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Our Offerings

We are the preferred global partner to the pharmaceutical, biotech and nutrition markets. We enable a healthier world by supporting our customers on the path to commercialization. Combining technological insight with world-class manufacturing, scientific expertise and process excellence, we help our customers deliver new and innovative medicines that help treat a wide range of diseases.

We cover a broad portfolio of services within the biopharma industry. Our capabilities span biologics, small molecules (including highly potent active pharmaceutical ingredients such as cytotoxins), bioconjugates and cell and gene therapy. We support projects from research, discovery and pre-clinical stages, through clinical trials to commercialization and our expertise extends across both drug substance and drug product. We also offer innovative capsules, dosage form solutions and health ingredients for pharmaceutical and nutraceutical companies.

Innovation in 2021

Continuous innovation is one of the defining characteristics of the pharmaceutical industry that helps patients to live healthier lives. As a contract development and manufacturing organization (CDMO), we provide technological solutions for a large variety of customer needs during the different stages of drug discovery and manufacturing.

Research & Development (R&D) represents a vital tool to ensure future success. It provides technological competence, a profound understanding of unmet medical and customer needs, and long-term insight necessary for strategic decisions and investments. Combined with our extensive development and manufacturing experience and knowledge of industry trends, our offering addresses unique challenges related to production, characterization, formulation and speed.

Our R&D focus areas often overlap and create strong synergies, leading to transformational cross-divisional projects impacting our business and the wider industry. Our key innovation projects are summarized below.

Winning the Molecular Lottery - Solving the Pairing Challenge of Bispecific Antibodies

Therapeutic antibodies entering the clinic are constantly growing in number and complexity. Since they can simultaneously bind two different antigens, bispecific antibodies can provide access to new mechanisms of action that are not accessible with traditional monoclonal antibodies.

However, it is a significant challenge to ensure correct heterodimerization (the correct pairing between the heavy and light chains) during the manufacturing of bispecific antibodies. Our proprietary bispecific platform technology provides a solution to this problem through the elimination of the native

disulfide bond between the heavy and light chain of one of the bispecific arms. It is replaced by a newly engineered disulfide bridge, thereby allowing only correct heterodimerization to occur.

With an average of 30 bispecific antibodies entering the clinic every year, our solution for producing bispecific antibodies ensures better manufacturability and clinical profile. This increases manufacturing efficiency, as well as easing downstream processing and purification.

Developing Therapies for Local Pulmonary Delivery

Monoclonal antibody (mAb) formulations are becoming more popular as a select therapy for various lung indications, including lung cancer, asthma and lung infections. However, the administration routes of these antibodies remain limited, with the majority being administered parenterally. Our R&D teams across our Small Molecules, Biologics, and Capsules & Health Ingredients divisions have opened the door to the possibility of better outcomes for patients with non-small cell lung cancer by developing a spray-dried formulation for inhalation.

The team developed a method for stabilizing the mAb in a solid-state by utilizing inhalation-friendly excipients. The particle engineering and formulation conditions were optimized to preserve the activity of the mAb while allowing for the production of particles appropriate for inhaled delivery.

As a result, the mAb is delivered through a dry-powder inhaler utilizing Capsugel® Vcaps® Plus capsules to patients in lower dosages with fewer side effects. This self-administration system can potentially result in better compliance and improved outcomes. Additionally, this spray-dried inhalation platform has the potential for positive impacts on other diseases such as asthma, chronic obstructive pulmonary disease (COPD), lung infections and other lung cancers.

The spray-dried project demonstrates how we bring a unique combination of science, technology, creativity and commitment to our projects while leveraging expertise and a global network across our organization.

Unleashing the Power of Exosomes

Exosomes are extracellular vesicles with a diameter of 30-150 nanometers that can carry various cargo, including proteins, small molecules, DNA, RNA, metabolites, and lipids. These vesicles, naturally released by cells into their surrounding fluid, can be selectively taken up by neighboring cells without eliciting an immune response. As such, these extracellular vesicles are rapidly emerging as a novel therapeutic platform.

However, the manufacturing process is not yet clearly defined. This is impacting the industry's ability to develop scalable solutions that would unlock the full potential of exosomes. The major challenges of the manufacturing process lie in the characterization and control. In general, isolation and purification have proved to be challenging due to issues with separating exosomes from other extracellular vesicles and particulate impurities.

We are pioneering in this field as the first company to build out CDMO capability for supporting exosome-based therapeutics. In addition, our R&D team developed a complete set of measurement tools that enable upstream and downstream process development, quality assessment and control, and product characterization. Along with other dedicated analytical techniques being developed, the toolbox includes a novel single exosome analysis using nanoscale flow cytometry to analyse exosome products at a very high resolution. This novel approach significantly improves the process and helps ensure pure populations of exosomes. This new method enables faster development for exosome-based therapies as they progress through clinical trials.

Providing Earlier Support for Antibody Drug Conjugates (ADCs)

ADCs are complex bioconjugates typically used as chemotherapy, allowing the selective delivery of a potent cytotoxic agent into a tumor. These bioconjugates comprise three molecular components: a mAb, a potent cytotoxic agent and a linker connecting the other two components.

This rapidly growing therapeutic platform benefits from an increasing diversity of bioconjugation technology. There are currently more than 500 bioconjugate molecules in the market, with ADCs representing more than 41% of the entire bioconjugate pipeline. Most of these ADC molecules are still in the discovery and early clinical phases, which means that these projects could potentially greatly benefit from early de-risking and developability assessments to ensure better outcomes during the proceeding manufacturing stages.

We have created a selected range of scalable state-of-the-art technologies that enable rapid expression of proteins and allow for scalable next-generation bioconjugates development. Recently, we have implemented a new offering which combines our expertise and external technologies to support customers in the pre-clinical stage to define bioconjugates lead candidates. These additional early development services provide a better knowledge base for bioconjugate architecture and technology selection, as well as lead selection and optimization.

Personal Perspective

Stefan Stoffel

Head, Group Operations

During 2021, we successfully implemented our new organizational structure with a clear focus on driving value across divisions, while leveraging synergies and establishing best practices and global standards.

Despite continuing global supply disruptions arising from the COVID-19 pandemic, we successfully delivered an unprecedented

portfolio of growth projects. In addition, we continued to fast-track and scale up the production of COVID-19 vaccines, to support the fight against the ongoing pandemic.

While we anticipate that delivery and distribution issues will continue in 2022, we expect to continue to manage the impact, as long as conditions remain comparable with the last two years. At the same time, we should ensure our internal processes keep up with the overall growth of the business. Therefore, we are embedding Lean working practices across the organization to drive agility and efficiency and achieve a more streamlined approach to delivery. This will enable us even better to meet our customer needs and expectations. Working in close alignment with our divisions and external suppliers while staying focused on implementing key strategic priorities will help us to achieve our goals.

Our top priority for 2022 is to improve the delivery of our large portfolio of growth projects and to secure supply continuity. We have introduced several programs to ensure that we maintain a competitive advantage in the coming years, as a strategic partner to the healthcare industry.



Biologics

>515¹

Pre-clinical and Clinical
Large Molecules

>50¹

Commercial
Large Molecules

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

We continue to increase our presence across geographies to strengthen our integrated, end-to-end approach further. We offer manufacturing services for clinical and commercial material across our sites globally, from small-scale (1,000–2,000L) through mid-scale (3,000L and 6,000L) to large-scale (10,000L, 15,000L and 20,000L). We leverage our expertise in stainless steel, single-use and hybrid technologies to help de-risk the path to market for our customers.

Market Trends

The biopharmaceutical market has continued to develop favorably in 2021 and sales are expected to grow in the region of 11% (CAGR 2021 – 2026) across modalities¹. The associated increase in demand for outsourcing has led to healthy and sustained growth in the Biologics CDMO market, with a current forecast of 11 to 13% compound annual growth over the next four years².

This market evolution is being driven by a series of trends including growth in the molecule pipeline as well as new molecular formats and modalities often emerging from small, well-funded biotech. Expedited reviews and the need for speed to market have been pushed even further by the pandemic, combined with an increased focus on supply chain redundancy and preference for domestic development and manufacturing.

The high number of molecules being developed by small and virtual biotech companies is reflected in Lonza's biologics customer base with around three-quarters representing this group of companies. Smaller companies may not want to build in-house manufacturing capacity or the full range of expertise to bring their candidates to market and choose to outsource a broad range of activities from early-phase *in silico* optimization to formulation of the final drug product.

