Our Businesses

Group Operations

Overview

As a preferred global partner to the pharmaceutical, biotech and nutrition markets, we harness scientific innovation and manufacturing technology to enable our customers to serve their patients and consumers.

Our business is structured across four divisions: Biologics, Small Molecules, Cell & Gene and Capsules & Health Ingredients. Our services and products span from supporting early-phase discovery to custom development and manufacturing of active pharmaceutical ingredients, as well as innovative dosage forms for the pharma, consumer health and nutrition industries. Our scale and resources mean that we can provide a single integrated solution to meet our customers' complex needs.

Driving Operational Excellence

We take a systematic approach to improving efficiency and reducing waste as part of our Lean program. In 2022, we introduced our Lean principles with fundamental operational and behavioral components across our manufacturing organization. By 2023, our scope broadened to include all corporate functions.

Over the course of 2023, we extended our program to deliver more tangible outcomes while maintaining our existing focus on cultural and behavioral elements. We streamlined our processes, optimized resources and enhanced overall productivity while maintaining customer value. This involved a comprehensive approach that went beyond basic Lean principles, including the following key components:

- **Continuous Improvement**
  We have organized a series of events, which have focused on embedding a mindset of continuous improvement and value creation. These involve cross-functional teams collaborating to tackle issues, minimize inefficiencies and enhance processes. We are also conducting rigorous and robust analyses of our value streams, identifying all processes and activities that contribute to product or service delivery.

- **Employee Engagement**
  We have introduced new ways of working that encourage employees at all levels to suggest and implement efficiency improvements. We have more than 400 programs recorded in our Innovation Tracker to generate additional value and conserve valuable business resources.

- **Digitization and Automation**
  We are actively adopting technology and automation to streamline operations, decrease manual involvement and improve data-driven decision making. This includes implementing Virtual Reality training, robotics, real-time data analytics and advanced modeling tools.

- **Supplier Collaboration**
  We are engaging in close collaboration with our suppliers to optimize the value of our supply chain and enhance the quality of inputs.

- **Sustainability Focus**
  Our sustainability objectives are integrated into our Lean journey, with the aim of simultaneously managing our environmental footprint while improving our operational outputs.

- **Continuous Training and Education**
  We remain fully committed to delivering strong employee training and education to ensure our people remain equipped to deploy the latest Lean methodologies and best practices. Over the last two years, we have successfully achieved a Lean fundamentals training level of more than 50% across the organization, spanning from basic to advanced Lean skillsets.

Executing our Strategic Growth Projects

From conception to launch, we have a robust management process in place to ensure the successful delivery of our growth projects. The strategic selection of programs is based on meeting the current and future needs of our customers and our own selection criteria. Considerations include strategic relevance, commercial rationale, feasibility, and return on investment. This approach allows us to remain confident in our capability to create long-term value for our business.

From design to execution, our standardized approach allows us to bring efficiency at each stage of the process. The technical solutions and business case are refined at each stage with clear metrics agreed, prior to approval for investment. Progress monitoring throughout each stage allows for early issue detection and mitigation as well as ensuring execution remains on track and on budget.

At the start of each project, we select a dedicated end-to-end lead supported by a multifunction team. We track individual projects closely through steering committees and monitor the portfolio of all projects. This close monitoring is overseen at structured intervals by both the Executive Committee and Board of Directors, and learnings are incorporated into the program on a continuing basis.

Growth Projects in Action: The Visp (CH) Ibex® Biopark
As part of our ongoing commitment to constant innovation, we launched a new biological development and manufacturing concept in Visp, in 2017. The Ibex® Biopark is a flexible, modular, development and manufacturing complex capable of supporting activities across multiple technologies and business models (including customer dedicated or multi-purpose).

The concept of these manufacturing complexes involves pre-investment in the shell building, which then enables a fast fit-out and the ability to leverage pre-existing infrastructure.

In the case of dedicated assets, customers have complete freedom in the facility design and implementation. Contracts are designed to take the project specific objective and risk into account, through re-purposing or ramp-down fees. For multi-purpose assets, this model gives us the opportunity to de-risk our investment by securing anchor customers.

The first two facilities became ready for fit-out in 2019 and we have seen significant progress since then, with two further buildings completed in 2023. A total of five facilities currently host a range of modalities including:

- a large-scale mammalian cell culture facility through a joint venture with Sanofi,
- a mid-scale facility for microbial development,
- end-to-end capabilities for antibody-drug conjugate manufacturing,
- facilities for commercial mRNA manufacturing, where we delivered the drug substance for a COVID-19 vaccine. Given the Moderna termination, it is currently being re-purposed to another modality. The cost for re-purposing is covered by termination and de-commissioning fees,
- a drug product filling service,
- a dedicated microbiome facility for Bacthera, our joint venture with Chr. Hansen (now Novonesis).

With a substantial proportion of capacity allocated to customers before it comes online, our model allows us to meet customer needs and manage risk, while ensuring we are set up to deliver long-term success.

Personal Perspective

Maria Soler Nunez
Head, Group Operations

"Across our site network, we deliver value for our customers through our combined focus on quality, safety and operational excellence."

Biologics

>660[1]

pre-clinical and clinical large molecules

>55[1]

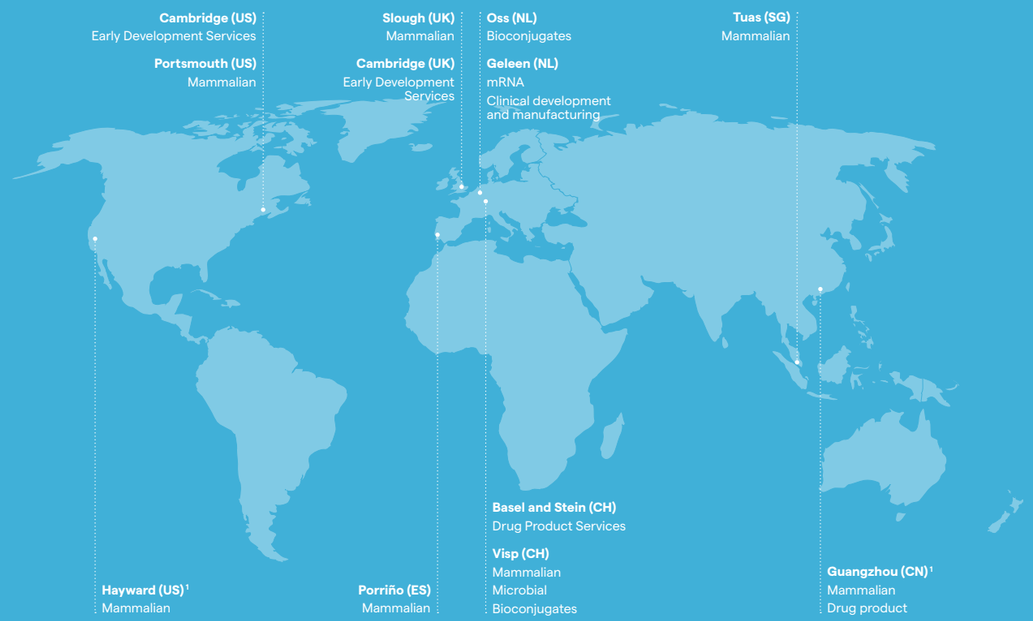
commercial large molecules

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

The Biologics division comprises a full-service CDMO, providing development and manufacturing services to pharma and biotech companies across a wide range of biologic modalities, including mammalian, microbial, bioconjugates, mRNA, and drug product services. In addition, it offers licensing services to technologies used in the development of drugs.

We offer innovative development and manufacturing services and technologies, from drug discovery to market supply, and from drug substance to drug product, across various molecule types. Our end-to-end offering ensures customers benefit from high levels of expertise, along with the speed and ease of doing business with a single strategic partner. Through our global network we are close to our customers and support supply chain resilience.

