

## 2.2 Business Model, Strategy, and Goals

### Market and Strategic Positioning

As a leading partner of the biopharmaceutical industry, Sartorius Stedim Biotech helps its customers to develop their production processes and manufacture biotech medications and vaccines more efficiently.

Biopharmaceuticals are integral components of advanced medicine and are used to treat many illnesses, mostly of a serious nature. However, long development times and complex production make these medications very expensive. This leads to high healthcare costs in industrialized countries and to the situation that patients in less developed countries are often excluded from treatment with such drugs. The development of a biopharmaceutical medication is a long haul: it takes more than ten years on average to bring a new drug out on the market, costing more than two billion euros. On top of this, biotechnological manufacturing processes for such high-tech medications are demanding and must be developed individually for each biologic compound. As a pioneer and technology leader in the biopharma sector, Sartorius Stedim Biotech with its products and services is enabling its customers to make their production processes easier and more efficient so that advanced therapeutics can reach the market faster and become accessible for more people worldwide. Therefore, the United Nations' sustainability goal "Good Health and Well-Being" is an integral component of Sartorius' business model.

The maturity and intensity of competition in this comparably young industry are successively increasing. To support customers in meeting this challenge, Sartorius Stedim Biotech is constantly developing its portfolio further. A key competitive advantage is the broad understanding of applications based on its clear focus on the sector. The company is thoroughly familiar with customers' value-added chains and understands the interaction of the employed systems particularly well. A further success factor of the company is that it offers highly differentiating technologies. The innovative power rests on three pillars: the company's own specialized product development, alliances with partners, and the integration of innovations through acquisitions.

With the biopharma industry, Sartorius Stedim Biotech is focusing on an attractive market that is characterized by strong growth momentum in view of long-term trends and significant innovative strength. Medical progress provides positive impetus, leading to the discovery and approval of new biopharmaceuticals. The biopharmaceutical industry is thus increasingly relying on advanced therapies, such as cell and gene therapeutics and biotech tissue products. Further primary growth drivers are a growing world population and an increase in age-related diseases in industrialized countries. In addition, rising incomes in emerging countries are leading to improved access to healthcare and rising demand for medications. Biosimilars, the generic versions of reference biologics that have lost their patent protection, account for a share of the biopharma market that is currently still small but especially fast-growing. As a result of these factors, the volumes of biotech medications and the demand for the appropriate production technologies are steadily increasing, with market growth largely independent of business cycles.

### Products & Services

Sartorius Stedim Biotech offers a broad portfolio of products that focuses on all major steps in the manufacture of a biopharmaceutical, as well as in process development as prerequisite procedures. The product range includes cell lines, cell culture media, and other components for the development and manufacture of advanced therapies, bioreactors, and a wide range of products for the separation, purification, and concentration of biological intermediates and finished products, as well as solutions for their storage and transportation. Sartorius Stedim Biotech also offers data analytics software for modeling and optimizing

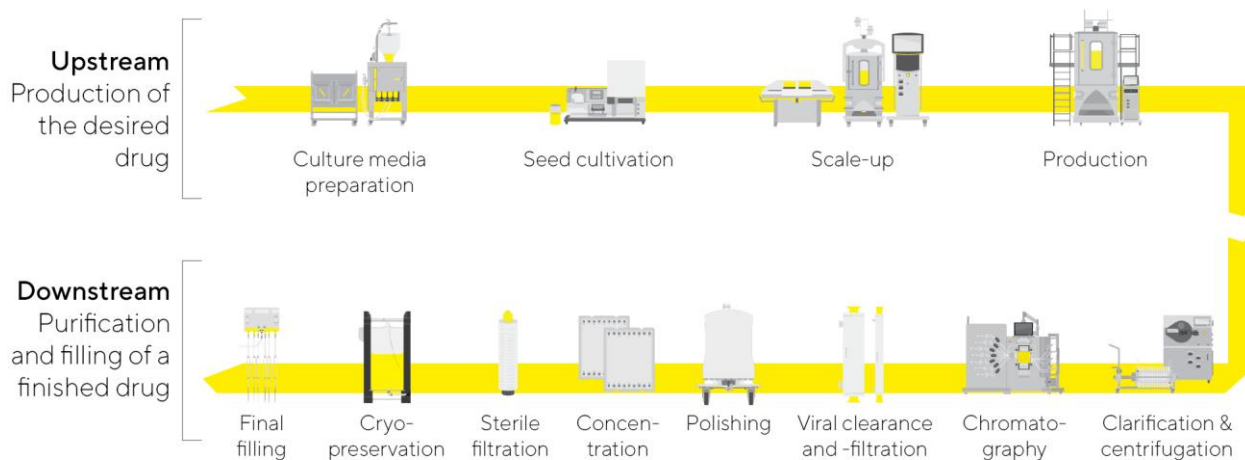
processes of biopharmaceutical development and production. In its core technologies, the company has leading market positions with high double-digit market shares.