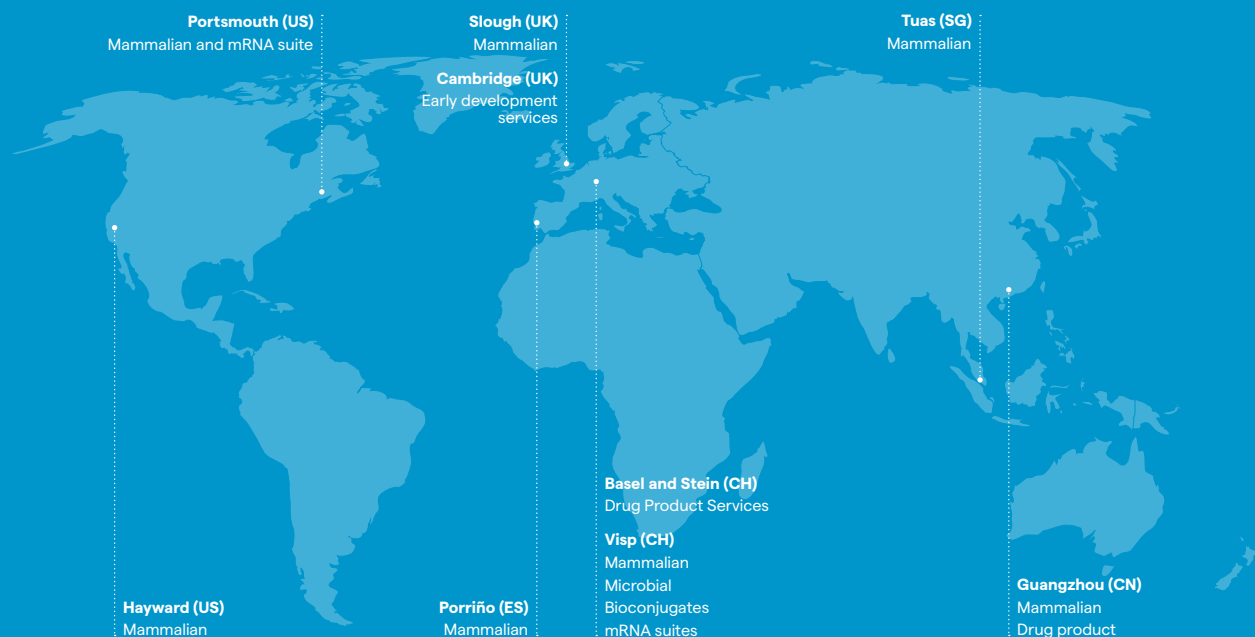
The emergence of novel therapies to target unmet medical needs is changing the product landscape. Increasing molecular complexity is creating demand for in-depth expertise in development and manufacturing services along with the technology to enable sustainable expression and scale up of new molecular formats. Platform technologies for bioconjugation or expression of bispecific antibodies for example can significantly accelerate development and production timelines and experienced CDMOs that can help customers accelerate time to market and de-risk investment are in demand.

¹ EvaluatePharma (2021)

² 2020-2025 CAGR in USD; Source: Frost & Sullivan (2021), Lonza internal analysis

³ Pharmaprojects (August 2021)

Our Global Development and Manufacturing Footprint



The development of mRNA vaccines and subsequent manufacturing at a global scale to respond to the COVID-19 pandemic represents a leap forward in Biologics development. Currently, there are around 220 mRNA candidates in development³ and nucleotide-based therapies and vaccines are expected to grow at 62% CAGR (2021-2026)¹. The pandemic has focused CDMO activity on rapid scale up of production for commercial supply but the demand for outsourced early-phase development services and technology is growing in line with this new generation of molecules.

Our Offerings

We are a leading contract development and manufacturing partner for biopharmaceuticals, serving our customers throughout their product lifecycle, from preclinical development, through trials, to launch and market supply. We partner with customers of all sizes, from start-ups to large biotechs and major pharmaceutical companies.

We have one of the most complete and flexible CDMO portfolios in the Biologics industry, consisting of mammalian and microbial expression systems as well as capabilities for bioconjugation and mRNA manufacturing. We are expanding drug formulation and drug product development and manufacturing to provide our customers with simplified and de-risked supply chains.

Mammalian remains a major production technology for the biopharma industry. With more than 20 years of experience in mammalian cell culture, we have established a respected and leading position in the mammalian space. We have a fully integrated portfolio of services, from late discovery through to commercial supply.

We also use robust technologies, such as our proprietary GS Xceed[®] Expression System for mammalian expression. As the pipeline becomes more complex, we have complemented this established platform with other molecular tools, for example PiggyBac[™] for stable expression of large DNA cargos and ByLok[™] Technology for the discovery and design of bispecific antibodies. By providing a toolbox designed to meet the needs of developing new molecular formats, we can improve speed to the clinic or market while helping to reduce the costs and delays associated with low yields and poor batch quality.

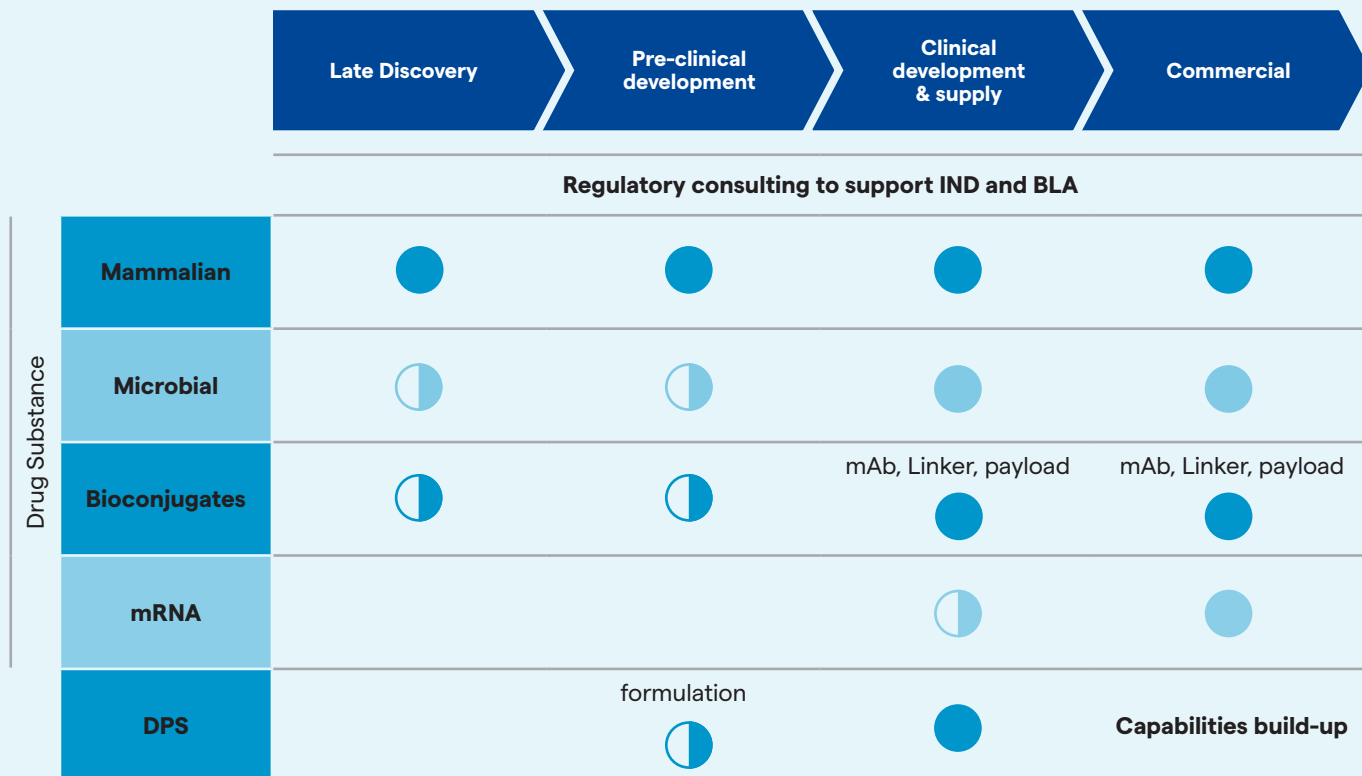
We have an extensive breadth of mammalian manufacturing capacities - from small-scale, single-use systems to mid- and large-scale stainless steel assets across the US, Europe and Asia. We can offer our customers phase-appropriate capacity and respond to the increasing need for regional manufacturing.

Within our **Microbial** business, we have a presence in every step on the path to commercialization. Microbial cell-derived molecules are produced exclusively in Visp (CH) and customers benefit from more than 30 years of expertise in this technology. Our offering of mid- and large-scale commercial manufacturing is supported by proprietary expression systems. These target the growing biotherapeutics development pipeline and, in particular, certain classes of more complex molecules largely being developed by smaller biotech companies.

We have extensive experience in microbial processes using advanced engineering and process development capabilities. Our toolbox contains well-established technologies for efficient, scalable and regulatory compliant processes. Our XS Technologies® platform for microbial expression includes *Escherichia coli*, *Pichia pastoris* and *Bacillus subtilis* expression systems.

Bioconjugates are a growing class of biopharmaceuticals and another important pillar of our Biologics business. We were among the first CDMOs to support the commercialization of bioconjugates and have a broad and established capability in manufacturing these complex molecules. We offer support activities from late discovery through to commercialization, with all elements of the complex supply chain, including the production of biomolecule, synthetic payload, linker and subsequent conjugation at our Visp (CH) site.

In 2021, we were recognized as best ADC contract manufacturing provider by the World ADC Summit. The award is testament to our simplified supply chain approach for the production of complex ADCs under one roof, making life-saving treatments accessible for our customers and their patients.



mRNA technology and its potential has truly emerged in the past two years. We have pioneered the commercialization of this modality through successful delivery of the Moderna COVID-19 vaccine drug substance. By making considerable pre-investments in our Ibex® concept in recent years, we were able to optimize pre-planned manufacturing capacity, enabling our customer to commercialize at speed during the pandemic.

The potential therapeutic value of mRNA technology is not limited to COVID-19 vaccines. mRNA has the potential to transform the way we manage and treat many illnesses and infections. As we move forward, we are already looking to build on this first-mover advantage to capture future opportunities and complete our offering across the value chain.

