
Lonza

Our Businesses

Our Offering

Lonza is a preferred global partner to the pharmaceutical, biotech and nutrition markets. We optimize scientific innovation and manufacturing technology to enable our customers to serve their patients and consumers.

By combining technological insight with world-class manufacturing, scientific expertise and process excellence, we help our customers to deliver new and innovative medicines that help treat a wide range of diseases.

Our services and products span from early-phase discovery to custom development and manufacturing of active pharmaceutical ingredients to innovative dosage forms for the pharma and consumer health and nutrition industries. Our scale and resources mean we can provide a one-stop solution for our customers.

Our business is structured to meet our customers' complex needs across four divisions: Biologics, Small Molecules, Cell & Gene and Capsules & Health Ingredients.

Capabilities offered by Lonza

		Pre-clinical & phase I	Phase II & Phase III	Commercial
Biologics	Mammalian	✓	✓	✓
	Bioconjugates	✓	✓	✓
	mRNA	✓[1]	✓[1]	✓
	Microbial	✓	✓	✓
	Drug Product	✓	✓	✓[2]
Small Molecules		✓	✓	✓
Cell & Gene		✓	✓	✓
Capsules & Health Ingredients		✓	✓	✓

[1] Process Development and Analytical Development as of 2023, cGMP manufacturing as of 2024
[2] Full commercial as of 2026

Innovation

Strategic innovation continues to drive progress and advancement across the healthcare industry. Specifically, innovation in pharmaceutical manufacturing directly impacts the market by providing critical tools to support the future success of novel drug candidates. By boosting efficiency and effectiveness in healthcare manufacturing, innovation enables developers to focus on the rapid development of novel and complex modalities that target unmet medical needs.

As a preferred CDMO, we leverage our substantial expertise and experience to drive innovation across multiple modalities and throughout the drug development process from discovery to development, manufacturing, and commercialization.

We believe that investing in research and development (R&D) is essential to meeting our customers' long-term needs. Our R&D network supports innovation across all our divisions and modalities, leading to strong synergies and inventive projects that have the potential to deliver benefits to the wider industry and – ultimately – to the lives of our customers' patients. Our key cross-divisional innovation areas are summarized below.

Integrating artificial intelligence, machine learning and robotics into the drug development and manufacturing journey

In recent years, digitalization and industry 4.0 has become the cornerstone of innovation. This global trend has wide-reaching implications for many industries including medicine, life sciences and healthcare manufacturing.

At Lonza, we are integrating various digital technologies into the drug development and manufacturing journey. "Bioprocessing 4.0" is about digitally connected process that supports improved speed, flexibility and efficiency, while managing cost. Such connected and integrated technologies can unlock greater depth of process knowledge, supported by advanced data management capabilities, which can be used to optimize and control processes.

We are already implementing machine learning algorithms (ML) and artificial intelligence (AI) into our processes to navigate the complexity and speed requirements of manufacturing novel treatments. Examples of how AI has been implemented include using computer vision technologies in quality assurance for product quality optimization, and developing hybrid approaches for process scale-ups that combine AI, mechanistic models and statistics.

AI, ML and big data management are used in our R&D teams to support computer-aided drug design, protein profile assessment, engineering mammalian expression systems with DNA element design, and for predicting side effects for novel therapies. In small molecule development and manufacturing, ML algorithms and automated solutions are implemented in retrosynthesis and synthetic route optimization, toxicological assessment of new chemical entities, and formulation design.

In addition, our Drug Products Services team has developed an AI image analysis tool that aids in the fast detection and classification of particles. There is a primary focus on detecting polysorbate degradation products, which are crucial for maintaining the stability of proteins to extend their shelf-life. This detection technology aims to deliver therapeutics of the highest quality by optimizing sub-visible particle imaging for formulation development.

Another application of digitalization lies in workflow automation. Digitally sustainable operations for managing laboratory work and documentation can facilitate a smooth transition from manual, paper-based documentation processes to a fully electronic system that meets regulatory requirements. Lonza's MODA® Platform represents a comprehensive laboratory data and manufacturing management solution across multiple systems and scales. It has been implemented across selected areas of our manufacturing network to boost process efficiency and quality.

Supporting the development and manufacturing of emerging modalities

While standard monoclonal antibodies continue to dominate the mammalian pipeline, we are witnessing an uptake of new molecular formats into the global drug development pipeline. We continue to build on our established track record with biologics such as monoclonal antibodies. However, we are increasingly focused on developing and enhancing our strong capabilities in more complex biologics such as bispecific antibodies, bioconjugates and mRNA.

A major trend is the increased focus on bispecific antibodies which, unlike standard monoclonal antibodies, can recognize more than one antigen. In the past 20 years, almost 300 bispecific antibody-based drug candidates have entered the clinic. We support the development and manufacturing of these complex formats by leveraging more than 30 years of experience in supporting protein manufacture.

In the cell and gene therapy field, we see rapid growth in the area of in vivo therapy, where genetic material is delivered to target affected cells inside a patient's body. Scalable manufacturing platforms are vital in supporting the timely and reliable supply of such therapies. We have been involved in developing manufacturing platforms for new vectors for these therapies, which aim to reduce immunogenicity and improve organ tropism. Alongside supporting novel vectors for gene therapies, we are also active in the field of exosome-based therapies. As a leader in this space, we have created a CDMO offering supporting this novel therapeutic platform, including manufacturing, purification and analytics.

Personal Perspective

Maria Soler Nunez
Head, Group Operations

In 2022, we delivered an extensive portfolio of growth projects across our operations, while navigating the challenges arising from continuing supply disruptions. We also built important foundations in key areas such as automation, supply chain and data management, as well as implementing a responsible sourcing program, to embed ethical, social, governance and environment-related principles in our procurement management processes and to support sustainability and decarbonization in our value chain.

There is a continuing need to balance immediate business needs with mid- to long-term strategic ambitions. We must also remain attentive and prepared to manage any challenges arising from the current macroeconomic conditions. Specifically, we anticipate possible future issues relating to material supply, rising inflation and potential energy shortages. To ensure business continuity and success, we are already allocating relevant resources to mitigate known risks, while remaining responsive to unforeseen eventualities.

Looking to 2023, we are focused on supporting the business in successfully delivering its strategic growth projects and maintaining a competitive advantage through operational excellence. We will also continue to strengthen our focus on sustainability across our operations. These ambitions are strongly supported by established Lean operating principles, which improve productivity and ensure we continue to deliver on our customers' needs.

Biologics

>600[1]

pre-clinical and clinical large molecules

>55[1]

commercial large molecules

[1] Including mammalian, microbial, bioconjugates and cell and gene therapy products (personalized medicines are included for pre-clinical and clinical molecules only, early development services are included for pre-clinical molecules only)

We are a full service CDMO, active across a wide range of Biologics modalities, including mammalian, microbial, bioconjugates, mRNA and drug product services to the biotech and pharma industry. Throughout 2022, we continued to further strengthen our integrated end-to-end approach and expand our global network to match market and customer needs.

In particular, we offer clinical and commercial manufacturing services across our global network, from small-scale (1,000 to 2,000L) through mid-scale (3,000L and 6,000L) to large-scale (10,000L, 15,000L and 20,000L). Our expertise in stainless steel, single-use and hybrid technologies, and development and innovation capabilities helps our customers to de-risk the path to market.

Market Trends

The biopharmaceutical market has continued to expand in 2022 and is expected to grow by a compounded annual growth rate (CAGR) of around 8% over the next five years[1]. Historically, the biopharmaceutical market pipeline grew 11% per year over the last 10 years[2]. Positive growth is expected to continue in the future.

Looking at the Biologics CDMO market, the associated rise in demand for outsourcing has led to continued growth, with a current forecast of 12% growth (CAGR) over the next four years[3].

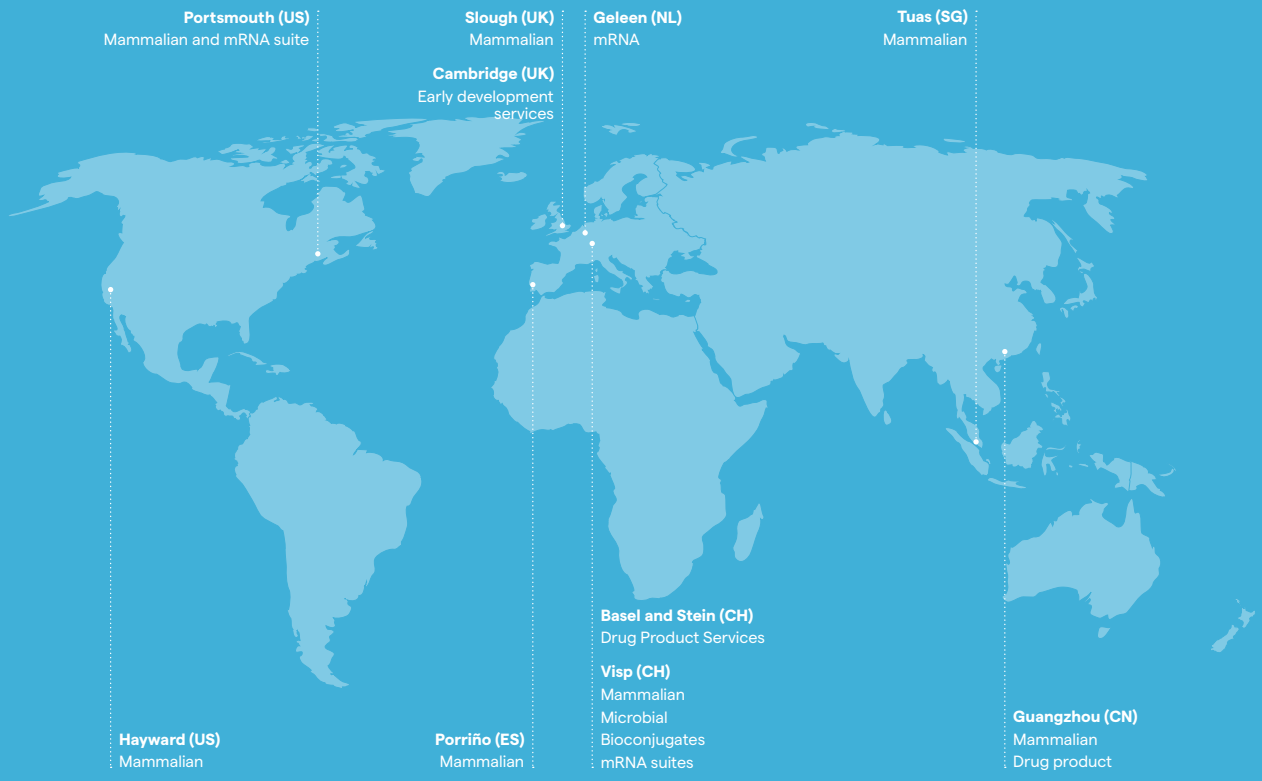
We are seeing significant growth in the biologics development and manufacturing pipeline worldwide. An increasing number of new applications for drug approvals are being filed by emerging and small biotechs. These early-stage companies usually do not have in-house capacity on which to rely for early testing, scale-up development and manufacturing. For these customers, collaborating with a well-established CDMO can significantly simplify the development process and supply chain, in addition to improving speed and success rates across a wide range of modalities.