Our Global Development and Manufacturing Footprint



[1] To be decommissioned by 2025

Market Trends

The biopharmaceutical market continued to expand in 2023 and is expected to achieve a compound annual growth rate (CAGR) of around 8% over the next five years[1]. Historically, the pipeline has increased 9% annually over the last ten years[2].

The biologics CDMO market continues to show positive growth, with an expected CAGR between 9 and 11% over the next five years[3], as the outsourcing trend continues. The growth in CDMO capacity continues to outpace capacity in customers' own facilities, as large and small players increasingly rely on manufacturing partners to support, complement and de-risk their journey to market. Partnering models help attract customers, enabling capital preservation, direct access to leading expertise, de-risked supply, and regulatory support.

Large pharmaceutical organizations contribute the majority share of CDMO revenues due to commercial manufacturing activity. Small biotech businesses represent a higher proportion of the molecule pipeline, where outsourcing is built into business models to conserve capital resources. While funding has affected this segment in the short term, we expect this to normalize in the medium term.

Strong and continued growth is reflected across all phases of molecules in the biologics pipeline. This is matched by the increased diversity of modalities for the molecules in development, with new biologics drug types and novel indications a key growth factor.

Looking at the market dynamics of the individual modalities:

- In mammalian we expect that manufacturing demand will continue to outpace supply, especially for large-scale manufacturing. We see strong potential for large-volume monoclonal antibody treatments currently in clinical trials. These include high-volume products, such as Alzheimer's treatments and other potential blockbusters.
- The growth potential for bioconjugation is strong, with the global drug sales for antibody-drug conjugates (ADCs) expected to grow by around 20% CAGR over the next five years[1]. There is a lack of available capacity across the industry and a high demand for outsourcing due to the complexity of the supply chain and manufacturing. Customers are looking for CDMOs that cover the entire ADC value chain, across modalities, to help manage complexity and risk. Lonza has a strong position with its end-to-end offering.
- Growth in the microbial market is driven by a promising drug sales outlook with a CAGR of 7% from 2023 to 2028[2] and a robust molecule pipeline, which is set to rise by around 4% CAGR in this period[3]. Demand for large-scale manufacturing is strong and outstripping CDMO market capacity. Customers look to experienced manufacturing partners adept at designing and running bespoke large-scale plants and managing the complexities of microbial tech transfer and scale-up. In this regard, we are well-positioned to respond to market needs.

[1] 2023 – 2028 CAGR in USD (ex CGT); Source: Evaluate Pharma; Lonza internal analysis
[2] Source: Citeline Biologics trends (ex CGT)
[3] 2023 – 2028 CAGR in USD (ex CGT); Source: Frost & Sullivan (2023); Lonza internal analysis

[1] 2023 – 2028 CAGR in USD; Source: Evaluate Pharma
[2] 2023 – 2028 CAGR in USD; Source: Evaluate Pharma
[3] Source: Citeline and Lonza internal analysis (2023)

Our Offering

We work across the entire spectrum of customers, from small biotech to large pharmaceutical companies. We offer different manufacturing scales and development services and support customers throughout the molecule's lifecycle from clinical to commercialization.

Lonza has one of the most complete offerings across technologies and scale. It also offers a wide range of services, including regulatory services. We can deliver tailored services that meet customer specific needs. We bring deep and long-standing industrial expertise in commercial delivery, with rigorous standards of quality, safety, efficiency and value providing a unifying thread across all our modalities.

Mammalian
Our largest network and set of capabilities lie in mammalian, which positions us well for the outsourcing trend. In addition, pharmaceutical companies continue to invest in R&D, we see a healthy pipeline of molecules across all phases. The outsourcing trend and the growing molecule pipeline, including commercial stage, will continue to drive demand for large-scale manufacturing. We anticipate that capacity will remain tight for the next five years, as we see the continuing trend towards outsourcing and the sustained commercial demand for manufacturing services.

We are focused on the development of our pipeline to feed commercial demand and de-risk our business model. We take pride in supporting customers early and working with them through the molecule lifecycle. With a strong reputation for commercial capabilities, we are also dedicated to supporting customers through the early stages of drug development. We cover the full scope of mammalian development and manufacturing services for all molecule types and build retention through development services, including licensing of proprietary IP.

In May 2023, we opened a new facility in Cambridge (US) as part of our extended early-stage offering. Located close to the Boston biotech community, the new facility enables customers to de-risk and optimize drug candidates at an early stage.

In 2024, we will ramp-up our new clinical assets in Portsmouth (US) that will support customers who want to produce in the United States at small scale. It will also enable the consolidation of demand from clinical to launch in one location, Portsmouth (US), and enable the shutdown of Hayward (US).

In 2024, we will also execute the ramp-down of our activities in Guangzhou (CN) and consolidate demand in other locations.

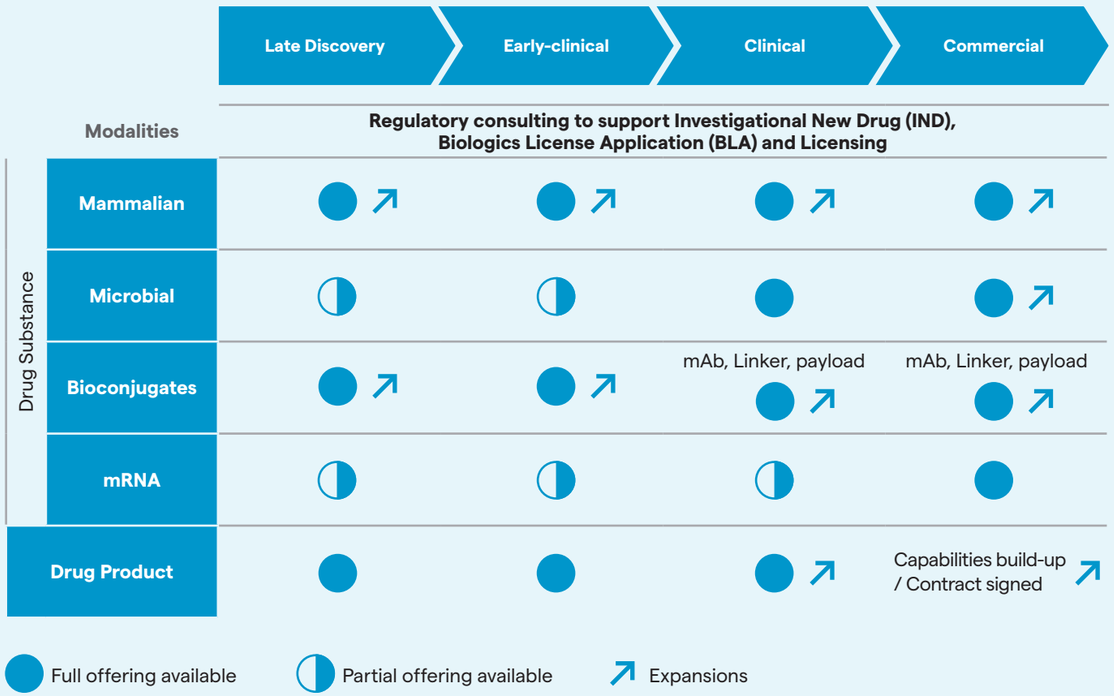
Bioconjugates
We provide robust expertise and experience in drug conjugation. This modality can be applied to different products, such as antibody-drug conjugates (ADCs). ADCs consist of an antibody that can identify and locate a target cancer cell, a cytotoxic payload to kill the cell, and a chemical linker to bind these two components together. ADCs are revolutionizing the cancer treatment landscape. The production process is highly complex and integrated. It requires deep technical expertise, leading technology, and well-controlled facilities to ensure safety, quality, and efficacy.

We develop and produce all ADC components, drawing on expertise across divisions. Today, we manufacture the majority of commercially available ADCs, and we see significant further growth potential. In 2023, we delivered more than 300 batches across 32 programs, which represents a fourfold increase compared to five years ago. Batch sizes also increase as more products reach commercialization.

The ADC platform is a great example of Lonza investing early in new modalities and capabilities. In addition, we are committed to investing in R&D and innovation to meet future demand alongside market needs for more diverse and complex ADCs. In 2023, we acquired Synaffix, a company with strong proprietary conjugation technology, to keep on offering the best possible platforms to our customers.