Our **Drug Product Services (DPS)** focus is on parenteral dosage forms, including products for injection and infusion for intravenous, subcutaneous, intraocular and other routes of parenteral administration. Services include options for monoclonal antibodies, other biologics including novel formats, noncytotoxic bioconjugates, peptides, viral vector and small molecules that require a parenteral dosage form.

To meet the growing need for end-to-end services and de-risked supply chains, we are actively expanding our drug product capabilities. We are expanding in Europe and China to further extend the value chain and complement our existing strong development offering in Switzerland.

Personal Perspective

Jean-Christophe Hyvert

President, Biologics and Cell & Gene Divisions

With strong demand for COVID-19 therapeutics, the development of increasingly complex molecules and higher manufacturing demand for new and existing medicines, we made significant investment in people, assets and capabilities in 2021.

An important focus for 2021 was how to welcome new colleagues and develop our people during the pandemic. We created a comprehensive virtual onboarding program for new joiners, as well as a modular mentoring and training program for existing employees.



We brought new growth projects online despite the ongoing challenges arising from the COVID-19 pandemic. We produced our first batches out of the new mid-scale facility in Portsmouth (US) and first mammalian batches in Visp (CH) and Guangzhou (CN) and brought online development and services capabilities in Visp and Singapore, in addition to our existing centers in the UK and California. We also announced growth initiatives across business units, including in drug product services, bioconjugates, mammalian, mRNA and microbial to ensure the flexibility and breadth of scope of our services and to further develop our integrated offering.

Demand for drug product across all modalities has been high this year with much of the CDMO capacity being reserved for COVID-19 vaccines and increasing demand for integrated offers and speed. As a result, we invested in additional capacity in Switzerland and China, complementing the drug product manufacturing capacity at the Visp site, which is expected to come online in 2022.

Looking to the future, we will continue to evaluate our network across our three key regions (US, Europe and Asia) to balance customer proximity and cost efficiency. We will also ramp up our new mRNA lines in Visp and Geleen (NL). Finally, we will also continue to maintain an active approach to business model innovation, and new technologies to support specific customer needs.



IBEX

Ibex[®] Solutions

Ibex[®] Solutions

Ibex[®] Solutions is a biopark of pre-built facilities supported by a flexible and responsive business model. Three innovative offerings - Ibex[®] Design, Ibex[®] Develop, and Ibex[®] Dedicate - span the complete product lifecycle of a biopharmaceutical from preclinical to commercial stages, from drug substance to drug product, all under one single contract. Our goal is to get new medicines and vaccines to our customers' patients faster and give customers the flexibility to manage supply, addressing drug development uncertainty and market demand changes.

Ibex[®] Design and Develop

Ibex[®] Design and Ibex[®] Develop cover the development and clinical manufacturing phases, supporting companies preparing for clinical trials up to the launch of their product. Completed in 2021, the facility that houses these offers is highly automated and employs single-use technology (1,000L and 2,000L bioreactors). They deliver clearly defined packages and timelines, essential for small companies with limited time and funds.

Ibex® Dedicate

Ibex® Dedicate is a fully customizable and flexible manufacturing solution, tailored to the customer's precise operational and business needs. The offering enables companies with products in late clinical and commercial stages to respond quickly to changes in market demand, de-risk their programs and simplify their supply chain.

The model of a technology-agnostic shell ready for fit-out with a relatively low initial investment has proved its worth for us and our customers, enabling various modalities to ramp up in record time. We now have a multi-purpose facility supporting: large- and small-scale mammalian, microbial, conjugation and mRNA. It serves as a testimony to our breadth of knowledge across modalities.



Highlights and Initiatives

Our Biologics division benefited from sustained customer demand in 2021, with high levels of capacity utilization and batch success rates. The business was able to meet high levels of demand by bringing online new facilities while also approving significant new expansions across multiple modalities.

In 2021 and beyond, our top priorities focus on strengthening our end-to-end offerings, increasing our presence across modalities and geographies, leveraging global capabilities to offer an agile delivery model and enhancing technological edge through further innovation.

Building Flexible Capacity

To strengthen our global network and to support market demand and future growth, we continued to invest in new capacities, including in Portsmouth (US), Visp (CH), and Guangzhou (CN).

We announced CHF 850 million of [investment](#) to build two new state-of-the-art mammalian facilities in Portsmouth and Visp. In Portsmouth, a new next-generation facility supporting late-phase clinical and commercial development and manufacturing will add capacity for up to eight 2,000L single-use bioreactors. The facility will help meet the increasing market demand for small- to mid-scale mammalian-derived biologics and support the implementation of high titer and high throughput platform processes. Combined with our industry-leading services in process characterization and process validation, the facility will offer customers an optimized path through Biologics License Application (BLA) to market and the flexibility to meet challenges in product forecasting during the initial years of product launch. It is expected to be completed in 2023. In Visp, a new large-scale facility with the latest manufacturing technology will expand capacity by six 20,000L bioreactors to meet increasing market demand for biologics (see *more in section Ibex® Solutions*).

Another milestone in 2021 was the start of operations at our Guangzhou site. By the end of the year we had delivered our first cGMP batches. Furthermore, as part of our continued investment in China and in line with our strategy to provide integrated end-to-end solutions to customers, we will offer combined drug substance and drug product manufacturing services at the Guangzhou site, expected to come online in 2022 (see *more in section Expanding End-to-End Offerings*).

Ibex® Solutions – Our Commitment to the Full Lifecycle of Customer's Products

In 2021, our Ibex® Solutions offering remained highly attractive to customers. Modules in our first manufacturing complex are now fully allocated. The range of technologies, clearly highlights the value of the concept. Technologies include mRNA, microbial, mammalian and bioconjugation.

Building on the success of our Ibex® Dedicate model, in 2021, we approved investment for additional [expansion](#) into a second manufacturing complex in Visp (CH) and work has already started. The investment will provide a new large-scale mammalian drug substance manufacturing facility with six 20,000L bioreactors due to be operational by 2024. A significant proportion of this new capacity is already contracted, including by a major biopharmaceutical partner for large-scale monoclonal antibody supply for antibody-drug conjugates (ADC). This [collaboration](#) represents a significant development of an existing customer relationship where we already provide highly potent payload, drug-linker and conjugation services. The partnership enables the customer to access commercial-scale production of all elements of its ADC at one site, ensuring security of supply while delivering significant economies of scale.

We also signed new programs in Ibex® Design and Develop, including with [Immunitas Therapeutics](#), [aTyr Pharma](#) and [BlueJay Therapeutics](#). These collaborations are aimed at helping biotech companies to advance their innovative medicines from gene to investigational new drug (IND). For example, as part of our agreement with aTyr Pharma, our Ibex® Design will deliver GMP drug substance and drug product batches to support the company as it advances its novel therapeutic antibody from preclinical to clinical stages.

Providing the Expertise and Tools to Scale Complex Medicines

By combining established expertise across three development sites - Slough (UK), Visp (CH) and Guangzhou (CN) - with leading expression systems and molecular biology tools, we are able to support the specific needs of customers by developing complex molecules and new molecular formats.

For example, we will deliver a program for [Ankyra Therapeutics](#) designed to reduce time to clinic for its novel fusion protein, a cytokine-based immunotherapy developed for intratumoral injection.

For production of many new molecular formats such as nanobodies, designed ankyrin repeat proteins (DARPs) and single-chain antibodies, microbial systems may be more productive. As part of our continued focus on expanding the [microbial service offering](#) supporting clinical and commercial programs, we also expanded our development laboratories in Visp by 50%. This new capacity will consolidate the microbial footprint at the Visp site and add new high throughput equipment and automation processes to drive efficiency and project delivery.

In 2021, we also continued to drive improvements in our internal innovation portfolio as well as extending partnerships with external innovators to provide a molecular biology toolbox tailored to the changing needs of cell line development and protein expression.

Expanding Clinical Development and Manufacturing in Asia

As part of our continued investment in Asia, we [expanded](#) our mammalian development services in Singapore. The expansion will double the existing footprint at our labs and establish additional capacity for cell culture, purification and analytical services for mammalian biologics. We will also invest in the latest technology for mammalian processes and analytical development.

During 2021, we fully validated our clinical drug substance facility in Guangzhou (CN) and announced the addition of clinical drug product capacity. This provides a full-service offering targeted to the growing needs of Chinese biotech or other companies wishing to access the Chinese market. The response has been extremely positive and we now count [Junshi Biosciences](#), [Pinteon](#) and [ValenzaBio](#) among our customers in this fully operational facility.

The collaboration with Junshi Biosciences demonstrated our strengths in providing high-quality and reliable services for local pharmaceutical companies under the CDMO model. The agreement builds on an existing relationship and will accelerate the development and manufacturing of Junshi's various biologics products, including its current and future antibody-based product pipeline. The main production platform will utilize our GS Xceed[®] Expression System.

Expanding End-to-End Offerings

Strengthening our Drug Product Services (DPS) offering has been a priority in 2021. To support this, we have announced several key expansions. Since setting up DPS in 2016, we have expanded our offering in Basel (CH), Stein (CH), Visp (CH) and Guangzhou (CN). These new investments enhanced our global drug product manufacturing and fill and finish capacity to three sites, including four vial lines and one flexible filling line.