The market is continuing to drive progress with new molecular formats and modalities emerging to target unmet medical needs. These new advances create demand for development and manufacturing expertise. The increasing complexity of the molecules entering the clinical pipeline is driving demand for experienced CDMOs that can help customers in drug development de-risk investment and accelerate time to market.

A rising number of more complex biomolecular formats are entering the global pipeline. These include bioconjugates, fusion proteins, recombinant proteins, and bispecific antibodies (bsAbs). In this context, the need for a deeper and earlier understanding of the biological mode of action is becoming more important. The resulting demand for services to develop and manufacture these complex biomolecules is expected to rise proportionately in the coming years.

[1] Evaluate Pharma "2022 World Preview Report" (2022)
[2] Citeline Trend Analysis (2022)
[3] Frost&Sullivan - Growth Opportunities in Biologics Contract Development and Manufacturing Market, 2022
[4] Evaluate Pharma (2021)

Our Global Development and Manufacturing Footprint



BsAbs may be described as molecules that recognize two different antigens or epitopes, compared to conventional monoclonal antibodies (mAbs) that can only recognize one. Bispecific antibodies range from small proteins – two linked antigen-binding fragments – to large molecules with other attached domains. This biotherapeutic class offers improvements in treatment precision and flexibility. Specifically, bsAbs may play a meaningful role for patients receiving cancer care, by creating a more accessible form of treatment for patients who are unable to travel to receive care. It appears that bispecific proteins and other complex protein formats will come to dominate the drug development pipeline in the next five to ten years.

Looking at drug product sales, the market has historically been dominated by oral dosage forms for small molecules, but there is an increasing focus on injectable forms, driven by biologics. These injectable forms look set to become the largest drug product market segment over the next three years. Such a shift in market tectonics is expected to lead to a significant market need among pharma and biotech customers for CDMO support in the fill and finish space[4].

Our Offering

As a leading CDMO for biopharmaceuticals, we serve our customers across their product lifecycle from pre-clinical development, through trials, to launch and market supply.

Our portfolio is one of the most complete in the Biologics industry. It includes mammalian and microbial expression systems, as well as capabilities for bioconjugation and mRNA manufacturing. We are currently expanding drug formulation and drug product development and manufacturing to provide our customers with simplified and de-risked supply chains. We are also investing in innovation to support our customers with leading development services, and other manufacturing technologies, such as perfusion or conjugation capabilities.

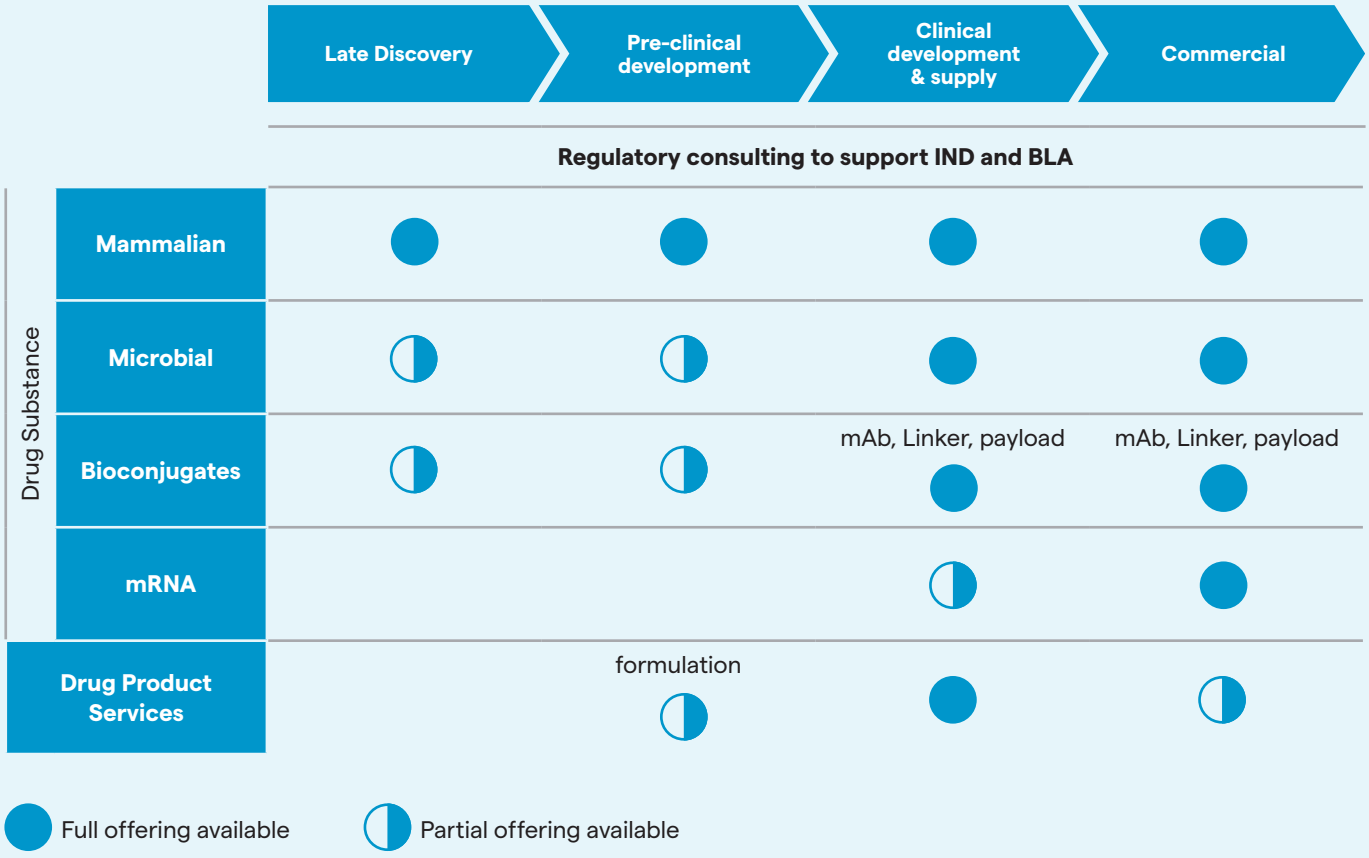
Mammalian is and will remain a critical manufacturing technology for the pharma and biotech industry. We hold a leading position in this space, backed by more than 30 years of experience in manufacturing mammalian cell culture. Alongside this established track record, we provide an integrated range of services that span late discovery to commercial supply.

As the pipeline for mammalian expression becomes more complex, we use our proprietary GS Xceed® Expression System in combination with other molecular tools, such as GS PiggyBac® for stable expression of large DNA cargos and bYlok® Technology, for the discovery and design of bsAbs. These molecular tools have been designed to meet the needs of new and complex molecular formats. They carry multiple customer benefits by improving speed to market as well as helping to reduce costs and delays that may arise from low yields or poor batch quality.

Our extensive mammalian manufacturing capacities include small-scale, single-use systems to mid-scale and large-scale stainless steel assets. With facilities located across the US, Europe and Asia, we can offer our customers phase-appropriate capacity and can respond to the increasing need for regional manufacturing hubs.

Within our **Microbial** business, we support customers at every step on the path to commercialization, including strain development, cell banking, process development, and process optimization. With more than three decades of experience manufacturing microbial products at our Visp (CH) site, along with our established regulatory expertise, we have an unparalleled track record of delivering commercial supply. Our proprietary XS Technologies® expression systems support our mid-scale and large-scale commercial manufacturing offerings. These expression systems target the biotherapeutics pipeline, which continues to show sustained growth. They also support multiple classes of more complex molecule development projects to meet the specialized needs of smaller biotech customers.

Our microbial customers also benefit from our extensive experience and capabilities in advanced engineering and process development. Our toolbox can deliver a scalable, efficient and compliant process with established and reliable technologies. Our XS Technologies® platform for microbial expression includes Escherichia coli, Pichia pastoris and Bacillus subtilis expression systems.



