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Pharma Biotech & Nutrition

Our Offerings

As the world’s largest company for contract development and manufacturing, our Pharma Biotech & Nutrition segment is recognized for its reliable, high-quality services, regulatory track record, global footprint, innovative technology platforms and extensive experience.

Our vision is to enable our customers to meet some of the greatest challenges in patient treatment. Our broad capabilities span across biologics, small molecules (including highly potent active pharmaceutical ingredients such as cytotoxins), bioconjugates, cell and gene technology, and live biotherapeutics. We manage projects from pre-clinical stage through to commercialization, from established therapeutics to advanced personalized medicines, and our expertise covers both drug substance and drug product.

In February 2019, we changed our structure, combining Pharma & Biotech and Consumer Health & Nutrition into the Lonza Pharma Biotech & Nutrition (LPBN) segment. With this structure, we can leverage our innovation programs and technology platforms across the nutrition-pharma spectrum, most importantly in the pharma and nutritional capsules businesses.

In 2019, the LPBN segment comprised the following offerings:

CDMO service businesses:
- Small Molecules
- Mammalian & Microbial
- Cell & Gene Technologies

Product businesses:
- Bioscience
- Capsule Systems
- Nutritional Ingredients

Our Global Footprint

With 37 sites across three continents and 11,148 employees, we capitalize on our global footprint and have the flexibility to address regional and even local marketplace needs.

- >730 Preclinical and Clinical Small¹ and Large² Molecules
- >310 Commercial Small¹ and Large² Molecules
- >200 Billion Capsules Produced⁴

¹ Including active pharmaceutical ingredients (API), highly potent API (HPAPI) and dosage form and delivery systems
² Including mammalian and microbial, cell & gene therapy products, applied protein services and drug product services
³ Including mammalian and microbial and cell & gene therapy products
⁴ Including pharma and nutritional hard capsules
Biologics Services

Portsmouth, USA
Mammalian
- Commercial manufacturing

Hayward, USA
Mammalian
- Clinical manufacturing

Visp, Switzerland
Bioconjugates
- Clinical development & manufacturing
- Commercial manufacturing

Mammalian
- Clinical development & manufacturing
- Commercial manufacturing

Microbial
- Clinical development & manufacturing
- Commercial manufacturing

Basel/Stein, Switzerland
Drug product services
- Clinical & commercial development
- Clinical & commercial manufacturing

Cambridge, UK
Pre-clinical candidate risk assessment
- Manufacturability & immunogenicity
- Non-GMP research product supply

Slough, UK
Mammalian
- Clinical development & manufacturing

Porriño, Spain
Mammalian
- Commercial manufacturing

Guangzhou, China
Mammalian
- Clinical development & manufacturing

Tuas, Singapore
Mammalian
- Clinical development & manufacturing
- Commercial manufacturing

Cell & Gene Technologies

Portsmouth, USA
Cell & gene technologies
- Clinical & commercial manufacturing

Houston, USA (including El Rio)
Cell & gene technologies (including viral vector manufacturing)
- Clinical & commercial development & manufacturing

Kingston, Canada
Cell & gene technologies
- Clinical development

Geleen, Netherlands (including Maastricht)
Cell & gene technologies
- Clinical & commercial development & manufacturing

Tuas, Singapore
Cell & gene technologies
- Clinical development & manufacturing

Tokyo, Japan
Cell & gene technologies
- Clinical & commercial development & manufacturing

Small Molecules

Quakertown, USA
Particle engineering and drug products
- Dosage forms & delivery solutions

Tampa, USA
Particle engineering and drug products
- Dosage forms & delivery solutions

Bend, USA
Particle engineering and drug products
- Dosage forms & delivery solutions

Visp, Switzerland
Drug substance
- API development & manufacturing

Monteggio, Switzerland
Particle engineering and drug products
- Dosage forms & delivery solutions

Ploermel, France
Particle engineering and drug products
- Dosage forms & delivery solutions

Edinburgh, UK
Particle engineering and drug products
- Dosage forms & delivery solutions

Nansha, China
Drug substance
- API development & manufacturing
OUR BUSINESSES

Capsule Systems

Greenwood, USA
Pharma & nutritional capsules

Puebla, Mexico
Nutritional capsules

Colmar, France
Pharma & nutritional capsules

Bornem, Belgium (including Komec Helsen)
Pharma & nutritional capsules

Sagamihara, Japan
Pharma & nutritional capsules

Suzhou, China
Pharma & nutritional capsules

Jakarta, Indonesia
Pharma & nutritional capsules

Haryana, India
Pharma & nutritional capsules

Nutritional Ingredients

Benicia, USA
Nutritional ingredients

Cohasset, USA
Nutritional ingredients

Fort Smith, USA
Nutritional ingredients

Nansha, China
Nutritional ingredients

Bioscience

Walkersville, USA
(Bioscience)

Durham, USA
Bioscience

Rockland, USA
Bioscience

Verviers, Belgium
Bioscience

Cologne, Germany
Bioscience

Copenhagen, Denmark
Bioscience

1 cGMP Sterile manufacturing
2 Capabilities to become available from 2020
3 Locations connected to another site
4 Facility owned and operated by Nikon CeLL innovation Co. Ltd. under Nikon-Lonza partnership
Financial Highlights

Lonza Pharma Biotech & Nutrition (LPBN) achieved continued double-digit sales growth above guidance for 2019. The realigned segment includes the nutritional hard capsules business (acquired with Capsugel), as well as a small portfolio of nutritional ingredients and formulation services. We delivered CHF 4.2 billion sales in full-year 2019 and a CORE EBITDA of CHF 1.4 billion while investing in strategic growth projects, a number of which are expected to commence operations from the end of 2020.

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<table>
<thead>
<tr>
<th>Pharma Biotech &amp; Nutrition</th>
<th>2019</th>
<th>Change in %</th>
<th>2018 Restated¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales</td>
<td>4,167</td>
<td>11.0</td>
<td>3,755</td>
</tr>
<tr>
<td>CORE EBITDA</td>
<td>1,371</td>
<td>10.0</td>
<td>1,246</td>
</tr>
<tr>
<td>Margin in %</td>
<td>32.9</td>
<td></td>
<td>33.2</td>
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<tr>
<td>CORE EBITDA excl. IFRS 16</td>
<td>1,347</td>
<td>8.1</td>
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<tr>
<td>Margin in %</td>
<td>32.3</td>
<td></td>
<td>33.2</td>
</tr>
<tr>
<td>CORE result from operating activities (EBIT)</td>
<td>1,125</td>
<td>10.3</td>
<td>1,020</td>
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<tr>
<td>Margin in %</td>
<td>27.0</td>
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<td>27.2</td>
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<tr>
<td>CORE result from operating activities (EBIT) excl. IFRS 16</td>
<td>1,123</td>
<td>10.1</td>
<td>1,020</td>
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<tr>
<td>Margin in %</td>
<td>26.9</td>
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<td>27.2</td>
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<table>
<thead>
<tr>
<th>Sales (Million CHF)</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>1,596</td>
<td>1,786</td>
<td>2,733¹</td>
<td>3,755²</td>
<td>4,167</td>
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</tbody>
</table>

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<table>
<thead>
<tr>
<th>CORE EBITDA (Million CHF)</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>418</td>
<td>526</td>
<td>826¹</td>
<td>1,246²</td>
<td>1,371</td>
</tr>
</tbody>
</table>

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¹ Reported pro-forma full-year 2017 financial results include Capsugel full-year 2017 financial results
² Restated to reflect the 2019 realignment of Lonza’s segments into Pharma Biotech & Nutrition and Specialty Ingredients
Innovations in Pharma Biotech & Nutrition

We have a broad view on the industry, and a depth of experience in developing and manufacturing therapies. Our scientific teams focus on devising credible, game-changing solutions that create value for our customers today by delivering the medicines of tomorrow.

Our research and development (R&D) group is focused on the following thematic areas: expression systems and bioprocessing, media for cell culture, viral vectors, autologous and allogeneic cell therapies, microbiome drug products, hard capsule design and specialty polymers, oral drug dose forms, chemical active pharmaceutical ingredients (APIs) and parenteral formulation & delivery. Our global R&D network spans 14 sites and our Collaborative Innovation Center in Israel; examples of key projects are outlined below.

Scaling Next Generation Biologics

As market demand continues to rise for more potent and effective therapeutics, biologic pipelines are evolving from standard antibody formats to next-generation biologics (NGBs) such as dual-targeted bi-specific antibodies. There is a real need for robust and scalable expression platforms that can keep pace with this shift towards more complex protein formats and this can prove challenging for traditional expression systems.

Using advanced molecular biology, we are building new capabilities into our proprietary GS Xceed™ expression system to solve this challenge and to make sure NGBs can scale. We recently launched our GS piggyBac™ transposon technology for stable expression of large molecules and multigene vectors for the production of bi-specific antibodies. Current research is focused on fine-tuning expression of individual genes using inducible and tunable promoters.

Lonza Pharma Biotech & Nutrition Focus Areas
Improving the Viral Vector Bottleneck

Cell and gene therapies currently rely heavily on viral vectors to deliver DNA into cells — both in vivo and ex vivo — but producing these vital components is a major bottleneck in manufacturing and contributes to the high cost of goods. We are already working in this critical area.

Viral vectors are complex to make, with many steps often required to bring the components of the virus and the relevant gene together in the right format. This often results in a low percentage of correctly packaged genes. Our R&D teams are focused on developing producer cell lines for the main viral vectors in use today, e.g. lenti virus, adeno-associated virus (AAV) and adenovirus. Building on our knowledge of molecular biology and mammalian expression systems, our goal is to precisely control the production of the different elements needed and increase the proportion of correctly packaged viral vectors.

In addition, the purification of viral vectors is inefficient and results in considerable loss of product. Our R&D teams are developing new methods for capturing and purifying loaded virus which, when combined with producer cell lines, will be a significant step forward in the industrialization of cell and gene therapy manufacturing.

Towards Continuous Manufacturing

The move from the current industry standard of batch-fed manufacturing towards continuous bioprocessing has been a focus for the industry for a number of years. It promises to greatly enhance throughput from a given facility and reduce future CAPEX demands as well as the cost of goods for our customers. However, it is a complex process that involves aligning a number of different technologies.

Our in-house R&D teams are working with a consortium of partners to bring the necessary elements together. For example, intensifying the process of growing cells up to the production volume (N-1 perfusion) can significantly reduce time but requires advances in cell lines, media, cell retention devices and automation. These are all key areas of focus for our bioprocessing R&D team.

In addition, our team is working to integrate several proprietary Lonza technologies, including advanced in-line sensors (Raman spectroscopy) and controllers — Modular Automated Sampling Technology (MAST™), with predictive modelling and machine learning to run the optimal bioprocess — that delivers on time, error-free outputs (the so-called ‘Golden Batch’).

Together with development in downstream processing and analytics for real time release, the different elements needed for end-to-end continuous manufacturing are starting to line up. The potential for bringing the highest quality of medicines to patients rapidly and in a more cost efficient way will ensure we make continuous bioprocessing a key focal point for our customers and our own business.

Specialty Oral Dosage Forms for Controlled Release

Our R&D team is developing a commercial technology platform capable of tuning the release of some oral medicines. This enables the customization and control of the drug’s specific pharmacokinetic profile.

The platform technology either solubilizes or suspends drug crystals within a lipid matrix to form lipid multiparticulates (LMPs). Formulations can be designed to control the release of the active drug from the LMP using pore formers.

The spherical particles are also uniquely suited for functional coatings for tastemasking applications which can provide significant patient benefits, particularly in the growing areas of pediatric and geriatric medicines.
The Technical Operations [TechOps] organization comprises more than 8,000 Lonza employees. They are united by a clear focus on delivering unmatched customer solutions to improve health globally, develop our talent and leverage our internal know-how through best in class technologies and sustainable business practice.

TechOps was established in early 2019, bringing together various departments including Operations, Quality, Strategic Growth Investments & Engineering and Procurement. United by an objective of improving cross-functional alignment and efficiency, the team centrally manages the development and manufacturing operations across all business units. All TechOps departments have a clear vision and mission with shared common objectives. The organization is united in its efforts to enable sustainable business growth by delivering solutions to our customers and ultimately to their patients.