Financial Performance in Full-Year 2021

Comparison vs. Prior Year

2,699m

Sales (CHF)

+24.7%¹

979m

CORE EBITDA
(CHF)

+17.8%

36.3%

CORE EBITDA
Margin

-2.4ppts

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

In 2021, we expanded our network in [Switzerland](#). Our center of excellence for drug product development is based in Basel. We are currently adding more labs to further support the pharmaceutical development for early and late clinical stages and increase our process development and characterization capabilities. Alongside this, in our main drug product site in Stein, we are installing a new aseptic fill and finish line. This investment will allow us to process various modalities, including monoclonal antibodies, bioconjugates, viral vectors, and other gene therapy products. These two investments will complement our Visp site's drug product manufacturing capacity, expected to come online in 2022 as part of the lbex® Solutions offering.

We are also establishing drug product manufacturing capacity for clinical trial and commercial supply in China by installing a new drug product fill and finish manufacturing line at our [Guangzhou](#) site. Expected to be completed in 2022, the sterile, multi-product fill and finish line will support the filling of liquid and lyophilized products. This expansion will establish our capacity to offer our customers in China and worldwide combined drug substance and drug product manufacturing services for clinical trial and commercial supply.

mRNA – Expanding Commercial Capacities and Building for the Future

In May 2020, we announced a ten-year strategic collaboration agreement to enable the manufacture of Moderna's Spikevax COVID-19 vaccine and additional Moderna products in the future. Our initial agreement provided for the installation of three production lines at our Visp (CH) site and one further production line in Portsmouth (US).

In 2021, we further expanded our collaboration with Moderna to extend our mRNA drug substance manufacturing and we announced an additional four production lines, doubling our mRNA production capacity. In Visp, we [announced](#) three new production lines, which are coming online in Q1 2022. We also built an additional [production line](#) at our site in Geleen (NL), on an accelerated timeline. We were able to leverage our existing infrastructure at the site to provide a fast build-out and ramp-up of operations.

Innovation Spotlight

Enabling delivery of cutting-edge therapeutics

For the rapid development of next generation CHO host cell lines, access to an in-house gene editing technology is critical. CRISPR is a flexible gene editing technique, which facilitates the precise 'cut and paste' of DNA in order to engineer optimized production cell lines. In December 2020, we signed an agreement with Arbor Biotechnologies to evaluate their proprietary CRISPR platform.

Based on data from the initial evaluation, we have initiated an extensive research program. We will use the gene editing technology to precisely engineer the production machinery of our proprietary CHO host cell. This will further enhance its capabilities and pave the way for tailored solutions for manufacturing of new molecular formats. Giving our customers access to next generation CHO hosts will enable delivery of cutting-edge therapeutics to address currently unmet patient needs.

Improving parenteral drug product stability and safety

Polysorbates are highly efficient protein stabilizers widely used in biotherapeutics. However, their wide industrial implementation is connected to challenges around their degradation. The compounds arising from enzymatic degradation of polysorbates (free fatty acids) pose a significant challenge to the drug product quality and safety because their presence leads to the formation of visible and sub-visible particles.

Our Drug Product Services team has developed and implemented a new rapid test to measure the potential level of polysorbate degradation based on detecting the activity of lipases, enzymes responsible for polysorbate degradation in drug formulations. This new diagnostic tool has been submitted for patent protection and has already helped several of Lonza's customers identify the root cause for polysorbate degradation in their products, aided process improvements and improved product stability and patient safety.



Small Molecules

>265¹

Pre-clinical and Clinical
Small Molecules

>195¹

Commercial Small Molecules

² Including active pharmaceutical ingredients (API), highly potent API (HPAPI), dosage form and delivery systems and particle engineering

Currently we have a global network of six sites across Europe, USA and China covering drug substance, particle engineering and drug product development and manufacturing. This footprint allows us to remain geographically aligned with the major growth markets in the biopharmaceutical industry. These key markets account for more than 60% of overall global pharmaceutical growth.

Market Trends

Small Molecules are a key driver for biopharmaceutical sales and account for approximately 60% of global market revenue.¹ Demand is driven by improved global access to medicine, demographic trends, public health initiatives and pricing reviews², as well as new drug launches.

The small molecules market is fragmented and growing at different rates, with an overall average increase of around 5%.³ One of the fastest growing areas is highly potent active pharmaceutical ingredients (HPAPI), which is currently showing 8-10% growth.^{3,4}

Oncology continues to be the therapeutic area with the largest number of active compounds in development at 37.5% of all drugs in the clinic.⁵ This strong oncology pipeline is helping the growth in HPAPI to outgrow the wider market.⁶ Many small molecule oncology therapies require specific manufacturing technologies, such as containment for bioconjugate payloads and bioavailability enhancement for poorly soluble compounds.

About 80%⁷ of the clinical pipeline in small molecules comes from small and emerging companies. Their business models tend to focus on fast time to market to secure a competitive edge. Our small molecules offerings are designed to meet the need for accelerated timelines so that our small biotech partners can rely on rapid early-stage clinical supplies to gain this advantage.

There is also a trend towards increasing levels of complexity in small molecules. This is seen with longer synthetic pathways, demanding expertise in the management of complex supply chains. Complexity is also seen in drug product formulation, with low solubility exhibited by 70% of clinical candidates, requiring techniques for bioavailability enhancement.⁷

¹ 2020 revenues for small molecule chemistry by Evaluate Pharma

² IQVIA Market Prognosis Global 2021-2025

³ Source: Lonza internal analysis based on IQVIA, EvaluatePharma, Citeline and other third-party data

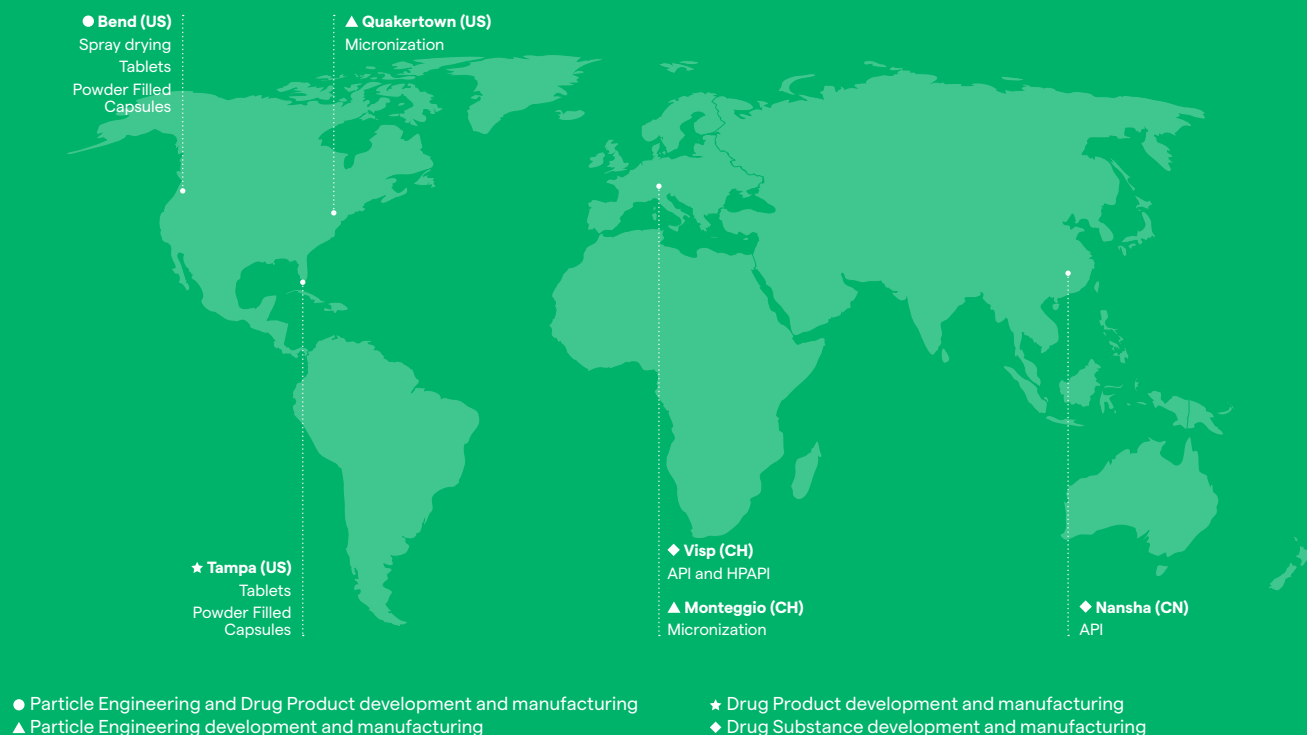
⁴ 2020-2026 CAGR in USD

⁵ Informa; Pharma R&D Annual Review 2021

⁶ RBC Capital Markets; Equity Research Report 2021

⁷ Source: Lonza internal analysis based on PharmaCircle and other third-party data

Our Global Development and Manufacturing Footprint



Our Offerings

We support our customers across all aspects of design, development and manufacturing by offering integrated drug substance to drug product solutions, including particle engineering and drug product packaging. We have an established and differentiated offering, and particular expertise with complex small molecules. Our integrated service offering provides substantial value to our customers as it simplifies interfaces, reduces costs and accelerates timelines across the entire drug development pipeline.