As one of the first CDMOs to support the commercialization of **bioconjugates**, we have a broad and established capability in manufacturing these complex molecules. Representing a growing class of biopharmaceuticals, they are an important pillar of our Biologics business. Our offering covers all elements of the complex supply chain, from late discovery through to commercialization, including the manufacturing of monoclonal antibodies, linkers and payload, and other components. We support the development and manufacturing of protein modalities, including the option for early tuning and de-risking. The offering includes the synthesis and purification of small molecule linkers and payloads prior to bioconjugation, supported by a toolbox of modality-agnostic technologies. The bioconjugation toolbox concept offers our customers access to a selected range of robust and scalable advanced technologies that meet the unique needs of these complex molecules.

mRNA technology has the potential to transform the way we manage and treat many illnesses and infections. We pioneered the commercialization of this modality through the successful delivery of the drug substance for Moderna's COVID-19 vaccine. The possibilities for this technology have truly emerged in the last three years and we are working to capture future opportunities by completing our offering across the value chain. To support this ambition, we are building additional mRNA and lipid nanoparticle (LNP) process and analytical development labs, as well as clinical cGMP capabilities at our site in Geleen (NL). These expanded development services are expected to come online at the beginning of 2023, with cGMP readiness scheduled for early 2024.

Our **Drug Product Services (DPS)** offering focuses on parenteral dosage forms. Our portfolio includes products for injection and infusion for intravenous, subcutaneous, intraocular and other routes of parenteral administration. Our integrated modality-agnostic offering and extensive regulatory expertise can support monoclonal antibodies as well as other biologics including novel formats. It also supports noncytotoxic bioconjugates, peptides, viral vector and small molecules.

Personal Perspective

Jean-Christophe Hyvert
President, Biologics Division

Demand for commercial capacity has been strong and sustained throughout 2022. We are investing in commercial assets, backed by customer agreements across modalities including mammalian, microbial and conjugation. The ramp-up of new facilities continued in 2022, including our mid-scale 6K mammalian facility and the opening of two new bioconjugates suites. We are making progress on the commissioning of our mid-scale microbial facility and the build-out of our new large-scale facility in Visp (CH), supported by strong customer demand. We also saw continued interest in Ibex® Dedicate, providing customized solutions across different technologies and much-needed flexibility during late-phase trials.

We are investing in innovation and developing our early clinical offering for pharma and biotech customers, to ensure the support of our global network for the migration of molecules through clinical stages. Alongside our new bYlok® bispecific pairing technology, we added new development capabilities in Slough (UK) for the discovery and design of complex proteins. We are also enabling biotech customers to unlock faster timelines, from gene to Investigational New Drug (IND) filing in 11 months for classic mAbs and 13 months for bispecifics, in addition to customized solutions tailored to specific customer needs. Finally, we continue to build our end-to-end network as we invest in commercial drug product capacity and ramp up additional drug product lines in Stein (CH), as well as conjugation capacity and capabilities in Visp (CH).

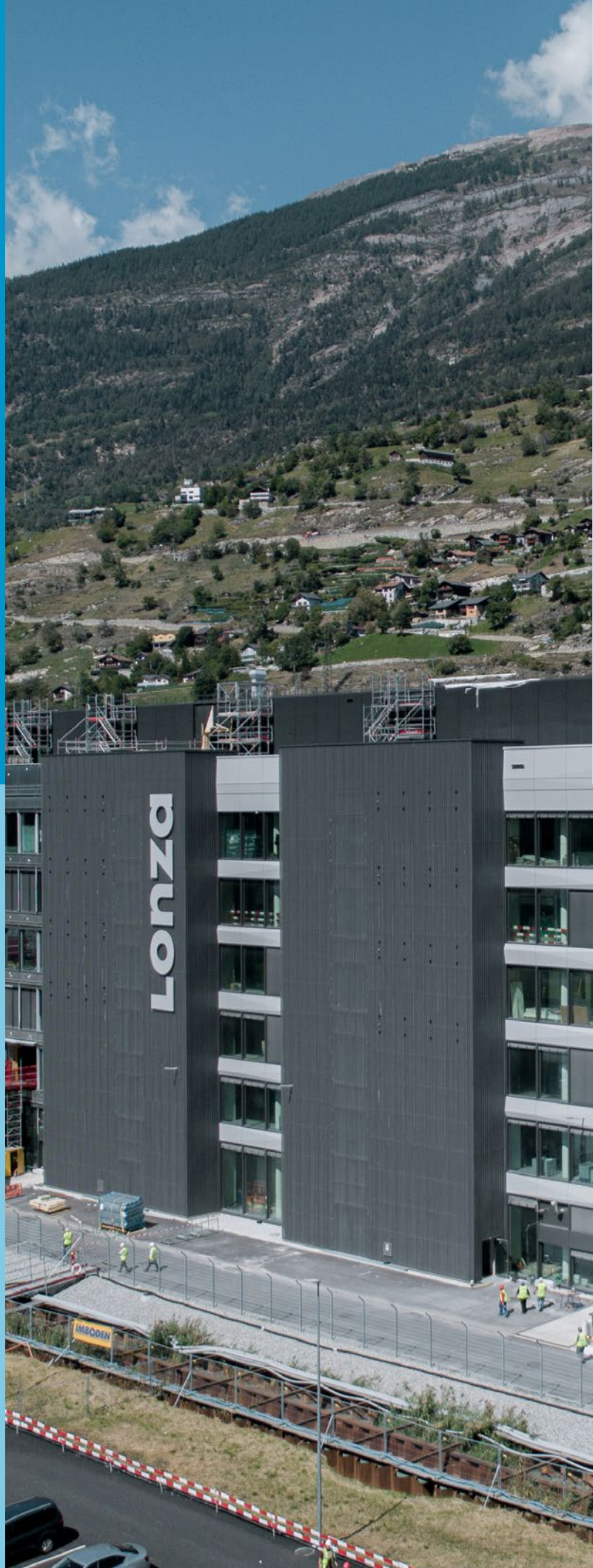
Customer needs continue to evolve and market demand fluctuates in line with a general market slowdown in clinical trial recruitment and biotech funding. In this context, we are building flexibility into our offer and network, enhancing our capabilities and investing in our people. These combined efforts will ensure that we are ready to adapt to shifts in customer expectation and market need.

Looking ahead to 2023, our priority is to continue on our strategic journey: building our global network across modalities, end-to-end offering and clinical development expertise. We will continue to ramp up new assets and deliver against our planned growth. Our goal is to provide full lifecycle support, from preclinical development through trials to commercial launch. Whether our customers are developing innovative mRNA therapies or complex bioconjugates, we will continue to support them with best-in-class facilities, innovative technologies and talented people across the network.

Ibex®
Solutions

Ibex® Solutions
Ibex® Solutions comprises a series of advanced manufacturing facilities which combine to form an extensive biopark in Visp (CH). The facilities are supported by a flexible and responsive business model with three innovative offerings: Ibex® Design, Ibex® Develop and Ibex® Dedicate. These three offerings span the complete product lifecycle of a biopharmaceutical from pre-clinical to commercial stages, from drug substance to drug product. Our Ibex® customers benefit from a complete and tailored portfolio of services under a single contractual framework. Ibex® Solutions enables our customers to bring their new medicines and vaccines to their patients at speed, while providing the flexibility to actively manage supply constraints, drug development uncertainty and market demand changes.

Ibex® Design and Develop
Biologics development and clinical manufacturing phases are covered by Ibex® Design and Ibex® Develop. These offerings support companies at any stage from clinical trials up to product launch. Completed in 2021, the facilities benefit from high levels of automation and employ single-use technologies (1,000L and 2,000L bioreactors). Ibex® Design and Ibex® Develop are focused on supporting customers with limited time and funds by providing clear timelines and defined packages.



Ibex® Dedicate
Ibex® Dedicate provides a flexible manufacturing solution, which can be customized to our customers' specific operational and commercial needs. With the support of Ibex® Dedicate, customers with products in late clinical and commercial stages are able to manage risks by responding dynamically to changes in market demand by simplifying their supply chain. Multiple modalities have been able to ramp up in record timeframes using Ibex® Dedicate shells. These are technology agnostic spaces that are ready for fit-out with a relatively low initial investment. Our multi-purpose facilities currently support a broad range of customer needs across large-scale and small-scale mammalian, bioconjugation, microbial and mRNA.

Highlights and Initiatives

In 2022, strong sales growth in Biologics was supported by a robust underlying performance and a peak in COVID-related sales. The business experienced sustained levels of customer demand for commercial capacity. By bringing new facilities online during the year, such as the 6K mid-scale mammalian facility in Portsmouth (US), and building new capacity, including the large-scale mammalian facility in Visp (CH), we will continue to meet sustained customer demand. As an example, in a new agreement with GSK, we will commence activities to manufacture a marketed product in our 20K mammalian facility. This marks the beginning of a wider strategic partnership with GSK.

We also approved a series of significant new expansions across multiple modalities, including a commercial drug product facility in Stein (CH).

Looking to 2023, our top priority is to continue to provide strong manufacturing and development expertise to our customers and deliver on our ambitious growth projects across modalities. We will also work on continuing to leverage our expertise in product introductions and technology transfers to optimize current capacity. Finally, we will maintain targeted investment in internal and external innovation to strengthen our technology offering.

Speed to Clinic
With pressing clinical needs and the biotech sector facing tight funding schedules, getting new molecules into the clinic quickly is critical. In 2022, we launched two new DNA to Investigational New Drug (IND) service offerings aimed at supporting innovative biotech companies. For standard monoclonal antibodies (mAbs), we now offer material for toxicity studies in five months and for IND filing in 11 months. For more complex bsAbs, we can offer unprecedented timelines of seven and 13 months to toxicity and IND, respectively. In addition, we are creating more flexible offers for customers that have specifics needs for their complex molecular formats.

These timelines are achieved through our experienced development teams and our proprietary GS piggyBac® cell line engineering technology together with GSv9® Media and Feeds, as well as high throughput systems such as the Beacon™ Optofluidic Technology.

To strengthen our clinical manufacturing offering, we continued to build new mammalian capacity in Portsmouth (US). The expanded facility, complete with six 2,000L n-1 perfusion-enabled bioreactors, is expected to be due for completion in 2023. In Singapore, we completed the expansion of an additional 1800m^2 of lab space at the end of 2021 and this came online earlier in 2022.