The benefits and synergies of these close connections are already observable. The calibre of our technical operations is of particular value and relevance at a time when the business has such a high number of strategic growth investments running concurrently. More than five significant projects are scheduled to start up over the course of 2020, spanning Europe, the US and the Far East (China). The range of growth investments span the LPBN business units, with the intention of expanding our Small Molecules and Biologics capabilities. This is a significant undertaking and requires optimal levels of collaboration amongst all TechOps departments.

Lonza is technology-agnostic in finding the best ways to serve the different needs of our customers. A large component of our investments is linked to disposable technologies, but we also continue to use stainless steel to deliver efficiency and stability in the production of larger drug volumes. In this area, we have experience and a track record spanning more than 30 years.

We are now redirecting that established expertise to deliver advances in new technologies, including cell and gene therapy. In 2020 we will significantly increase the number of new projects becoming operational, with offerings that serve a wide range of needs or scale, alongside the highest ever number of pre-approval inspections (PAI). We serve many hundreds of different customers, each of whom benefits from our continuously increasing portfolio, our broad technological offering and global reach.

Alongside our growth projects, we are making a significant investment in people. We attract a broad range of biological and chemical experts, as well as operations professionals, to work at our sites. In the manufacturing complex of our Ibex Solutions™ in Visp (CH), we have a workforce comprising more than 30 different nationalities, working alongside local employees. We are proud to make this investment and understand that it supports our long-term growth and success.

In addition to our focus on people, we work to remain at the forefront of technological advances in our industry. We understand that our focus on digital and data technologies will enable us to achieve breakthrough business results and sustain competitive advantage. We are able to combine existing and established technologies with new innovative approaches to achieve synergies and improve our service offerings. Such opportunities enable us to experiment, invent, learn and grow as a business.
Looking at the wider market, we see strong demand for LPBN services across all our modalities. Specifically, there have been increasing levels of demand in antibody drug conjugates (ADC), highly potent active pharmaceutical ingredients (HPAPI), clinical stage mammalian and a healthy market for complex proteins in mammalian. In response to this market growth, we have made significant and continued capital expenditure (CAPEX) investments, many of which will start to come online throughout the course of 2020 and beyond.

Our manufacturing and technological investments have brought us to an inflection point; we are beginning to invest in the people and production costs associated with our new facilities and offering, but we will not begin to see returns until the following financial years. For instance, at our Ibex Design™ & Develop™ (DD) facility in Visp (CH), we will commence a ramp-up program in 2020, to ensure that facilities are operational and new recruits are fully trained. However, commercial ramp-up and sales will not happen until 2021.

As we review our long-term strategic direction, we must consider the range of options provided by our experience and capabilities across modalities as well as future market opportunities. We see a strong market and increasing demand, but we must make choices and prioritize by geography and modality, ensuring we focus on the areas of greatest future potential value. We are working to make calculated investments in new areas, while managing the risk associated with such investment. This is, for instance, our approach in the microbiome space, where we are currently working with a joint-venture (JV) partner, Chr. Hansen, where we bring our respective expertise to form an integrated marketing offering. Similarly, in personalised medicine, we are making calculated advances; we are working towards a first CAR-T immunotherapy patient treatment from our Cocoon™ autologous cell therapy manufacturing equipment.

As we look to the future, it is important that we carefully consider our strategic choices in a fast-moving global market and industry context. We see that there is a burgeoning ecosystem of small pharma companies in China, supported by strong access to venture capital (VC) funding as well as strong expectations of biologics growth. We are also seeing hubs of technological and pharmaceutical innovation in the US, with which we must engage and connect if we are to maintain our strong reputation for healthcare manufacturing technologies.

As well as refining our geographical focus, we must also carefully consider how we structure and invest in our modalities. Specifically, we must balance our returns from our high-revenue and high-margin modalities with the need to invest in our smaller high-potential modalities. This will allow us to deliver against our current targets, while setting up the business for long-term success.

As we review our approach to investment, we must maintain a careful balance between managing risk and capitalizing on future growth opportunities. More important still is our focus on the plans and needs of our customers. Our commercial function is only as strong as our relationships with our customer communities. We understand that our success depends on our ability to meet their needs and the needs of the patients they serve.
We serve our customers by delivering consistent and high-quality chemicals and biopharmaceuticals throughout the product lifecycle. Using advanced technologies in our extensive contract development and manufacturing services portfolio, we deliver products such as highly potent active pharmaceutical ingredients (HPAPI), cytotoxins, chemical intermediates, customized API, other recombinant proteins for the clinic or market as well as mammalian and microbial expression systems, bioconjugates, cell & gene technologies.

Integrated Offerings in CDMO Service Businesses

Customized API

Drug Substance Development

- Chemical intermediates, customized API, including HPAPI, Cytotoxics
- Oral dosage forms & delivery systems

Drug Substance Manufacturing

Drug Product Development

Drug Product Manufacturing

Delivery & Product Differentiation

Patient Healthcare

Small Molecules

- Mammalian and microbial expression systems, bioconjugates, cell & gene technologies
- Parenteral drug product services

Biologics

Patient Healthcare

Technology Platforms Along Pre-Clinical to Commercial, Science & Regulatory Expertise

Small Molecules

>350 Preclinical and Clinical Small Molecules¹

>270 Commercial Small Molecules¹

Biologics

>380 Preclinical and Clinical Large Molecules²

>40 Commercial Large Molecules³

¹ Including active pharmaceutical ingredients (API), highly potent API (HPAPI) and dosage form and delivery systems
² Including mammalian and microbial, cell & gene therapy products, applied protein services and drug product services
³ Including mammalian and microbial and cell & gene therapy products
Small Molecules

Market Trends

We see continued strong underlying market growth of 6% for drugs based on small molecules. The continuing role of small molecules is apparent in recent approval trends with 83% of 2019 approved FDA drugs being small molecules. In 2019, early phase drug candidates based on chemical technologies have continued to grow driven by increased investment in new therapeutic treatments (e.g. oncology indications); streamlined regulatory approval processes; and demand for increasingly specialized medicines inclusive of orphan disease applications.

Specialty medications are usually defined as high-cost, high-complexity medicines. These are often associated with biologics although small molecules today still represent 60% of all innovative drugs. The demand for these specialty medications continues to increase especially in highly developed areas such as USA, Europe and Japan. As a result, sales of specialty medications are growing at roughly twice the rate of traditional drug products whose growth rate is primarily driven by increased access to medicines in heavily populated countries such as China and India. More than 25% of drug products in development are highly potent active pharmaceutical ingredients (HPAPIs). The highly potent nature of these active pharmaceutical ingredients (APIs) means that they are highly toxic and require specialized manufacturing and handling capabilities.

In addition, dosage form and delivery of complex small molecule drugs pose challenges including the prevalence of poor solubility in highly potent compounds. An estimated 70% of new compounds require an enabling technology to reach sufficient bioavailability.

Our Offerings

We remain a global leader in the contract development and manufacture of drug substances or API, leveraging our expertise in more complex molecules, economies of scale, our many years of experience in manufacture, and the dedication and expertise of our employees.

We offer world-leading expertise and capabilities for the safe and efficient development and manufacture of HPAPI. With more than 20 years of experience in HPAPI, we have progressed more than 30 drug products to commercialization. Our specialized capabilities include handling HPAPI to exposure levels to 100ng/m³ across all manufacturing scales, as well as specific expertise in rapidly scaling up drug substances for commercialization.

Our HPAPI handling capabilities include contained processing for particle engineering as well as specialized drug product for highly potent/low dose applications, inclusive of liquid and semi-solid oral drug product as well as sterile fill and finish. This integrated offering adds substantial value to our customers as it simplifies interfaces, reduces costs and accelerates timelines. Lonza is an established partner in early development programs (preclinical through to Phase II) for drug products. The majority of early development is associated with addressing bioavailability and drug delivery challenges as well as accelerated development for clinical trials.

Our industry-leading bioavailability enhancement services portfolio includes all primary technologies for handling solubility, dissolution rate and/or drug delivery challenges. It also includes proprietary capabilities developed over 25 years. We have predictive modelling tools for rapid technology selection, specialized processing techniques and phase-appropriate equipment, which all complement our product development teams’ experience in meeting required bioavailability targets for new compounds or improving existing drug product performance.

Our Global Footprint

With a global network of eight sites in Europe, USA and China covering drug substance and drug product development and manufacturing, we are geographically aligned with the major growth drivers of the biopharmaceutical industry, e.g. small / emerging biopharma companies that hold the majority of the early phase pipeline for new molecules.

At our Visp [CH] facility, we have a well-established base for current good manufacturing practices (cGMP) chemical synthesis with more than 40 years’ track record in the production of highly potent active pharmaceutical ingredients HPAPI and their intermediates. The seven ISO-certified plants within the Visp complex provide more than 600m³ of reactor volume and a full range of capabilities across an array of chemical technologies to service customer requirements.

The Nansha-based [CN] production of drug substance complements our Visp site in ensuring high quality, secure supply of active ingredients to global biopharma customers.

In the USA, we provide particle engineering, bioavailability enhancement and drug delivery services from our sites in Quakertown, PA [USA], Bend, OR [USA] and Tampa, FL [USA]. Additionally, in 2019, we completed the expansion of our solid oral dose development and manufacturing capabilities and capacity at our Tampa site. The expansion enables the team to provide more integrated services for customers across early-stage product development, clinical trial material manufacture and development, clinical trial material manufacture.

3. Source: Evaluate Pharma (2019) (no generics or biosimilars considered)
5. Sources: Internal Analysis; FDA (2019)
commercialization of innovative drug products. It will also further strengthen our speed-to-market capabilities.

Additional capacity for design, development and manufacturing services across drug products is available from our sites in Monteggio (CH), Ploërmel (FR) and Edinburgh (UK).

Discover More

For further information about our offerings in small molecules, including our expertise in HPAPI and other active pharmaceutical ingredients, visit our [website](#). Click [here](#) for a 360° Virtual Tour of our facilities. Visit our [Capsugel](#) and [Micro-Macinazione](#) websites.

**Highlights and Initiatives 2019**

Throughout the year our small molecule business continued to benefit from innovative business models (including tailored capacity optimized to customer needs), formulation and encapsulation capabilities. Lonza’s HPAPI offerings have made a positive contribution, with a number of new long-term contracts signed.

**Drug Substance Development and Manufacturing**

Our API / HPAPI offerings have positively contributed to our 2019 performance with a number of new long-term contracts signed. Examples include:

- **AstraZeneca** signing a [long-term manufacturing agreement](#) with us for the delivery of a number of HPAPI based products from our Visp (CH) site. To meet this increased demand, we will expand our Visp-based HPAPI development and manufacturing capacities, with planned operations to start from July 2020. This investment will add two 4m³-scale, multi-purpose production lines for HPAPI manufacturing to complement our existing range of production capacities from lab to large commercial scale.

- A [previously-announced](#) long-term agreement to produce drug substance payloads for antibody drug conjugates, was expanded in 2019 to accommodate higher production commitments by a major biopharmaceutical partner. The inherent expansion, which includes two new suites designed specifically for the production of ADC payloads, is based on a tailored agreement that ensures flexible and secure supply at reduced cost.

- **Several substantial new contracts for manufacturing** were also secured for our Nansha (CN) drug substance development and manufacturing site.

Leveraging our leading expertise in addressing bioavailability challenges, we launched SimpliFiH™ Solutions. This service package is designed for innovator companies, especially small / emerging companies that require development and manufacturing partnerships for early-stage development and first-in-human studies. This new offering consists of streamlined service agreement packages to further reduce time, cost and complexity for early clinical studies, demonstrating our continued commitment to constant innovation and adding value for our customers.

**Drug Product Development and Manufacturing**

The first long-term commercial supply agreement for a spray dried dispersion-based drug product was signed with a biotech company partner. Our Bend, OR (USA) site utilizes proprietary spray-dried dispersion technology to provide sufficient drug bioavailability to a highly insoluble kinase inhibitor drug substance. This agreement provides supply security to the client whose new drug product is expected to be granted regulatory approval in Q1 2020.

