

# Our Businesses

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# **Group Operations**

## Driving Operational Excellence and Standardization

In our continued drive for improved efficiency, we accelerated our transformation through the implementation of Operational Excellence initiatives across multiple sites in 2024, expanding beyond manufacturing to include our enabling functions. The Lean Lab programs have enhanced the efficiency of our Quality Control operations, while the standardization and automation of business processes, supported by advanced digital tools, have further streamlined workflows across the organization.

We made progress in our digital transformation journey, particularly within our supply chain, procurement and maintenance functions. This included streamlining processes, increasing automation, and driving greater operational efficiency. For instance, our new paperless maintenance initiative saves three tons of paper annually. At the same time, we maintained a strong focus on responsible sourcing and the decarbonization of electricity use, in line with our sustainability goals.

Alongside these efforts, we remained committed to addressing customer needs while fostering an environment of employee engagement and development, ensuring that our people are empowered to drive continuous improvement and innovation.

### **Executing our Strategic Growth Projects**

Our project management framework, guiding initiatives from initial concept to final delivery, helps drive the effective execution of our growth strategies. We apply a rigorous selection process that aligns with both our customers' evolving needs and our own long-term success, focusing on factors such as strategic alignment, market potential, feasibility and return on investment. This comprehensive approach reinforces our confidence in generating sustained value for the business.

Throughout the project lifecycle, we employ a streamlined, stage-gated approach that drives efficiency and accountability. At every phase, we refine both the technical solutions and the commercial case, with clearly defined metrics and approvals to guide investment decisions. Continuous progress tracking facilitates early issue identification and resolution, helping to align timelines and budgets more effectively.

Each initiative is led by a dedicated project lead and supported by a cross-functional team. We ensure close oversight of individual projects through regular steering committee reviews, while the broader project portfolio is monitored by the Executive Committee and the Board of Directors at key intervals. This governance structure helps keep execution on track while enabling us to incorporate valuable lessons, so we can continually refine our project capabilities.

### **Growth Projects in Action**

### Building a New Dedicated Facility for the Vertex T1D Cell Therapy Portfolio

As part of our ongoing commitment to innovation, we are building a dedicated 130,000 ft<sup>2</sup> facility in Portsmouth (US) to support the manufacture of the Vertex portfolio of investigational stem cell-derived, fully differentiated insulin-producing islet cell therapies for people living with Type 1 Diabetes (T1D).

The dedicated facility will complement our global cell and gene technologies manufacturing network, which supports customers in developing, de-risking, commercializing, and scaling their emerging therapies. Under the terms of the collaboration, Vertex will leverage our scientific, regulatory and manufacturing expertise, along with our global manufacturing network and first-hand experience in the commercial manufacture of cell therapy products.

The new facility is located next to the existing Lonza Portsmouth site, enabling us to leverage the existing infrastructure, capabilities and talent. The construction is progressing in line with plan, with the exterior structure successfully completed in June 2024, just 13 months after commencement. GMP operations are expected to begin by the end of 2026.

The new facility will leverage Lonza's Sustainable Design Standard<sup>1</sup>, which prioritizes energy and water efficiency alongside the integration of sustainable technologies into all large investment projects. In partnership with Vertex, this new asset will be the first Lonza near-zero GHG emission manufacturing facility. The main technical sustainability elements include full electrification, use of renewable electricity and a 1.5 megawatt solar photovoltaic installation.

### Strategic Expansion of Drug Product Facilities in Switzerland

In 2024, we made solid progress on our key drug product expansion projects in Stein (CH). We are ramping up drug product manufacturing capabilities to support our customers from clinical to large-scale commercial supply. This strategic expansion will strengthen our end-to-end offering by delivering services from development to manufacturing, and from drug substance to drug product. Installations and construction activities continue to progress and the facility is expected to become operational in 2027.

The site in Stein builds upon our existing drug product capabilities in Switzerland which include:

- A Center of Excellence in Basel (CH) supporting pharmaceutical development, analytical development, clinical quality control and non-GMP pre-clinical drug product manufacturing
- Two drug product manufacturing lines in Stein, including a flexible, small-scale line designed for filling antibody drug conjugates (ADCs) which will be GMP-ready in H1 2025
- A drug product manufacturing asset in Visp (CH), including a liquid and lyophilized vial isolator line, operational since Q1 2023

## Personal Perspective

### Maria Soler Nunez

Head, Group Operations

Our business model is designed for longterm growth through strategic investments, operational excellence and a customer-centric approach. With targeted growth initiatives and continuous improvement, we support our customers' evolving needs so we can build strong partnerships and deliver lasting impact.

<sup>1</sup> Sustainable Design Standards provide a framework to help us reduce energy and wate consumption, GHG emissions, and waste production across growth assets. The landmark investment in Stein includes:

- Process facilities such as preparation areas, compounding suites and filling lines under isolators (covering liquid and lyo vials, as well as pre-filled syringes), with capabilities to also support ADCs
- An automated warehouse for cold and ambient temperature storage
- A facility supporting automated, semi-automated and manual visual inspections, dispensing and sampling areas, deep freezers and thawing units for drug substance
- A central utility facility
- An office and lab building



### **Our Global Development and Manufacturing Footprint**



large molecules<sup>1</sup>

commercial large molecules<sup>1</sup>

<sup>1</sup> 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 <sup>2</sup> Our new organizational structure, announced in December 2024, will become

operational on 1 April 2025 with three integrated business platforms: Integrated Biologics Advanced Synthesis and Specialized Modalities, Cansules & Health Ingredients, which we plan to exit at the appropriate time, will operate as an endent business platfo

Market Trends

The biopharmaceutical market continued to expand in 2024 and is expected to achieve a compound annual growth rate (CAGR) between 8 and 10% in the next five years<sup>3</sup>. Historically, the clinical molecule pipeline within the market has increased between 9 and 10% per annum over the last ten years<sup>4</sup>.

The biologics CDMO market continues to show positive growth, with an expected CAGR between 9 and 11% over the next five years<sup>5</sup>, as the outsourcing trend continues. The growth in CDMO capacity continues to outpace capacity in customerowned 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 by enabling capital preservation, direct access to leading expertise, de-risked supply, and regulatory support.

Large pharmaceutical organizations contribute the majority 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.

<sup>5</sup> 2024 – 2029 CAGR in USD (ex CGT) ; Source: Frost & Sullivan (2024); Lonza internal analysis

The Biologics division<sup>2</sup> 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 licenses for a variety of different technologies used in the research and development of new therapeutics.