Our integrated offering supports customers in accelerating timelines and reducing complexity on the journey to commercialization.

Microbial
With licenses to manufacture eight commercial products and a track record in large-scale complex protein and vaccine production, our microbial business unit is a leader in late-phase and commercial supply for customers looking for reliability and quality of supply. Our expertise is drawn from over 30 years' experience and more than 70 GMP technology transfers into Lonza. With our proprietary XS Technologies® expression systems, state-of-the-art development labs, and GMP manufacturing scales spanning 70 liters to 15,000 liters, including a new mid-scale production facility, our facility in Visp (CH) enables us to offer services that meet our customers' needs across the entire product lifecycle.



Personal Highlight

Jean-Christophe Hyvert
President, Biologics Division

"In Biologics, we continued to build our pipeline, strengthened our manufacturing network, in particular for ADCs, and built our technology portfolio with the acquisition of Synaffix. We signed multiple dedicated long-term customer programs, which reflect the value of our offerings. 2023 was our strongest signing year on record."

Drug Product Services

Our Drug Product Services (DPS) business unit focuses on parenteral dosage forms. We help customers address various challenges across formulation, analytical, process development and drug product manufacturing. We have built deep expertise in areas including formulation, and have expanded into clinical and commercial fill and finish.

The DPS portfolio includes expertise in drug product injection and infusion, covering various routes of parenteral administration such as intravenous, subcutaneous and intravitreal. With a growing team of more than 500 professionals, we offer an integrated approach, across various biologics modalities. This includes standard monoclonal antibodies as well as more complex molecule formats such as bispecific antibodies, fusion proteins, recombinant proteins and bioconjugates, including ADCs.

DPS partners with the Drug Substance business units to offer end-to-end solutions, including drug substance and drug product. There is increasing demand for integrated solutions that decomplexify and secure supply with one CDMO.

A Global Center of Excellence for Drug Product Development
Our global Center of Excellence for Drug Product Development is located in Basel (CH). It is recognized for its industry-leading expertise in formulation and analytical development. It also has a leading reputation for the testing of parenteral dosage forms throughout drug development and manufacturing, which supports high safety and quality standards for drug products delivered to patients.

In addition to this core offering, we provide a unique range of specialized pharmaceutical services, encompassing particle identification, excipient and surfactant characterization, extractables and leachables assessments, testing for container closure integrity and drug/device combination services.

Biologics Drug Product Manufacture – Global Drug Product Manufacturing Network
Building on our expertise in drug product development, we have expanded our global fill and finish capacity, starting with the establishment of a GMP facility in Stein (CH) dedicated to the clinical and commercial supply of drug products in liquid and lyophilized forms. Located just 30 km from Basel (CH), the site has undergone significant expansion to become a thriving manufacturing campus, affirming its status as Lonza's global Center of Excellence for drug product manufacturing.

Drug Product Growth Project
To continue expand capacity, 2023 marked the commencement of construction on a new commercial scale fill and finish facility in Stein (CH), with initial completion scheduled for 2026. With an investment approximately CHF 500 million, this new flexible facility is located on the same campus as our existing drug product facility, allowing us to leverage our existing infrastructure, capabilities, and talent. The multi-purpose facility consists of several connected buildings, spanning across 18,000 m^2, and housing four filling lines. The facility encompasses liquid, lyo, and pre-filled syringe capabilities, along with a customer-dedicated ADC filling line.

The design will embrace the latest developments in sustainable construction, taking a modern approach to carbon reduction and responsible energy use, including the installation of a photovoltaic roof.

The addition of this commercial scale fill and finish facility will support the delivery of full end-to-end drug manufacturing services and support customers across the entire product life cycle.

mRNA
We pioneered the large-scale commercial manufacturing of mRNA medicines during the COVID-19 pandemic, in record time. It is a testament to our adoption of new technology and the strength of our development and manufacturing know-how that we can deploy new offerings. Since then, mRNA technology has advanced in multiple therapeutic areas, with many projects now in early development. To support these projects, we have opened a new integrated mRNA/lipid nanoparticles (LNP) manufacturing complex at our cell and gene therapy site in Geleen (NL), leveraging local expertise and providing development opportunities for our employees. The expansion includes IND-enabling, clinical and small-scale commercial manufacturing services. It also includes areas for process and analytical development, cGMP manufacturing and Quality Control for mRNA and LNP necessary for formulating mRNA-based medicines.

Licensing
Our Licensing business unit manages access to our Intellectual Property (IP) to allow companies to develop new therapeutics to incorporate proven technologies to help speed-up their development. Our differentiated licensing offering is particularly suited for pharmaceutical, biotechnology companies and research institutions conducting early research. Built on more than 35 years of continuous innovation, our GS® gene expression system is a core component of a more comprehensive set of expression technology solutions that span diverse therapeutic modalities. We serve more than 500 active licensing customers and more than 200 prospective licensees under Research Evaluation Agreements. More than 80 approved therapeutics reach millions of patients each year, helping us to achieve our purpose of enabling a healthier world.

Ibex® Solutions
Ibex® Solutions comprises a series of advanced manufacturing facilities that 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 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 comprehensive and tailored portfolio of services under a single framework. Ibex® Solutions enable our customers to bring their new medicines and vaccines to their patients at pace, while providing the flexibility to actively manage supply constraints, drug development uncertainty and evolution in market demand.

2023 Highlights

Over the course of the year, we have continued to experience strong sales of 17.6% CER. This was driven by new projects coming online, alongside base business expansion. Our investments have focused on supporting the clinical pipeline and building world-class infrastructure at critical sites including Visp (CH).

Looking ahead to 2024 and beyond, we anticipate that core sales growth, excluding Moderna, will outpace market growth, driven by large commercial contracts and future commercial expansion. We will continue to invest further to consolidate our position as a CDMO partner of choice.

Enhancing our Technological Edge through Targeted Innovation
Innovation plays a crucial role in helping us to maintain our market advantage. We can now support certain customers moving from gene to IND filing in approximately 11 months or less for standard monoclonal antibodies and approximately 13 months for more complex proteins[1] or customers who want a specific approach. This speed and efficiency attracts customers who wish to accelerate clinical development and want a flexible approach.

Our focus on continuous bioprocessing and process intensification aims to improve productivity and reduce the cost of goods sold.

We are integrating digital technologies into the drug development and manufacturing journey to help improve speed, flexibility and efficiency while managing costs.

New Ibex® Solutions Customer Collaborations
We have signed an Ibex® Dedicate program with our customer, Vaxcyte, to support their journey to commercialization for the global manufacturing of broad-spectrum pneumococcal conjugate vaccines (PCVs). This agreement extends a long-term relationship that provides Vaxcyte with a custom-built manufacturing suite in Visp (CH). Equipment installation is expected to begin in 2024.

In addition, two new bioconjugation suites for the commercial supply of ADCs will be added as part of an extension of a long-term collaboration with a major global biopharmaceutical partner. The extension builds on an existing partnership for end-to-end ADC manufacturing, including payload, monoclonal antibody (mAb) manufacturing, and bioconjugation. The agreement will increase the current dedicated bioconjugation capacity fourfold and is expected to generate around 180 new jobs upon completion, with operations expected to commence in 2026.

[1] Terms and conditions apply; certain molecules are not suitable for this offering

New Facilities to Meet Demand
Early in 2023, we completed the expansion of our bioconjugation facility in Visp (CH) to enhance our capability for clinical and commercial supply across development and manufacturing, including drug product. We completed a new cGMP clinical and commercial drug product line, marking a significant milestone in the growth of our Drug Product Service offering. These continued investments in Visp (CH) are designed to provide a flexible solution for customers of all sizes in one location.