We signed an [agreement](#) with Chiasma for the commercial supply of their late clinical phase product Mycapssa®. Combining Chiasma's technology with our liquid-filled hard capsule delivery systems provides the potential to improve the treatment options for adult patients with acromegaly. We have provided early stage development and specialized encapsulation services for this new orphan application.

We are providing commercial supply of a new drug product using our proprietary Xcelodose® Precision Powder Micro-Dosing Technology. This agreement is the first instance in which this specialized equipment, designed for supporting rapid clinical trial studies, will be used for the commercial supply of a specialized encapsulated drug product. Lonza has developed micro-dosing best practices through more than fifteen years' experience across hundreds of compounds.

In addition, our team in Tampa, FL (USA) supported Takeda’s brigatinib program, a new oral, once-daily monotherapy for treating non-small cell lung cancer. We provided the product, method and process development support to meet accelerated timelines to bring this breakthrough treatment to patients.
Market Trends

The reporting year was a significant period for the mammalian and microbial market, with worldwide biopharmaceutical sales currently at USD 258 billion and estimated to grow at a CAGR of 9% over the next six years. There has been strong venture capital (VC) funding for biotechs, which has supported this healthy growth in development and had a positive impact on outsourcing to custom manufacturers like Lonza.

The product landscape is changing rapidly and is getting more complex from a regulatory perspective, with an increasing need for new molecule design, manufacturing technologies and process improvement capabilities for biologics. Mammalian will remain the preferred production technology and has the highest growth potential due to pipeline increase and improvements in manufacturing technology. However, the sales of new molecular formats is predicted to grow at up to three times the rate of standard monoclonal antibodies (mAbs) through to 2025, including antibody drug conjugates (ADCs) and bi-/multi-specific antibodies, among others. Bispecifics and other more complex molecules also require new technologies for expression systems. These will include improved cell lines and manufacturing advances, such as continuous production.

New challenges are also brought by accelerated approval pathways such as FasTrack and Priority Review, which have increased pressure to quickly deliver therapies to the patients who need them most.

In biologics, many companies recognize that development failures often relate to poor formulation and poor drug product design. All biologics for systemic administration are parenteral and are administered by injection, infusion or implant. Such modern subcutaneously administered products require a high product concentration, which requires a careful formulation development to cope with the resulting risks of high viscosity and aggregation. Other modern products, such as in immuno-oncology, require very low doses alongside careful design of the drug administration setup. This is critical to ensure that the low quantities are actually reaching the patient.

Product failure at the formulation or final-filling stage accounts for significant cost and timeline challenges. Specialized expertise in drug product development, manufacturing and testing is required to ensure fast commercialization and robust production.

A growing number of molecules in the pipeline are expected to be owned by small and virtual biotech companies, who may not have the in-house expertise to bring those to the market and therefore have a higher propensity to outsource. Biotech is outsourcing more than 70% of its services to external partners.

In smaller biotech, this number reaches between 90 and 100%, as secured funding is used for developing therapies, not manufacturing for clinical stage trials.

VC funding is critical in this space – and biotech companies with a strong manufacturing partner receive better funding. VC funds have now begun to set up virtual biotech companies. Such virtual companies do have only a skeleton crew of managers. Therefore, high levels of communication, coordination, and trust among partners are prerequisites to deliver a successful outsourced project. Additionally, there is a burgeoning ecosystem of small pharma companies in China, supported by strong access to VC funding and bolstered by expectations of biologics growth.

Our Offerings

We are a leading contract development and manufacturing partner for biopharmaceuticals. Our offerings include a wide range of contract development and manufacturing services from sequence optimization, cell line construction, process development and optimization, and manufacture of drug substance and drug product for mAbs and other recombinant proteins from mammalian cell culture and microbial fermentation in small to large scale. Additionally, we specialize in development and manufacturing of bioconjugates which exemplifies our competency in developing and manufacturing complex molecules. We work in partnership with customers of all sizes, from start-ups to large biotechs and pharmaceutical companies.

In 2019, we offered a broad portfolio of drug substance and drug product development services, as well as clinical and commercial supply manufacturing in mammalian and microbial expression systems. Currently our development and manufacturing product portfolio includes active pharmaceutical ingredients (APIs) for life-saving medicines, including cancer treatments and orphan drugs for rare diseases where no alternative treatment exists.
For our customers in late discovery phase, our Applied Protein Services offering includes technologies and programs designed to assess and mitigate risks, reduce attrition and improve the quality and safety of therapeutic proteins in a cost-efficient and timely manner. These technologies include our Epibase® in silico and in vitro, immunogenicity screening, and our antibody humanization and deimmunization services. Our Sentinel APART™ Platform serves as a tool for antibody aggregation prediction and re-engineering, and our manufacturability assessment service is used to help predict and mitigate manufacturing risk. Early-stage customers also benefit from our mammalian and microbial-based Lightpath™ material supply services for their research and proof-of-concept studies. We also complement these services with developability assessment services to support our customers' lead candidate selection. More information on our late discovery services is available online.

When a lead candidate is selected, our industry-leading expression technologies, including the GS Xceed® Gene Expression System for mammalian expression and XS® Microbial Expression Technologies for microbial expression, are used to create commercially relevant cell lines or strains for protein production. Our GS Expression System® now underpins dozens of commercially available products, plus hundreds of others in clinical trials. We are continuously building on our established and trusted platform to ensure it remains a powerful solution for next generation bioprocessing, including the expression of increasingly complex proteins and continuous processing.

Following the creation of a new cell line or strain, we engage in a program of process development and scale-up studies that creates a robust process suitable for transfer to current good manufacturing practices (cGMP) sites. Once a process has been established, we can manufacture products to support not only preclinical activities, but also clinical trial material. In addition to developing a process at Lonza, we are also able to transfer into Lonza many product and process technologies that have been developed by our customers.
Ibex™ Design is our offering for customers’ preclinical and Investigational New Drug (IND) needs through to clinical Phase I. It includes a pioneering gene-to-drug product package for antibodies and antibody-like molecules, delivering drug product within 12 months and at least 1 kg of drug substance. This package also includes the reservation of a manufacturing slot for clinical resupply. Customers can benefit from our proven GS Xceed® Gene Expression System bioprocess platform and a holistic development strategy with the endpoint in mind.

Ibex™ Solutions consist of three innovative contract development and manufacturing organization (CDMO) offerings that span the complete product lifecycle of a biopharmaceutical – from preclinical to commercial stages, from drug substance to drug product, all in one location.

The three offerings Ibex™ Design, Ibex™ Develop, and Ibex™ Dedicate have been developed as a response to a dynamic market and evolving needs. The home for Ibex™ Solutions is the Lonza biopark in Visp (CH), which leverages Lonza’s existing infrastructure, support networks and a stable and highly skilled workforce.
**Ibex™ Develop** helps companies seamlessly and rapidly transition from clinical Phase II to commercialization. Co-location at one site eliminates the need for tech transfers, and accelerates the path to market. This offering enables biologics license applications (BLAs) to be submitted within 22 months from the start of process characterization. Eliminating the need for tech transfers, driving process optimizations and creating operational efficiencies are all expected to accelerate the path to market.

With **Ibex™ Dedicate**, a fully customized commercial supply solution for our customers’ products, Lonza is able to offer complete product lifecycle management in one site. A pre-built shell and faster ramp-up could save our customers up to 30 months total time to market. Ibex™ Dedicate allows our customers to delay their capacity build decisions and better manage investment risk. Moreover, our technology-agnostic supply solutions provide for flexible ownership and operating models for mammalian and microbial production, vaccines and cell and gene therapies.
Our Drug Product Services (DPS) team in Basel (CH) focuses on parenteral dosage forms and offers solutions for customers developing therapeutic proteins, peptides, cell and gene therapies as well as small molecules that require a parenteral dosage form. These products are for injection, infusion, intravenous, subcutaneous and intraocular routes of administration.

The DPS team provides a complete portfolio of services for parenteral dosage forms, including formulation development, simulated clinical administration setup and testing, analytical method development and quality control. Further services include primary packaging and device design and integration, drug product process development, and manufacturing of parenteral dosage forms for stability testing and preclinical or clinical testing.

There are also special services including surfactant characterization and characterization of excipient degradation, extractables and leachables assessment, and container-closure integrity and device testing. Our experts have multiple years of experience in the development, manufacturing, testing and commercialization of parenteral dosage forms and related regulatory requirements. Many of our experts have extensively researched and published in this area.

Our customers benefit from seamless integration of pharmaceutical ingredients and drug substance development for rapid and reliable entry into the clinic and for robust late-stage development. In addition, our DPS team offers best-in-class analytical and specialized services for routine processes and troubleshooting in pharmaceutical manufacturing.
Our Global Footprint

Today our mammalian manufacturing offerings have a global footprint, and the company’s strength is providing the best option for our customers whatever their manufacturing strategy or stage of development.

We have the capability to produce clinical and commercial material across our sites globally, from small-scale (1,000–2,000L) through mid-scale (6,000L) to large-scale (10,000L and 20,000L). Lonza leverages its expertise in stainless steel, single-use and hybrid technology to de-risk the path to market for customers. We produce mammalian-derived biopharmaceuticals in highly advanced current good manufacturing practices (cGMP) multi-product facilities, in a global network across three continents: Slough (UK), Portsmouth, NH (USA), Tuas (SG), Porriño (ES), Visp (CH) and Hay ward, CA (USA).

Our Slough (UK) site is the center of excellence for preclinical to clinical development and manufacture of mammalian-derived biotherapeutics. Our Portsmouth, NH (US) facility has been designed specifically for the production of therapeutic proteins derived from mammalian cell culture. In 2020, a new 6,000L mammalian suite, designed to manufacture next-generation molecules, is expected to be operational in Portsmouth. Our facility in Tuas, (SG) offers the full breadth of mammalian development and manufacturing services, from DNA to commercial cGMP products. In Porriño (ES), we specialize in the custom manufacture of recombinant proteins mammalian-derived. In Visp (CH), we offer our innovative Ibx® Solutions offering for biologics product lifecycle management for mammalian-derived biologics, microbial as well as bioconjugates. Our microbial center of excellence in Visp offers drug substance manufacturing solutions at capacities up to 15,000L and biosafety level 2 capabilities at all scales. Additionally, our bioconjugate team in Visp is one of the industry leaders in process development and cGMP manufacturing of clinical and commercial bioconjugates, including antibody drug conjugates (ADCs).

The newest addition to our mammalian manufacturing network is in Hayward, CA (US) — a site focused on clinical production of mammalian derived therapeutic proteins.

In China, as the country opens up to multinational companies, we are bringing our expertise in clinical development services and manufacturing. In 2020, a new mammalian site will be operational in Guangzhou (CN). The Guangzhou site will provide development and manufacturing services for early to late clinical and commercial launch projects. The new site will house a 17,000m² multiproduct facility using single-use technology, with significant adjacent expansion land secured.

In Switzerland, we have acquired our first sterile drug product fill and finish facility. The facility in Stein (CH), complements our Pharma Biotech & Nutrition current parenteral drug product services in Basel (CH) and is the first facility for clinical production and commercial launches. It will enable us to build on existing parenteral drug product development and testing capabilities, and offer an end-to-end service to our customers for clinical supply and launch.

Highlights and Initiatives 2019

During the reporting year, we saw ongoing strong momentum for our clinical and commercial offerings in 2019. Commercial agreements signed for new and existing assets provide meaningful sales visibility for the mid- and long-term. Commercial capacities for 2020 are largely committed.

Our integrated clinical service offerings gained traction, with shortened development and manufacturing timelines, guaranteed delivery of drug product for IND (Investigational New Drug) applications and secured supply for subsequent clinical and commercial requirements.

