the drug development process, offering expert guidance and treating every project like we would our own. This is why we don't just offer fully integrated discovery to commercial supply services but clinical, regulatory, and IP support.

We understand that clients want to develop the most clinically optimal construct and therefore want to assess multiple candidates at an early stage before committing to the intensive stages of development. We have the flexibility to take multiple constructs on, producing small quantities for clients to perform efficacy studies, while ensuring that each construct meets manufacturability criteria.

One of the other ways that we have adapted our capabilities is the build-out of our upcoming Warsaw site, where as well as establishing a state-of-the-art large-scale manufacturing plant, which will initially add 4 × 2000 L to our existing drug substance manufacturing capacity, we also plan to add range of single-use bioreactors from 50 L to 500 L aimed at supporting clients with smaller capacity needs. This means we can support the increasing demand for early-stage clinical trial material and orphan drugs at optimal costs.

All this knowledge has been gained through the development of our own biologics and through collaborations with partners like Bioeq AG and Sandoz, both biosimilar partnerships.

We continue to see a rising demand for the rapid development of biosimilars, and because of this we have developed our range of biosimilar-expressing cell lines ready for partners to move into production and manufacturing to accelerate their program. We understand the cost-of-goods pressures clients face and have developed lines that are more productive than the originators without compromising on critical quality attributes

Our range of regulatory and IP landscaping expertise complements our development and manufacturing solutions to help us map a course for our clients and support their biosimilar or novel biologics project through to commercial supply. As our capacity and capabilities have grown, we are looking to expand our client base globally, especially in the North American market and biotech hubs of California and Boston. P

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Polpharma Biologics is a biopharmaceutical company with state-of-the-art facilities across Europe. Polpharma Biologics has multiple international centers of excellence specializing in cell line development, product and process development, clinical manufacturing, commercial-scale production, and regulatory affairs. They work with their partners to advance their biological pipeline (biosimilars and novel biologics) by providing top-quality contract development and manufacturing services to the industry.

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