Following the groundbreaking of the new commercial drug product facility in Stein (CH) in January 2023, we secured our first additional dedicated line for the commercial cGMP filling line at the site in October 2023. The extended agreement with a major biopharmaceutical partner will enable the aseptic filling of highly potent ADCs and lyophilization under containment. With operations starting in 2027, these additional filling capabilities further strengthen our capacity and flexibility in supporting both the clinical and commercial supply of bioconjugates.

Strengthening our Bioconjugates Offering
We announced the acquisition of Synaffix B.V. to further strengthen our bioconjugates offering. The Synaffix technology platform, which includes payload and site-specific linker technologies, will enhance our integrated ADC services, including our early-phase offering. Combining our development and manufacturing capabilities with the Synaffix platform will provide customers and licensees with a comprehensive service to rapidly discover, develop, scale-up and commercialize novel and differentiated ADCs.

Microbial
Our new mid-scale 4,000 liters microbial facility is operational, with the first batches manufactured in 2023. Final regulatory authority approval and ramp-up of the asset is underway. To complement this increase in manufacturing capacity, our new purpose-built development services labs were established and have been fully operational since early 2023, with our customers benefiting from a new state-of-the-art automation room and pilot facility.

Financial Performance in Full-Year 2023
Comparison vs. Prior Year

3,719m +17.6%[1]
Sales (CHF)

1,294m +5.4%
CORE EBITDA (CHF)

34.8% -2.7ppts
CORE EBITDA Margin

[1] Sales growth, expressed as a percentage (%), are at constant exchange rate (CER)

Innovation Spotlight

Helping to Improve Patient Outcomes through Innovative Cell Lines

Targeted therapy employing monoclonal antibodies (mAbs) represents a powerful immunotherapy tool in oncology. These mAbs function by directly or indirectly killing cancer cells. This process is facilitated through antibody-dependent cellular cytotoxicity (ADCC), a key mechanism underlying targeted antibody-based immunotherapy approaches. ADCC is an important mechanism of therapeutic action and refers to the process where antibodies bind to infected or non-host cells, leading to the elimination of those cells. Since many cancer patients show limited responses to standard mAb therapies, developing therapies with improved ADCC-eliciting properties can help enhance their therapeutic success.

To help meet pressing market and patient needs, Lonza has developed our new GS Effex® cell line that increases ADCC function and therapeutic potency of the mAb product. Derived from our GS Xceed® cell line, our GS Effex® cell line is compatible with Lonza's GS Gene Expression System® and platform processes. The GS Effex® cell line is stable, productive and scalable and, as part of the GS System®, allows for reliable cell line construction and reduced risk during product development.

Our continued focus on leveraging our expertise and experience across various fields and modalities helps us to bring innovative solutions to our customers and their patients. The new GS Effex® cell line will help enable our customers to deliver cutting-edge therapeutics that address unmet patient needs.

Bringing New Molecular Formats Closer to the Clinic

The global biologics pipeline has witnessed an uptake of new and more complex molecular formats, including antibody fragments, bi- and multispecific antibodies. Almost 300 bispecific antibody-based drug candidates have entered the clinic in the last two decades[1]. More complex proteins, especially those without a conserved domain, bring unique challenges related to their purification and manufacturing, as standard platform processes cannot be applied, which can lead to delays and added costs.

Overcoming these hurdles and getting these exciting products to the clinic as quickly as possible while balancing cost and risk requires innovative and tailored solutions. Our teams focused on helping customers to reduce timelines and develop new processes. This was achieved by identifying and resolving technical bottlenecks related to clone selection and applying state-of-the-art proprietary analytical methods and process and purification development.

As a result, Lonza has launched a number of different integrated drug substance/drug product DNA-to-IND programs over the past two years. Subject to molecule evaluation, Lonza can support customers in bringing certain molecules to IND in reduced estimated timelines depending on the molecule type: mAbs (11 months or less)[2], bispecifics (13 months)[3], Fabs and Fc-fusion proteins (14 months)[4] and scaffold and recombinant proteins (15 months)[4]. In addition, we can offer tailored solutions to customers depending on their need for speed. These programs are backed by over 35 years of experience in developing and manufacturing biologics, state-of-the-art technologies and the use of cell lines and innovative processes that are commercially viable and designed to fit all scales. In addition, the programs can also provide drug substance for toxicology testing to help find adverse safety issues before making potentially costly mistakes when scaling up to GMP production.

With this suite of DNA-to-IND offerings, customers can increase the speed of applicable products to IND through an end-to-end solution. Lonza's cross-functional project teams and subject matter experts can further tailor these development strategies to help meet customer and product-specific needs.

[1] Kang J, Sun T and Zhang Y (2022) Immunotherapeutic progress and application of bispecific antibody in cancer. Front. Immunol. 13:1020003. doi: 10.3389/fimmu.2022.1020003
[2] From DNA transfection to Delivery of IND-Enabling CMC Modules. Subject to terms and conditions; certain molecules are not suitable for this offering
[3] From DNA transfection to Delivery of IND-Enabling CMC Modules. Typical timelines, subject to molecule evaluation, and terms and conditions; certain molecules are not suitable for this offering
[4] Terms and conditions apply; certain molecules are not suitable for this offering

Small Molecules

>220[1]
pre-clinical and clinical small molecules

>140[1]
commercial small molecules

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

Our Small Molecules division supports customers throughout their journey from clinical to commercialization, across drug substance and drug product. We provide contract development and manufacturing services for customers including large pharmaceutical and small biotech companies.

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

Market Trends

Small molecules remains an attractive and growing market with 52% of all molecules in clinical development comprised of small molecules (approximately 10,000 molecules). In the next five years, the clinical market for the number of small molecules is estimated to grow by 30%[1].

In 2023, the outsourced small molecules market was valued at $70bn and we estimate that this market will grow at 4 to 6% per year through to 2028[2]. Our primary focus is to support the development and manufacturing of innovative products and we expect this segment to grow at the higher end of this range.

Growth is driven by three main therapeutic areas, including Oncology, CNS and Endocrine (in particular diabetes). Thirty percent of FDA small molecules new molecular entities (NME) approvals are targeted towards oncology, a disease area estimated to sustain double-digit sales revenue growth per year through to 2028. Looking at the oncology market, small molecules make more than 60% of FDA NME approvals, of which approximately 90% are administered orally.

The required potency of products that destroy cancer cells means that they are often highly potent and need high containment manufacturing capabilities. We have a long and successful history of developing processes to manufacture highly potent active pharmaceutical ingredients (HPAPIs). In such complex containment environments, manufacturing experience and expertise is as critical as process control.

Increasingly, new therapies are on expedited timelines for approval and our quality system and regulatory experts support customer filings. This is a particularly important service for small companies who may not have in-house capabilities.

Our Offering

We are focused on helping customers develop and manufacture innovative small molecules. Over the last 40 years, we have developed a leading reputation, supported by our commitment to science, technology and delivery.

[1] Lonza internal analysis, Citeline
[2] Lonza internal analysis, FDA, Evaluate Pharma

We work in close partnership with our customers, helping them to solve patient challenges and support molecule progression through clinical stages. Our team of experts support development throughout the product lifecycle, from pre-clinical stages through to commercialization. Entry points in this lifecycle can vary from early clinical development to late-phase or commercial supply.

Our Small Molecules services can broadly be split into three categories: Drug Substance, Drug Product and Particle Engineering, which forms a bridge between Drug Substance and Drug Product.

Our **Drug Substance** services relate to the development and manufacturing of active pharmaceutical ingredients (APIs). Our **Particle Engineering** services relate to our micronization and spray dry dispersion technologies which support enhanced bioavailability. Finally, our **Drug Product** services support oral and inhaled formulations of APIs in tablet and capsule dosage forms.

Our current portfolio includes more than 150 commercial programs and more than 200 clinical programs. These are delivered by a global asset network capable of supplying a range of volumes to meet both clinical and commercial demand. Our ability to provide integrated supply chains for products, within or across divisions, is a compelling customer offering to simplify ways of working.

In Drug Substance, we continue to build on our existing capabilities in developing and manufacturing highly potent small molecules, especially the payload and linker manufacturing of antibody-drug conjugate (ADC) products. These represent a particularly attractive market segment within the high potent API category.