Developing and Scaling Complex Medicines
We support the specific needs of customers with leading expression systems and molecular biology tools. This is achieved by combining established expertise across our four development sites in Slough (UK), Visp (CH), Singapore (SG) and Guangzhou (CN).

We are committed to developing a toolbox of expression systems for all types of business that can license our technology platforms for use in-house. For example, we entered into a licensing agreement with Luzhu Biotechnology Co., Ltd., for the use of our GS Xceed® Gene Expression System with GS piggyBac® transposon technology, for the development of scalable, robust and reliable expression processes.

At the beginning of the year, we announced the launch of our new design and discovery platform bYlok®. This new engineering approach for bsAbs has the potential to streamline future clinical manufacturing. The bYlok® technology was developed to meet the challenge of designing, developing and manufacturing bsAbs molecules at scale without implications of cost and time to market.

We also extended our Early Development Services in Cambridge (UK) to include bioconjugates, launching integrated solutions for molecule design, lead generation and optimization. The extended offering provides unique tools to assess the manufacturability and immunogenicity of proteins and protein engineering tools for the protein part of bioconjugates.

Sustainable End-to-End Supply
We announced an investment of approximately CHF 500 million to build a new large-scale, commercial drug product facility in Stein (CH). This investment fulfills our strategic commitment to complete the value chain in Biologics, so that customers can benefit from an end-to-end service. This is achieved through an integrated model, to increase flexibility, simplicity and speed to market.

The new flexible facility will be constructed on the same campus as our current clinical drug product facility, allowing us to leverage our existing infrastructure, capabilities and talent.

Ibex® Solutions – Our Commitment to the Full Lifecycle
In 2022, our Ibex® Solutions offering remained highly attractive to customers. Modules in our first manufacturing complex are now fully allocated. The range of technologies housed in the first complex – including mRNA, microbial, mammalian and bioconjugation – clearly highlights the broad value of the concept.

Building on the success of our Ibex® Dedicate model, we announced the opening of a new, custom-built, bioconjugation facility within Lonza's Ibex® Dedicate manufacturing complex in Visp (CH).

The facility will play a key role in the scaled manufacturing of Kodiak's lead therapeutic candidate KSI-301 to support a potential global commercial launch. Once fully operational – and if the therapy is approved for commercial use – the facility is expected to have the capacity to supply over 10 million dose equivalents of KSI-301 annually. The strong relationship between Kodiak and Lonza has led to a multi-year commercial collaboration.

mRNA – Expanding Commercial Capacities
We are expanding our capabilities in mRNA to support market growth and customer demand. We are building additional mRNA and lipid nanoparticle (LNP) process and analytical development labs, as well as clinical cGMP manufacturing capabilities at our site in Geleen (NL) to meet the demand of biotech with early clinical pipelines. These investments are designed to support the next generation of mRNA therapies. The start of development activities and tech transfers is expected in Q3 2023 with cGMP readiness scheduled for early 2024. In addition, fill and finish for LNP-encapsulated mRNA is expected to be available from Q1 2024 from our Stein (CH) facility.

In 2022, we also announced a collaboration with Touchlight to expand our end-to-end offering for mRNA manufacturing with an additional, differentiated source of DNA raw material, Touchlight Doggybone DNA (dbDNA™).

Access to this technology expands the options for our customers beyond the traditional method of working with plasmid DNA (pDNA), while continuing to benefit from our integrated mRNA manufacturing offering.

Financial Performance in Full-Year 2022
Comparison vs. Prior Year

3,274m
+21.7%[1]
Sales (CHF)

1,228m
+25.4%
CORE EBITDA (CHF)

37.5%
+1.2ppts
CORE EBITDA Margin

[1] Sales growth is at constant exchange rate (CER)

Innovation Spotlight

Gene editing for improved cell line development

Continuing to develop modern gene editing tools may ultimately lead to significantly improved platforms for protein expression. Access to a gene editing technology is critical for developing next-generation host cell lines. One example is the use of clustered regularly interspaced short palindromic repeats (CRISPR), a flexible gene editing technique that enables a precise "cut and paste" of DNA to engineer optimized production cell lines.

Our R&D Cell Engineering team in Cambridge (UK) has evaluated several CRISPR-Cas-based nuclease platforms and initiated an extensive research program to develop the enhanced next-generation Chinese hamster ovary (CHO) cell line. Microbial R&D in Visp (CH) has produced the CRISPR-Cas proteins for evaluation and then transferred production to an external supplier to secure long-term supply for the production of these enhanced cell lines. Expected to be launched in 2023, our new cell lines will enable customers to deliver cutting-edge therapeutics that address unmet patient needs.

Precise execution of bispecific antibodies at scale, from design to delivery

The number of bispecific antibodies in development is accelerating due to their broad therapeutic applications and benefits. Generating these complex biomolecules can, however, be challenging. Downstream processing requires specialized processes that can be time and resource intensive, as multiple cell lines are often required to produce one product.

For an IgG-type bispecific molecule, mispairing of the heavy chain (HC) and light chain (LC) can yield multiple combinations of incorrectly paired molecules. Up to ten pairing variations from two independent parental antibodies are possible, with only one being the intended molecule. This year, we launched the patented, proprietary platform technology bYlok®, which solves the assembly challenge associated with these sophisticated molecules. The bYlok® technology was recognized as one of the best innovations of 2022 by *The Medicine Maker*.

The bYlok® technology provides an elegantly engineered approach that drives correct HC-LC pairing by introducing simple disulfide bond modifications. bYlok® technology can be used on existing Fc-based bispecifics, and it allows for expression from a single cell line and purification using standard downstream processing steps. This increases manufacturing efficiency, and eases downstream processing and purification. In studies, our R&D team combined bYlok® technology and our proprietary GSquad™ vector system to generate cell lines that express high concentrations of bispecific antibodies. Such a positive outcome from this integrated technological approach demonstrates the strength of our analytical capabilities.

Small Molecules

>225[1]

pre-clinical and clinical small molecules

>135[1]

commercial small molecules

[1] Including active pharmaceutical ingredients (API), highly potent API (HPAPI), dosage form and delivery systems and particle engineering

The Small Molecules division offering covers drug substance, particle engineering and drug product development and manufacturing. With a global network of five sites across Europe, the US and China, our geographical footprint remains aligned with the biopharmaceutical industry's major growth markets. These markets account for more than 60% of overall global pharmaceutical growth[1].

Market Trends

Small molecules represent the largest single drug class, accounting for more than 40%[2] of the global biopharmaceutical market by revenue and more than half of clinical pipelines. Currently, demand is driven by improved global access to medicine, demographic trends, public health initiatives, new drug launches and pricing reviews.

The three therapeutic areas driving revenue growth in Small Molecules are Oncology, Immunology and Antidiabetics. The growth in the Oncology market directly impacts the demand for highly potent active pharmaceutical ingredients (HPAPIs) since they have been associated with inhibiting cancer growth and demonstrated usefulness in cancer treatment, alongside treating diabetes and autoimmune diseases. The growth of the HPAPI market is outpacing the overall API market[3], resulting from a wide range of potential uses and benefits for patients, and by the improvements in their precision and bioavailability. Currently, approximately 30% of the small molecules pipeline consist of HPAPIs[4].

In the manufacture of HPAPIs, there are multiple potential benefits from collaborating with an established CDMO partner, such as Lonza, that has demonstrated expertise in developing highly-potent products and experience in navigating the challenges of containment. Specifically, we see that oncology therapeutics comprise a higher concentration of molecules requiring containment, and we continue to invest in this area of growing demand.

Small and emerging companies own 84%[4] of small molecules clinical pipelines and we see a continuation of the trend for accelerated approvals. We work in partnership with small biotech companies to meet the need for accelerated timelines, while continuing to provide robust and scalable manufacturing solutions.

[1] IQVIA: Market Prognosis Global 2021-2025
[2] Evaluate Pharma (Dec 2022)
[3] Chemanager Online
[4] Citeline and internal Lonza Market Analysis
[5] Internal 2022 MI analysis of 100 FDA approved drugs
[6] Internal 2022 MI analysis of pipeline molecules out of Pharma circle

Our Global Development and Manufacturing Footprint

● Particle Engineering and Drug Product development and manufacturing
▲ Particle Engineering development and manufacturing
★ Drug Product development and manufacturing
◆ Drug Substance development and manufacturing

Small molecules are becoming increasingly complex. As an example, longer synthetic pathways have risen by 75% in the last two decades[5]. This new development demands expertise in the management of complex supply chains, a breadth of assets and in-depth knowledge of product and process. Drug product formulation is also becoming more complex. Low solubility is exhibited by more than 75% of clinical candidates, and techniques such as Spray Dried Dispersion are often required to enhance bioavailability[6].

Our Offering

We offer integrated drug substance to drug product solutions, supporting customers across all aspects of design, development and manufacturing, including particle engineering and drug product packaging. This service offering provides substantial value to our customers across the entire drug development pipeline by simplifying interfaces, reducing costs and accelerating timelines.

With a deep expertise in complex small molecules, our established and differentiated offering serves the complex needs of our customers. We are one of the market leaders in the development of highly potent active pharmaceutical ingredients (HPAPI) and specialized handling, such as containment for bioconjugate payloads.

Our HPAPI offering addresses multiple challenges facing our customers, as we can customize assets to meet the specific needs of their molecules. Taking an integrated approach allows us to progress from clinical to commercial manufacture within a single site.

We currently provide integrated development and manufacturing across monoclonal antibody, payload-linker and conjugation and are continuing to make significant investments in this area. At our Visp (CH) site, we also develop and manufacture payloads for bioconjugates.