We offer innovative development and manufacturing services and technologies across various molecule types, from drug discovery to market supply, and from drug substance to drug product. 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 can be close to our customers and support supply chain resilience.

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 as key growth factors.

There are specific market dynamics at play in selected modalities:

 Venture capital funding in biopharma rebounded in 2024, marking a strong year with over 20% year-on-year investment growth, breaking a two-year downward trend. This increase was largely driven by higher average funding per round<sup>6</sup>, with later-stage investments seeing the most significant growth. Early-stage and seed funding also showed first signs of recovery. Additionally, the number of mega-rounds exceeding \$100 million grew significantly, reinforcing the trend of "fewer but larger" deals<sup>7</sup>. This funding resurgence will likely contribute to higher pharma R&D spending in 2025, with an estimated growth of approximately 3%<sup>8</sup>, which may lead to increased demand for outsourcing services across the CDMO sector. At Lonza, early-stage demand is already recovering, with a more than 40% increase in early-stage inquiries in 2024<sup>9</sup>.



• 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. In addition, there is an increasing demand for existing commercial mammalian derived drugs arising from growing patient populations.

- The future potential of bioconjugation is strong, with global drug sales for antibody-drug conjugates (ADCs) expected to grow by around 20% CAGR over the next five years<sup>1</sup>. There is a lack of available capacity across the industry, while the demand for outsourcing arising from the complexity of the supply chain and manufacturing process is high. Customers are looking for CDMOs that cover the entire ADC value chain across modalities, to help manage complexity and navigate risk. In this market context, Lonza provides a robust endto-end offering, supporting customers in bringing their treatments to market.
- Growth in the microbial market is driven by a promising drug sales outlook with a CAGR of 7% from 2024 to 2029 and a robust molecule pipeline, which increased around 4% CAGR between 2018 and 2023<sup>2</sup>. This trend is anticipated to continue in the next five years. Demand for large-scale microbial

manufacturing is strong and is outstripping CDMO market capacity. Customers look to experienced manufacturing partners that can design and manage bespoke large-scale plants and navigate the complexities of microbial tech transfer and scale-up. In this regard, we are well-positioned to respond to market needs.

### **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, as well as supporting customers throughout the molecule lifecycle – from lead optimisation, to pre-clinical, through to clinical and commercial phases, including Biologics License Application (BLA) support services. We have one of the most complete offerings across technologies and scales, offering a wide range of services, including regulatory services. We can deliver tailored services that meet specific customer 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 modalities.

<sup>&</sup>lt;sup>3</sup> 2024 – 2029 CAGR in USD (excl. CGT); Source: Evaluate Pharma; Lonza Biologics target market

<sup>&</sup>lt;sup>4</sup> Source : Citeline Biologics trends (excl. CGT).

<sup>&</sup>lt;sup>6</sup> Source: Jeffries Pharmaceutical Services: December Biotech Funding (06 January 2025). Source: J.P.Morgan: 2024 Biopharma Industry Insights (January 2025).
Source: Evaluate Pharma: Global Pharma R&D Reported Expenditures (January 2025).

<sup>&</sup>lt;sup>9</sup> Source: Internal analysis

Source: Evaluate Pharma 2024-2029 (2024)

<sup>&</sup>lt;sup>2</sup> Source: Citeline Analysis (2024)

### Mammalian

Our largest network - spanning across scales, capabilities, technologies and geographies - lies in our Mammalian business unit. We are seeing the addition of a healthy number of new molecules entering our pipeline across all phases. Several late phase molecules are set to enter commercial stage in the near future, securing our commercial growth and driving demand in large-scale manufacturing. The ongoing trend for outsourcing, combined with the increased demand for existing molecules, and the arowing number of molecules expected to reach commercialization in the near future, offers a market opportunity in the coming years.

We will continue to strengthen our robust pipeline by maintaining a strong focus on lifecycle management and integrated solutions with Drug Product Services and Bioconjugation services. We remain committed to providing a full spectrum of mammalian development and manufacturing services for all molecule types. We will continue to invest in innovation to ensure speed and success in the early stages, while maintaining reliability and quality of commercial supply.

In 2024, we ramped-up our new 2,000L assets in Portsmouth (US) to support customers seeking small-scale manufacturing in the United States. The facility now consolidates demand across stages at a single site, from clinic to launch and scale-up, with 6,000L and 20,000L bioreactors. This development facilitated our consolidation, which led to the planned decommissioning of our sites in Hayward (US) and Guangzhou (CN).

The successful acquisition of the Vacaville site (US) secures long-term commercial supply for our customers. Vacaville is one of the largest biologics manufacturing facilities in the world, with a total bioreactor capacity of around 330,000 liters. This was supported by the technical completion of the largescale facility in Visp (CH), which adds six 20,000L bioreactors to meet increasing market demand for biologics.

## Bioconjugates

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 the two components together. ADCs have the capacity to revolutionize the cancer treatment landscape, but 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 provide robust expertise and experience in drug conjugation. The application of this targeted modality is expanding beyond its historical use in ADCs for oncology to address medical needs in other areas, including indications such as muscular disorders and rare diseases, as well as treatment modalities like vaccines and ophthalmology.

We are a leader in the manufacturing of commercially available ADCs, and we see significant further growth potential. Since 2006, we have produced more than 1,400 cGMP batches for more than 70 programs. Our production capacity is increasing with new assets coming online, leading to close to 400 batches in 2024. Additionally, batch sizes are increasing as more products reach commercialization, reflecting growing market demand.

We develop and produce all ADC components, drawing on expertise across divisions. The business benefits from a high level of integration with other modalities, including Mammalian, HPAPI and Drug Product. In 2024, we invested in all five technology areas needed for manufacturing bioconjugates at different scales, as outlined in the graph on the right, further strengthening our integrated supply chain. As a result, our bioconjugates offering now spans drug substance and newly added drug product manufacture for early clinical and commercial supply, including an early development focus on payload and site-specific linker technology.

This increased capacity includes the expansion of early development capability and laboratories offering expertise and speed in process development and scale-up for a wide range of bioconjugation approaches (including mAbs, proteins, and different types of linker and payloads such as cytotoxic molecules, oligonucleotides, polysaccharides, and radio labelled molecules). This accelerates time to market, while ensuring long-term supply capabilities.



### **Enabling Early** Innovation

### Meeting Market Demand for **Commercial Manufacture**

We are continually investing in R&D and innovation to meet future demand alongside market needs for more diverse and complex ADCs. Our position at the forefront of bioconjugation innovation has been strengthened through the acquisition of Synaffix and the integration of its leading technology platform into our offering.