Candidates in the small molecules pipeline are increasingly complex and are often accompanied by a decrease in bioavailability due to their limited solubility. We help customers to address these challenges through a portfolio of bioavailability enhancement technologies, phase-appropriate and proprietary processing equipment and drug delivery capabilities. Our site in Bend (US) is recognized as a global leader in improving bioavailability, leveraging our scientific expertise and spray dried dispersion technology.

The following two new offerings have progressed towards market introduction in 2023:

Physiologically-Based Pharmacokinetic (PBPK) Modelling
Poor oral absorption in drug candidates can delay critical pre-clinical and clinical studies, leading to extended timelines and costs for drug manufacturers. With low solubility molecules becoming more prevalent, we offer deep expertise in the application of PBPK modelling to help customers better understand the risks to absorption and develop better formulation strategies.

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 Products
Tablets, encapsulated powder and multiparticulates, injectables

Financial Performance in Full-Year 2023
Comparison vs. Prior Year

901m +11.2%[1]
Sales (CHF)

283m +14.1%
CORE EBITDA (CHF)

31.4 +1.1ppts
CORE EBITDA Margin

[1] Sales growth, expressed as a percentage (%), are at constant exchange rate (CER)

PBPK modelling simulates the dynamic physiological factors impacting oral performance. When coupled with *in vitro* testing and experience in addressing key formulation challenges such as bioavailability, it has proven to be effective in applications throughout the drug development cycle.

Retrosynthesis Technology
The complexity of small molecule APIs is rising and this is creating significant challenges to timely clinical readiness. We are leveraging innovative technologies including Artificial Intelligence (AI) to help our customers accelerate clinical readiness, reduce costs and improve supply chain decision making for their drug substances.

2023 Highlights

Our commercial and clinical portfolio is strongly represented across the main therapeutic growth areas. In 2023, the Small Molecules division achieved more than 10% growth, with the majority driven by the manufacturing of newly introduced products. Particular milestones were reached in 2023, as multiple oncology products on which we collaborate with our customers received FDA approval.

Our global network of sites offer different services to deliver a highly connected supply matrix. This allows us to support a range of volume needs through clinical progression and niche to high volume for commercial products.

Solid Form Services Expansion
We completed the expansion to our Solid Form Services (SFS) offering by expanding our facilities in Bend (US) to meet accelerated timelines for increasingly complex molecules. The enhanced facility includes remodeled and dedicated laboratory space, primarily used to support biotech and mid-size pharma companies in developing early-stage compounds.

The offering complements our API development services and first-in-human services, aimed at the rapid advancement of small molecules.

Enhanced Powder Characterization Capabilities
Our Small Molecules site in Tampa (US) has been upgraded to include universal powder flow testing alongside automated particle size and shape analysis capabilities. The addition of new capabilities at this site is enabling a greater understanding of the behavior of powdered drug substances, excipients and blends used in the development of new dosage forms.

Personal Highlight

Gordon Bates
President, Small Molecules Division

"In Small Molecules, we continue to adapt our capabilities and commercial offerings aligned with market needs, further augmented with additional capacity to meet sustained customer demand, particularly supporting highly potent API products. Looking ahead, we will continue to focus on the acquisition of early-phase clinical projects to help drive future growth."

Innovation Spotlight

Lonza Route Scouting Services: Retrosynthetic Pathway Optimization Enabled by Integrated Supply Chain Intelligence

Looking at the global development and manufacturing pipeline, the complexity of small molecules is increasing and this can bring longer synthetic routes to access the target molecule. Over the last decade, the number of chemical steps from raw materials to an active pharmaceutical ingredient (API) increased on average from 8 to more than 20 steps[1,2]. More than 50% of the approved drugs in 2022 contained at least one chiral center and the associated regulatory demands for enantiomeric purity further complexify the task of process chemists[3]. The key features for a successful synthetic route include safety, high overall yield, high productivity (space-time-yield), impurity purge understanding, waste reduction, freedom-to-operate and a robust supply chain for starting materials and intermediates.

Next-generation computer-aided synthesis design technologies (CSDTs) offer synthetic organic chemists a powerful tool for managing greater molecular complexity. Distinguished by predictive route design capabilities, advanced CSDTs are increasingly adept at emulating retrosynthesis analysis. This is the logic by which synthetic chemists iteratively reduce complex molecules into progressively simpler structures, until commercially available starting materials are identified[4,5].

Building on our existing experience in supporting the development and manufacturing of small molecule APIs, we have developed a new offering that combines our extensive proprietary commercial data with a leading CSDT. By leveraging this technology, our experts can make synthetic strategy decisions that factor in real-world starting material costs, starting material availability at scale and supply chain intelligence.

This innovative service offering aims to significantly reduce project timelines by providing a higher incidence of shorter synthetic routes with faster access to starting materials at scale. This integrated approach underscores how Lonza's subject matter expertise and the use of advanced tools can synergistically transform chemical process development, ultimately leading to improved customer processes.

[1] Carey, J.S. *et al.* Analysis of reactions used for the preparation of drug candidate molecules. *Org. Biomol.* Chem., 2006, *4*, 2337–2347
[2] Eastgate, M.D. *et al.* On the design of complex drug candidate syntheses. *Nat. Rev. Chem.* 2017, *1*, 1-16
[3] Ceramella, J.; Iacopetta, D.; Franchini, A.; De Luca, M.; Saturnino, C.; Andreu, I.; Sinicropi, M.S.; Catalano, A. A Look at the Importance of Chirality in Drug Activity: Some Significative Examples. *Appl. Sci.* 2022, *12*, 10909
[4] The retrosynthetic analysis methodology and theory underlying it were acknowledged with the 1990 Nobel Prize in Chemistry, awarded to E.J. Corey: Press release. NobelPrize.org. Nobel Prize Outreach AB 2023: https://www.nobelprize.org/prizes/chemistry/1990/press-release/
[5] In silico approaches to retrosynthetic planning were first described by the E.J. Corey in the 1960s: Corey, E.J.; Wipke, W.T. Computer-Assisted Design of Complex Organic Syntheses: Pathways for molecular synthesis can be devised with a computer and equipment for graphical communication. *Science* 1969, 166, 178-192

Cell & Gene

>20
years of Cell and Gene cGMP manufacturing experience

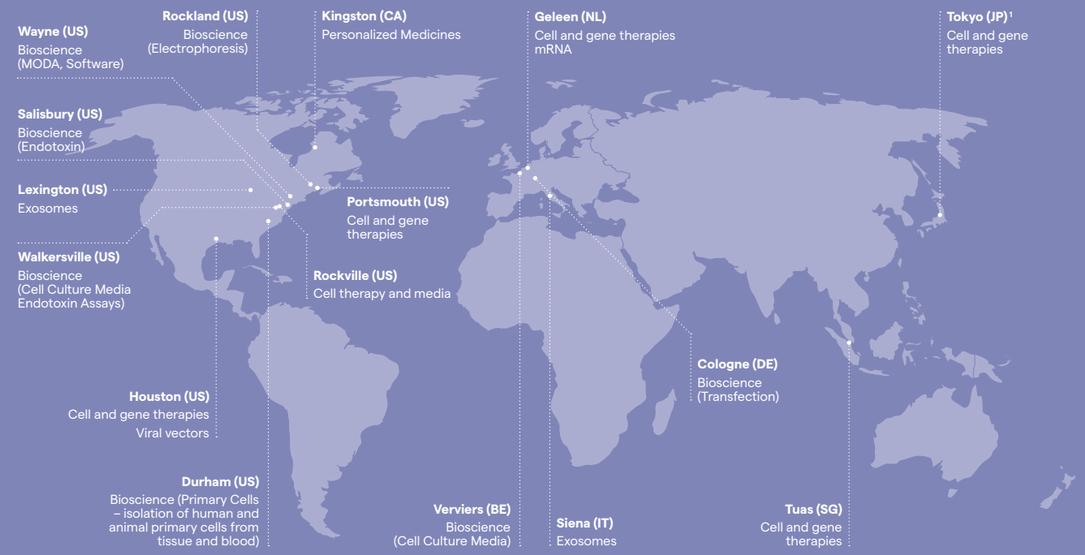
>200
process development projects

~60
active, pre-clinical therapies supported by Bioscience

~130
active, clinical and commercial therapies supported by Bioscience

Our Cell & Gene division provides comprehensive solutions that accelerate the development, manufacturing and commercialization of novel life-changing treatments. We also offer tools and technologies that enable cell and gene innovators to develop, de-risk and industrialize their therapies.