Protein Expression

In 2019, we announced the next stage in the evolution of our GS Xceed® Toolbox. As the formats of innovative therapeutic proteins become more complex and harder to express, we are looking for new solutions to improve productivity for our customers. The launch of GS piggyBac® technology enables the insertion of large DNA cargos into transcriptionally active and genetically stable areas of the genome. It allows the generation of stable pools of cells with high levels of protein expression. A further partnership with Synpromics to develop inducible promoters capable of turning gene expression “on or off” in response to signals in the cell environment, should enable fine-tuning of bioproduction. Both technologies are designed to provide even higher yields and enhanced performance and to support the expression of a growing number of challenging proteins including bi-specific antibodies and other new molecular formats.
Clinical Development and Manufacturing
We are committed to supporting a new generation of merging and even virtual Biotech companies looking to take innovative therapies into the clinic and beyond. An example of this is the partnership announced between Citryll and Lonza to manufacture NETosis Inhibiting Antibody CIT-013. This drug candidate offers new treatment options for various human diseases including lupus, vasculitis, pulmonary fibrosis and organ damage due to sepsis. Scientific teams from the two companies have been working together to develop Citryll’s lead antibody candidate CIT-013. Lonza’s in silico immunogenicity assessment services were used to improve the quality and potency of the candidate. Using our GS Xceed® System, we will create a cell line for the product and manufacture cGMP drug substance at our Slough (UK) site. Drug Product for this compound will be carried out at our recently acquired facility in Stein (CH).

Ibex™ Design and Ibex™ Develop
First customers for our innovative full-service, single-site clinical offering Ibex™ Design and Ibex™ Develop in Visp (CH) are committed. This constitutes 100% of 2020 available clinical manufacturing capacity one year ahead of planned operations.

One example is the extension of our partnership with Genmab to cover preclinical and clinical development and manufacturing for a significant portion of Genmab’s pipeline in Ibex™ Solutions. Our Ibex Design offering enables Genmab to take their candidates from gene to IND in 12 months and then move to reserved manufacturing capacity in Ibex Develop for clinical manufacturing and BLA submission when Genmab needs it. The agreement aims to provide Genmab with security of supply and to enable Genmab to move rapidly into clinical manufacturing with the flexibility needed to manage an extensive pipeline through the demands of clinical trials.

Commercial Drug Substance Manufacture
Following the recent U.S Food and Drug Administration (FDA) approval of the Prior Approval Supplement (PAS) for second-generation-process Andexxa®, Portola Pharmaceuticals, Inc. and Lonza announced the start of commercial supply of the recombinant coagulation factor from Lonza’s Porriño (ES) facility. The production at our 10,000L mammalian facility in Porriño will be supplemented by additional large-scale capacity in Ibex™ Dedicate at our Visp (CH) site. The two sites will ensure the flexible supply of Andexxa® to patients.

Additionally, we have recently signed a new Ibex™ Dedicate deal with a major multinational pharmaceutical company for the manufacturing of a commercial microbial-derived product.

To satisfy increasing global demand for biosimilars, we have signed a contract with Celltrion to manufacture Remsima drug substance in our commercial facility in Singapore that will cover market needs in Europe and North America. The partnership will provide cost-effective biologics for greater patient benefit worldwide.

Bioconjugates
To meet increasing clinical, launch and commercial market demand, we started an expansion of our bioconjugation facility in Visp (CH). Now supporting the majority of commercially approved ADCs, we see the need to further expand based on signed commitments from customers.

Many bioconjugates are on expedited programs and the existing expertise at the facility, combined with proximity to clinical and commercial manufacturing of antibody, linkers and payload, will reduce risk and increase speed on the path to market for our customers.

Parenteral Drug Product Services
Our Drug Product Services (DPS) continued to expand ahead of plan, responding to positive demand from customers. Since entering the field of Drug Product Services at the end of 2016, we have met considerable demand from the market and have already announced various expansions. In 2019, we acquired a sterile fill and finish cGMP facility from Novartis, and we are currently already expanding capacity. From 2020 we will expand development and testing labs into a larger building in Basel (CH) with an additional 8,000 m² and we plan to hire additional experts. In Visp (CH), the Ibex™ Solutions DPS fill and finish cGMP facility is progressing well and planned to be operational from end 2021.
Cell & Gene Technologies

Market Trends

Cell and gene technologies are seen as the new frontier in medicine. 2018 was a critical year for regenerative medicine financing, with investments of more than USD 13 billion. In 2019, the level of venture capital (VC) financings already exceeded that of 2018. The influx of capital into the field of cell and gene therapy is testament to their potential to transform the way patients are treated, providing potentially curative or life changing patient outcomes.

Currently there are more than 1,000 regenerative medicine clinical trials, with five landmark commercial approvals in the past two years. We are at an inflection point with an increasing number of products moving to late-stage and commercialization. By 2025, the US Food and Drug Administration (FDA) expects to approve 10 to 20 cell and gene therapy products per year.

The manufacture of such medicines brings new challenges. For example, the small, patient-scale batch sizes for autologous products require automatized solutions to enable scalability and efficiencies in manufacturing to meet commercial demand for certain larger indications. Furthermore, getting these drugs to patients around the globe can present logistical challenges. For allogeneic cell and viral vector gene therapies, there is a challenge in scaling-up to increase batch sizes and treat more patients per batch. Today the cost of production still represents a major hurdle on the way to the market. New technologies must be developed to enable robust and efficient manufacturing and yield replicable high-quality medicines. These challenges need to be addressed to bring affordable curative medicines to patients globally.

Our Offerings

We are at the forefront of this new frontier, with our comprehensive offering that spans products and services for allogeneic and autologous cell therapies, as well as viral vector gene therapies. Our competitive advantage resides in the combination of an integrated offering beyond manufacturing, with unmatched process development expertise and industrialization capabilities. We can offer in-house tissue acquisition, dedicated cell and gene therapy regulatory expertise, to an integrated supply chain orchestration system. Together, these services provide an end-to-end offering from concept to commercialization.

We enable our customers to de-risk their process early and fully industrialize their therapy via our unmatched experience in process development across cell and gene therapy modalities, supplemented with a full access to available technologies, all located under one roof in Houston, TX (USA). This provides customers with the best chance of success for commercialization.

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1 Alliance of Regenerative Medicine (2018)
2 Alliance of Regenerative Medicine (2019)
3 Food and Drug Administration (2019)
Our Modalities in Cell & Gene Technologies

- **Autologous**

- **Allogeneic**

- **Viral Vectors**

We are already well-positioned with our extensive experience in cell processing, process development and manufacturing of cells and viral vectors under current good manufacturing practices (cGMP). Our tailored manufacturing solutions are built around a broad service offering including process development, bioanalytical services and global regulatory support. These offerings, combined with a global footprint spanning the United States, Europe and Asia, enable us to support our clients throughout clinical development and commercial production.

Our Global Footprint

At our Houston, TX (USA) facility, we offer development and cGMP services for cell and gene therapies, including viral vector production. The range includes a wide selection of cell and virus types, including T-cells, dendritic cells, pluripotent stem cells (PSCs), mesenchymal stem cells (MSCs) and adenoviral, adeno-associated virus (AAV) and lentiviral vectors. Our Portsmouth, NH (USA) cell therapy cGMP provides clinical and commercial cGMP manufacturing.

In Europe, our dedicated cell and gene therapy manufacturing sites in Geleen and Maastricht (NL), provide capacity for both process development, analytical services, clinical and commercial cGMP manufacturing.

In Asia, we provide clinical and commercial cGMP cell therapy manufacturing from our Tuas (SG) site. We also partner with Nikon CeLL innovation Co., Ltd in Japan to provide our customers with process development, analytical services, clinical and commercial cGMP manufacturing specifically for the Japanese market.

Our global research and development (R&D) footprint is also growing. This is reflected in the ramping up of R&D capabilities in Houston, TX (USA), at the Israel Collaborative Innovation Center in Haifa (IL), and with the opening of R&D labs in Rockville, MD (USA).

Discover More

Additional information about our services, such as process development, cGMP manufacturing, assay development, analytical and all other related services, is available on our [Cell & Gene Technologies website](#).
Highlights and Initiatives 2019

During the reporting year, our Cell & Gene Technologies business benefitted from continued sales momentum in a dynamic market environment, with strong interest in offerings including process development and commercial manufacturing. We signed a significant number of clinical and commercial contracts with new customers.

Despite the strong commercial momentum, our Cell & Gene Technologies business is addressing the continuing need to improve productivity. The team is focused on improving contractual excellence to reflect the value of our services, optimize our network, and deploy meaningful operational excellence.

In 2020, the business expects at least five late-stage registrations within our global network. In the coming year, we will continue to focus on improving operational excellence and on delivering seamless service, removing supply chain challenges in autologous cell therapy and ensuring patient safety in personalized therapies while working on a “vein-to-vein” offering.

Clinical and Commercial Programs

During 2019, there was a strong interest in our offerings, including process development and commercial manufacturing capacity with new customers signed. We have signed a manufacturing service agreement with Cellectis for our Geleen (NL) site, for the clinical manufacturing of Cellectis’ allogeneic UCART product candidates targeting hematological malignancies. We have also established a strategic collaboration with Prevail Therapeutics, for its pipeline of novel AAV-based gene therapy programs to be developed and manufactured at our Houston, TX (USA) site.

Another example includes the strategic collaboration between Lonza and Dinaqor AG to advance Dinaqor’s preclinical programs for the treatment of cardiac myosin-binding protein-C (MYBPC3) cardiomyopathies, a genetic condition that can result in heart failure. The process development and manufacturing will be located at our Houston site.

In addition to these new partnerships, we have expanded existing collaborations with our long-term partners — Gamida Cell and Mesoblast. We have established a commercial manufacturing agreement with Gamida Cell for Omidubicel, a Phase III investigational advanced cell therapy designed to enhance the life-saving benefits of hematopoietic stem cell (bone marrow) transplant. Under this multi-year agreement, we will construct dedicated production suites at our Geleen (NL) site, for the anticipated commercial launch.

We announced the signing of a commercial manufacturing agreement with Mesoblast for the production of MSC-100-IV, a mesenchymal stem cell-based therapy pending commercial approval by the Food and Drug Administration (FDA) for steroid refractory acute graft versus host disease. The two companies have formed a strategic alliance since 2011 for the clinical and long-term commercial production of Mesoblast’s off-the-shelf (allogeneic) mesenchymal Precursor Cell portfolio of products. Production of MSC-100-IV will be carried out in the existing suite in our cGMP facility in Tuas (SG).

Partnerships

Pursuing the goal of seamless service for our customers and their patients, we announced two partnerships to enable a ‘vein-to-vein’ delivery network. Vineti will provide a supply chain orchestration platform that allows easy access to fully electronic end-to-end control of material, and reduce the time that biopharmaceutical developers need for system selection and integration. Cryoport will provide transport and delivery of patient tissues on a global basis, ensuring seamless service for our customers and their patients. We will work with these two new partners to remove the supply chain hurdles faced by developers of personalized therapeutics.

Personalized Medicine

In March, we started to bring our Cocoon™ autologous cell therapy in-a-box manufacturing device to the clinic as a pilot project with Sheba Medical Center, the largest hospital in Israel. This collaboration is a key part of the development program for the Cocoon™ platform. It will confirm the benefits of using our closed, automated “cGMP-in-a-box” concept to more efficiently manufacture personalized cell therapies where the patients need it. This will enable treatment of a larger patient population.
Market Trends

The microbiome is increasingly a foundation for new therapies in dermatology, endocrinology, cancer, central nervous system and cardiovascular indications. Biopharma companies are developing Live Biotherapeutic Products (LPB) that aim to restore microbiome populations missing in disease or remove harmful ones. There are currently around 100 LPB therapies in the clinical pipeline with five nearing commercial launch. However, most of these are small companies with limited specialized in-house manufacturing capabilities.

The biggest challenges facing companies developing LPB are the difficulty of identifying and growing strict anaerobic bacteria, or cocktails of bacteria, and then maintaining anaerobic conditions in an oral dosage form that delivers the bacteria to the intestine.

Establishing an Offering in 2019

In 2019, a 50/50 strategic joint-venture (JV), was established between Lonza and Danish company Chr. Hansen for developing and manufacturing live biotherapeutic products for pharma and biotech customers. The JV got approval to start operations under the name BacThera.