Through a unique combination of technology access, discovery services, and manufacturing capabilities, we help drive the next wave of innovation in ADCs by accelerating timelines and reducing complexity on the journey to commercialization.

To further extend our offering and complement our intellectual property on site-specific conjugation, we collaborated with leading bioconjugation technology providers to offer state-of-the-art solutions.

The resulting Lonza Bioconjugation Toolbox offers a variety of conjugation technologies, linkers, and payloads to drug developers seeking to de-risk the development of drug candidates from the very beginning by preventing pitfalls and dead ends in later development stages.

To meet growing market demand for large-scale manufacturing, we are expanding our bioconjugation capacity in Visp (CH) by building two multipurpose manufacturing suites. The expansion will provide additional manufacturing capacity for launch and commercial supply to meet growing market demand

Furthermore, as part of an extended long-term collaboration, we will build a customerdedicated bioconjugation suite in Visp to support the manufacture handling and containment of highly-potent modalities at a commercial scale.

### Drug Product Manufacture for Bioconjugates

Our network has continued to adapt to the evolving ADC landscape and the increasing number of commercial molecules in the ADC pipeline. To allow us to deliver on the expected progression of ADC drug candidates through to commercialization, we expanded our offering to include filling lines specifically designed to manufacture pre-clinical, clinical, or commercial batches of highly-potent compounds

The expansion includes new GMP filling lines for ADCs at our sites in Stein (CH) and Basel (CH). These assets, specifically designed to produce pre-clinical batches of highly potent compounds, directly support essential pre-clinical activities for ADC drug programs, such as toxicology testing and stability.

This approach aims to provide a seamless end-to-end solution for drug developers and support the industry's goal of advancing and commercializing these life-saving therapies to benefit patients worldwide.

### Microbial

With mandates 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 guality. In 2024, we celebrated our 40th anniversary of working in the microbial space, building on a legacy of expertise and innovation. Our journey includes more than 70 GMP technology transfers into Lonza, reflecting our long-standing commitment to quality and innovation. With our proprietary XS Technologies® expression system, state-of-the-art development labs, and GMP manufacturing scales spanning from 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.

### Drug Product Services

Our Drug Product Services (DPS) business unit provides fully integrated, phase-appropriate solutions to drug product development and manufacturing. It addresses formulation, process design, and primary packaging. Our approach helps our customers to bring a drug product to market. Furthermore,

we support customers in addressing various challenges across formulation, analytical, process development, and drug product manufacturing. In the last five years, we have expanded from drug product development services 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 700 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 de-risk supply through strategic partnership with a single CDMO.

### **Our Integrated Service Offering**



### mRNA

We pioneered the large-scale commercial manufacturing of mRNA medicines during the COVID-19 pandemic, in record In 2024, our Biologics division reported sales in line with the time. It is a testament to our adoption of new technology, prior year (-0.5% CER), with growth from sustained commercial and the strength of our development and manufacturing demand offset by the loss of COVID-related mRNA business knowledge, that we can deploy new offerings at speed. Since and the related termination impact in 2023. Growth was mainly then, mRNA technology has advanced in multiple therapeutic driven by strong performance in Mammalian and Bioconjugates. areas, with many projects now in early development. To support these projects, we have opened a new integrated mRNA/lipid To strengthen our ability to meet customer needs, we continued nanoparticles (LNP) manufacturing complex at our cell and investing in the expansion of our end-to-end offering, supporting gene therapy site in Geleen (NL), leveraging local expertise the entire drug lifecycle from early development to commercial and providing development opportunities for our employees. manufacturing. The expansion includes IND-enabling, clinical and small-scale commercial manufacturing services. It also includes areas for **New Facilities to Meet Growing Demand** process and analytical development, cGMP manufacturing and In 2024, we strengthened our offering in our Mammalian guality control for mRNA and LNP necessary for formulating business, which represents the largest set of capabilities mRNA-based medicines. across our network. Through the successful acquisition of

### Licensina

Our Licensing business manages access to our licensable Intellectual Property (IP), enabling companies to incorporate proven technologies and accelerate the development of new therapeutics. Our differentiated licensing offering is particularly suited for pharmaceutical, biotechnology companies and research institutions conducting early research. The business drives innovation and strategic partnerships, enabling both start-ups and major players in the industry to leverage our industrial capabilities and reach. Our Evolving IP offering spans multiple modalities. With decades of continual innovation, our GS® mammalian 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, alongside more than 200 Research Evaluation Agreements. More than 85 approved therapeutics contain Lonza's out-licensed IP, reaching millions of patients each year. To strengthen our Bioconjugates services and keep offering the best possible platforms to our customers, we acquired and integrated Synaffix in 2023, a company with strong proprietary conjugation technology.

Furthermore, in order to better support early-stage customers across the biologics network, our Early Development Services (EDS) team is now centralized within our Licensing business unit, enabling improved support for early stage, pre-clinical customers with a complete end-to-end service solutions across all modalities. The advanced capabilities of EDS align seamlessly with the business focus on fostering innovation and supporting customers.

### 2024 Highlights

the Genentech Vacaville site in California (US) from Roche, we have significantly extended our capacity for large-scale mammalian drug substance manufacturing in the US, the world's largest pharmaceutical market. This acquisition has created a significant West Coast commercial manufacturing presence close to San Francisco's pharma and biotech hub, complementing our existing East Coast manufacturing site in Portsmouth, as well as our international network across Europe and Asia Pacific. With a total bioreactor capacity of around 330,000 liters, the Vacaville site is one of the largest biologics manufacturing facilities in the world. We plan to invest approximately CHF 500 million to further upgrade the facility and add capabilities to meet demand for the next generation of mammalian biologics therapies. The acquisition has significantly extended manufacturing capacity for current commercial customers and new molecules on the path to commercialization within our network.

Additionally, the commencement of commercial GMP operations in our new large-scale mammalian facility in Visp (CH) is scheduled for H1 2025. Due to specific demand, the facility will be further equipped with the latest N-1 perfusion technologies for the production of next-generation monoclonal antibodies. The addition of six 20,000L bioreactors in Visp, alongside the Vacaville acquisition, further strengthens our ability to meet the long-term commercial supply needs of our customers.

In 2024, we also released the first GMP batch at our nextgeneration mammalian manufacturing facility in Portsmouth (US). This marks a significant milestone, allowing the facility to help meet the increasing market demand for small- to midscale volumes of mammalian-derived biologics and support the implementation of high-titer and high-throughput platform processes.