Our Global Development and Manufacturing Footprint



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

Market Trends

Cell and gene therapies have demonstrated the potential for transformative efficacy and are now being recognized as having viable commercial potential. In the last two years, we have seen a slowdown in funding in the market, mostly impacting pre-clinical and early clinical pipelines. In parallel, we are also seeing a shift of market focus to late phase and commercialization and this is driving strong growth. Over the next five years, we forecast the cell and gene CDMO market to grow by approximately 15%[1].

In the cell and gene CDMO market, reduced levels of funding in the pharma and biotech space have contributed to the trend of increased outsourcing over in-house development, which requires larger, long-term investments in CAPEX. Furthermore, the increased number of commercialized cell and gene therapies increases value for CDMOs supporting those therapies and producing cell and gene therapies for patients. The cell and gene space is still an emerging field and relies on highly manual processes that are not yet fully established. Access to expertise and know-how remains a key driver to successful manufacturing, further contributing to an increase in outsourcing to experienced, established CDMOs like Lonza in the cell and gene market.

With a track record of efficient and reliable manufacturing and strong capabilities to support our customers in bringing their products to market, we are well positioned to capture future market value.

Our Offering

Our Cell & Gene division comprises three synergistic business units that provide a combination of products and services. Our Cell & Gene Technologies business unit offers CDMO services and is becoming a “commercialization engine” for cell and gene therapies. The Bioscience business unit delivers specialty products that support the growth of the biologics and cell and gene markets. The Personalized Medicine business unit focuses on the Cocoon® Platform and has the aim of revolutionizing cell therapy manufacturing through automation.

Together, our business units address key customer challenges and needs. In addition, our CDMO expertise enables us to tailor and innovate our products and services.

Cell & Gene Technologies
Our value proposition is predicated on quality, expertise and trust. Over the last twenty years, we have established a leading position based on our process development and GMP manufacturing experience. With a robust position in key modalities, from process development to commercial manufacturing, our offering is one of the most complete in a highly fragmented industry.

Cell and gene processes are predominantly smaller-scale and still highly manual. As a result of leveraging our strong manufacturing expertise and reputation to deliver highly complex therapies, we have gained and also retained a large proportion of outsourced, late-stage clinical and commercial cell and gene products in the CDMO industry. As of 2023, Lonza manufactured three of the 12 outsourced commercial cell and gene therapy products approved in Europe and the United States.

Bioscience
Our Bioscience business unit has a strong portfolio of products and services that support the growth of the biologics and cell and gene markets. Our customers rely on our offering to deliver improved reliability, reduced variability, ease of use, high performance and cost efficiency. Our Bioscience products and services range from cell culture and discovery technologies for research, to quality control tests and software for biomanufacturing.

For example, Endotoxin testing is a critical test required to ensure the safe release and use of every parenteral product delivered intravenously to a patient. In 2023, we launched a new microplate reader, the Nebula® Absorbance Reader, as part of our Endotoxin and pyrogen testing portfolio to support QC labs. The updated reader provides improvements in accuracy, consistency and greater flexibility for use.

Personalized Medicines
The cell therapy production process is extremely complex. It can take four to six weeks between collecting the cells and infusing the treatment back to the patient. Furthermore, current solutions are not sufficiently scalable to meet patient demand.

Our Cocoon® Platform is a functionally closed, highly flexible and scalable autologous cell manufacturing solution, addressing many of these challenges.

- It provides point-of-care treatment, which can mitigate delays, shipping complexity and related costs.
- It is highly automated, which reduces both the costs associated with manual intervention and the risks associated with human error.
- It is scalable, as multiple instruments may be connected in the future, which has the capacity to save significant clean room space.

To date, we have installed more than 100 Cocoon devices and currently work with more than 20 customers. Through our large-scale, point-of-care manufacturing partnership with Galapagos, we have been able to consistently deliver treatments with vein-to-vein turnaround times in as little as seven days.

[1] Lonza internal analysis, Citeline

2023 Highlights

In 2023, our Cell & Gene division delivered top line growth driven by a complementary portfolio of products and services as well as operational excellence. As the market matures, we are working to facilitate the commercialization of more therapies, which remains the cornerstone of our strategy.

Investments in Novel and Disruptive Technologies
The cell and gene market is dynamic and new modalities and technologies are gaining traction. Our long-term success depends on our capability to drive innovation and invest strategically in novel technologies. As part of our commitment in this space, we have entered into a strategic partnership with Vertex to accelerate the development and commercialization of Vertex's potentially transformative cell therapies for Type I Diabetes. We are building a new dedicated facility in Portsmouth (US), spanning more than 130,000 square feet. This will complement our global cell and gene technology manufacturing network. The facility is anticipated to create up to 300 new jobs when operating at peak capacity.

Innovative Cell Culture Media Solutions
In Bioscience, we continue to maintain a focus on innovation as a means of driving competitive advantage, by developing products like cell culture media that deliver superior performance levels. Our two new cell culture media launches in 2023 underline our commitment to innovation as a means of meeting key customer needs. Our TheraPEAK® T-Vivo can be used to accelerate CAR T-cell therapy development without using human or animal serum, thereby solving a critical market need. TheraPro®, optimizes productivity and quality for therapeutic monoclonal antibody production. This fully scalable and versatile system has been developed to support customers with protein manufacturing.

Both TheraPEAK® and TheraPRO® are GMP based solutions that are chemically defined, of non-animal origin and are designed to take therapies from discovery through to commercialization. The new medium delivers greater consistency and process control and simplifies regulatory approval to support faster time-to-market.

Personal Highlight

Daniel Palmacci
President, Cell & Gene Division

"In Cell & Gene, we celebrated the groundbreaking of a new cell therapy manufacturing facility in Portsmouth (US) to support the development and commercialization of the Vertex type 1 diabetes cell therapy portfolio."

Overview of our Cell & Gene business units

Cell & Gene Technologies	Bioscience	Personalized Medicine
Contract development and contract manufacturing of cell and gene therapies, viral vectors, exosomes	Life science solutions to enable research, development, manufacturing and testing of therapeutics	Breakthrough technology to accelerate the industrialization of cell and gene therapy manufacturing
• Scientific know-how and expertise across the full range of cell & gene therapy modalities, including emerging technologies • Industrializing processes for clinical and commercial cGMP manufacturing • High-quality, state-of-the-art, regulated and inspected cell & gene therapy facilities globally	• 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 provide greater access to patients • Multiple unit operations integrated into a single system • Supports centralized or decentralized manufacturing model

Financial Performance in Full-Year 2023
Comparison vs. Prior Year

696m +6.6%[1]
Sales (CHF)

64m -44.8%
CORE EBITDA (CHF)

9.2% -7.5ppts
CORE EBITDA Margin

[1] Sales growth, expressed as a percentage (%), are at constant exchange rate (CER)

New Monocyte Activation Test Systems
We launched two new rapid monocyte activation test (MAT) systems to streamline and simplify rabbit-free testing. The PyroCell® MAT Rapid System and PyroCell® MAT Human Serum (HS) Rapid System will replace our current MAT system kit offerings. They contain PeliKine Human IL-6 Rapid ELISA kits that reduce time to results from two days to two hours.

Enhanced Electronic Batch Record Execution
As part of our continued investment in the MODA® Platform, we upgraded the MODA-ES® Module v4.0 to help pharmaceutical customers expedite batch release by minimizing paper-based processes. The improved module has a number of new features to simplify processes, materials and item management, as well as enhancing approvals, data tracking and connectivity.