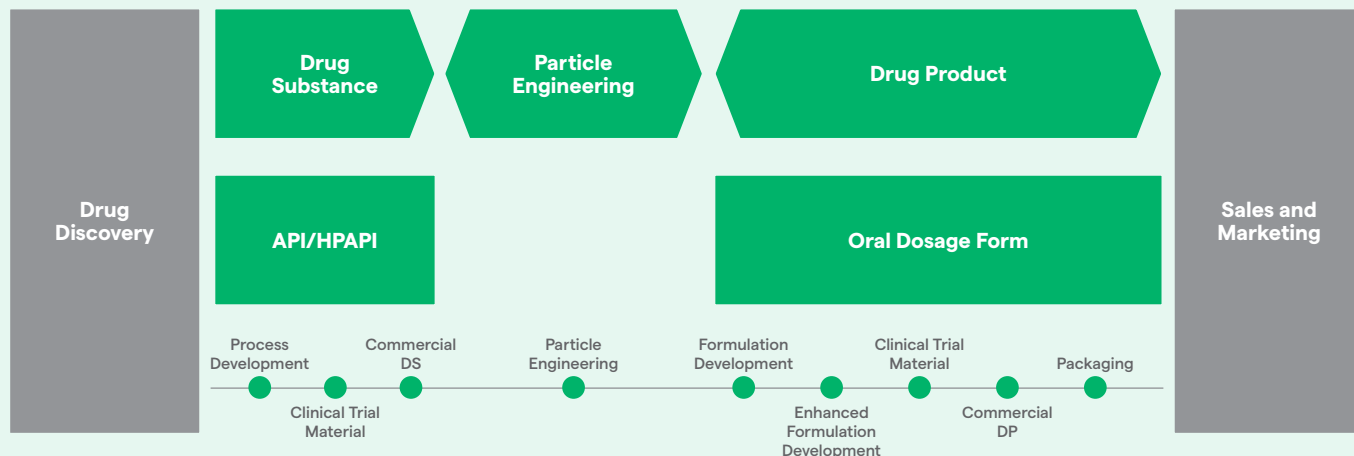
We are well established in the area of **HPAPI**. Our current offering provides advantages by addressing multiple challenges for customers who are working in this space. Our customers also benefit from our ability to customize our assets to meet the specific needs of their molecules. This is complemented by our integrated approach, which allows us to progress from clinical to commercial manufacture within a single site.

We also develop and manufacture **payloads for bioconjugates** at our Visp (CH) location and provide integrated development and manufacturing across antibodies, payloads, linkers and conjugations and sterile fill-finish. Since 2019, we have manufactured more than 30 HPAPI and approximately ten different bioconjugate payloads at our Visp site.

A key component of our integrated services is **particle engineering** across drug substance and drug product development and manufacturing. It is often required to meet today's drug delivery challenges, particularly poor bioavailability. Our particle engineering technologies include particle size reduction, spray drying, hot melt extrusion and melt-spray-congealing, all of which may be used for addressing a range of formulation challenges. Phase-appropriate assets are in place for our particle engineering technologies to support accelerated timelines to clinic and commercialization.

We are an established partner in early development programs and we continue to strengthen our early phase services. The [SimpliFiH®](#) Solutions is an integrated offering designed to reduce the timeline from initial idea to first-in-human (FiH) clinical verification. It addresses the bioavailability challenges that can be associated with new and complex molecules and can reduce Phase 1 timelines by three months compared to traditional approaches.

Our Integrated Service Offering



Financial Performance in Full-Year 2021 Comparison vs. Prior Year

767m

Sales (CHF)

+11.6%¹

215m

CORE EBITDA
(CHF)

+12.0%

28.0%

CORE EBITDA
Margin

+0.3ppts

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

Highlights and Initiatives

The Small Molecules business saw a significant number of new programs signed and the successful ramp-up of large assets in 2021. We continued to meet high levels of demand by approving new capacity expansions, which are all on track.

In 2021, we introduced an improved level of focus into the Small Molecules business by completing the strategic divestment of our Ploermel (FR) and Edinburgh (UK) sites. These divestments marked our exit from both soft gels and liquid-filled hard capsules for the pharma market.

Our business priorities are focused on strengthening our portfolio in the highest value areas of the market. We continue to work on expanding our capabilities in complex and highly potent products, strengthening our early phase offerings, deploying new agile manufacturing solutions and finding new ways to innovate.

Drug Substance Development and Manufacturing

In response to customer demand, we continued to invest in our offering by expanding manufacturing assets and development services.

In April 2021, we announced our plans to build [a new small molecule manufacturing facility](#) in Visp (CH). The new complex will include a customer dedicated manufacturing line for antibody–drug conjugate (ADC) payload molecules. The CHF 200 million investment is supported by a capital contribution and long-term collaboration with a major biopharmaceutical partner.

Taking inspiration from our Ibex® Solutions offering in Biologics, the new facility will also include a pre-built shell, allowing for optimal flexibility. The design will allow us to provide customized assets to meet customer needs and the pre-built modules will support a flexible approach and accelerate timelines to commencing operations. These advantages are important in a dynamic market and we are confident that it will be an attractive option for many customers. The facility will offer several opportunities for future small molecule expansions, including drug substance, particle engineering technologies such as spray drying dispersion and drug product.

Looking to the future, we also plan to grow our capacity across our three other existing production bases in Nansha (CN), Bend (US) and Tampa (US). In 2021 we announced [new investments](#) in good manufacturing practice (GMP) HPAPI laboratories and mid-scale manufacturing assets at our API manufacturing center in Nansha. These are expected to come online by Q3 2022. The investment of more than CHF 20 million will support our clinical-phase pipeline and allow us to provide a smoother transition from small-scale to large-scale manufacturing. With these expanded capabilities at our Nansha site, we continue to support the next generation of innovative and life-saving treatments with our customers around the world.

To enhance our capabilities in meeting accelerated timelines for increasingly complex molecules, we have [expanded our solid form selection services](#) based at our Bend site. The increased service capabilities and dedicated team complement our previously established SimpliFiH® Solutions first-in-human services, consisting of phase-appropriate drug substance and drug product development and manufacture. Our expanded solid form selection services offering is designed to meet the early-stage molecule development needs of biopharma players.

We are also on track with constructing new suites for the development and clinical manufacture of drug product intermediates and drug products utilizing spray-drying, hot-melt extrusion and melt-spray-congeal processing. These are due to be completed during Q2 2022.

Integrated Service Offering

Our comprehensive set of capabilities from drug substance through to drug product development and manufacturing enable us to support our customers with their development pipelines. As an example, we are [collaborating with Allarity Therapeutics](#) to provide an integrated solution for process development and manufacturing of drug substance and drug product for the clinical development of their oncology drug dovitinib. The collaboration will leverage our global network, utilizing our Visp (CH) and Bend (US) sites.

Personal Perspective

Gordon Bates

President, Small Molecules Division

During 2021 our Small Molecules team was proud to have played a key role in the supply of five innovator drugs approved by the US Food and Drug Administration (FDA) that will benefit patients across multiple therapeutic areas.

New manufacturing assets in Visp (CH) providing additional capacity came online in 2021 and are already delivering commercial product to customers across bioconjugates and Highly Potent Active Pharmaceutical Ingredients (HPAPIs).

We were also pleased to approve further investments in development and manufacturing capacity expansion across our global network. Construction activities are well under way for a new CHF 200 million small molecule manufacturing complex, alongside a dedicated manufacturing plant to support our customer Aurinia's approved product LUPKYNIS. Both plants in Visp will be operational in 2023. Additional early-phase capacity expansion at our facilities in Nansha (CN) and Bend (US) will start operations in 2022.

As we look ahead, we will continue to adapt to the needs of our portfolio of customers, ranging from small biotech through large pharma, with enhanced ways of working and increased capacity to provide security of supply across all stages of the product lifecycle.



Innovation Spotlight

Spray Drying Process Innovations for Bioavailability Enhancement

The majority (>70%) of new drug molecules in today's pharmaceutical pipeline are often limited in their oral bioavailability and new methods are essential in delivering these drugs to the body.

We are an industry leader in spray dried dispersions (SDD), which has become the go-to technology for improving the oral absorption of poorly soluble drugs. SDDs are produced by dissolving the drug and a polymer in a volatile organic solvent, then atomizing and using a heated drying gas to rapidly dry particles in a chamber. However, in extreme cases, poor solvent solubility prevents economical SDD manufacture.

To address these more challenging drug molecules, we have developed and commercialized innovative spray drying processes to improve dissolved drug concentration while avoiding environmentally unfriendly chlorinated solvents. Technologies include the use of new solvent mixtures and volatile processing aids to ionize drug and supersaturated solutions via "solvent shift". The addition of these new approaches to our existing superheated solvent technology expands and differentiates our offering in formulating our customers' drug candidates, by supporting improved outcomes in dosage form viability.

Cell & Gene

>20

cGMP Cell & Gene
Technologies Experience

>150

Process Development
Projects

286

Primary Cell Types

314

Bioscience Products Filed
with Regulatory Agencies

With our global network spanning three continents, we are supporting customers from research through to commercial production.

Market Trends

Cell and gene therapies are a new frontier in medicine. Rapid developments in this field have the potential to change the way patients with cancer or genetic diseases can be treated. These novel drug candidates have the capacity to provide improved patient outcomes and, in some cases, may even prove to be curative.