### Annual Report 2024

Within our Microbial business, we <u>completed</u> an expansion at our facility in Visp (CH) which adds mid-scale manufacturing capacity for the clinical and commercial supply of microbiallyproduced biologics. This expansion increases flexibility for our customers and complements the existing small-scale and large-scale microbial manufacturing assets at the site.

We continued to strengthen our drug product services offering with the addition of new assets and the introduction of an offering for cytotoxic ADCs. In 2024, we completed the expansion of our footprint in Basel (CH) with an additional building, equipped to support late-stage clinical and commercial projects with additional quality control and bioanalytics capacity. The expansion also includes lab space for handling highly potent substances required for cytotoxic ADCs. Furthermore, we are bringing a flexible clinical filling line online that will allow us to fill cytotoxic ADCs.

Construction is also underway for our new commercial largescale fill-finish facility in Stein (CH). This facility will enable us to provide customers with a commercial-scale supply of pharmaceutical products in different formats, including vials and syringes.

### Advancing Bioconjugation

In 2024, Bioconjugates benefited from continued strong demand across both clinical and commercial services.

We expanded our filling capacity in Stein (CH) with a new customer-dedicated filling line for the commercial supply of ADCs. Once completed, this will enhance our comprehensive, end-to-end development and manufacturing services for ADCs, simplifying the path from DNA-to-IND and beyond for our customers.

Building on a successful long-term relationship where Lonza manufactured all key elements of bioconjugates at a commercial scale, we have further <u>extended</u> our collaboration with a major global biopharmaceutical partner. The extended agreement will expand the dedicated bioconjugation footprint for the customer with the construction of a new bioconjugation suite at our Visp (CH) site. We will also provide commercial-scale monoclonal antibody (mAb) manufacturing services for a new ADC targeting solid tumors. The new bioconjugation suite will occupy approximately 800m<sup>2</sup> of manufacturing space and will support the manufacture, handling, and containment of highly-potent modalities. Furthermore, we are <u>expanding</u> our bioconjugation capacity in Visp by building two multipurpose 1,200L manufacturing suites. The new suites will occupy approximately 2,000m<sup>2</sup> and double our multipurpose capacity for the launch and commercial supply of bioconjugates. The flexible multi-customer suites are designed to run the increasingly complex and variable processes needed to manufacture ADCs and other bioconjugates maturing through the drug pipeline.

We have seen high interest in our strengthened ADC offering through our acquisition of Synaffix. To further enhance our offering in this space, we have expanded the Synaffix footprint in the Netherlands, enabling us to offer increased Early Development Services capacity to companies developing novel therapeutic candidates. Furthermore, in 2024, Synaffix <u>collaborated</u> with BigHat Biosciences on the development of machine learning-enabled ADC. This collaboration showcases how drug developers can leverage a fully integrated range of services within our Biologics division.

**Financial Performance in Full-Year 2024** Comparison vs. Prior Year







Personal Perspective

Jean-Christophe Hyvert President, Biologics Division

2024 was a year of focused and strategic growth for our Biologics business. As integrated service offerings become increasingly important, Lonza remains at the forefront of this trend. We successfully completed the acquisition of our largescale manufacturing facility in Vacaville from Roche, significantly enhancing our manufacturing capacity to continue to serve commercial customers and support the development of new molecules.

<sup>1</sup> Sales growth at Constant Exchange Rates (CER).

<sup>2</sup> Sales growth at Constant Exchange Rates (CER), adjusted for COVID-related mRNA business.

## Expanding Collaboration through Integrated Service Offering

Early in 2024, we signed a collaboration <u>agreement</u> with Acumen Pharmaceuticals to manufacture their novel therapeutic sabirnetug for the treatment of Alzheimer's Disease (AD). Sabirnetug targets toxic soluble amyloid beta oligomers, a primary cause of AD, and is the first of its kind in clinical development. Our new, next-generation single-use manufacturing facility in Portsmouth (US) will support the production of sabirnetug, potentially bringing new treatment options to patients suffering from AD. In line with our strategy to offer an integrated end-to-end offering for biologics manufacturing, we <u>extended</u> the successful relationship with Acumen later in 2024 to enable the commercial launch of sabirnetug. The extension will provide drug product manufacturing services for early phase and potential commercial supply from our Visp (CH) site.

# Innovation Spotlight

### Intensified Bioprocessing Using Advanced Digital and Process Analytical Technologies

To bring innovative solutions to our customers and their patients, we continue to focus on leveraging our expertise and experience across multiple areas and modalities. A key innovation focus area in 2024 was the development of novel mammalian expression platforms and bioprocessing technologies to significantly increase productivity and improve process robustness for our clinical and commercial customers.

We have developed and implemented technologies across several clinical and commercial assets to intensify biomanufacturing and significantly increase product titers. When combined with innovative purification technologies, these high titers result in very high-yielding processes. In addition, we have successfully developed and implemented several in-line testing process analytical technologies (PATs), which allow us to improve process robustness through machine learning (ML) and automation.

As part of our digital initiatives, optimizing the use of ML technologies to meet the needs of the business has also been a key research focus. We have developed several machine learning algorithms which have allowed us to advance our mammalian expression and bioprocessing platforms. Such tools have been applied to improve both the speed and predictability of our cell line construction offering.

The new intensified processes, supported by ML-based analysis and selection tools, will help our customers deliver innovative therapeutics that address unmet patient needs.



### **Our Global Development and Manufacturing Footprint**

# **Small Molecules**

>205 re-clinical and clinical small molecules<sup>1</sup>

>125

commercial small molecules<sup>1</sup>

<sup>1</sup> Including active pharmaceutical ingredients (API), highly potent API (HPAPI),

dosage form and delivery systems and particle engineering. <sup>2</sup> Our new organizational structure, announced in December 2024, will become operational on 1 April 2025 with three integrated business platforms: Integrated Biologics, Advanced Synthesis and Specialized Modalities. Capsules & Health Ingredients, which we plan to exit at the appropriate time, will operate as an independent business platform

Our Small Molecules division<sup>2</sup> supports customers throughout their journey from clinical development to commercialization, across drug substance and drug product. We provide contract development and manufacturing services for customers including large pharmaceutical and small biotech companies.

### Market Trends

Small molecules remain an attractive and growing market, with 54% of all molecules in clinical development comprising of small molecules (approximately 9,000 molecules)<sup>3</sup>. The small molecules clinical market experienced 28% growth<sup>4</sup> between 2018 and 2023, and we anticipate this trend to accelerate further over the next five years.