While Chr. Hansen contributes its know-how in developing, upscaling and manufacturing bacteria strains, we bring capabilities in pharma contract manufacturing and formulation and drug delivery technologies, including the enTRinsic™ capsules.

BacThera Offerings Overview

STAGE 1: 2019–2022
Development services

Approx €45 million shared investment
~50 staff initially
• Serving start-up and small biotech with pre-clinical & clinical development projects
• Service offering focused on process development and small batches

STAGE 2: 2022
Phase III & commercial batch services

Approx €45 million shared investment*
~120 staff
• Serving a mixture of biotechs and their acquirers [e.g. large pharmacos] as clinical projects commercialize
• Service offering expanding to large batch sizes for Phase III and commercial production

* based on customer demand

Our Global Footprint

BacThera will operate from its headquarters in Basel (CH). In addition, the JV will upgrade existing facilities in Hørsholm (DK), and equip new facilities in Basel to serve pre-clinical to Phase II projects. Further facilities will be developed as the pipeline matures.

1 A Live Biotherapeutic Product is a biological product that contains live organisms, such as bacteria and that is applicable to the prevention, treatment or cure of a disease or condition of human beings [excludes vaccines]
Product Businesses

Bioscience

Market Trends

Market trends support all four areas in which Lonza Bioscience operates: Therapeutic Cell Culture Media, Research Tools, Testing Solutions and Quality Control Software.

The global media market was estimated in 2017 at USD 1.4 billion with a 10% CAGR over the next 10 years. This market is expected to reach USD 4-5 billion driven by existing biologics (recombinant proteins and vaccines).¹

In the Discovery market, recent developments in Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) and non-viral, ex-vivo gene therapy are driving demand for alternative technologies, like nucleofection, whilst new applications in in vitro toxicology and immunotherapy are driving demand for liver cells and immune cells, supporting custom cell biology services.

Several developments and trends drive demand for offerings in the informatics and testing markets. Large Pharma and Biotech companies are actively adopting global, integrated and automated solutions in quality control and manufacturing environments. Traceability and data integrity within current good manufacturing practices (cGMP) is becoming a critical part of the manufacturing and release process for a lot of these companies. With Cell and Gene therapy on the rise, there is an increasing need for cost-effective and flexible IT systems, which can be rapidly deployed to improve decision making, quality and compliance needs.

¹ Sources: Meticulous (2018); BCC research (2015); Markets and markets (2015); Seed planning; METI; Kuick Research, Med Market Diligence, Transparency market research, Roots analysis cell therapy manufacturing market (2017 – 2027)
Our Offerings

With our product offerings in media, research tools, testing solutions and quality control software, we help our customers leverage the therapeutic potential for transformational technologies in cell and gene therapy and biologics.

Our offerings provide advanced cell biology and cell engineering solutions, Quality Control (QC), safety testing tools and software. Collectively, these support the life-science industry from discovery through to manufacturing.

We serve customers in academic and government institutions and major biotech and pharmaceutical organizations across the globe. Bioscience customers are discovering, developing and manufacturing critical disease-treating drugs and therapies, and we provide tools to support their activities and ensure the highest degree of patient safety and regulatory compliance. With our product offerings we help our customers leverage the therapeutic potential for transformational technologies in cell and gene therapy and biologics.

Our therapeutic cell culture media are used in the production of therapeutics, including antibodies, antibody drug conjugates (ADCs), vaccines, cell and gene technologies applications and other biologics.

Our Discovery Solutions offer human cell-based tools for basic research, drug-discovery and translational research targeting cardiovascular, respiratory, neurological, metabolic, cancer and other disease areas.

Our Testing Solutions offer endotoxin-detection assays that are applied in pharmaceutical product-release testing, medical device testing and dialysis clinics. They help to ensure the safety of injectable drugs, implantable medical devices and dialysis equipment.

The fully integrated MODA™ Software Solutions streamline quality-control processes and offer insight into manufacturing operations, with quick access to management, compliance and trending data.
Our Global Footprint

Our Bioscience business serves customers across the world with a network of seven key production sites.

In Europe, the team at our Cologne (DE) site is dedicated to the manufacturing and sales of a non-viral transfection method, which enables a more efficient identification of new targets for pharmaceuticals and therapies. Our second site in Verviers (BE) is the European distribution center for Bioscience Solutions research products and produces cell culture media for bioproduction, cell and gene therapy and research applications. Our Copenhagen (DK) site specializes in custom manufacturing unique agaroses for chromatography purposes.

In the USA, our Walkersville, MD (USA) site is the North American distribution center for Bioscience Solutions research and as well as producing cell culture media, we also manufacture endotoxin testing reagents, automation and software solutions for the quality control of parenteral drugs, medical services and biomanufacturing products.

Further sites in the USA include Durham, NW (USA), which is a Center of Excellence that specializes in the manufacture of primary cells for research, drug discovery and drug development. In Wayne, MI (USA), we provide software solutions for environmental monitoring and electronic batch recording. In Rockland, ME (USA), we provide life science researchers with state-of-the-art products for use in molecular biology as well as cell based assays for clinical diagnostics, rapid cell health and activity screening and other applications.

Discover More

Additional information about our offerings, such as process development, current good manufacturing practices (cGMP), assay development, analytical and all other related services, is available online. Explore our worldwide sites by location via our 360° Virtual Tours.
Highlights and Initiatives 2019

The Bioscience Solutions business saw increased demand, based on favorable market trends in drug discovery and cell therapy. We are continuing to make progress with operational improvements.

**Therapeutic Cell Culture Media**

With over 40 years of expertise in media development, we introduced eCHO™ Basal Medium and Feed. eCHO™ Medium is a new serum-free, chemically defined, hydrolysate-free and non-animal origin medium to enhance late-stage cell viability, accelerating protein purification and allowing for the production of a consistently increased amount of proteins per cell.

Our leading TheraPEAK™ X-VIVO™ Cell Culture Media have seen strong growth in 2019, supporting the CAR-T process and other treatments under development in the cell therapy market. Our Bioscience Solutions and Cell & Gene Technologies groups are joining forces to promote a full offering in cell and gene therapy, helping customers to successfully navigate the path from early discovery to commercialization, and get new treatments to patients faster.

Bioscience Solutions and our Mammalian and Microbial Development and Manufacturing groups are intensifying their collaboration in order to help customers in the biologics market using our GS-CHO™ Media as an integral part of our GS Gene Expression System®.

**Research Tools**

Bioscience continues to shape the cell and gene therapy market, with integrated solutions and our cell biology expertise both positioned to support cGMP cell processing workflows, including those based on Lonza’s Nucleofector® Transfection Technology. Market adoption of the 4D-Nucleofector® LV Transfection Device increased as we accelerated efforts to support cGMP workflow requirements and establish Nucleofector® Technology as the standard for non-viral transfection in cell and gene therapy applications.

In 2019, we developed a line of high-quality cryopreserved pooled donor suspension hepatocytes, DonorPlex™ Hepatocytes. In addition, we added Verified for Spheroids™ Human Hepatocytes, which are pre-screened for their ability to promote spheroid formation in 3-dimensional cell culture platforms, supporting toxicology, disease modelling and Drug Metabolism and Pharmacokinetics (DMPK) studies.

Customers working on immunology applications can take advantage of the largest available portfolio of immune cells, due to the private label partnership between Lonza Bioscience and AllCells. This partnership expands our broad offering of hematopoietic cells supporting an array of applications in drug discovery, toxicity testing, cell therapy and personalized medicine.

To meet specific, individual research application needs, we have expanded our CellBio Services, a comprehensive portfolio of unique, custom solutions. Researchers across pharmaceutical and contract manufacturing organizations can now choose from an extensive range of services, including cell line expansion and banking, media production, cell isolation, cell characterization, transfection services, and three-dimensional (3D) cell-culture services.

**Testing Solutions**

Due to sustained interest from new and existing customers, we continue to expand our global availability of the world’s first fully automated, plate-based robotic solution PyroTec™ PRO Robotic Solution for endotoxin testing. The platform marks a milestone in endotoxin detection, allowing pharmaceutical manufacturers to replace manual, error-prone processes with a fully automated solution, integrating instruments, endotoxin reagents and software offering quick time-to-result. In addition, our PyroGene™ Recombinant Factor C Assay, is gaining traction in the market, as regulatory authorities have started accepting the assay as an alternative method for endotoxin testing.

**Quality Control Software**

During the reporting year, the Bioscience business experienced strong interest in the MODA™ Platform. We launched the next-generation electronic batch record execution solution, MODA-ES™ Software Platform, designed to provide a cost-effective, easy to use solution to batch record challenges, by consolidating and managing batch and quality data generated by non- or semi-automated manufacturing processes.
Pharma Hard Capsules

Market Trends

In 2018, the global hard empty capsules (HEC) market was above 700 billion capsules (units). In 2020, the global growth for the capsule market is anticipated to be modest in value for pharma, and comprise approximately 70% of the capsule market globally. Within Pharma, demand has been driven by more complex drugs requiring specialized dosage forms to overcome bioavailability challenges, such as oncology and orphan drugs, as well as by volume growth in pharmerging markets driven by off-patent drugs. Moreover, the majority of new developments are in the generic space and more than half of NCE [New Chemical Entity] developments are currently in specialty polymers, underlining the current market trend in non-gelatine base alternative for capsules. From a geographic perspective, Pharma HEC sees increasing demand in the Asia-Pacific markets, as well as consolidated demand in developed markets. Asia is a key growth driver, especially in generic drugs and the traditional Chinese medicine segment in China.

Our Offerings

The pharma hard-capsule business continues to build on the Capsugel® brand and track record of ingenuity, credibility and flexibility to deliver a positive experience and drive added value creation for our customers. Our proprietary and patent-protected technologies, significant expertise in capsule polymer science and product and process design capabilities, all help our customers meet their target product profiles and commercial objectives. Business continuity for capsule supply to the biopharmaceutical industry is unmatched with eight production sites located in Europe, USA and Asia.

Leveraging this extensive experience in two-piece hard capsule design and manufacturing, we have also been able to deliver an unmatched value-added service portfolio. Following our commitment to deliver high-quality products, we have established standards and systems to oversee internal and external quality performance by establishing a global quality organization, with an integrated supply chain, technical and operational engineers, color lab support and global regulatory expertise.

Our acquisition of Capsugel, with its unique hard-capsule science and engineering, has allowed us to provide the broadest range of capsule polymers, sizes and designs in the global pharmaceutical industry. We also offer integrated product design, development, clinical supply and commercial manufacturing services to our customers around the world. The diversified customer base includes companies that make branded, generic and specialty pharmaceuticals, as well as biotech products and over-the-counter medicines.

Our Global Footprint

At our Greenwood, SC (USA), we provide hard capsule manufacturing, as well as the product development and manufacturing of liquid and multi-particulate filled hard capsules.

In Europe, our dedicated hard capsule manufacturing sites are in Bornem (BE) and Colmar (FR), with Colmar also offering finished product design and development and manufacturing of liquid and multi-particulate filled hard capsules. Both sites also serve as our R&D Centres of Excellence.

In Asia, our presence spans from Suzhou (CN), Jakarta (ID) and Haryana (IN) to Sagamihara (JP). Our Sagamihara facility provides capacity for hard capsule manufacturing, product development and manufacturing and multi-particulate filled hard capsules.

Highlights and Initiatives 2019

The pharma hard capsules business saw ongoing demand for specialty polymer and dry powder inhalation (DPI) offerings. The business was supported by new product launches but challenged by market conditions in the US and slower growth in developed markets. Several long-term agreements were signed.

In 2019, we launched Lonza Engine™ line for clinical and commercial scale processing equipment inclusive of specialized encapsulation technology which complement our capsule product line offering.

From early-stage development to commercial solutions, the hard-capsule business continues to offer the broadest portfolio of gelatin, hydroxypropylmethylcellulose (HPMC) and other specialized polymers for capsule production tailored to specific pharmaceutical applications. Supporting the fast growth of the HPMC lines, we re-launched Capsugel® Vcaps® Plus HPMC capsules globally. In addition, our specialized capsules for DPI applications were launched, branded as Zephyr® capsules, building on more than 20 years of experience in DPI encapsulation applications. Zephyr® capsules are supported by DPI and bioavailability enhancement formulation services to serve the growing number of pulmonary delivery route solutions.