Cell and gene continues to be an area with rapid growth in investment and product pipelines. In 2021, the cell and gene therapy sector has seen strong clinical pipeline growth, commercial progress and record breaking investment. As of end of 2021, globally there were more than 2,700 cell and gene therapy products in development from pre-clinical through pre-registration stages¹. The sector had the highest annual number of regulatory approvals of new cell and gene therapy products¹. In terms of investment, in 2021 the sector received the highest annual financing to date. Companies in the sector raised more than \$23 billion, which is 16% increase from 2020².

There is a clear increase in the portfolio of therapies. The CDMO market outlook for Cell & Gene Technologies (CGT) shows mid-teens growth for the pre-clinical and early phases. This increases to the mid-twenties for the late-stage and commercial phases³. A compound annual growth rate for the whole CGT CDMO market is expected to reach more than 15% (CAGR 2021-2023)³. As customers gain greater visibility of the potential commercial success of their therapy, there is a greater appetite for longer contracts, which provide benefits to both customer and supplier.

The manufacture of these treatments also brings new challenges that range from the need for specialized media and other critical raw materials to gene-editing tools and IT. For example, the small patient-scale batch sizes for autologous products require automated solutions. This is critical to enable scalability and efficiencies in manufacturing to meet commercial demand for certain larger indications. Furthermore, getting these treatments to patients around the globe can present logistical challenges and requires stringent data integrity and vein-to-vein traceability. This is driving an increasing need for cost-effective and flexible IT systems, which can be rapidly deployed to improve decision making, quality and compliance needs. For allogeneic cell and viral vector gene therapies, there is a challenge in scaling-up and optimizing processes to increase yields and treat more patients per batch, while continuing to meet highest quality standards.

¹ ASGCT Gene, Cell, & RNA Therapy Landscape Q4 2021 Quarterly Data report

² ARM's virtual 2022 Cell & Gene State of the Industry Briefing, January 10th 2022

³ 2021-2023 CAGR for CGT Market in USD; Source: Informa Citeline and Lonza internal analysis

Our Global Development and Manufacturing Footprint



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

The cost of production still represents a major hurdle on the path to commercialization. New technologies that enable robust and efficient manufacturing to achieve replicable and high-quality treatments will be a cornerstone in the growth of the cell and gene therapy market. Innovation in manufacturing will be essential for the long-term success of bringing these therapies to patients.

Nonetheless, market growth is driven by improved clinical efficiency, allowing an increasing number of products to move towards late-stage and commercial phases, supported by accelerated approval pathways. Looking across the industry, the high potential of the market is becoming increasingly clear.

Our Offerings

Our Cell & Gene divisional portfolio is concentrated around three business areas: Cell & Gene Technologies, Personalized Medicine and Bioscience. As we work to address the complexities in research, development and manufacturing, the division looks set to transform the way we treat patients with cancer or genetic diseases. By providing the critical raw materials and enabling technologies together with expertise to support the development and commercialization of innovative therapies, we help de-risk and accelerate the path to market.

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

We provide an integrated offering of key services beyond traditional manufacturing, to meet customer needs end-to-end. These services include:

- Dedicated CGT [regulatory support](#) from initial regulatory submission to market authorization for fast-track approvals
- In-house [tissue acquisition](#) services with customized solutions to navigate the complexities of tissue sourcing
- Leading vein-to-vein partners for supply chain orchestration, apheresis network management, transport and logistics
- CGT media products, transfection technologies such as our proprietary [Nucleofector® device](#) and Bacterial Endotoxin Testing (BET)

We also provide a service offering and expertise in emerging and promising cell and gene therapy modalities such as:

- [Exosome-based](#) therapeutics manufacturing capabilities
- [Induced Pluripotent Stem Cell](#) (iPSC) manufacturing expertise
- Stem cell high-throughput large scale manufacturing
- Autologous and allogeneic immunotherapies manufacturing solutions
- [Viral vector](#) manufacturing for gene therapy including the production of adeno-associated virus (AAV), lentiviral and oncolytic viral vectors

Personalized Medicine is a start-up business unit developing breakthrough technologies to industrialize autologous cell therapies. A prominent part of this business is our Cocoon® Platform, a closed, automated system for patient-scale cell therapy manufacturing.

Our Bioscience business is a provider of specialty raw materials and enabling technology solutions. We provide our customers with the tools to develop, manufacture and test therapeutics, covering the entire journey to market, from gene to patient. Serving customer communities across academia, biotech and pharma, we can support all therapeutic modalities including cell and gene therapies, injectable drugs, vaccines and bio-manufacturing.

Personal Perspective

Jean-Christophe Hyvert

President, Biologics and Cell & Gene Divisions

The cell and gene industry continues to grow at an accelerated pace. As more programs are approved, reliability and quality is critical to bringing treatments to market. To meet our customers' needs, we have continued to invest to grow our network and capabilities, strengthen execution and differentiate through innovation.

Exosomes are emerging as a new modality for advanced therapies. The addition of two new sites in Lexington (US) and Siena (IT) has enabled us to enhance our extensive offer in this space and enable the manufacturing of new therapies.

In 2021, our proprietary Cocoon® Platform was used in a clinical trial with Triumvira where the first patient has been dosed with TAC-T cell breast cancer treatment. This development brings patient-scale therapy to solid tumors and has the potential to significantly improve clinical outcomes for some breast cancer patients. The Cocoon® Platform brings scalability, reliability and cost effectiveness at point of care.

We have also improved synergies between our Bioscience media business and our CDMO services. This has helped us to meet the demand for shorter timeframes for media and buffers, specifically with Moderna and Ibex® Solutions. Intercompany media sales have more than doubled and we have now started to co-develop media across some of our businesses.

Looking ahead to 2022, we plan to further develop our portfolio of services and products. We will continue to integrate the two new exosomes sites into our organization, and establish our position as a partner of choice for the late-stage clinical and commercial manufacturing of cell and gene therapies. This work will build on the success of the 2021 Pre-Approval Inspection (PAI) at our site in Houston (US).



Highlights and Initiatives

Across the Cell & Gene division in 2021, there was strong customer demand. The business saw improved synergies between the Bioscience business unit and our CDMO services, such as increased media and buffer supply to biologics programs and growing interest in technologies such as Nucleofector® for cell and gene therapies.

Our business priorities are focused on driving profitable growth in Cell & Gene Technologies, strengthening the Bioscience offering for the cell & gene market, driving the adoption and commercialization of the Cocoon® Platform and further accelerating the synergies between the three business areas.

As anticipated, the Cell & Gene Technologies business achieved a positive margin in Q4 2021. We will continue to work towards securing long-term sustainable and profitable growth. With an increase in the volumes of customer products as they progress towards commercialization, we expect to see fewer changeovers at our facilities. This will also help in achieving more established production processes and higher asset utilization rates, which will in turn improve our operational efficiency and reduce our costs.

Expansion into Emerging Modalities

In 2021 we continued to invest in innovative modalities by expanding our Exosomes manufacturing offering with Codiak Bioscience's exosome manufacturing site in Lexington (US) and Exosomics' Service Unit in Siena (IT). Exosomes are emerging as a new modality for advanced therapies and could become the next frontier in biotherapeutics.

Our [collaboration with Codiak](#), one of the most advanced companies in this modality will help drive the growth of the whole industry. The acquisition provides for worldwide access and sub-licensable rights to Codiak's high-throughput perfusion-based cGMP process, which we will make available to all Lonza customers for their exosome manufacturing needs. A Center of Excellence, established jointly, will leverage the strengths of both companies to advance developments in exosome production, purification and analytics.

With the addition of the [Exosomics' Service Unit](#) in Siena (IT) to our network, we have gained access to experienced talent, state-of-the-art knowledge and the ability to advance this therapeutic area further. Under the terms of the agreement, we will gain access to expertise and capabilities in the exosome field including analytics and characterization.

Financial Performance in Full-Year 2021

Comparison vs. Prior Year

602m

Sales (CHF)

+26.6%¹

106m

CORE EBITDA
(CHF)

n/a

17.6%

CORE EBITDA
Margin

+14.9ppts

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

Clinical and Commercial Programs

Building on the success of the FDA Pre-Approval Inspection (PAI) completed in 2021 in Houston, we further established ourselves as the partner of choice for the late-stage clinical and commercial manufacturing of cell and gene therapies. Our track record in the cell and gene therapy space has the capacity to bring hope to many patients. In 2021, we announced an [agreement with Aruvant Sciences](#) to manufacture its gene therapy, ARU-1801, a potential cure for sickle cell disease that can be given with one low dose of chemotherapy. We have already started process development and technology transfer activities at our Houston (US) site.

Our [collaboration with PsiVac](#) is another example of how cell and gene therapies are paving the way for more options to treat serious diseases. We have been granted the exclusive rights to manufacture Ixovex-1, a unique, patented oncolytic virus designed to provide personalized therapy for cancer patients. Process development activities are under way at our Houston facility, with a Phase 1 clinical trial planned for Q2 2022.

Personalized Medicine

Building on our experience, the Cocoon® Platform is already allowing us to tackle the traditional challenges of autologous cell therapy. We aim to enable our partners to provide personalized immunotherapies to critically ill patients faster, at a higher quality and lower cost. As we continued the commercialization efforts of the Cocoon® Platform during 2021, we entered into several collaborations with partners who are eager to establish a reliable, efficient and cost effective manufacturing process for scaling their therapies to market.