In 2024, the outsourced small molecules market was valued at USD 75 billion<sup>5</sup> and we estimate that this market will grow at 6 to 7% per year through to 2029<sup>6</sup>. 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, oncology, Central Nervous System (CNS) and endocrine (in particular diabetes and weight loss). Thirty percent<sup>7</sup> of small molecules New Molecular Entities (NME) approvals by the U.S. Food and Drug Administration (FDA) are targeted towards oncology, a

<sup>5</sup> Source: Small Molecule CMO/CDMO Market Outlook from 2024 to 2034. <sup>5</sup> Source: S nall Molecule Contract Manufacturing: CDMO Market Ove

<sup>9</sup> Source: Citeline, Pharmacircle 2024

disease area estimated to sustain double-digit sales revenue growth per year through to 20298. Small molecules account for more than 60%<sup>7</sup> of FDA NME approvals, of which approximately 80%<sup>9</sup> are administered orally.

The required toxicity of products to 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. To support these timelines, our quality system and regulatory experts can support customer filings. This is a particularly important service for small companies who may not have in-house capabilities.

### **Our Offering**

We focus on helping customers develop and manufacture innovative small molecules. Over the last 40 years, we have built a leading reputation in this space, supported by our commitment to science, technology and delivery.



▲ Particle Engineering development and manufacturing

We work in close partnership with our customers, helping them In Drug Substance, we continue to build on our existing to address challenges and support molecule progression through capabilities in developing and manufacturing highly potent small clinical stages. Our team of experts supports development molecules, especially the payload and linker manufacturing of throughout the product lifecycle, from pre-clinical stages antibody-drug conjugate (ADC) products. These represent a through to commercialization. Entry points in this lifecycle particularly attractive market segment within the HPAPI category. can vary from early clinical development to late-phase or commercial supply. Candidates in the small molecules pipeline are increasingly

complex and are often accompanied by a decrease in Our Small Molecules services can broadly be split into three bioavailability due to their limited solubility. We help customers categories: Drug Substance, Drug Product and Particle to address these challenges through a portfolio of bioavailability Engineering, which forms a bridge between Drug Substance enhancement technologies, phase-appropriate and proprietary and Drug Product. processing equipment, and drug delivery capabilities. Our site in Bend (US) specializes in improving bioavailability, leveraging Our Drug Substance services relate to the development and our scientific expertise and spray-dried dispersion technology.

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

In 2024, our Small Molecules division reported sales growth of 9.3% CER compared to the prior year at a strong CORE EBITDA margin of 35.7%, driven by high commercial demand, strong Our current portfolio includes more than 125 commercial operational performance and the division's continued portfolio programs and more than 205 pre-clinical and clinical programs. shift to high-value products and complex service offerings. These are delivered by a global asset network capable of The division signed the highest number of new customers and supplying a range of volumes to meet both clinical and programs compared to previous years. Furthermore, three commercial demand. Our ability to provide integrated supply drug products manufactured by the business received FDA chains for products, within or across divisions, is a compelling approval in 2024, and the batch success rate in commercial customer offering that simplifies ways of working. manufacturing exceeded 99%.

Drug Substance development and manufacturing

### 2024 Highlights

<sup>&</sup>lt;sup>3</sup> Source: Citeline, pre-clinical excluded,

<sup>&</sup>lt;sup>4</sup> Source: Citeline

urce; Lonza internal analysis, FDA, Evaluate Pharma.

<sup>7</sup> Source: Intern multi-year Analyses of FDA NME Approvals. <sup>8</sup> Source: EP 2024.



### **Our Portfolio of Services**



**Financial Performance in Full-Year 2024** Comparison vs. Prior Year



**351**m +20.6% CORE EBITDA (CHF)



Looking ahead, we will continue our focus on being a strong development and manufacturing partner to support our Building on more than 20 years of experience in the spraycustomers during the entire lifecycle of their products. This drying of biologics, such as monoclonal antibodies (mAbs), includes introducing new offerings and expanding our capacity oligonucleotides and peptides, we now offer spray-drying of to meet evolving needs. biologics for clinical supply and beyond.

### **Developing New Offerings**

In 2024, we launched two new market offerings: Al-enabled In 2024, we continued to invest in adapting our capabilities route scouting, and spray-dried biologics for pulmonary delivery. and commercial offerings in line with market needs. We Together with the Physiology Based Pharmacokinetics and augmented this with additional capacity to meet sustained Solid Form Services offerings, these new advances further customer demand, particularly in relation to complex molecules and HPAPIs. strengthen our positioning as a strong development partner, accelerating growth in our early-phase pipeline.

### **AI-Enabled Route Scouting Service**

To support our customers in advancing their therapeutic candidates, our Bend (US) site is globally recognized for Active pharmaceutical ingredients (API) synthesis is becoming its expertise in improving bioavailability, a critical factor in increasingly complex and lengthy, often requiring more than addressing the poor solubility of many small molecule drugs. 20 synthetic steps. We have implemented an Al-driven solution We continue to invest in this area and have the Bend site in that accelerates this process. Our new Al-enabled route 2024 by adding new clinical bottling and labelling capabilities scouting service provides customers with synthetic pathways for tablets and powder-filled capsules. In addition, we expanded that are more resilient from a supply chain perspective and the site to include clinical manufacturing of spray-dried protein formulations for pulmonary delivery, aligning with growing offer insights into optimal route design for both clinical and commercial manufacturing. industry trends.

Personal Highlight

Gordon Bates President, Small Molecules Division

We remain committed to being a strong development partner driven by science. In response to positive market dynamics, and listening to our clients' needs, we are planning for future growth by strengthening our early-phase offerings, and investing in additional development and manufacturing capacity to be present throughout the full product lifecycle.

### Spray-Dried Biologics for Pulmonary Delivery

### **Expanding Capabilities**

# Innovation Spotlight

### Leveraging Modern Tools to Optimize Process Chemistry

Staying competitive in the CDMO space requires ongoing investment and continuous improvement, with a strong focus on advancing digitalization in the development and manufacture of therapeutic drugs. Our Small Molecules division is focused on addressing the increasing complexity of small moleculebased drug candidates. A key piece of this puzzle is that the intricate structures of modern drug candidates require multiple synthetic steps to produce them. To address this growing challenge, we are utilizing Al-enabled route scouting to identify chemically feasible synthetic pathways that can be optimized for performance, efficiency and manufacturability.

The growing complexity of APIs also presents challenges in identifying the optimal synthetic conditions for a given reaction step. Once our experts have identified the best synthetic route for a molecule, we implement high-throughput experimentation (HTE) to address this. HTE enables researchers to accelerate development by running multiple reactions in parallel – and allows for the rapid testing of a broad spectrum of reagents, solvents, catalysts, and conditions. This approach helps identify optimal reaction conditions early in the project, reducing the number of experiments and reagents needed, thereby lowering the cost of goods and shortening timelines.