1 Source: Internal Analysis
2 Including Pharma and Nutritional Hard Capsules
Market Trends

The broader nutrition industry (CHF 590 billion retail selling price)\(^1\) continues to grow with segments such as joint health, sports nutrition and digestive health forecast to grow at 7-9% (CAGR 2019 – 2024)\(^1\). The nutritional capsules market, however, is expected to grow in line with the overall capsules market of moderate GDP+ growth. More consumers are proactively looking to protect their health, improve their wellbeing, and live longer, healthier lives. With today’s busy lifestyle, consumers are seeking convenient methods of getting nutrients through supplements and functional foods. Consumers are also looking for greater transparency in the products they buy. They also want to understand how a product was made and where it came from. Trusted products offering clean-label, natural, non-genetically modified organism (GMO), plant-based credentials and information on ingredient sourcing and processing, are of great consumer interest. In addition, the convergence of the food and pharma market continues with an increasing range of supplements, functional foods, and nutraceuticals to promote and expand healthspan.

Our Offerings

We offer specialty ingredients, formulation know-how and inventive oral delivery solutions backed by industry-leading service capabilities and global regulatory expertise to help our customers take their innovative and differentiated nutritional products to market in the shortest time possible. Now fully incorporated into Lonza, the former Capsugel business serves pharma, over-the-counter (OTC), and nutrition customers with gelatin and specialty polymer hard capsules as well as fully formulated specialized finished dosage forms.

We strive towards fully integrated solutions, from initial concept to ready-to-market product commercialization. In addition to our broad capsule range, we offer a select portfolio of high-quality nutritional ingredients across joint health, active nutrition, digestive and immune health, weight management, sports activities, and pet nutrition. Our customers benefit from our rich consumer market insights and long-standing expertise in pharmaceutical delivery science, which has enabled us to develop a comprehensive range of proprietary dosage forms and delivery technologies. These include targeted delivery, liquid-filled hard capsules, soft gels, capsule-in-a-capsule or tablet-in-a-capsule solutions and lipid multi-particulates.

Nutritional Capsules and Nutritional Ingredients Offerings Overview

- **Healthy Aging**
  - UC-II\(^®\) | Relora\(^®\) | Meratrim\(^®\)
- **Sports Nutrition**
  - Carnipure\(^®\) | ZMA\(^®\) | UC-II\(^®\)
- **Digestive & Immune**
  - ResistAid\(^®\)
- **Hard Empty Capsules**
  - Vegetarian – Vcaps\(^®\), Vcaps\(^®\) Plus, Plantcaps\(^®\), DRcaps\(^®\)
  - Gelatin, Gelscaps, Sprinkle Caps
- **Formulation Technologies**
  - Liquid Multi-Particulate
  - Beadlet technology
  - Micronization
- **Finished Dosage Forms**
  - Improved Performance
  - Modified/Targeted Release
  - Enhanced Consumer Experience

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1. Source: Euromonitor
The innovative capsules in our portfolio enable customers to improve the bioavailability, targeted delivery, swallowability, scent and taste masking of their nutrionals. Consumer experience is enhanced, while product owners enjoy the benefits of superior brand differentiation.

Our Global Footprint

We serve customers in more than 100 countries around the world thanks to a state-of-art network of 11 production and R&D sites across three continents. In addition to the manufacturing sites we share with the pharma hard capsules business in Greenwood, SC [USA], Bornem [BE], Colmar [FR], Sagamihara [JP], Suzhou [CN], Jakarta [ID], and Haryana [IN], we also have a Capsugel® capsule manufacturing site in Puebla [MX].

On the nutritional ingredients side, our UC-II® Undenatured Type II Collagen [joint health] is primarily manufactured in Fort Smith, AR [USA], and will be supplemented by Greenwood, SC [USA]. We produce our Carnipure® L-carnitine for human nutrition, and CarniKing® for pet nutrition in Nansha [CN], an FSSC 22000 certified plant. In addition, our ResistAid®, an arabinogalactan uniquely sourced from local larch trees to support immune health, is produced in Cohasset, MN [USA].

We created additional capacity within the existing footprint in 2019, with plans to further expand our Greenwood, SC [USA] facility in mid-2020. This integrated facility will offer capsule manufacturing, ingredient production, and finished dosage forms at the same site.

Discover More

For further information about our businesses, visit one of the following webpages: Capsules & Food Supplements / UC-II® Lifestyle in Motion™ / Capsugel / Consumer Health / Nutrition website

Highlights and Initiatives 2019

The nutritional hard capsules business was negatively impacted by increased competition. This was exacerbated by softer demand for conventional gelatin hard capsules and slower growth than anticipated in specialty polymer empty capsules, particularly in mature markets. The business started to implement commercial countermeasures with first impact in Q4 2019. The nutritional ingredients business experienced softer performance, mainly related to supply issues.

In 2019, we have helped several customers launch new products or reformulate existing ones by combining innovative nutritional ingredients, optimizing formulations and tailoring capsule delivery technologies. Overall, we see solid growth opportunities for nutritional capsules, as well as combined ingredient and capsule offerings.

Nutritional Hard Capsules

Following the launch of the industry’s first clean-label and food-colored capsules in 2018, we have continued to bring new consumer-driven capsule innovations to the market in 2019.

For instance, we introduced Vcaps® Plus White Opal® capsules, our first commercially available titanium dioxide-free semi-opaque [TiO2] capsules designed to address the changing regulatory environment alongside a growing demand for opaque capsules in Europe. Solutions in our wider plant-based range also include our innovative dosage forms, such as vegetarian Plantcaps® capsules.

Our vegetarian Vcaps® Plus capsules can now also be tinted using natural coloring foodstuffs to achieve a vibrant color that offers outstanding brand differentiation without compromising on a clean-label positioning. To date, Red Radish, Spicy Yellow, Blue Spirulina and Purple Carrot Vcaps® Plus capsule colors have been launched in Europe. Purple Carrot capsules were successfully launched in the United States, while Blue Spirulina capsules are also available in Canada.

Nutritional Ingredients

Our premium, science-backed UC-II® ingredient for joint health successfully entered new markets, regions and applications in 2019. We introduced different innovation concepts for joint health, featuring UC-II® undenatured type II collagen in combination with other trending ingredients combination. Examples include vitamin K2, which was delivered in a Licaps® liquid-filled hard capsules to offer an all-in-one bone-and-joint health solution. We also expanded the applications for our UC-II® ingredient in pet nutrition, with a focus on supporting pet health and well-being.

Putting the spotlight on our performance nutrition expertise, we launched a new sports nutrition ingredient, Oceanix™ marine phytoplankton, based on highly active antioxidant enzymes. This unique ingredient is sustainably sourced from the ocean and meets the rising demand for natural, non-GMO, and vegan supplement products, bringing together sports performance and wellness benefits.

The Carnipure® L-Carnitine ingredient for sports nutrition also became a key component of our newly launched MuscleGuard™ formulation, a vegan solution for optimizing gains in muscle mass and strength. The MuscleGuard™ formula brings together our Carnipure® L-Carnitine ingredient, Creatine and Leucine with vitamin D in a proprietary ratio that was demonstrated by a clinical study1 to deliver a 63% increase in muscle strength, mass and activity in older people.

1 Bellamine, et al. Nutr Metab. 2017
Specialty Ingredients

Market Trends

The Specialty Ingredients sector is in a time of evolutionary change with new markets opening up, primarily driven by an improved standard of life and growing middle classes in developing markets. There is also an increased demand for personalized health and a push towards environmentally friendly and sustainable products. All these opportunities come with challenges, as the sector faces increased complexity in global regulatory requirements and raw material shortages (with associated price volatility). There is also increased competition with the rapid rise of Chinese chemical producers and the new and innovative market entrants challenging established players.

We are well positioned to overcome these challenges and capitalize on existing opportunities to drive growth and accommodate increased demand.

Our Offerings

In Lonza Specialty Ingredients (LSI), we are focused on further strengthening our market leadership in microbial control solutions to protect our environment and ourselves from harmful microbes. Our businesses deliver customer-focused, innovative and smart solutions for a wide range of consumer and industrial markets, as well as wood applications and agricultural offerings along a common microbial control solutions platform.

A key challenge for our customers is the increasingly complex and evolving regulatory landscape. We can help them by applying our deep understanding of both current and future regulations to enable them to achieve performance and regulatory compliance.

We also provide solutions for composite materials and processing additives for high performance industries, performance chemicals and intermediates as well as custom development and manufacturing.

In 2019, the LSI segment comprised the following offerings:

- **Microbial Control Solutions**
- **Specialty Chemical Services**

In 2019, we announced the decision to carve-out the LSI segment, with the intention of operating independently whilst remaining part of the Lonza Group. This will allow us to grow and strengthen our leading role in the microbial control solution market, as well as operate more efficiently. We expect to complete the process by mid-2020.

Our Global Footprint

With representations in 28 countries across 5 continents and 2,504 employees, we take care of our customers and their global, regional or local requirements.
**OUR BUSINESSES**

**Microbial Control Solutions**
- Huddersfield, UK
- Auckland, New Zealand
- New Plymouth, New Zealand
- Trentham, Australia
- Penang, Malaysia
- Suzhou, China
- Port Shepstone, South Africa
- Salto, Brasil
- Rochester, USA
- Williamsport, USA
- Mapleton, USA
- Conley, USA
- Kalama, USA
- Valparaiso, USA

**Specialty Chemical Services**
- Visp, Switzerland
- Kouřim, Czech Republic
- Nansha, China
- Nanjing, China
- Lake Charles, USA
Financial Highlights

Lonza Specialty Ingredients (LSI) has experienced headwinds during 2019. Sales declined 3.2%, resulting in CHF 1.7 billion revenues for the segment. Pricing initiatives, operational improvements and cost control measures resulted in a CORE EBITDA of CHF 302 million and a solid 17.8% CORE EBITDA margin. We will continue to focus on driving recovery for our business, delivering the carve-out and developing a new market-oriented and efficient organization. Over the course of 2019, we have worked to develop the structure of our business to reflect more accurately the underlying technology platforms. The business is now set up with a leading portfolio of Microbial Control Solutions (MCS), supported by a division of dedicated Specialty Chemicals Services (SCS).

### Specialty Ingredients

<table>
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<th>2019</th>
<th>Change in %</th>
<th>2018 Restated</th>
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<tr>
<td>Sales</td>
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<td>CORE EBITDA</td>
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<td>CORE result from operating activities [EBIT]</td>
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<td>Margin in %</td>
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<tr>
<td>CORE result from operating activities [EBIT] excl. IFRS 16</td>
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<tr>
<td>Margin in %</td>
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### Sales

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<td>1,749</td>
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<td>2019</td>
<td>1,693</td>
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### CORE EBITDA

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<th>Million CHF</th>
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<td>2017</td>
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<tr>
<td>2018</td>
<td>303(^2)</td>
</tr>
<tr>
<td>2019</td>
<td>302</td>
</tr>
</tbody>
</table>

\(^1\) Reported pro-forma full-year 2017 financial results include Capsugel full-year 2017 financial results

\(^2\) Restated to reflect the 2019 realignment of Lonza's segments into Pharma, Biotech & Nutrition and Specialty Ingredients
Innovations in Lonza Specialty Ingredients

Our Specialty Ingredients business development team focuses on innovation to anticipate the evolving needs of the marketplace. All our LSI businesses are addressing a wide range of consumer-oriented and industrial markets, as well as wood applications and agricultural offerings along a common microbial control platform. The focus is on innovative and smart microbial control solutions for resource protection and a consumer-centric healthy environment. There is also a developing focus on increasingly challenging regulatory requirements that carry both risks and opportunities for competitive differentiation.

Regulatory Stewardship
The changing regulatory landscape is impacted by multiple factors; chemical regulations are becoming more stringent and increasing in number, difficulties and enforcements. Global regulatory scenarios are becoming increasingly complex, with local adaptations especially in emerging markets. There is a greater concern over the environmental impact of biocides driven by consumer and non-governmental organizations; new potential health concerns are also being raised.