We offer particle engineering services across both drug substance and drug product development and manufacturing. It is a key component of our integrated service and is often required to meet drug delivery challenges, such as low levels of bioavailability. Our technologies include particle size reduction, spray drying and melt-spray-congeal technology, all of which address different challenges in drug product formulation.

To support accelerated timelines to clinic and commercialization, we offer phase-appropriate assets alongside our particle engineering technologies. We have also invested to establish dedicated early phase clinical manufacturing centers to complement our fast to clinic offering.

Complete Life Cycle Offering

Design
Small- / Lab-scale

Develop
Clinical scale development, manufacture and packaging

Manufacture
Commercial scale manufacture and packaging

Our Portfolio of Services

Drug Substance Intermediates
GMP intermediates

Drug Substance
Full range of API inclusive of HPAPI, cytotoxic payloads for ADCs

Drug Product Intermediates
Micronized API, spray dried dispersions

Drug Product
Tablets, encapsulated powder & multiparticulates, injectables

Financial Performance in Full-Year 2022
Comparison vs. Prior Year

819m +5.9%[1]
Sales (CHF)

248m +15.3%
CORE EBITDA (CHF)

30.3% +2.3ppts
CORE EBITDA Margin

[1] Sales growth is at constant exchange rate (CER)

SimpliFiH® Solutions is an integrated offering designed to reduce the timeline from initial idea to first-in-human (FiH) clinical verification. It addresses bioavailability challenges often associated with new and complex molecules and can reduce Phase 1 timelines by three months compared to traditional approaches.

Highlights and Initiatives

In 2022, existing commercial products and the clinical pipeline drove sustained customer demand in the Small Molecules division. We have a robust order book of future committed business, which provides mid-term visibility and security. It means our assets are highly utilized, which can create longer lead times to onboard new programs and customers. To address this, we have invested to expand our capability to meet ongoing demand for early phase programs.

Our priority is to strengthen our portfolio in the highest value areas of the market. Market and customer segmentation is focused on companies that are most likely to benefit from our specialized service offerings and capabilities in complex and highly potent products. We continue to strengthen our early phase offerings in these areas through innovation and by deploying new agile manufacturing solutions.

In 2022, we consolidated our particle reduction size capabilities with the divestment of our former site in Quakertown (US). Our micronization and milling capabilities are now centralized in our Monteggio (CH) site. This maximizes potential synergies arising from the Monteggio (CH) site's proximity to our Visp (CH) API manufacturing center.

Growth Investments

In line with our sustained focus on growth investments to meet customer demand, we continued to expand our manufacturing assets and development services in 2022. Our expansions in Nansha (CN), Tampa (US) and Bend (US) were successfully executed and came online in 2022. In Nansha (CN), we have extended the capacity and capabilities of our development and kilogram-scale cGMP manufacturing laboratories for the clinical supply of HPAPI. The laboratories are part of a previous announcement in 2021 to expand the mid-scale manufacturing capacity at the Nansha (CN) site and add additional capabilities in our global HPAPI manufacturing network.

We also announced plans to expand inhalation capabilities at our Tampa (US) site. The investment will include additional inhalation testing capacity, specialized in development, clinical and commercial manufacturing of small molecule-based therapies targeting respiratory diseases and disorders. The expansion will also establish additional capacity for dry powder inhaler (DPI) product development services.

In addition, we completed a dedicated early phase clinical manufacturing facility in Bend (US) to expedite product delivery, a crucial step in the journey towards clinical trials. The new facility provides additional capacity for solutions to address complex bioavailability challenges in clinical projects, as well as additional capabilities for development and clinical manufacture.

To enhance our ability to meet accelerated timelines for increasingly complex molecules, we have increased capacity for the manufacturing of antibody-drug conjugates (ADC) payloads at our Visp (CH) site. This expansion underlines the strategic position of ADCs in our portfolio and reflects our continued focus and momentum in this area. We develop and produce all components of these increasingly important therapies, including cytotoxic payloads, antibodies and the required linkers. The additional capacity for ADC payloads supports the entire development and manufacturing pipeline, from feasibility studies to commercial supply.

Integrated Service Offering

We support customer development pipelines with a comprehensive set of capabilities, from drug substance through to drug product development and manufacturing. As an example, we are collaborating with Vivesto to supply clinical material for its investigational drug candidate, Cantrixil.

We have also announced the extension of our collaboration with Forbion, a venture capital firm and BioGeneration Ventures (BGV), its joint venture partner. This partnership will now include the development and manufacturing of small molecules. The extended collaboration will provide services relating to small molecules for both Forbion and BGV portfolio companies that are active in the biopharmaceutical space.

Looking to the future, strong ongoing clinical pipelines continue to drive demand for our Small Molecules offering. We recognize signs of a potential slowdown, with biopharma investment across the industry reduced to 2019 levels following a temporary peak during the pandemic[1]. In addition, the number of clinical trials underway for non-COVID therapies is yet to return to pre-pandemic levels and a 25% reduction in USFDA approvals was observed in 2022[2]. Whilst we are actively monitoring the impact of these global trends on our business, we nonetheless continue to expect strong demand for our services, supported by a robust order book of future committed business from our existing customer base.

[1] Jeffries, equity research, Dec 11, 2022
[2] Novel Drug Approvals for 2022 | FDA

Personal Perspective

Gordon Bates
President, Small Molecules Division

2022 was a year characterized by organic growth and new collaborations. Our expansions in Nansha (CN) and Bend (US) are both now complete and operational for early-phase clinical manufacturing programs. We maintained a strong pipeline of committed business throughout 2022 and entered a new clinical portfolio deal with a large pharmaceutical company.

Across the network, our manufacturing assets are well utilized. Whilst this is reflective of sustained demand, we continue to balance utilization levels with the necessary lead times to successfully onboard new customer programs. While adding new capacity, we will also focus on driving operational excellence across our global network. We look forward to new facilities coming online in Visp (CH) to further build our manufacturing capacity in the years ahead.

In 2023, we will focus on successfully executing our order pipeline and realizing our committed investment projects. As we expect sustained demand for our services, we aim to further expand our capacity and drive operational excellence to unlock future growth potential across our portfolio.

Innovation Spotlight

Spray Drying Process Innovations for Bioavailability Enhancement

Dry powder inhalers for inhalation drugs provide a non-invasive and easy-to-use delivery method for patients with respiratory diseases. Inhalation delivery includes both pulmonary (lung) and intranasal delivery, using a wide range of APIs including small molecules, prodrugs, peptides, oligonucleotides, proteins and antibodies.

For both pulmonary and intranasal delivery, particle engineering is critical to achieving a drug's target product profile in the body. Our particle engineering expertise includes spray drying (for intranasal and pulmonary delivery) and micronization (for pulmonary small molecules delivery). Recent innovations by the R&D and product development teams at the Bend (US) site focus on improving spray drying particle engineering and formulation for our customers.

A simultaneous spray drying process was introduced in 2022. Here, innovative combined formulations of small molecules and biotherapeutics for pulmonary delivery can be manufactured in a single process step. Building on a successful program in 2021, new processes and analytical equipment are being onboarded to enable clinical manufacturing of inhaled biotherapeutic APIs in early 2023. Finally, bespoke atomization and collection technology were also implemented into our inhalation spray drying processes to improve throughput, reduce nitrogen consumption and improve product yields. Together, these innovations will enable new therapies with faster timelines to improve the lives of patients with respiratory diseases.

Cell & Gene

>20
Years of C&G cGMP manufacturing experience

>200
Process Development Projects

>200
pre-clinical therapies supported by Bioscience

>150
clinical and commercial therapies supported by Bioscience

Our offering includes development and manufacturing services, products, solutions, testing and automation platforms. We also offer tools and technologies to enable cell and gene innovators to develop, de-risk and industrialize their therapies. We support customers from research to commercial production through our global network spanning three continents.

Market Trends

With almost 2,800[1] products in development across the industry, the cell and gene therapy sector has seen tremendous growth and interest over the last few years. Novel treatment candidates demonstrate the potential to change the way patients with cancer and genetic diseases are treated.

In 2022, the market saw clinical pipeline growth. Autologous products make up around 40% of the cell and gene therapy pipeline, followed by allogeneic products (around 30%) and in vivo viral vector products (around 30%)[1].

While the autologous cell therapy area grew significantly in the last five years, it is showing signs of slowing down, partly due to the impact of the COVID-19 pandemic on patient treatment. Nonetheless, while allogeneic cell therapy surpassed other modalities in 2022, autologous cell therapy is expected to remain the primary market category in the near future.

Immune cell-based therapies dominate the market, with T-cells and natural killer (NK) cell products driving interest due to their potential to address potential bottlenecks of autologous cell therapies, including cost-of-goods, scale-up efforts, and the ability to ramp up or down based on demand. Viral vector continues to benefit from healthy market growth both as a therapy and raw material.