Innovation Spotlight

Developing Reliable Manufacturing Platforms for Viral Vector-Based Therapies

Viral vectors represent the most effective methods of therapeutic gene transfer and have been used to treat a wide range of acute and chronic conditions. One of the most vital components of the viral vector manufacturing is ensuring sufficient manufacturing capacity and output, as these therapies often require scale-up during development and commercialization. With the majority of viral vector candidates being in the pre-clinical stage, developing a reliable and scalable viral vector manufacturing platform is key to ensuring the future success of these therapies.

Viral vectors can pose challenges in terms of scale-up, purification and quality control. Our teams in Houston (US) have developed a robust manufacturing platform for transient transfection in suspension bioreactors. This is designed to address challenges and offer our customers an established and reliable solution for viral vector manufacturing. Furthermore, we are also developing stable viral vector cell lines that will transform the cost and scale of manufacturing to support industrialization.

The resulting process, coupled with advanced proprietary analytics, leverages our long-standing history in developing and manufacturing viral vectors and enables us to produce adeno-associated viral vectors (AAVs) or lentiviral vectors with high productivity and purity. This contributes to a reduction in the cost of goods and improving manufacturing timelines.

Capsules & Health Ingredients

>30
Product Offerings

80
Capsules and Dosage Delivery Form Patent Families

~40
Ingredient Patent Families

Our Capsules and Health Ingredients (CHI) division offers high-quality capsules and encapsulation technology to the global pharmaceutical and nutraceutical markets. With a focus on process, product and service innovation, our network supports more than 7,000 customers with the design, customization and manufacture of hard empty capsules, capsule filling equipment, differentiated dosage form solutions and science-backed health ingredients. These are designed to meet evolving consumer requirements and patient needs.

Market Trends

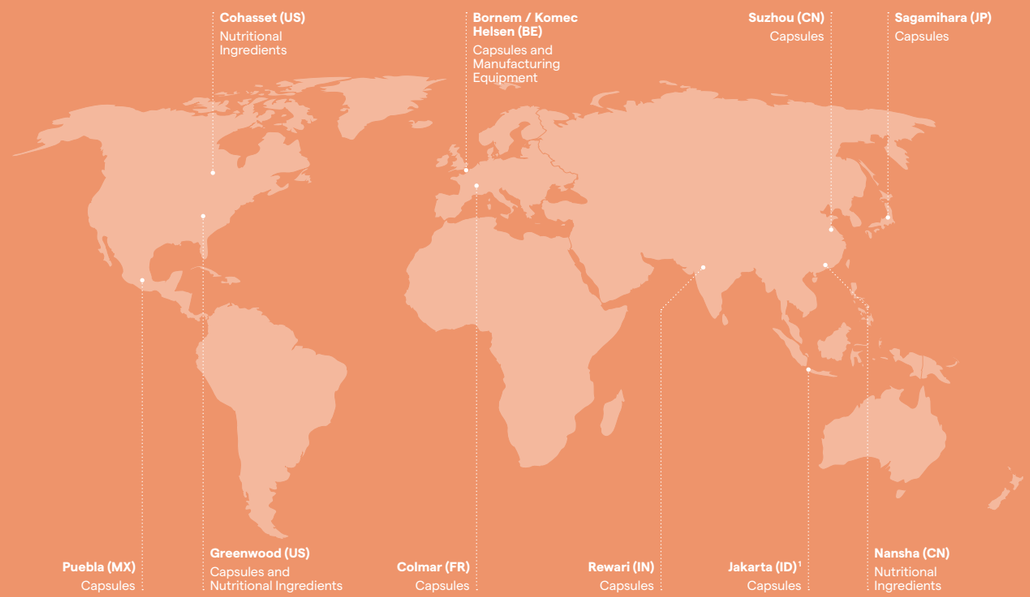
The **pharmaceutical market** is robust and largely acyclic, with high qualification and registration requirements. Pharmaceutical companies are currently looking to strengthen supply chains of raw materials with redundancies, manage increasingly tighter compliance standards and innovate with greater dosage form functionality. Here, we support customers by addressing drug development and ingredient formulation challenges, as well as offering a long-lasting partnership throughout the complex pharmaceutical development process.

For the **nutraceutical market**, we anticipate slightly higher growth in hard empty capsules compared with the pharmaceutical market. The market looks set to strengthen in the longer term, as consumers increasingly focus on proactive health management. We deliver a tailored end-to-end product development and contract manufacturing service. This enables us to bring concepts to reality in a matter of weeks, to capture the rapid changes in consumer nutrition market trends.

We have seen a post-pandemic decline in demand in both the pharmaceutical and nutraceutical industries. This has been driven by softer consumer demand for over-the-counter and preventative health treatments as well as customer destocking programs. However, we anticipate that demand will stabilize during 2024. Both markets are projected to grow at around 2 to 3% per year in the next five years[1].

[1] Capacity Utilization figures from 2019, based on recent Kline & Co (Q4 2022) and Ascendant Mfr (Q2 2023) interviews

Our Global Development and Manufacturing Footprint



[1] To be decommissioned by the end of 2024

Our Offering

CHI is well-placed to increase its presence in both the pharmaceutical and nutraceutical segments, with strong customer service as well as manufacturing and automation expertise, delivered by multi-disciplinary teams that are skilled in delivering customized solutions from discovery and concept to commercialization. We also provide a portfolio of capsule filling equipment and supporting technical services to meet our customers' fill and finish needs.

Broad Portfolio of Hard Empty Capsules
We offer a wide range of gelatin and plant-based Capsugel® capsule options with a variety of release profiles and encapsulation technologies. These are designed to meet evolving technical and regulatory requirements and market demands, such as vegetarian, vegan, organic and clean-label solutions. We have the largest global capsule manufacturing capacity in the world, with the capability to produce billions of capsules per year across our global production network. We supply customers in every major geographical region with standard and customizable capsules. In addition, we provide novel and functional capsules for increasingly complex and sensitive therapeutic requirements.

Innovative Dosage Form Solutions
Our Dosage Form Solutions (DFS) business is built on our strong capsule expertise and provides our nutraceutical customers with an unmatched end-to-end contract manufacturing service. These dosage forms range from simple liquid formulations, using our proprietary liquid sealing technology, to complex multi-dose and timed-release systems. In 2023, we expanded our capacity by more than 15%. Alongside our formulation and encapsulation expertise, we also support our customers by co-creating finished products and providing product branding support.

Active Lifestyle Health Ingredients
We provide multiple science-backed health ingredients for the growing active lifestyle market. Our offering includes products that support healthy human nutrition, targeting global consumer trends including joint health, muscular strength, energy, endurance and weight management. Our portfolio includes premium brands such as UC-II® for joint health, Carnipure® for energy, and a range of other branded products targeting immune and digestive health.

2023 Highlights

Our 2023 highlights reflect our combined commitment to long-term collaborative partnerships, supported by continuing innovation and investment in process, product and service innovation.

Process innovation
Leveraging our in-house design, technical and engineering teams, we advanced the development of our next-generation proprietary hard empty capsule manufacturing technology. The installation of the first full production line was initiated in late 2023 and will be operational by Q1 2024. This new technology is set to increase individual line capacity by 15% while concurrently reducing weight and dimensional variability. It will also enable us to reduce our net carbon footprint and set a new product quality standard. Following the first line installation in 2024, we will prepare the roll out of this new technology across our manufacturing network in the coming years.

For our DFS customers, we have successfully extended our proprietary Liquid Encapsulation Microspray Sealing (LEMS®) technology to our Designed Release DRcaps® capsules to improve product quality and stability. Read more in the Innovation Spotlight section on page 58.

Product Innovation
2023 was the first full year since the launch of our enteric Enprotect® capsule in 2022. Enprotect® is a novel enteric delivery technology. This bi-layer capsule withstands degradation in the stomach to support targeted enteric drug delivery.