Because of the heavily regulated nature of the microbial control platform, the choice of chemicals available is shrinking while the requirement for new and established products is increasing. These challenges offer us opportunities to differentiate against our competition by using our deep scientific and regulatory knowledge and expertise. Our leading position in Microbial Control Regulatory enables us to address and meet market challenges and offer solutions, which protect our customer's brands and the environment.

Our extensive portfolio of approved active substances is a major competitive advantage when traditional biocides such as methylisothiazolinones [MIT] become more strictly regulated due to health and environmental concerns. In response to an increasing global demand for MIT-free biocide formulations, we have expanded our portfolio of preservatives with two active broadband biocides for the wet-state preservation of water-based paints, adhesives and construction chemicals. For more information, see Microbial Control Solutions.

Market-driven Innovation
Growing awareness of health risks increases demand for innovative, safe and sustainable hygiene and microbial-control solutions, which deliver infection control, clean-label preservation, a safe and healthy living environment and a sustainable use of resources.

We have an incremental innovation pipeline with a high number of very promising projects, which have the potential to convert into market leading innovations supporting the Specialty Ingredients innovation platform in microbial control.

Our market-led microbial control innovation spans from single highly effective anti-microbial ingredients to formulated microbial solutions. Our know-how in formulation expertise and application technology enables our customers to access formulated turnkey solutions, which meet the complex requirements of our customers' applications.

In the areas of hygiene and disinfection, we offer industry-leading innovative blends of anti-microbial ingredients that provide safe and effective protection against bacteria, molds and other contaminants while satisfying increasingly strict global regulations.

Collaboration and Start-up Funding
In early 2018, we launched with the Prolog Lonza Consumer Fund, an exclusive Venture Capital Fund in partnership with Prolog Ventures to invest in potentially game-changing, consumer-centric start-ups focused in North America.

The Fund offers value by providing early-stage, high-growth companies with access to our global resources and expertise. In return, we can gain insights into innovative business models and technologies, evolving consumer trends and changing demands, and new digital routes to market. By tapping into the entrepreneurial ecosystem, we aim to expand our future business growth opportunities.

In 2019, Prolog Ventures' first funding has been released to bio-Clarity™, a digitally native brand known for its skincare products. Specifically formulated for the treatment of acne in teenagers and young adults, bioClarity™ is rapidly growing in popularity among Generation Z and Millennials. The investment enables us to collaborate in a high value niche market, to prototype customized solution offerings and to benefit from bioClarity™’s expertise in consumer targeted social media marketing.

In the last three years, we have established collaboration with Universities that can help us further develop and maintain our leading position in microbial control. We have established collaborations with the University of Sofia [a world leading school in colloid science and formulation], Sheffield University [a leading research center on bacterial adhesion and biofilm], Manchester University [with world-class Physical and Microbiology departments] and Oxford University.

In collaboration with Manchester University’s School of Biological Sciences and School of Physics and Astronomy, we have been awarded a grant from Innovate UK, a non-governmental public body operating as part of the United Kingdom Research and Innovation organization. With this support we are working on combating antimicrobial resistance [AMR] through developing the understanding of the interaction between microorganism and biocide and enabling market expansion through sales growth from active ingredients and formulated products.
Personal Perspective

Sven Abend
Chief Operating Officer Specialty Ingredients

2019 has been a transformational year for the Specialty Ingredients segment (LSI). We have worked to refocus our business, define the priority growth areas, enhance our market and customer offer and review the organizational structure to improve our agility and alignment with the wider business.

In Q1 we transferred the Consumer Health & Nutrition business into the Pharma & Biotech segment, allowing us to focus more closely on strengthening our microbial control platform. This is our major growth driver and a business in which we already hold a leading market position.

Following the Group announcement of its intention to commence a carve-out of the Specialty Ingredients segment from the wider Lonza Group business, we began to prepare for operational, commercial and financial independence, while remaining within the Lonza family. This step has enabled LSI to structure its business for optimal performance as a standalone entity.

LSI now comprises two divisions, focusing on different markets and operating distinct technology and asset platforms: Microbial Control Solutions (MCS), our growth driver, delivers future-proof Microbial Control technologies and related applications to consumer-facing and resource protection markets. Our Specialty Chemical Services (SCS) is an asset-driven business with attractive growth levels in technically demanding industries and applications, as well as capabilities in custom development and manufacturing.

To better serve the specific needs of these very different businesses, we aligned portfolios and adapted the size of our organization to best support the business in the long-term. Notably, we integrated our business critical enabling functions, such as customer service, to further increase our efficiency and service quality.

Over the past year, we have also significantly improved our operational excellence. For instance, we have integrated our supply chain and simplified our asset management. The combination of these efforts will allow us to build a sustainable and competitive standalone entity that delivers the best possible operational efficiency and is responsive to changing business needs.

Turning to our external context, we have faced challenges in our markets, but we are confident that we will benefit from greater stability in 2020. Through 2019, we have experienced challenges in our supply chain with shortages of some key raw materials, as well as softer demand in our end-markets, caused by a combination of trade disputes, higher tariffs and stricter regulation.

We have worked assiduously through all of these challenges to create a leaner business with greater flexibility and a strong focus on operational quality and efficiency. The team has embraced many changes over the course of 2019, while steadily driving the business forward. We are confident that we have set ourselves up for improved performance in 2020, with innovative offerings and greater agility to navigate the regulatory landscape, as well as a stronger customer focus.
Wood Protection
Our wood protection products deliver technologies that enhance the performance and increase the longevity of wood, one of the world’s greatest renewable resources. We manufacture high-quality formulated products that protect wood from mold, insects, fungal decay and fire to help make the most of wood as a sustainable and adaptable construction material. Our proven preservative technologies extend the service life of lumber, ensuring it can be used as a high performance material. Sapstain and mold control treatments keep lumber clean all the way from the sawmill to consumers’ doors. Our heavy-duty industrial offerings protect wood in the harshest environments, including utility, railway, marine and agricultural applications. Our market-leading formulations for glue line protection of strand and veneer-based engineered wood products secure the future of wood against alternative materials. We support our customers with our flagship brands of Wolman®, Tanalith®, Dricon® and AntiBlu®.

Material Protection
Our Materials Protection business offers solutions that include anti-microbials, corrosion inhibitors, lubricants, and a variety of other specialty additives. These products are used across a range of industries including Metal Working Fluids, Powdered Metal, Polymers and Textiles, and Oil and Gas. Our Metal Working Fluid products, such as Densil®, Omicide®, Proxel®, Lonzabac® and Vanquish® protect our customers fluid systems from harmful bacteria and fungi, lengthening the use of a fluid system therefore providing sustainable solutions, that reduces system costs and waste. Our Arcawax® Powdered Metal lubricants are recognized as the high quality industry standard lubricant, reducing the likelihood of wasted materials and increasing our customers manufacturing efficiency.

Over the last four decades, products made from polymer blends are becoming an increasing part of a consumer’s life. We have served the polymer industry with unique customer-specific product solutions of high quality and consistency. These additives, such as Acrawax®, Glycolube® and Glycomul® are either protecting the polymer matrix (for e.g. lubricants) or are providing a unique property to the overall system such as its anti-static, anti-fogging effect. Typical examples for end applications would be car interior & under the hood, consumer electronics, ophthalmic and medical devices.

Our anti-microbial products, in particular Vanquish® and Zinc Omadine® are also additives of choice in applications such as carpet backing, bath mats, shower curtains, wallboards, plastic fencing, roof tiles etc. A growing consumer trend in the textile industry, specifically in sports active wear is to have anti-microbial additives as part of the formulation to minimize the bad odors caused by the bacteria from perspiration. Our products are part of a significant number of premium athletic brands.
In the Oil and Gas market, we provide high performance biocides, such as Bardac®, Barquat®, Vantocil® and Dantogard®, corrosion inhibitors Uniquat®, Akolidine® and hydrogen sulfide scavengers SourBan®, that are used to protect oil and gas production systems from aggressive corrosion conditions.

Paints & Coatings
We are a global leader for Paints & Coatings which includes providing wet state preservation for waterborne architectural paint and other formulations in the building and construction market space. Additionally, we play a critical role in the protection of marine vessels from marine antifouling and offer best in class technology for paint dry film protection against defacement from algae and fungi. We are an innovation leader by providing effective solutions that are oriented to microbial control versus just biocides. Innovation efforts include providing slow release technologies and an increasing focus on using inert raw materials to provide efficacy in coating systems.

Customers know us through the global brands of Proxel®, Omadine®, Densil® and Umigard®. Each brand conveys our leadership position in the various applications for microbial control ranging from protection on a home owner facade to the hull of an ocean going vessel.

Professional Hygiene
As a global leader in registered biocides, preservatives and antimicrobial formulations, our hygiene business offers solutions for disinfecting and sanitizing surfaces in industrial and institutional settings. This includes schools, food-processing plants, restaurants, grocery stores, hospitals, operating theaters and health clinics. Our products help prevent the spread of infection and are available in a range of formats, including concentrates and ready-to-use liquids, wipes, and solids. Our global registrations portfolio includes the U.S. Environmental Protection Agency [EPA], the Canadian Therapeutic Products Directorate [TPD], the EU Biocidal Products Regulation [BPR] and the China and Japan Ministries of Health, as well as many other regulatory agencies around the world.

We also provide regulatory and toxicology expertise, supporting compliance with global regulatory regimes. Our robust data packages and innovative, market-focused research and technology offerings enable our customers to stay at the forefront of industry developments. Product innovation and strong regulatory leadership will continue to be the strategic cornerstones of our professional hygiene offering together with our high levels of customer support.

Home & Personal Care
Within Home Care, our focus remains on ensuring that our homes remain healthy places, by providing new and innovative solutions to clean, sanitize and disinfect our rooms and surfaces. Our innovative research and development [R&D] programs, aligned with industry-leading regulatory and toxicology expertise, allow us to offer convenient and effective solutions to the many microbial challenges we face in the home.

Our Personal Care business serves the global beauty and well-being markets. We are the leading producer of dandruff-fighting ingredients, built on Zinc Pyrithione – the world’s most recognized and widely accepted anti-dandruff active. In addition, our Zinc Omadine® brand is recognized as the global standard for cosmetic anti-dandruff treatment products.

We further strengthen our position with well-established and next generation preservation systems, as well as our functional ingredients, such as specialty plant-based emulsifiers and aesthetic modifiers across all of personal care formulations.

With custom-developed biological fermentation and technologies perfected for pharmaceutical companies, the personal care team continues to deliver premium-positioned bio-active functionals, which enhances the consumer experience and uniquely improves the performance of finished products targeting leave-on skin and scalp care.

Crop Protection
Our Crop Protection business offers customers a range of agro-chemistry and formulations for global agricultural markets. We have a leading position in the supply of Meta® Metaldehyde, the active of choice for controlling mollusks. We have invested significantly in registration packages across the world. To support the farming community, we have also extended our molluscicide offer to include Axcela® pellets, a ready-formulated product for use in a wide range of global agricultural needs.

Developed in collaboration with our distribution partners in different regions, we have an ever-increasing range of products to help farmers maximize the effectiveness of their crop protection products. We offer crop-protecting fungicides, insecticides, herbicides, foliar nutrients and additives. To provide full support to the farming community, we also offer post-harvest sanitation solutions such as FREXUS®. This line of products ensures effective sanitization in the food, beverage and farming industries.
While general demand for microbial control applications was solid in 2019, the Microbial Control Solutions business saw mixed performance, which was related to its various end-markets.

**Wood Protection**

During 2019, Wood protection experienced stable demand, but saw an increased competitive environment and pricing pressure, especially in the US market.

The increasingly stringent regulatory landscape in the European wood protection market, combined with the ongoing Biocidal Products Directive (BPR) evaluation of creosote [a common preservative system used for high-performance timber applications], has generated increased market interest in modern technologies such as our new Tanasote® preservative. Tanasote® is an innovative oil-based alternative to traditional creosote, expected to be available by the end of 2020.