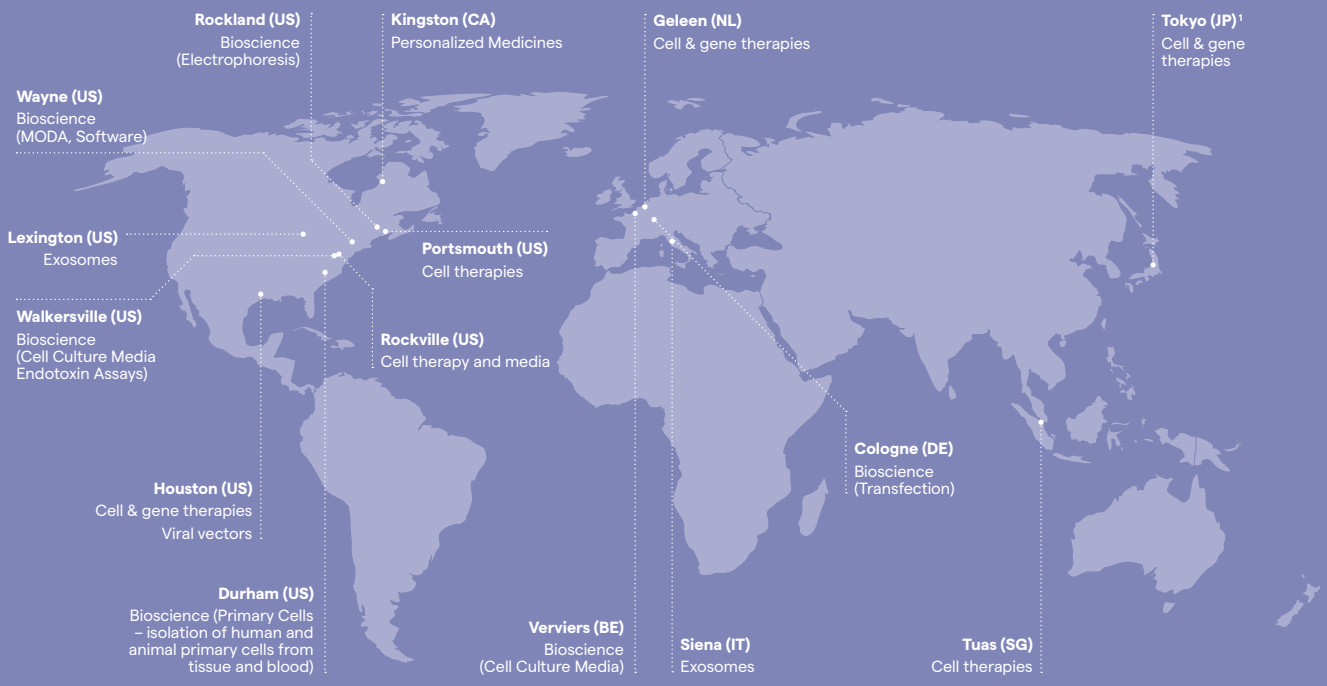
There is a developing market tension as funding across the biotech industry is decreasing while competition in rare disease areas is increasing. In this context, speed to clinic and market is set to become even more critical, alongside access to complex manufacturing technology, safety and efficacy.

Regulators are paying increasing attention to the cell and gene therapy space. Despite accelerated pathways, cell and gene therapies remain subject to the same approval processes as traditional biologics. Ensuring safety and efficacy is not the only focus. Therapy developers also need to demonstrate the mechanism of action, process robustness, scalability and potency of their drug candidates. In response to these imperatives, process and analytical development are expected to play an increasingly important role towards commercialization.

The cost of production remains a significant hurdle on the path to commercialization. This means that investing in platforms that increase productivity and offer flexible manufacturing ramp-up or ramp-down in response to demand is becoming more important to success. As a result, companies need to consider commercialization challenges from the early phases of drug development.

[1] Citeline Pharmaprojects Pipeline Search July 1, 2022, internal analysis

Our Global Development and Manufacturing Footprint



[1] Facility owned and operated by Nikon Cell innovation Co. Ltd. under Nikon-Lonza partnership

New emerging modalities and tools continue to grow within the cell and gene therapy sector, including exosomes, induced pluripotent stem cell (iPSC)-based immunotherapies, allogeneic versions of autologous CAR T-cells, NK cells, and *in vivo* gene editing. Continuing innovation in therapy development and manufacturing will be essential for long-term success and commercial viability. In this context, CDMOs are likely to take a more prominent role in the path to commercialization, supported by robust quality systems, expertise and an accelerated approach to scalable manufacturing.

Our Offering

Our broad offering includes development and manufacturing services, products, solutions, testing and automation platforms. We also offer tools and technologies to enable our customers to develop, de-risk and industrialize therapies, from basic research to commercialization.

Our Cell & Gene division includes three business areas: Cell & Gene Technologies, Personalized Medicine, and Bioscience.

Cell & Gene Technologies (CGT) is focused on providing an integrated range of CDMO services that span the full value chain of cell and gene therapy modalities (allogeneic and autologous therapies and viral vector).

Our integrated service proposition relies on two core pillars of CDMO services:

- **Process development:** leveraging our large team of expert scientists in process development to provide a step-by-step approach to the phase-appropriate development of robust, reproducible and commercially viable processes. This is based on current GMP (cGMP) design considerations and de-risking the path to commercialization. With an increase in demand for best-in-class process development services, we announced in 2022 the significant expansion of our process development laboratories at our Houston (US) and Geleen (NL) facilities.

- **Clinical and commercial manufacturing:** Best-in-class services are enabled by large teams of highly-skilled manufacturing personnel operating in dedicated suites within commercially approved cell and gene facilities.

Additional CDMO services include:

- Regulatory consulting: support to achieve successful fast-track approval for accelerated regulatory pathways and special designations.
- Bioassay services: full analytical methods lifecycle including development, optimization, qualification and validation of tailored assays. This is supported by a library of pre-developed, fast-qualified assays towards IND filing, first-in-human or later-phase trials.
- Tissue Acquisition: customized research and GMP Tissue Acquisition services for allogeneic and autologous cell therapy.

We provide these service offerings across a wide range of modalities to bring our customers the expertise they need for their therapies. These include:

- Autologous cell therapy: end-to-end development and manufacturing services to achieve commercial viability.
- Allogeneic cell therapy: flexible and scalable development and manufacturing services to bring allogenic cell therapy from concept to patient.
- Viral Vectors: advanced viral vector technologies and easy access to proprietary novel vectors to support gene therapy applications.
- Exosomes: 2D/3D cell culture and the latest exosome characterization technology.
- iPSCs: proprietary cGMP iPSC custom generation, expansion and differentiation services for tailor-made, fully cGMP iPSCs production.

The **Personalized Medicine** business develops breakthrough technologies to accelerate the industrialization of cell and gene therapy manufacturing. A primary focus is our Cocoon® Platform, a functionally closed, highly flexible and scalable cell manufacturing solution. The Cocoon® integrates multiple unit operations including isolation, cell selection, activation, transduction/transfection, expansion, and harvest into a single system. This degree of process automation has the potential to drive down costs and provide greater access to patients. The Cocoon® Platform is commercially available and being deployed across a number of clinical programs in centralized and point of care manufacturing settings.

Our **Bioscience** business provides a range of solutions for customers working at different stages of the therapeutic journey across multiple modalities, from cell & gene therapies to recombinant proteins, vaccines, and injectable drugs. Our expertise in primary human cell biology tools enable customers to develop more predictive models and accelerate the path to IND. We are also a trusted, committed partner for critical raw materials and technologies that enable better processes and quality decisions for bioprocessing customers.

Our offering includes:

- **Discovery tools**
  - Primary human cells and assays for *in vitro* models
  - Specialized research use only (RUO) media for primary cell culture
  - Non-viral transfection systems for gene modification & related drug discovery screening

Personal Perspective

Daniel Palmacci
President, Cell & Gene Division

Since joining Lonza in November 2022, I have been impressed with the focus on meeting customers' needs and driving technological innovation across the Cell & Gene division.

In our Cell & Gene Technologies business unit, our people are unlocking opportunities to capture the high commercial and therapeutic potential of this rapidly growing market. Following commercial approvals for two therapies produced at our Houston (US) site in 2022, we now manufacture three commercially available cell and gene products. We have also invested to expand our process development capabilities at our laboratories in Houston (US) and Geleen (NL) to meet evolving customer needs.

While we continue to see healthy growth in the clinical pipeline, there has been some reduction in the availability of biotech funding. In this context, operational excellence has become increasingly important, to ensure that value is optimized through efficiency. To support our customers in this area, we continue to focus on driving continuous improvement to enhance delivery and quality across our network.

As I commence my first full year with Lonza in 2023, I am greatly looking forward to leading the Cell & Gene division into its next chapter of growth. Our key priority for the coming year is to build our pipeline to support the development and commercialization of innovative therapies. We will continue to offer customers an integrated and accelerated approach to project scale-up, supported by robust quality systems and strong levels of technical expertise.

Overview of our Cell & Gene business units		
Cell & Gene Technologies Contract Development and Contract Manufacturing of cell and gene therapies	**Bioscience** Life science research to develop and test therapeutics	**Personalized Medicine** Breakthrough technology to accelerate the industrialization of cell and gene therapy manufacturing

• Scientific expertise to develop the GMP process, including characterization (Assays)
• Commercial viability: scaling-up, automating, optimizing and industrializing
• Global network of manufacturing sites, dedicated and established suites and expert personnel
• Quality systems & regulatory compliance
	• Discovery tools to help advance life-science research with biologically relevant results
	• Bioprocessing media for large-scale manufacturing of biologics and therapies
	• Endotoxin and Pyrogen testing of raw materials, in-process samples and manufactured product
	• Informatics paperless solutions combining manufacturing and laboratory data into a single source to expedite product release
		• Primary focus is the Cocoon® Platform for cell therapy manufacturing
		  • Highly flexible and scalable solution offers the potential to drive down costs and provider greater access to patients
		  • Multiple unit operations integrated into a single system
		  • Supports centralized or decentralized manufacturing model

Financial Performance in Full-Year 2022
Comparison vs. Prior Year

693m
+13.6%[1]
Sales (CHF)

116m
+9.4%
CORE EBITDA (CHF)

16.7%
-0.9ppts
CORE EBITDA Margin

[1] Sales growth is at constant exchange rate (CER)

- **Bioprocessing Solutions**
  - For Further Manufacturing (FFM) cell culture media for the manufacturing of protein, vaccines and cell & gene therapies
  - Large volume transfection systems for cell & gene therapy clinical production
  - Endotoxin/pyrogen testing solutions, including reagents and automation
  - Informatics solutions for GMP manufacturing and quality control

Highlights and Initiatives

In 2022, the Cell & Gene division benefitted from strong overall performance in the Bioscience business unit.