By combining AI tools and HTE, we can rapidly assess and optimize promising synthetic routes, which leads to accelerated process development for API synthesis. At our Visp (CH) site, we utilize a dedicated robotics system with broad and phase-appropriate experimentation capabilities, which can be implemented 24/7 across a full spectrum of potential reaction conditions.



**Our Businesses** 



Taxol

## Cell & Gene

25

years of cell and gene cGMP manufacturing experience

>250 process development projects

active therapies supported by Bioscience<sup>1</sup>

commercial batches delivered by our CGT CDMO network

<sup>1</sup> Third party therapies (excluding Lonza manufactured drugs). <sup>2</sup> Our new organizational structure, announced in December 2024, will become operational on 1 April 2025 with three integrated business platforms: Integrated Biologics, Advanced Synthesis and Specialized Modalities. Capsules & Health Ingredients, which we plan to exit at the appropriate time, will operate as an independent business platform

### Market Trends

Cell and gene therapies are rapidly evolving from innovative concepts into commercially viable treatments, as evidenced by nine Food and Drug Administration (FDA) cell therapy initial approvals in 2024. This upward trend is projected to continue, with numerous additional therapies expected to reach the market in the coming years.<sup>3</sup> Venture capital funding in the cell and gene therapy (CGT) field has stabilized to pre-pandemic levels<sup>3</sup>, and this is particularly benefiting companies with latestage products by supporting their clinical trial advancements. Concurrently, the cell and gene Contract Development and Manufacturing Organization (CDMO) market is anticipated to grow at an annual rate of 12%<sup>4</sup> over the next five years, driven by increasing demand for specialized manufacturing services and a robust pipeline of therapies.

To navigate regulatory complexities and manage financial constraints, many companies are turning to outsourcing. Cell and gene CDMOs such as Lonza play a pivotal role by providing regulatory expertise and scalable, cost-effective manufacturing solutions. This collaboration enables companies to concentrate on innovation, while relying on CDMOs to manage production and related compliance at clinical and commercial scales, to unlock the full potential of cell and gene therapies.

<sup>3</sup> Source: Alliance for Regenerative Medicine

<sup>4</sup> Souce: Lonza internal analysis

# industrialize their therapies.

**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, small molecules and cell and gene markets. The Personalized Medicine business unit focuses on the Cocoon® Platform, with the aim of revolutionizing cell therapy manufacturing through automation.

Our Cell & Gene division<sup>2</sup> provides comprehensive solutions

that facilitate the accelerated development, manufacturing

and commercialization of life-changing treatments. We also

offer tools and technologies that help enable cell and gene,

biologics and small molecule innovators to develop, de-risk and

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 founded on the quality, expertise and trust in our experience and track record. Over the last 25 years, we have established a leading position in contract development and manufacturing for cell and gene therapies. Our expertise spans a wide range of modalities across cell and gene, including exosomes-based therapies, iPSCs, MSCs, NKs and other allogeneic cell therapies, autologous CAR-T, TIL, HSC, TCR, T-reg gene therapies, and viral vectors including AAVs and LVVs among others. From process development to commercial manufacturing, our offering is one of the most complete and integrated in a highly fragmented industry.

### **Our Global Development and Manufacturing Footprint**



<sup>1</sup> The exosome asset will be transferred to Houston in 2025. <sup>2</sup> Facility owned and operated by Nikon Cell innovation Co. Ltd. under Nikon-Lonza partnership.

In 2024, we expanded our portfolio of commercial cell and gene Cell Culture Medium to support the growth and expansion of therapies and continue to be a trusted partner in supporting gamma delta ( $\gamma\delta$ ) T cells. These cells possess a unique capability late-stage clinical and commercial cell and gene products in to infiltrate solid tumors. By optimizing their expansion at clinical the industry. As of 2024, we manufacture the viral vector, cell scale, we offer a solution with the potential to revolutionize solid therapy or gene therapy for five commercial cell and gene therapy tumor drug development, paving the path for a healthier world. products in three continents: the United States, Europe and Asia. Our network of CGT manufacturing sites also completed Personalized Medicines The end-to-end process for the production of a cell therapy can a combined total of seven Pre-Licensing Inspections (PLI) and Pre-Approval Inspections (PAIs). be long and involves complex supply chain logistics and manual

manufacturing processes. At present, it can take four to six While expanding our portfolio of commercial products, we also weeks between collecting the cells and infusing the treatment launched a range of key offerings focused on the development back to the waiting patient. Furthermore, most of the current and manufacturing services to enable our customers' next manufacturing solutions are not sufficiently scalable to meet milestones: Investigational New Drug (IND) filing, tech transfer patient demand as cell therapies are approved for earlier lines and commercialization planning. of treatment or for more prevalent indications.

**Bioscience** Designed to address many of these challenges, our Cocoon® Platform is a functionally closed, highly flexible and scalable Our Bioscience business unit has a strong portfolio of products and services that support the growth of the biologics, small autologous cell manufacturing solution. The platform enables molecule and cell and gene markets. Our customers value decentralized manufacturing models that have the potential to our improved reliability, reduced variability, ease of use, high reduce vein-to-vein times, deliver fresh cells, improve physician performance and cost efficiency. Our expertise in primary control and enhance patient experience. It is highly automated, human cell biology tools help enable customers to develop which can help reduce both the costs associated with manual more predictive models and accelerate the path to IND. Our intervention and the risks associated with human error. It is Bioscience products and services range from cell culture and also scalable, as multiple instruments may be connected in the discovery technologies for research to cell culture medium, future, enabling the ability to save significant clean room space. guality control tests and software for biomanufacturing.

To date, we have installed more than 150 Cocoon<sup>®</sup> Instruments. and we work with more than 30 customers.

### Annual Report 2024



### 2024 Highlights

In 2024, we announced a long-term commercial supply agreement with Vertex for CASGEVY<sup>®</sup>. CASGEVY<sup>®</sup> is the first approved gene-In 2024, our Cell & Gene division reported sales growth of 1.1% CER compared to the prior year. This was driven by strong edited therapy using CRISPR/Cas-9, a Nobel-Prize winning gene operational performance in Cell & Gene Technologies and editing technology. This groundbreaking therapy offers a onepartially offset by softer performance in Bioscience. Compared time treatment option for patients with transfusion-dependent to 2023, the division significantly improved its CORE EBITDA beta-thalassemia or sickle cell disease, representing a significant margin, supported by Cell & Gene Technologies achieving advancement for patients. CASGEVY® will be manufactured positive margins and productivity measures in Bioscience. at our cGMP cell therapy facilities in Geleen (NL), with plans The business' long-term portfolio continued to shift towards to expand to our Portsmouth (US) site. Our Geleen site was increased commercial manufacturing. granted a GMP license by the FDA, the European Medicines Agency (EMA) and the UK Medicines and Healthcare Products Regulatory Agency (MHRA).