We successfully launched another new high-performance preservative formulation, Tanalith® K, for the treatment of utility poles, agricultural timbers, and other industrial products in Oceania. The product was launched with a flagship customer in 2019, providing the foundation for further rollout in 2020.

We have also expanded the geographic offering of our existing technologies, including our Excalibur® incising equipment and Auto-Treater® process control systems, to drive steady growth in targeted regions such as the Nordics, France and United Kingdom. We experienced further growth in the residential retail sector in North America through collaborative marketing partnerships with wood treatment customers and the big box retail channel.

**Material Protection**

In 2019, Polymers and Textiles faced softer market demand from the automobile industry and still suffered from a suboptimal supply of a BIT (1,2-Benzisothiazolin-3-one)-related intermediate. BIT supply began to regain stability in H2 2019 and Lonza expects a fully restored supply by the end of H1 2020.

Oil and Gas industry solutions performed strongly in 2019; these include corrosion inhibitors and biocides to protect vital operation systems. We launched a new oil and gas biocide, Bardac® 2210 Biocide, providing large cost performance improvements and significant lead time reductions with last leg field logistics. Leveraging our deep technical capabilities, the industrial team deployed novel rapid Deoxyribonucleic Acid (DNA) speciation techniques to help customers make better decisions about protecting their assets while concurrently reducing costs.
Moreover, we announced the approval of Densil® DN and Densil® DG-45 antimicrobials, by the United States Environmental Protection Agency (EPA) for use in all metalworking fluid systems. The Densil® DN and Densil® DG-45 products are globally recognized fungicides with a proven performance record. These antimicrobials are chemically stable over broad pH and temperature ranges, effective in systems with a high level of bacterial contamination and compatible with a variety of metalworking fluids and amine systems.

Paints & Coatings
Paints & Coatings showed good performance during the reporting year, despite the shortage of key raw material BIT.

In response to future global methylisothiazolinone (MIT)-label restrictions in biocide formulations, we introduced two new additions to the Proxel® range of preservatives. Proxel® LSR and Proxel® HBC Preservatives are dual-active, broad-spectrum biocides for wet-state preservation of water-based paints, adhesives and construction chemicals.

Professional Hygiene
Professional Hygiene saw positive performance in 2019, with continued strong disinfection sales into veterinary, biosecurity, food service and wipes.

In 2019, we expanded our hygiene offerings into the Indian and Middle Eastern markets to meet the increasing hygiene needs and standards resulting from socio-demographic, macro-economic and regulatory changes.

As part of our customer support program, we introduced new additions to our professional hygiene offerings. One example is our first hydrogen peroxide based hard surface disinfectant. Hydrogen peroxide is a sustainable active that breaks down naturally into water and oxygen. The NUGEN® EHP platform offers environmentally sustainable disinfection to consumers and cleaning professionals, who want to use more sustainable cleaning solutions without compromising core-cleaning performance. We have also expanded our hand hygiene offerings to include a Non-Alcohol Hand Sanitizer concentrate.

Our European Professional Hygiene business in the EMEA region continued to grow well above market average, mainly driven by the further implementation of our market-tailored “Survive the BPR®” initiatives. The value offered through our “Formulated Solutions” program has been well received by the market, and adopted by a steadily increasing number of customers. The initiative mainly targets mid-sized and smaller accounts which are looking to market biocidal products under their own brand, but for which we take care of all regulatory and technical support, ranging from product development to market authorization under the BPR. Customers may manufacture the biocidal end-use product in their own facilities under a license agreement, or purchase the readily formulated product directly. Our “Premium Support” initiative is targeted to key accounts in the hygiene market, building on our regulatory and technical expertise in the field of biocides. Customers value our specialist support to assure authorization of their products.

The list of tools to effectively manage pathogens that move with people, animals and food, is getting smaller. This is why we have started a holistic advocacy program aiming to educate consumers, users and scientists about the existing data that answers questions around human health, environmental fate, human toxicity and microbial resistance. An example is our current partnership with Manchester University, which is partially funded by the United Kingdom government to dispel the concerns surrounding Quaternary Ammonium Compounds resistance.

Home & Personal Care
During the reporting year, the Home & Personal Care business continued innovating in chemistries, applications and differentiated offerings. Home care disinfection saw positive performance in 2019, while Personal care preservation ended the year soft but saw an uptake in H2.

Driven by changing requirements of the US Food and Drug Administration (FDA) which have caused increasing moves away from Triclosan, we successfully introduced an effective microbial-control alternative - Lonzagard® BKC cGMP - to the home care market. Produced under current good manufacturing practice (cGMP) to meet the stringent US FDA regulatory requirements as a hand care antimicrobial active ingredient as well as a personal care or pharmaceutical preservative. In addition, during 2019, Lonza continued to invest in the development of Safety and Efficacy data required by the FDA for maintaining this hand hygiene tool for its use against microbial pathogens. These efforts allowed us to secure and renew long term agreements with multiple customers in consumer and professional service markets.

Globally, we have invested significantly in our consumer laundry hygiene program, helping to reduce energy and water consumption. Reductions in wash temperatures, coupled with lower water usage and shorter cycle times, have reduced the removal of micro-organisms during the washing process, leading to increases in the need for hygienic laundry products. Driven through our United Kingdom-based laundry development center, we have become an advanced and growing supplier of antimicrobial solutions in this area, currently best exemplified by our widely used Bardac® 2080 active ingredient.

In response to the changing and increasing regulatory requirements of home care preservation, we have repositioned our Sodium Omadine® antimicrobial, a preservative active, providing a viable isothiazolinone-free and solvent-free offer for formulators used in household products, such as laundry care, surface cleaning and air care.
As a leading anti-dandruff active supplier, we continue to innovate and expand our presence in the Personal Care market. Our anti-dandruff platform was successfully expanded in 2019 with pickup of supply in Europe. Our newest offering Piroctone Olamine, broadened our portfolio of anti-dandruff actives, supporting our position as a key partner for scalp health brands worldwide.

Helping our customers to develop consumer products that meet the latest global consumer trends, we have broadened our portfolio with four new offerings:

- The SYNETH™ range of naturally derived polyglycerol esters provides extremely versatile, nonionic emulsifiers and surfactants. They are designed to help formulators strike the perfect balance between functionality, aesthetics and mildness in skin and haircare products.
- Our H2OBioEV® bioactive functional is an innovative ingredient for skin rejuvenation. It is a multifunctional cosmetic ingredient that helps revitalize, rejuvenate and moisturize skin, for a healthier, more radiant and smoother look.
- The Modifect® EV bioactive functional is a multifunctional cosmetic ingredient designed to help provide a more youthful appearance. It helps to detoxify and fortify the skin against oxidative damage, showing a reduction in the appearance of age spots, a smoother skin texture.
- The NAB® Rhodiola Extract bioactive functional is a multifunctional adaptogenic plant extract, well-known for helping to protect the skin against the stresses of modern urban life.

Crop Protection

Crop Protection, especially molluscicides, faced ongoing customer destocking after a dry 2018 summer in Europe, aggressive competition from China and further dry weather in 2019.

During 2019, we successfully gained label extensions in a number of key agricultural and horticultural products. Label expansion includes the use of the fungicide Esteem® in grapes for wine production. This enables growers to control powdery mildew and suppress botrytis throughout the growing season. Other examples include Foschek® as a foliar application in avocados and the herbicide Oxy 500 for post plant pre-emergence weed control in potatoes.

The first important milestone has been reached in the USA with the registration of Barrachlor™ (Chlorothalonil). This is the first product coming out of our crop protection geographical expansion project.

After a successful launch in Q2 in Malaysia, the tank-mix adjuvants for crop protection — Celenco™ Ag+ has been further rolled out in Thailand. We will continue to expand the Celenco™ portfolio in Brazil by adding two new tank-mix products for herbicides based on water and oil.

The successful launch of our ready formulated Axcela® for slug and snail control in New Zealand in 2018 has been rewarded with first sales growth during 2019. In Australia we have successfully obtained registration for Axcela®. Label expansions for Metaldehyde formulations were also successful in Brazil and Japan in 2019.
Our SCS business provides solutions for composite materials and processing additives for technically demanding industries, like electronics, transportation and aerospace. We also provide performance intermediates & chemicals for many industrial applications, such as agro intermediates, food & feed ingredients, cosmetics, non-current good manufacturing practices (non-cGMP) intermediates, and custom development & manufacturing.

Performance Chemicals & Intermediates
We are a partner of choice for our customers, ensuring security of supply with the highest quality in specialty chemicals. We are committed to the highest environmental, health and safety standards in our two state-of-the-art sites in Visp [CH] and Nansha [CN]. Our cracker in Visp is the backbone of a comprehensive, fully backward integrated chemical network. Originating from this enabling technology, we offer a variety of performance chemicals based on special technologies like Hydrocyanic Acid- (HCN), Acetylene-, Ethylene- and Ketene/Diketene- chemistry.

We are also the leading manufacturer of vitamin B3. Our dedicated plants in Visp and in Nansha produce Niacin [nicotinic acid] and Niacinamide. As the leading supplier in the global feed and food industry, we are committed to providing nutritional ingredients of unsurpassed quality.

Composites
We are a leading supplier of specialized resins to the composite and high performance materials industry. We are also a leading supplier of Primaset® thermoset resins. In addition, we offer the Lonzacure® range of special curing agents for high performance materials such as Epoxy, Polymide, Polyurea and Polyurethane. Our composite thermoset resin systems are used in modern consumer electronics to help enhance performance, as well as in the production of lightweight, reliable structural and interior elements for passenger aircraft.

Custom Development & Manufacturing
Our Custom Development and Manufacturing Business has a strong footprint in the realization of modern plant protection products. Increasingly, we also use our extensive process development expertise to serve our other markets, namely Home & Personal Care, Hygiene, Food Additives and Supplements. In particular, the food markets benefit from our biotechnical custom development and manufacturing capabilities at our cutting edge fermentation plant in Kouřim [CZ]. Our services also include full life-cycle management for customers’ products.

Our products and services, offered to the agricultural markets derive from our strong focus on customer needs with a high level of expertise in chemical and biological technology. We support...
our customers in the production of modern herbicides, fungicides and insecticides, including biologically derived products, such as biopesticides. We can also offer full life-cycle management for customers’ products.

Highlights and Initiatives 2019

The SCS business was negatively impacted by ongoing geopolitical tensions, raw material supply challenges and unfavorable cyclical end-markets. The weak market demand for consumer electronics has been magnified by the US-China trade dispute, impacting the composites business in 2019. Custom manufacturing closed ahead of its 2018 performance level. Competitive pressure from China and supply chain challenges resulted in lower volumes of industrial intermediates. Demand for agrochemical ingredients was down, and the vitamin B3 business was impacted by lower volumes due to the African Swine Fever in Asia and low prices at the beginning of the year.

Performance Chemicals & Intermediates

In response to the growing demand for non-current good manufacturing practice (non-cGMP) intermediates for pharma, agro intermediates and food & feed applications, we invested in a capacity expansion in our Visp (CH) site to produce pharma and other intermediates.

Custom Development & Manufacturing

Based on our heritage and exceptional track record of more than 1,000 customized solutions for various markets, we launched the YOU initiative in 2019, to place our customer firmly at the center of our business (For more information, please go to our LinkedIn account). With our ability to offer chemical and biotechnological manufacturing services, building on a long legacy of technical excellence and process development expertise, we enable our customers to take their innovation to their markets in a rapid and reliable manner.

Our recent expansion into new markets shows early signs of success. For example the China Blue Sky initiatives – from the Ministry of Environmental Protection for The People’s Republic of China – revealed the need for a reliable, rapid supplier of key raw materials and solutions. We have the right technologies to solve customers’ challenges as they deal with supply problems caused by the changes in Chinese industry and sustainability requirements. With our cracker in Visp (CH), we are backward integrated into raw chemicals to solve customer supply issues.

Discover More

For further information about our businesses, visit one of the following websites: Lonza Specialty Ingredients / Wood Protection / Crop Protection / Personal Care / Professional Hygiene
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