In our Cell & Gene Technologies business, two additional cell and gene therapies manufactured at our Houston (US) site achieved FDA approval. However, delays in clinical trials and customer product challenges impacted sales growth.

Our Personalized Medicines business unit remained focused on key R&D initiatives and scaling manufacturing, with multiple clinical-stage therapies now being manufactured on the Cocoon® Platform.

The Bioscience business continues to experience strong customer demand across its portfolio, especially in testing and media. A strategic reconfiguration in Bioscience in 2022 will support the business to deliver innovative products at scale in the long-term, with an emphasis on capturing market share in growth modalities, specifically cell and gene therapies and next-generation biologics.

Clinical and Commercial Programs
Our site in Houston (US) is dedicated to cell and gene therapy development and manufacturing. In Q3 2022, two cell and gene therapies manufactured at the site were approved by the FDA for commercial use, demonstrating our continued focus on improving quality and operations in collaboration with regulatory authorities. ZYNTEGLO®, for the treatment of transfusion-dependent beta-thalassemia, and SKYSONA®, for the treatment of early, active cerebral adrenoleukodystrophy, are both produced by bluebird bio of Somerville, Massachusetts and were approved in August and September 2022, respectively.

Also in 2022, the CGT business enhanced the New Product Introduction (NPI) process to standardize the customer journey from early-stage development to commercialization. It provides a roadmap and a systematic approach to development and manufacturing, ensuring necessary quality standards are met for tech transfers, cGMP manufacturing and pre-approval inspection readiness. This NPI process has been designed to support more CGT customers in reaching commercialization.

Personalized Medicine
Through our Cocoon® Platform, we are addressing challenges traditionally associated with autologous cell therapy. The platform enables our partners to provide personalized immunotherapies to critically ill patients at a higher speed and quality, while managing the costs associated with such personalized treatments.

During 2022, we expanded the functionality of the Cocoon® Platform by releasing a second-generation instrument that includes integrated capabilities in cell binding, cell separation, and bead removal. The Magnetic Selection capability, which can be utilized at any point in the manufacturing process, provides a high level of customization and consistency and expands the end-to-end solution for cell therapy manufacturing. This innovative new functionality will further strengthen the Cocoon® Platform's leading role in the commercialization of cell therapies. Ultimately, it will help to advance discoveries into the clinic where they can benefit patients.

Moving forward, we will maintain our focus on building additional capability and functionality into the platform to address unmet market needs, while continuing to ensure system robustness and exceptional customer service. Our goal is to build an autologous cell therapy manufacturing capability focused on cancer and monogenic rare diseases, while building further on the high market potential of Cocoon®.

Bioscience
Across the year, we leveraged our expertise to develop new products that support the cell and gene market. One example is the launch of the PyroCell® Monocyte Activation Test - Human Serum System (PyroCell® MAT HS System), which uses human serum instead of fetal bovine serum for in vitro pyrogen testing. This new system exhibits enhanced sensitivity for the detection of non-endotoxin pyrogens as well as reduced interferences from complex drug products such as biologics-based pharmaceuticals.

In early 2022, we began offering large batch sizes of human cord blood CD34+ hematopoietic stem cells for creating humanized mouse models. These are critical for the preclinical safety testing of immunotherapies. We are currently one of the leaders in the market with this offering. The additional offering will facilitate the more rapid and cost-effective creation of large and HLA-matched humanized mouse cohorts to streamline biologics testing and research.

In August 2022, we launched the Nebula® Multimode Reader, the first multimode reader qualified for use with Lonza's turbidimetric, chromogenic and recombinant endotoxin detection methods. The new compact reader, designed to minimize laboratory footprint, is compatible with all of Lonza's quantitative endotoxin tests and allows for an easier selection of the best-suited assay for specific samples. This addition to our portfolio complements our competitive advantage in QC automation.

Innovation Spotlight

Developing novel analytical techniques for AAV-based therapies

The gene therapy field has achieved transformative progress over the past half-century, continually evolving to bring life-changing therapies to patients. Viral vectors lie at the heart of the field as a primary delivery vehicle of novel gene-based therapies. Recently, this area of the market has witnessed unprecedented growth, supported by a number of landmark regulatory approvals. This culminated in the recent regulatory approval of an adeno-associated viral vector (AAV)-based therapy for haemophilia B. As a part of our holistic standardized process for developing and manufacturing AAV-based products, we have developed novel analytical techniques to ensure stability and quality of these vector-based therapies. These will help our customers to have more control of their product and better navigate the regulatory path to commercialization.

Our teams in Houston (US) and Basel (CH) have developed several analytical techniques targeting the in-depth analysis of AAV capsid proteins, viral genome, and AAV infectivity. These projects aim to develop accurate and robust analytical methods to ensure the quality and safety of AAV-based therapies for clinical applications.

Capsules & Health Ingredients

~260
billion. 2022 Capsules Capacity

>30
Product Offerings

~40
Ingredient Patent Families

80
Capsules and Dosage Delivery Form Patent Families

Our broad range of high-quality capsules and health ingredients are manufactured across our global network, in ten locations spanning three continents. From multiple global innovation centers, with experienced, talented teams and state-of-the-art equipment, we also offer customers a variety of collaboration and innovation opportunities to support their end-to-end product development plans. To deliver a comprehensive service, we provide our customers with both local and international technical, quality and regulatory support.

Market Trends

The Capsules & Health Ingredients division primarily serves the pharmaceutical and nutraceutical markets.

In the **pharmaceutical market**, we saw growth in the supply of capsules for prescription drugs in 2022. While this area experienced reduced government spending[1], this challenge was partially offset by the higher use of over-the-counter (OTC) medications in H1, as part of the ongoing consumer response to the COVID-19 pandemic.

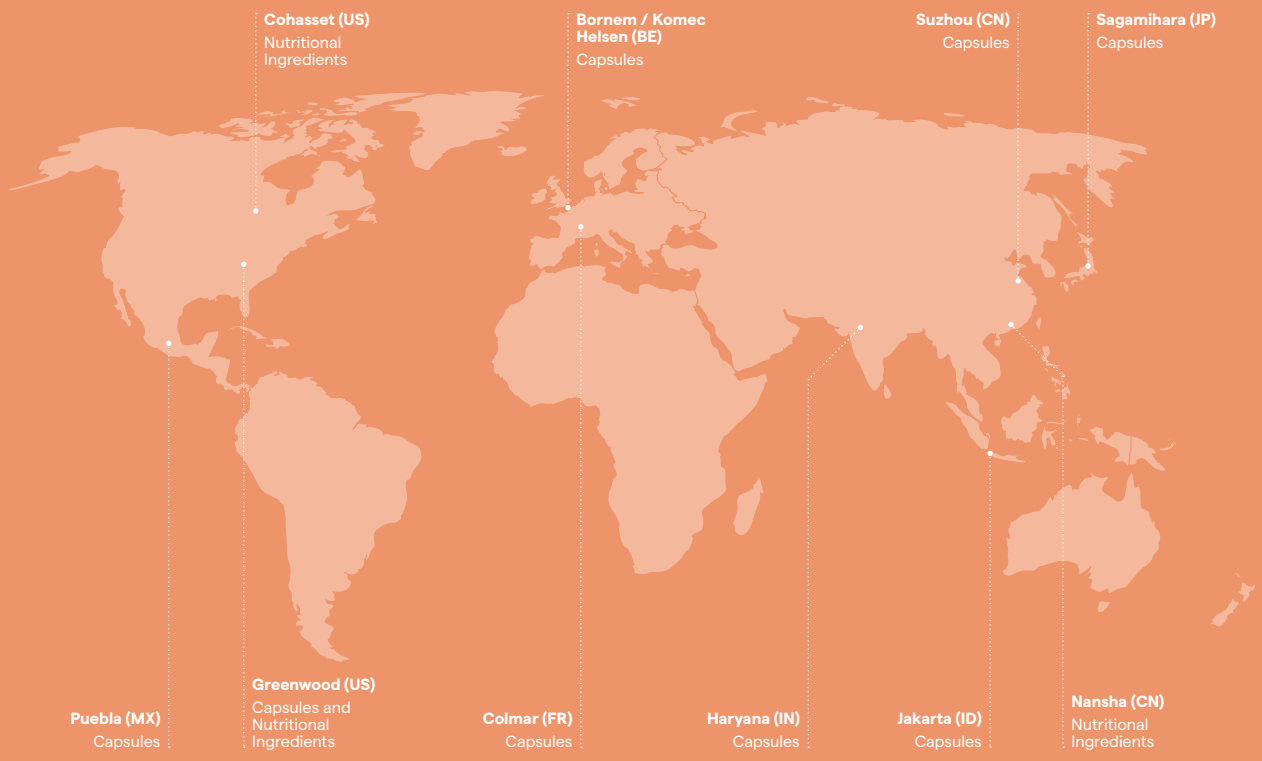
In supporting pharmaceutical development, the small molecule pipeline remained healthy with a stronger focus on solutions to support the delivery of new, more complex formulations and sensitive medications. We also saw increasing interest in our specialty capsules which are particularly valuable to therapies such as live bio-therapeutic products that often require gastric protection and targeted delivery profiles.

In the **nutraceutical** market, we saw strong demand for both capsules and health ingredients, across all three regions in H1. This was partially driven by the ongoing proactive consumer response to the COVID-19 pandemic. However, in H2, we experienced softer demand in vitamins, minerals and supplements as the impact of the pandemic reduced and recessionary concern, particularly in the Americas, negatively affected consumer spending on over-the-counter proactive health products. A consumer preference for 'free-from' products, alongside emerging regulatory requirements, meant that demand for clean-label capsules remained strong.

More widely, we saw continued interest in our innovation collaborations and complete solutions for both markets. These support more complex formulations and the end-to-end concept-to-commercialization delivery of nutraceutical products.