As part of our agreement with Triumvira, we successfully manufactured a TAC-T cell therapy [treatment](#) for a breast cancer patient. By transferring Triumvira's TAC-T cell treatment to our Cocoon® Platform, the company was able to accelerate development efforts and achieve IND approval in less than a year. This collaboration showed the potential of the Cocoon® Platform to manufacture therapies at third-party manufacturing sites using a decentralized manufacturing model. Our collaboration with Leucid Bio is another example where the Cocoon® Platform will be used in a decentralized model to optimize and streamline the manufacturing process for Leucid's CAR-T therapies.

The Cocoon® Platform is also demonstrating significant advantages in point-of-care manufacturing, as illustrated by our [collaboration](#) with CellPoint. The partnership is aimed at developing CellPoint's T-cell therapies for treating various cancers using our proprietary Cocoon® Platform, alongside our expertise in process development and regulatory approvals in several EU countries. Throughout 2021, we have been working with CellPoint to develop a manufacturing process that will allow a six- to seven-day vein-to-vein time frame to treat cancer patients. We also continued our collaboration with the Sheba Medical Center in Israel, where the Cocoon® Platform was used to deliver CAR-T cell immunotherapy treatments.

As we continue to commercialize the Cocoon® Platform, we will expand our collaborations with leading research institutes and academic clinical centers, including Stanford University, Fred Hutchinson and Parker Institute.

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

Bioscience

2021 marked the 20th anniversary of our Nucleofector® Technology and the launch of the next-generation [4D-Nucleofector® Platform](#). As molecular biology comes of age in medicine, our Nucleofector® technology is used increasingly to introduce DNA, RNA, proteins and other molecules such as CRISPR/Cas9 into cells for research and development of therapeutics. The device has been cited in more than 10,000 peer-reviewed publications since its introduction, clearly demonstrating its importance to researchers around the world. The next-generation 4D-Nucleofector® Platform brings user experience (UX) improvements that make the system even more intuitive and easy to use, firmly securing its place as a core method in cell-based research. Similar enhancements are planned for the high-throughput Nucleofection systems.

Throughout the year, we leveraged our expertise to develop new products that support the cell and gene space. We expanded our offering with [high-quality cryopreserved Leukopaks](#), which allow for more flexibility in immunology and cell therapy research.

Bioscience testing products have also supported the safe release of COVID-19 vaccines, resulting in increased sales as many companies scaled up manufacturing. Disruption caused by the pandemic focused efforts and investment on digital transformation projects, with increased interest in the implementation of electronic batch records and opportunities for our MODA-ES® Platform.

The pandemic has also raised awareness of the need for sustainable endotoxin testing. We have expanded our [PyroTec® PRO Automated Robotic Solution](#) for endotoxin testing to include options for rFC (a synthetic alternative to horseshoe crab-derived LAL tests). Through process optimization and automation of routine manual tasks, the PyroTec® PRO Automated Robotic Solution enables users to streamline and improve the performance of the QC laboratory, increasing lab efficiency and productivity.

Innovation Spotlight

Addressing the Urgent Need for Automation of Autologous Cell Therapy

Cell therapies, particularly patient specific (autologous) gene modified cell therapies, continue to flourish. The recent commercial approvals of gene modified cell therapies have shown incredible promise for the treatment of numerous oncological indications. However, the cost of these therapies will need to reduce significantly if this treatment paradigm is going to be competitive in the long term. Other biologics, or allogenic derived cell therapies, are possible alternative treatment options that have shown promise in early clinical trials and can potentially be provided at a much lower cost.

The key driver of cost for these gene modified cell therapies is manufacturing. Current manufacturing is labor intensive and cannot be scaled efficiently. We introduced the Cocoon® Platform in 2020 to address these limitations with the manufacturing of patient-scale cell therapies. The Cocoon® Platform is a closed and automated patient-scale bioreactor that performs the majority of the steps in the process. By closing and automating the manufacturing process, labor and facility costs are significantly reduced while quality and consistency are improved, leading to lower rates of batch deviations and failures.

In addition, the Cocoon® Platform provides the opportunity to add additional analytical capabilities to more closely monitor and optimize the manufacturing process. By partnering with companies like [Agilent](#), parameters like cell fitness and potential can be identified. This allows for real time adjustments to the manufacturing process, which may ultimately lead to a more potent and effective product. Automation is the only way that patient scale cell therapies can be manufactured at a cost that will be competitive in the long term. The Cocoon® Platform is leading the way in this field and is poised to be a leading solution, as the market continues to expand.



Capsules & Health Ingredients

~250

Billion Capsules Produced Annually in 2021

>30

Product Offerings

>44

Ingredient Patent Families

>54

Capsules and Dosage form Patent Families

Our wide range of products are manufactured in our established global site network across three continents. These sites also provide full technical, quality, regulatory and customer support. Our innovation centers provide state-of-the-art equipment, which enables us to collaborate and innovate with our customers.

Market Trends

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

In the pharmaceutical market, we saw modest growth in prescription drug usage as routine health regimens were impacted by COVID-19. This was slightly offset by the higher use of some over-the-counter medications. The new small molecule development pipeline remains healthy with a stronger focus on dosage forms that can support the delivery of new, more complex formulations and sensitive medications. We also saw interest in our dosage solutions from large molecule drugs, which often require better protection and improved bioavailability.

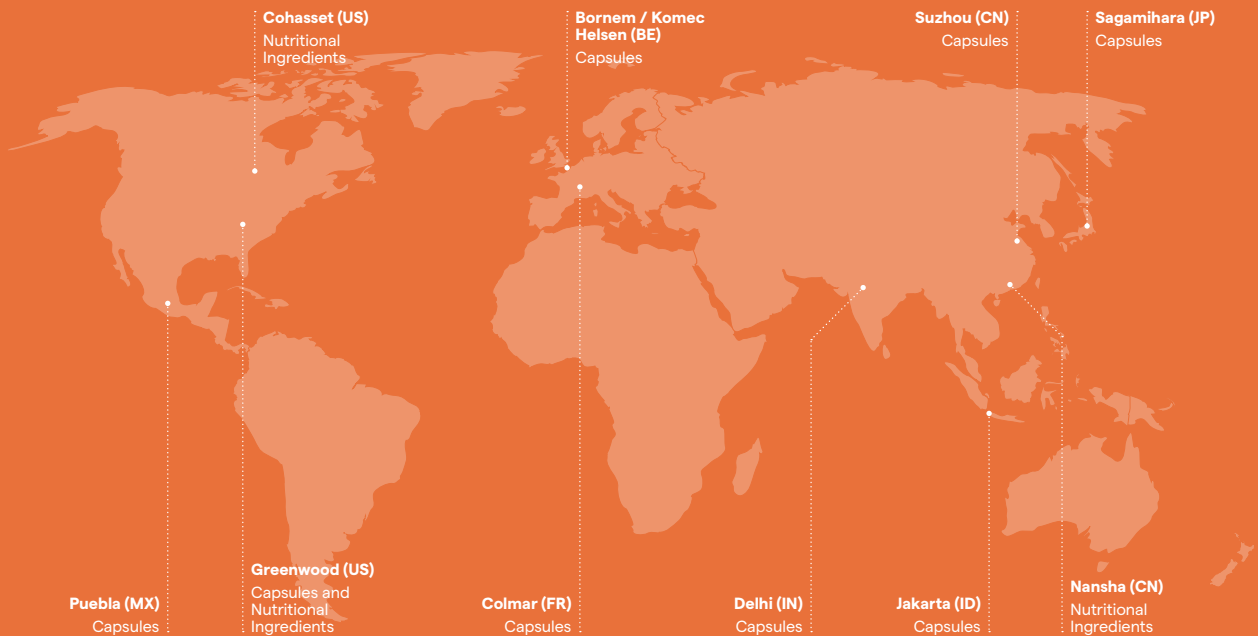
In the nutraceutical market, total demand grew from first-time consumers purchasing health supplement products. The strongest areas of interest were in immune, mood and active health products. Demand for clean label capsules remained strong, driven by consumer preference and emerging regulatory guidance for free-from products. We also saw continued interest in innovation collaborations and complete solutions, to support more complex formulations and end-to-end delivery of nutraceutical products to the market.

Our Offerings

Our Capsules & Health Ingredients business offers an innovative portfolio of dosage and formulation solutions for pharmaceutical and nutraceutical customers. We provide a large breadth of animal based, vegetarian, and clean label options with different release profiles and encapsulation technologies. This broad portfolio is produced from one of the largest global manufacturing network dedicated to production of dosage forms, providing our customers redundancy and local supply. Our focus is to help enable our customers to deliver their medications and health supplements to market safely, effectively and efficiently.

Our dosage solutions offer our customers a comprehensive range of high-quality capsules, dosage forms and delivery technologies. This combination allows our customers to customize their end medication or supplement and meet their unique product specifications and consumer preferences while complying with regulatory requirements. We also provide filling equipment and related technical services to optimize customers' fill and finish processes.