### Financial Performance in Full-Year 2024

Comparison vs. Prior Year



**108m** +58.8% (CHF)



## Personal Highlight

Daniel Palmacci President, Cell & Gene Division

> We have seen continued customer interest in our commercial offering within Cell & Gene, highlighted by our long-term supply agreement with Vertex to manufacture CASGEVY® for sickle cell disease and beta-thalassemia. Such agreements reflect our ambition to expand our portfolio of commercial products, with more additions expected in the mid-term.

### **Clinical and Commercial Programs**

We also entered into an agreement with Cabaletta Bio focused on the development and tech transfer of potentially curative targeted cell therapies for patients with autoimmune diseases. Under the terms of the agreement, we will supply Good Manufacturing Practices (GMP) products to support Cabaletta's current and planned clinical trials for resecabtagene autoleucel (rese-cel), including potential late-stage trials and preparations for commercial readiness.



### Annual Report 2024

Furthermore, in 2024, we placed a strong emphasis on delivering attractive and competitive solutions tailored to early-stage cell and gene therapy developers. We launched the "Early Advantage" range of standard bench-to-IND offerings, providing customers with pre-defined terms, accelerated timelines and a legal framework, designed to help them achieve their milestones efficiently. This offering has resonated strongly with the market, attracting a significant number of new customers.

### **Bioscience**

To meet the growing demand for endotoxin assay products, we commenced an expansion of our endotoxin assay production facility in Walkersville (US). The site manufactures the materials required to execute the endotoxin assay, which is used to help ensure the safety and compliance of parenteral drugs and medical devices. The upgraded facility will incorporate sustainable technologies and streamline manufacturing processes, reflecting our continued drive for operational excellence.

Our Cologne (DE) site manufactures Nucleofector® transfection technology utilized in the research, development, and manufacturing of novel therapeutics. To meet growth expectations, the site has expanded to a new facility to modernize and increase manufacturing capacity, streamline production and logistics processes and improve our throughput.

We are committed to providing the expertise and tools to support customer needs. Our MODA-ES® Platform, a next-generation manufacturing execution system for cell and gene therapies, enables a cost-effective transition to electronic record-keeping. The Champalimaud Foundation has <u>adopted</u> the platform to enhance and streamline cell therapy manufacturing, helping to make life-saving treatments more accessible for cancer patients with unmet medical needs.

# Innovation Spotlight

### Industrializing Viral Vector-Based Therapies through Advanced Platforms and Products

Viral vectors are among the most efficient methods of therapeutic gene transfer and have been used to treat a wide range of acute and chronic conditions. The field has recently undergone unprecedented growth and by the end of 2024, seven Adeno-associated virus (AAV) therapies were approved by the U.S. Food and Drug Administration (FDA) with approximately 600 further therapies in the development pipeline.

Patient access to these transformative therapies is currently limited by barriers including manufacturing scale, cost and process robustness. To help address this, we are driving the industrialization of AAV manufacturing through innovation in media, analytics, and platform processes.

Our Xcite<sup>®</sup> AAV transient transfection platform provides industry-leading productivity, quality and speed to clinic by leveraging proprietary cell line and plasmid engineering technologies. Our next-generation products in development are designed to significantly increase the scalability and robustness of AAV manufacturing while substantially reducing costs. These include a helper virus-free stable producer cell line platform, and a medium and enhancer for HEK293 cells.

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**Our Businesses** 



### **Our Global Development and Manufacturing Footprint**

# **Capsules & Health** Ingredients



years of capsule manufacturing experience product offerings

Net Promoter Score<sup>1</sup>

<sup>1</sup> The Net Promoter Score (NPS) is a metric used to measure customer loyalty and satisfaction with a company's products or services. In the B2B life sciences industry, benchmarks typically range between 40 and 45 (Source: Medalli

<sup>2</sup> Our new organizational structure, announced in December 2024, will become operational on 1 April 2025 in Q2 2025 with three integrated business platforms Integrated Biologics, Advanced Synthesis and Specialized Modalities, Capsules & Health Ingredients, which we plan to exit at the appropriate time, will operate as an independent business platform

Our Capsules & Health Ingredients (CHI) division<sup>2</sup> offers highguality capsules and encapsulation technologies 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 typically acyclic, with high qualification and registration requirements. Recently, Western markets have experienced an unprecedented post-COVID-19 destocking period, which is expected to ease in 2025. Pharmaceutical companies regularly look to strengthen supply chains of key materials, manage increasingly tight compliance standards, and innovate with dosage form functionality. Here, we support customers by addressing drug development and ingredient formulation challenges, as well as offering partnerships throughout the complex pharmaceutical development process. In particular, the launch of our Innovaform<sup>™</sup> development center enables cutting edge capsule-based formulation innovations together with our market-leading customers.

For the **nutraceutical market**, we anticipate slightly higher growth in hard empty capsules compared with the pharmaceutical market, as the period of post-COVID destocking has come to an end. The market looks set to strengthen in the longer term, driven by consumers' increasing focus on a proactive approach to health management and longevity. We deliver tailored endto-end product development and contract manufacturing services through our Dosage Form Solutions (DFS) business. This enables us to bring concepts to reality, in some cases as quickly as a matter of weeks, allowing us to capture the rapid changes in consumer nutrition market trends.

Both the pharmaceutical and nutraceutical markets are projected to grow at around 2 to 3% per year in the next five years<sup>3</sup>.



<sup>1</sup> To be decommissioned in 2025

### **Our Offering**

Our CHI division is well-placed to increase its presence in both the pharmaceutical and nutraceutical segments, with strong Our DFS business builds upon our strong capsule expertise and customer service, alongside manufacturing and automation provides our nutraceutical customers with an expert end-toexpertise delivered by multi-disciplinary teams that are skilled end contract manufacturing service. We support dosage forms in delivering customized solutions from discovery and concept ranging from simple liquid formulations using our proprietary to commercialization. We also provide a portfolio of capsule liquid sealing technology, to complex multi-dose and timedfilling equipment and supporting technical services to meet release systems. Our DFS program has been supported by our customers' fill and finish needs. The division is comprised capacity expansions across our network to further improve of three core businesses. speed-to-market. Alongside our formulation and encapsulation expertise, we also support our customers by co-creating finished Hard Empty Capsules products and providing product branding support.