[1] IQVIA institute

Our Global Development and Manufacturing Footprint



Our Offering

Capsules

We offer a wide range of animal-based, vegetarian and clean label Capsugel® capsule options with different release profiles and encapsulation technologies to meet a variety of application and patient needs. For our pharmaceutical customers, we provide pre-clinical and clinical solutions and specialized delivery applications. For our nutraceutical customers, we offer multipurpose, clean-label, performance-enhancing options.

Our global capsule manufacturing network is one of the largest in the world and is supported by local and global logistics, R&D, technical and customer service specialists. Customers work with us to customize their end medication or supplement to meet unique product specifications and consumer preferences while complying with regulatory requirements. Through this collaboration, we enable our customers to bring their therapies and health supplements to market safely, effectively and efficiently.

We also provide a scalable portfolio of capsule-filling equipment and supporting technical services to meet our customers' fill and finish needs.

Dosage Form Solutions

We support customers throughout the product development cycle with a truly collaborative, innovation-driven end-to-end service. In the pharmaceutical market, this can include supporting fast-track approvals and the growing specialty and orphan drug pipeline, which require a unique approach to active ingredient delivery. For the nutraceutical market, we offer "ready to go" formulations and unique liquid fill delivery technologies to rapidly bring novel supplements to market.

Health Ingredients

Specifically for the nutraceutical market, we provide multiple high-value, research-backed ingredients across a number of growing market platforms. Our offerings target global consumer concerns, including joint health, muscular strength, energy, endurance, weight management and recovery. Our deep technical expertise, extensive global market knowledge and trend-tracking capabilities enable us to support healthy living through improved human and pet nutrition. Our portfolio includes premier brands such as UC-II® for joint health, Carnipure® for energy and a range of other branded products targeting immune health, digestive and emotional health, heart health and blood sugar health.

Highlights and Initiatives

In 2022, the Capsules & Health Ingredients division's sales growth was mainly driven by price increases and pharma demand. We continued to serve evolving customer needs through innovation across a broad range of services and modalities. By developing new capsules and dosage delivery capabilities – mainly driven by specialty capsules – we have maintained a highly differentiated offering in our product portfolio and technologies.

More widely, our new Launch with Lonza™ services have been designed to further enhance collaboration with customers interested in our innovative and complete solutions for the pharmaceutical and nutraceutical markets. Our range of services also support more complex formulations and end-to-end delivery, in particular in nutraceuticals.

Capsules

Operations and Supply Chain

We delivered against our ambitious expansion plans at many manufacturing sites globally and our overall capacity has increased to around 260 billion capsules per year. The introduction of several operational and quality improvements has delivered positive results and focused actions have been implemented to improve customer experience and global supply reliability.

Leveraging our extensive in-house design, technical and engineering teams, we continued to develop our next-generation proprietary capsule manufacturing line, which will significantly improve output and reduce product variability.

Financial Performance in Full-Year 2022

Comparison vs. Prior Year

1,266m

+5.9%[1]

Sales (CHF)

418m

+1.0%

CORE EBITDA (CHF)

33.0%

-1.4ppts

CORE EBITDA Margin

[1] Sales growth is at constant exchange rate (CER)

Titanium Dioxide Free Capsules
In response to the European Union Commission's decision to ban the use of titanium dioxide (TiO_2) in food supplement products from mid-2022, we launched TiO_2-free white opaque hard gelatin capsules. These offer our nutraceutical customers the same whiteness and masking functionality as gelatin capsules containing TiO_2 whilst meeting the new TiO_2-free requirements.

In addition, our pharmaceutical customers are also proactively evaluating this capsule in response to potential future TiO_2 regulatory changes within their industry. We are delighted this new capsule was recognized with a Regulatory and Compliance Award at the Convention on Pharmaceutical Ingredients (CPhI) in November 2022.

Next Generation Enteric Capsule - Capsugel® Enprotect™
Our new Enprotect™ enteric capsule, launched in H2, has been designed to withstand degradation during stomach transit, releasing its contents in the intestine. In 2023, we will leverage this manufacturing technology for other applications, including an Enprotect™ capsule for anaerobic live biotherapeutic products.

More information about the Enprotect™ capsules can be found in the Innovation Spotlight section on page 64.

Personal Perspective

Christian Seufert
President, Capsules & Health Ingredients Division

Whilst our pharmaceutical market has remained robust, changing consumer preferences negatively impacted the nutraceutical market in 2022. We are addressing this more competitive environment through innovation, expanded end-to-end services and improved manufacturing agility.

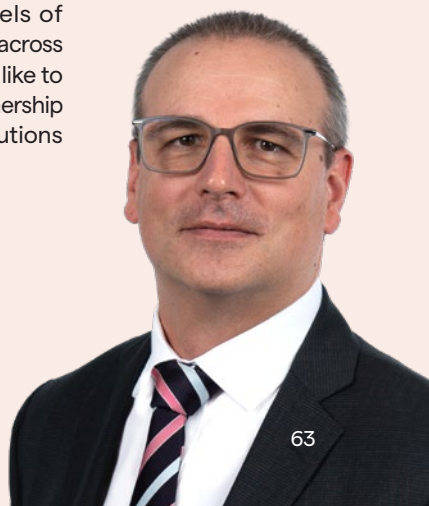
As part of our innovation agenda, we launched our new gelatin titanium dioxide (TiO_2)-free capsule and our enteric Enprotect™ capsule. Both capsules provide new platforms for more innovation going forward and I was particularly pleased to see our TiO_2-free capsule recognized at CPhI with a Regulatory and Compliance Excellence Award.

Complementing our approach to product innovation, we have expanded our end-to-end services with our Launch with Lonza™ program. Working closely with our customers, we have created value by optimizing product delivery and launch effectiveness.

Our customer offering has been further supported by capacity expansion across our network to improve delivery lead times, while maintaining quality and safety. We also continue to adopt lean operating principles across our existing assets to improve manufacturing efficiency and agility.

Looking forward, we will maintain our strong customer focus by improving our services in line with their needs. By focusing on product and process innovation, digital capabilities, manufacturing automation and our sustainability credentials, we will consolidate our position as a preferred strategic partner to the capsules and health ingredients markets.

Since joining in July 2022, I have been impressed by the strong customer relationships and the high levels of expertise and engagement shared across our colleague community. I would like to thank our customers for their partnership and our people for their contributions this year.



Dosage Form Solutions
A commercial scale melt spray congealing technology platform was installed in Greenwood (US), enabling the manufacture of high-quality, cost-effective lipid multi-particulates at a commercial scale. This proprietary solution helps to maximize ingredient functionality and expands application versatility for nutraceutical customers.

Health Ingredients
A new randomized, double-blind, placebo-controlled study found our UC-II® undenatured type II collagen supplement plays a role in delivering joint health benefits. The study was featured in two research publications:

- Schön et al. (2022). UC-II® undenatured type II collagen for knee joint flexibility: a multicenter, randomized, double-blind, placebo-controlled clinical study. *Journal of Integrative and Complementary Medicine*.
- Knaub et al. (2022). UC-II® undenatured type II collagen reduces knee joint discomfort and improves mobility in healthy subjects: a randomized, double-blind, placebo-controlled clinical study. *Journal of Clinical Trials*.

Innovation Spotlight

Next-generation enteric capsule for delivering acid-sensitive products into the intestine

Building on our extensive experience in generating novel and innovative solutions for oral solid dosage forms, we have developed a unique technique to build a bi-layer capsule that supports targeted intestinal delivery. The new Enprotect™ enteric capsule, launched at the end of 2022, has been designed to release its contents in the intestine. This is achieved by preventing degradation during stomach transit, which is normally caused by the presence of acids and enzymes.

The innovative capsule solution meets a pressing market need by offering a simple targeted delivery method without a need for additional coatings. This scalable and customizable solution can aid in delivering novel therapies to the distal small intestine, such as small peptides, RNA-based therapeutics, or live biotherapeutic products. The ready-to-use capsule will save pharmaceutical and nutraceutical customers time in the development and manufacturing stages, enabling them to bring new therapies to market faster.

Looking to 2023, we will leverage the first-of-its-kind Enprotect™ manufacturing technology for other applications. These will include a next-generation Enprotect™ capsule specifically for anaerobic live biotherapeutic products and other novel targeted-release capsule formulations.

Partnerships and Joint Ventures

Lonza and Sanofi entered into a strategic partnership in 2017 to build and operate a mammalian cell culture facility for monoclonal antibody production in Visp (CH). The large-scale facility, which utilizes 20,000L bioreactors, became operational in 2021.

Bacthera is a strategic joint venture (JV) which was established by Lonza and Chr. Hansen in 2019. The company is now a leading specialized CDMO dedicated to the Live Biotherapeutic Product (LBP) industry. Since 2020, it has offered drug substance and drug product development services for customers developing LBPs.

The company's sites in Hørsholm (DK) and Basel (CH) both received manufacturing and GMP licenses from their respective national health authorities in May 2021, to supply customers with LBP medicines for human clinical trials and ultimately develop commercial products.

In November 2021, Bacthera announced a collaboration with Seres Therapeutics, a leading microbiome therapeutics company, to manufacture SER-109, which is Seres' lead product candidate for recurrent Clostridioides difficile infection (rCDI). SER-109 has potential to become the first LBP to go into commercial production.

Moving forward, Bacthera will continue to expand its offering, including larger cGMP batch sizes for Phase 3 and commercial production. The company's ambition is to cover the entire drug substance and drug product supply chain for LBPs in an integrated offering.

As part of the Seres Therapeutics collaboration, a new Microbiome Center of Excellence will be located at our Ibex® Solutions campus in Visp (CH). With this new facility, Bacthera will offer fully integrated end-to-end live biotherapeutic development, clinical trial material manufacturing and commercial manufacturing services.

Legal Disclaimer

Forward-Looking Statements

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