We are leveraging this proprietary bi-layer technology to provide capsules with additional improved mechanical properties. This provides a new approach to conventional methods that require additional coatings, which often alter the capsule dimensions and produce inconsistent filling performance. Our bi-layer technology provides unparalleled efficiencies for customers versus traditionally coated tablets or softgels, which require a series of costly coating and drying unit operations. We aim to support multiple applications such as live bio-therapeutic, complex, targeted release or sensitive therapies and we are already exploring more than 200 unique opportunities with our customers.

Service Innovation
We strive to create an exceptional customer experience, as part of our differentiated offering earning exceptional scoring on our customer satisfaction surveys in 2023. Our development teams collaborate closely with our customers enabling the design of fully customized capsules and formulations using science-backed health ingredients. This service is accelerated through digitalization, which is integrated across our "build your own capsule" app, our data-led manufacturing programs and our full-scale production campaigns. Our full suite of concept-to-market services in our DFS business deliver innovative products and we successfully increased our pipeline by 360% from 2022 to 2023 by offering novel dosage forms and unique combinations.

Financial Performance in Full-Year 2023
Comparison vs. Prior Year

1,161m
-2.4%[1]
Sales (CHF)

327m
-21.8%
CORE EBITDA (CHF)

28.2%
-4.8ppts
CORE EBITDA Margin

[1] Sales growth, expressed as a percentage (%), are at constant exchange rate (CER)

Personal Highlight

Christian Seufert
President, Capsules & Health Ingredients Division

"In Capsules & Health Ingredients, we improved customer satisfaction and advanced our innovation roadmap. We advanced the development of our next-generation hard empty capsule manufacturing technology and extended our proprietary capsule sealing technology to additional polymer formulations."

Innovation Spotlight

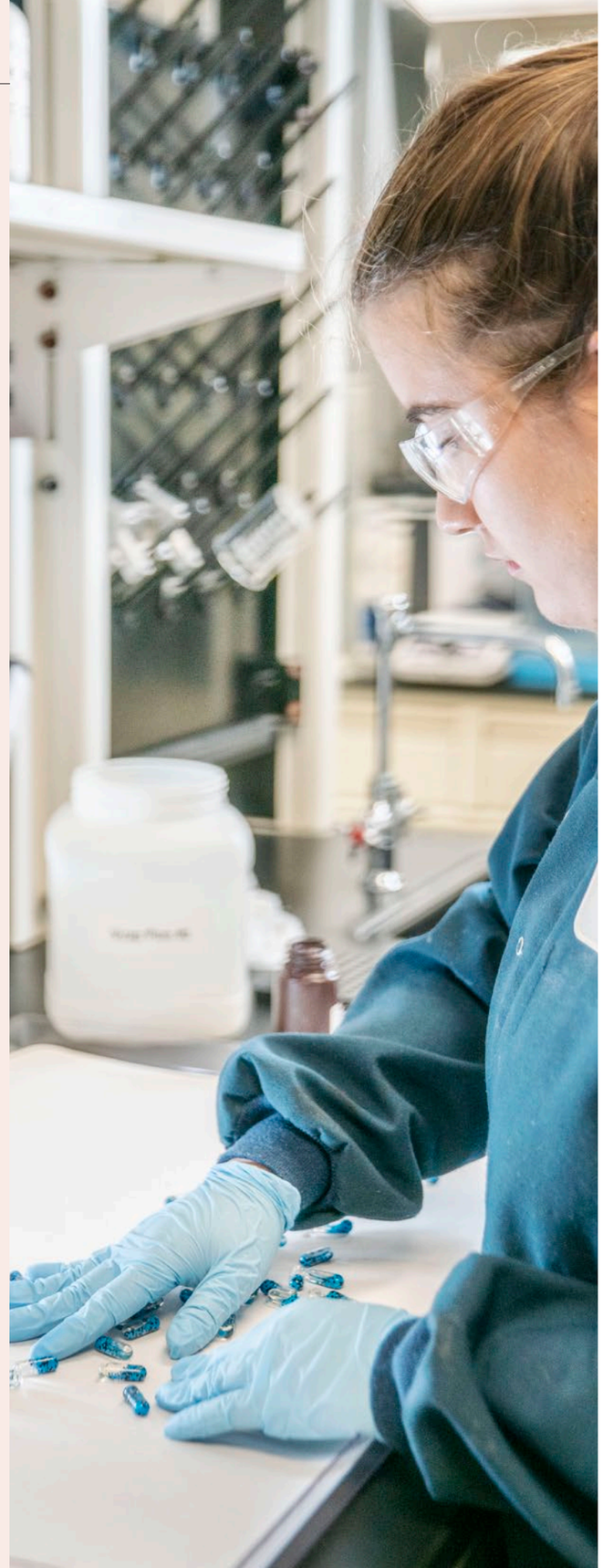
Our designed-released DRcaps® are innovative plant-based capsules that can help protect dietary supplement ingredients from stomach acidity[1]. Reducing manufacturing complexity and with a transparent, semi-opaque or fully opaque effect, they offer significant customer fill and finish benefits and end consumer appeal.

Due to their unique polymer formulation they have traditionally required banding to seal. Our proprietary Capsugel® LEMS® fusion technology, fuses the cap and the body of a standard polymer capsule, improving process reliability and product quality compared to other sealing technologies. We adapted this LEMS® technology to now also deliver outstanding fusion performance for our DRCaps® range, replacing banding as the sealing method. We are now able to reliably combine our DRcaps® capsules with our innovative liquid-fill platforms to offer nutraceutical customers higher quality designed-release options for their health supplements.

We have also progressed our cap in cap technology. In vitro testing has shown that adding a small DRcaps® capsule inside another as a DUOCAP® capsule increases the viability of probiotics by up to 46 times, compared with standard capsules[2]. Combining our cap in cap and LEMS® fusion technology offers nutraceutical customers a significantly improved targeted release profile for their probiotic ingredients in an aesthetically differentiated package.

Looking ahead to 2024, we anticipate the combination of our designed-release capsules, liquid fill platforms and expanded LEMS® sealing will become the preferred combination for many of our Dosage Form Solution (DFS) launches in the nutraceutical market.

[1] Source: DRCaps® Capsules Achieve Delayed Release Properties for Nutritional Ingredients in Human Clinical Study, 2014
[2] Comparison of protection and release behavior of different capsule polymer combinations based on L. acidophilus survivability and function and caffeine release, International Journal of Pharmaceutics, 2021



Partners and Joint Ventures

Lonza and Sanofi entered into a strategic partnership in 2017, establishing BioAtrium AG to build and operate a mammalian cell culture facility for monoclonal antibody production in Visp (CH). The large-scale facility utilizes 20,000 liters bioreactors.

Bacthera is a strategic joint venture (JV) which was established by Lonza and Chr. Hansen (now Novonesis) in 2019. The company is now a 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.

Bacthera'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 medications for human clinical trials and ultimately develop commercial products. In 2023, Bacthera acquired a GMP certified, microbial drug substance manufacturing facility in Léon (ES). This acquisition increases manufacturing capacity for LBPs with bioreactors of various sizes up to 3,500 liters and allows Bacthera to offer a more complete end-to-end solution to the entire LBP market.

In November 2021, Bacthera announced a collaboration with Seres Therapeutics, a leading microbiome therapeutics company, to manufacture VOWST (fecal microbiota spores, live-brpk; formerly known as SER-109). VOWST was approved by the FDA in 2023 and is the first and only FDA-approved orally administered microbiota-based therapeutic indicated to prevent the recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI (rCDI).

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 has been built 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.

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For publications and further information, please contact:

Lonza Group Ltd
Muenchensteinerstrasse 38
4002 Basel, Switzerland
Tel +41 61 316 81 11
www.lonza.com

Investor Relations
investor.relations@lonza.com

Media Relations
media@lonza.com

Share Register
c/o Computershare Schweiz AG
P.O. Box 4601 Olten, Switzerland
Tel +41 62 205 77 00
Fax +41 62 205 77 90
share.register@computershare.ch

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