Our Global Development and Manufacturing Footprint



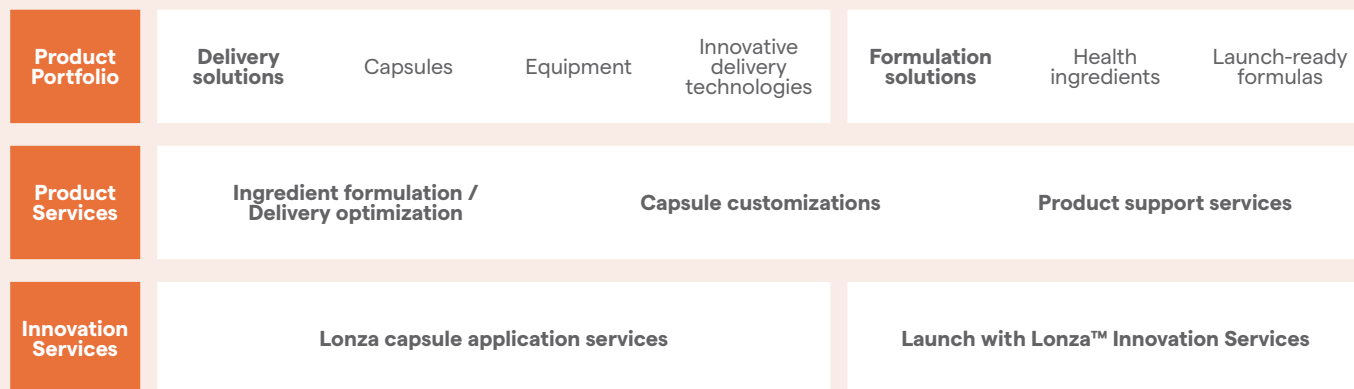
Our portfolio is fully supported through our global manufacturing, logistics, R&D, technical and customer service network.

In addition to our comprehensive dosage solutions, we offer formulation solutions with branded, scientifically backed, high-quality health ingredients to support active living through human and pet nutrition. Our portfolio includes premier brands such as UCII® for joint health, Carnipure® for energy and a range of branded products for weight loss, recovery and strength. We also provide launch-ready formulas which allow customers to use popular ingredients and go to market quickly, leveraging our technical and market knowledge.

Highlights and Initiatives

The business saw solid demand across product lines supported by particular regional interest from the Americas and APAC. We have delivered against our ambitious expansion plans and our global capacity increased to around 250 billion capsules annually.

Our Portfolio



Serving two distinct markets



Delivery Solutions

Our focus on innovation continued in 2021, with the development of new and innovative capsules and dosage capabilities. As an example, we invested further in the commercialization of our proprietary lipid multi-particulate technology, developing a commercial-scale manufacturing platform to meet high levels of demand. Lipid multi-particulate technology is a proprietary, innovative solution that helps maximize ingredient functionality and expands application versatility.

We have also been working with our customers to help navigate the complex regulatory framework changes in 2022. As the European Union Commission is looking to ban Titanium Dioxide (TiO₂) from food colorants, we are helping to convert customers to our TiO₂ free alternatives such as our White Opal® VCAPS® capsule. Alongside this, we offered additional testing for other harmful substances, such as Ethylene Oxide (ETO), to provide our customers with added assurance of our compliance with regulatory standards.

In addition, we have also introduced a number of operational and quality improvements. We completed the prototype of our next-generation proprietary capsule manufacturing machine, which will improve output while reducing deviations. It offers 15% higher throughput and 30% lower variability when in full production. Importantly, it can also be configured for a wider range of production outputs to meet evolving customer needs.

In 2022 and beyond, one of our top priorities is to drive greater levels of customer collaboration. In the Nutraceuticals market, our Dosage Form Solutions (DFS) helped introduce over 400 novel supplements, with the majority leveraging our unique dosage delivery technologies. Due to the popularity of these unique services, we expect to expand our DFS capacity and capabilities in 2022. Within the Pharmaceuticals market, we introduced our application lab (R&D innovation center) to selected customers and worked on a range of early-stage applications to solve different dosage delivery challenges. We expect to expand this innovation center in 2022 to take on more collaborations.

Financial Performance in Full-Year 2021

Comparison vs. Prior Year

1,204m

+5.6%¹

Sales (CHF)

414m

+9.5%
CORE EBITDA
(CHF)

34.4%

+1.6ppts
CORE EBITDA
Margin

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

Personal Perspective

Claude Dartiguelongue

President, Capsules & Health Ingredients (CHI)

As we look back on another challenging year, I am proud of how CHI has established itself and flourished as a new division. Over the course of the year, we have undertaken multiple strategic initiatives to grow our portfolio, expand our services, develop breakthrough technologies, better engage with our customers and improve efficiency. All remain on track and are delivering strong results. In response to the increasing global demand for capsules, we have delivered against our ambitious expansion plans and I am pleased to say that as of the end of 2021, we have the capacity to produce approximately 250 billion capsules annually across the world.



To support the value we place in our customer relationships, we piloted our customer experience program in EMEA with strong levels of success. The goal is to provide a systematic approach to interacting with and providing value to our customers. The pilot program has already improved our engagement with our customers and will help ensure that customer centricity remains one of our core capabilities.

The pandemic continues to bring uncertainty to both our business and our customers, and evolving demand forecasts continue to put our supply chain under pressure. As a result, securing our suppliers and maintaining supply chain continuity has been a key focus in 2021. On a positive note, the pandemic has allowed us to enter a new dialogue with our customers and move from short term transactional requests to a more collaborative partnership to address their long-term needs.

As we look to 2022, we plan to further expand our capsules capacity to meet global demand. Our priority is to build on our strong foundation and focus on innovative solutions across new technologies, services and capabilities. These include our LMP technologies, combination capsules, next generation enteric capsules, new ingredient claims and our concept to market innovations services. Enabling our customers to innovate will also bring new collaborations and mutual benefits.

Formulation Solutions

We furthered our commitment to our formulation solutions portfolio in 2021 by strengthening our collaboration with customers. One example was with Kaged Muscle, who was the first to introduce our new TWK10® sports probiotic under the Pro-biotic Premium Performance brand. The company also used our Capsugel® DRcaps® capsules, which offer a modified release profile beneficial for probiotics ingredients.

In addition, we announced the [expansion of our UC-II®](#) undenatured collagen ingredient line, which supplements joint health. The new UC-II® supplement is made with organic, non-GMO collagen, making it one of the only organic joint health supplements in the US. The new offering helps dietary supplement manufacturers differentiate their product in an increasingly competitive market.

Innovation Spotlight

Next Generation Enteric Capsule

We are developing a breakthrough technology platform to manufacture novel functional capsules. The first product in development is a next generation enteric capsule with optimal properties. This means it does not release or degrade during stomach transit and helps ensure a swift release in the distal intestine.

This new capsule will enable us to answer a pressing market need for more effective oral drug products. Indeed, many new drugs intended for oral administration are easily degraded by the acid and enzymes found in the upper gastrointestinal tract and thus require a truly enteric dosage form. Peptides, RNA-based therapeutics or Live Biotherapeutic Products are prime examples. This ready-to-use capsule will allow the customer to gain time in process development and manufacturing and bring new drug products to market faster.

Our main achievements in 2021 were the introduction of the commercial manufacturing process and machines and the confirmation of in vitro and in vivo enteric performance. The confirmation of the suitability of the capsule was achieved by working closely with lead users. The new capability to further customize the capsule to specific customer needs was another important achievement.



Associates and Joint Ventures

In 2017, Lonza and Sanofi entered into a strategic partnership, to build and operate a mammalian cell culture facility for monoclonal antibody production in Visp (CH). This large-scale commercial facility (20,000L bioreactors) provides a new model for CDMO-sponsor relations. Both companies have 50% of the available capacity, giving them substantial flexibility within the collaboration. The facility was completed and commenced operations in 2021.

In 2019, Lonza and Chr. Hansen established a 50/50 strategic joint venture (JV) for the development and manufacturing of live biotherapeutic products (LBP) for pharma and biotech customers. Operating under the name Bacthera, the JV has offered drug substance and drug product development services for customers developing LBP since the beginning of 2020. The company is located in Hørsholm (DK) and Basel (CH).

In May 2021, both of Bacthera's facilities were [granted manufacturing and GMP licenses](#) by the respective national health authorities. This is a major milestone for the company, as they are now ready to supply customers with LBP for clinical trials in humans and ultimately develop commercial products.

There are currently no commercially available LBP, however, we are supporting a [collaboration](#) between Bacthera and Seres Therapeutics to manufacture SER-109, which has the potential to become the first-ever LBP to be produced commercially.

Under the terms of the agreement, Bacthera will establish a dedicated facility for commercial manufacturing in its new Microbiome Center of Excellence, a manufacturing site dedicated to the production of LBPs located at our Ibex® Solutions campus in Visp. The new facility will enable Bacthera to offer fully integrated end-to-end live biotherapeutic development, clinical trial material manufacturing and commercial manufacturing services and support companies in overcoming challenges and related manufacturing risks.



Legal Disclaimer

Forward-Looking Statements

Forward-looking statements contained herein are qualified in their entirety as there are certain factors that could cause results to differ materially from those anticipated. Any statements contained herein that are not statements of historical fact (including statements containing the words “outlook,” “guidance,” “believes,” “plans,” “anticipates,” “expects,” “estimates” and similar expressions) should be considered to be forward-looking statements. Investors are cautioned that all forward-looking statements involve risks and uncertainty.

There are a number of important factors that could cause actual results or events to differ materially from those indicated by such forward-looking statements, including the timing and strength of new product offerings; pricing strategies of competitors; the company’s ability to continue to receive adequate products from its vendors on acceptable terms, or at all, and to continue to obtain sufficient financing to meet its liquidity needs; difficulty to maintain relationships with employees, customers and other business partners; and changes in the political, social and regulatory framework in which the company operates, or in economic or technological trends or conditions, including currency fluctuations, inflation and consumer confidence, on a global, regional or national basis.

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