We offer a wide range of gelatin and plant-based Capsugel® **Active Lifestyle Health Ingredients** capsule options with a variety of release profiles and encapsulation technologies. These are designed to meet evolving technical We provide multiple science-backed health ingredients for and regulatory requirements and market demands, such as the growing active lifestyle market. Our offering includes vegetarian, vegan, organic and clean-label solutions. We have products that support healthy human nutrition, targeting global the largest global capsule manufacturing capacity in the world, consumer trends including joint health, muscular strength, with the capability to produce billions of capsules per year across energy, endurance and weight management. Our portfolio our global production network. We supply customers in every includes premium brands such as UC-II<sup>®</sup> undenatured type major geographical region with standard and customizable Il collagen for joint health, Carnipure<sup>®</sup> L-carnitine for energy, capsules. In addition, we provide novel and functional capsules and a range of other branded products targeting immune and for increasingly complex and sensitive therapeutic requirements. digestive health.

<sup>3</sup> Capacity utilization figures from 2019, based on recent Kline & Co (Q4 2022) and Ascendant Mfr (Q2 2023) interviews.

### **Innovative Dosage Form Solutions**

### 2024 Highlights

In 2024, our Capsules & Health Ingredients division continued to maintain its leading position in Hard Empty Capsules (HEC), Dosage Form Solutions, and Health Ingredients in a challenging market environment. The HEC market has recovered at a slower than expected pace, while the pharmaceutical HEC market correction has been deeper and longer than anticipated. As a result, over the past couple of years, we have focused on optimizing our cost position in the short term through operational excellence in manufacturing, which has led to improved efficiencies, and cost-saving initiatives across all functions and regions. These efforts have partially offset the margin pressures caused by lower industry utilization.

In this context, we have taken further measures to optimize our production network, including the planned decommissioning of the Jakarta (ID) site in mid-2025, the closure of production lines at our capsule plants in Western markets, and targeted capital investments to <u>expand</u> production capacity with additional lines in China and India.

Furthermore, in 2024, we invested significantly into the longterm competitiveness of our business. We saw a positive early impact of our newly-introduced superior proprietary D90 capsule manufacturing technology.

### **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 first full production line became operational in Q1 2024. This new technology has increased individual line capacity by 15% while concurrently reducing weight and dimensional variability. It is also reducing our net carbon footprint and establishing a new product quality standard. Following the successful installation of the first line, we have initiated the roll out of this new technology across our manufacturing network, which will take several years.

### **Product Innovation**

Our commitment to product innovation was recognized by The This year marks the launch of the Innovaform<sup>™</sup> Accelerator Medicine Maker's 2023 Innovation Award. Our next-generation center at our Colmar (FR) site, designed to co-innovate with enteric capsule, Enprotect<sup>®</sup>, was the recipient of this award, pharmaceutical customers on formulation and encapsulation highlighting its cutting-edge design aimed at enhancing drug solutions. This new facility serves as a Center of Excellence to delivery for acid-sensitive active pharmaceutical ingredients. support the development of innovative drug delivery for oral and pulmonary administration, addressing challenges such as Building on this innovative technology, we have introduced the solubility and bioavailability in active pharmaceutical ingredients (APIs). It provides expertise and technology platforms for small molecules, peptide proteins, and nucleic acid-based therapies. This initiative aims to accelerate drug development timelines for our customers and reduce scale-up and manufacturing costs.

Building on this innovative technology, we have introduced the <u>Capsugel® Enprotect® size 9 capsule</u>, aimed at accelerating the pre-clinical development of acid-sensitive APIs. This smaller capsule format supports rodent studies and expedites the drug development process by enabling earlier, more accurate pre-clinical testing. The technology eliminates the need for additional coating and helps to ensure consistent API release in the small intestine while simplifying formulation and manufacturing. This innovation is expected to improve drug testing efficiency and enhance first-in-human timelines.

**Financial Performance in Full-Year 2024** Comparison vs. Prior Year





## Personal Highlight

### Christian Seufert

President, Capsules & Health Ingredients (CHI) Division

During 2024, we remained committed to delivering customer value while strengthening our overall cost competitiveness. In the short term, we implemented rigorous cost management across all sites and functions. For the long term, we advanced the deployment of our new proprietary hard empty capsule manufacturing D90 technology, delivering a significant improvement in quality standards, productivity and carbon footprint.

<sup>1</sup> Sales growth at Constant Exchange Rates (CER).

### Service Innovation

Furthermore, we <u>expanded</u> our service offering for orally delivered biologic therapies to support the unique development and manufacturing needs of smart capsules companies. The service offering leverages customized Capsugel<sup>®</sup> Enprotect<sup>®</sup> capsules using bi-layer manufacturing technology and it will be offered exclusively from the recently launched Innovaform<sup>™</sup> Accelerator in Colmar (FR).

# Innovation Spotlight

## Driving the Development of Customized Capsules for Targeted Release

Patients continue to favor oral administration of active pharmaceutical ingredients (APIs), but formulating such products is hindered by challenges related to the solubility and bioavailability of new APIs entering the development pipeline. We have been working on addressing these challenges by advancing innovative capsule delivery solutions.

In 2024, we launched the Innovaform<sup>™</sup> Accelerator, a new offering targeting dosage form and delivery challenges of small molecules, oral peptides, proteins, monoclonal antibodies and nucleic acid-based therapeutics. By co-innovating with developers, we aim to optimize the effectiveness of their APIs and improve manufacturing efficiency. The offering provides services for adapting formulation, capsules and encapsulation strategies to create the ideal delivery vehicle for each API.

The Innovaform<sup>™</sup> Accelerator supports the development and testing of delivery solutions based on Capsugel<sup>®</sup> Enprotect<sup>®</sup>. This technology platform was recently expanded to include a Size 9 capsule that addresses challenges faced in preclinical drug development. Specifically, this new small capsule supports the administration of actives and formulations to animal models, particularly rodents, to evaluate their effects in vivo. Conventional methods of oral administration present challenges, such as inconsistent dosing, poor drug absorption, and the risk of drug degradation in the gastrointestinal tract. Capsugel<sup>®</sup> Enprotect<sup>®</sup> Size 9 addresses these challenges by reducing the risk of dosing errors and ensuring consistency across experimental groups, improving the reliability and reproducibility of pre-clinical studies.



Our Businesses

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