The breadth of the company's product portfolio is one of the key factors that differentiates it from many of its competitors. Sartorius Stedim Biotech can provide customers with complete process solutions from a single source, as well as assisting with preceding project planning, process integration, and subsequent validation. The company's products are used in the manufacture of all classes of medical drugs, from vaccines and monoclonal antibodies to advanced viral vector-based gene therapeutics.

Repeat business with sterile single-use products accounts for about three-quarters of the company's sales revenue. These offer customers cost advantages, flexibility, and less resource usage, and thus a better ecological footprint compared with conventional processes employing reusable stainless steel components. The high share of recurring revenues is also bolstered by the strict regulatory requirements on the part of the customers. Because health authorities validate production processes as an integral part of an application for approval of a new medical drug, the components initially validated can be replaced only at considerable expense once they have been approved. Beyond this, the company's broad and stable customer base that is primarily addressed directly through a specialized sales force also contributes to this favorable risk profile.

The strong strategic positioning and the above-average expansion of the sector are a good foundation for profitable growth in the future as well.

### Technologies for the Entire Added-Value Chain in Biopharmaceutical Production



Schematic illustration

## Regulatory aspects

Sartorius Stedim Biotech's products are primarily used in the biopharmaceutical industry for critical production processes such as drug manufacturing. Our customers are subject to regulation by national regulatory authorities such as the Food & Drug Administration (FDA) in the USA, the European Medicines Agency (EMA) in Europe and other national and international bodies involved in the approval of new drugs and in the maintenance of approval status for these drugs. Compliance with the regulations of other relevant authorities (e.g. Environmental Protection Agency or Department of Agriculture in the USA) is also important. With regard to its own portfolio, some specific products of Sartorius Stedim Biotech are also subject to the same national regulatory authorities as our customers and subject to extensive approval, registration and reporting obligations in numerous countries. In these cases, the strict application of Good Manufacturing Practice, as described in the Eudralex guidelines Vol. 4 "The rules governing medicinal products in the European Union" and the ICH guidelines (International Council for Harmonization of Technical Requirements

for Pharmaceuticals for Human Use), is implemented to ensure that the products are placed on the market safely and in compliance with these regulations.

The strict regulation of the pharmaceutical industry and the increasing requirements of the responsible authorities for patient protection and product safety result in a high demand for quality on the part of our customers. Through extensive quality assurance processes as well as quality controls and the use of modern manufacturing techniques in a classified cleanroom environment, Sartorius Stedim Biotech ensures that all products meet the highest quality standards and the stringent regulatory requirements. Furthermore, these manufacturing techniques and processes are subject to continuous review as part of improvement processes and are optimized in line with current requirements. Quality controls are carried out both within the manufacturing processes and as part of test procedures on the end products. In addition, quality assurance is maintained through the rigorous implementation of quality management systems defined according to recognized industry standards such as ISO 9001 and, where applicable, ISO 13485. This ensures that critical or essential product properties are continuously fulfilled. A strict product approval process also ensures that only products that meet the agreed specifications are shipped.

The effectiveness of the existing quality systems is confirmed by the successful completion of regular customer audits as well as by certification in accordance with ISO 9001 and, where applicable, ISO 13485.

## Global Presence



### Americas

**Puerto Rico** – Yauco

**USA** – Ann Arbor (MI), Hopkinton (MA),  
Marlborough (MA), New Oxford (PA)

### Asia | Pacific

**China** – Peking, Shanghai

**India** – Bangalore

### Europe | Middle East | Africa

**France** – Aubagne, Cergy, Lourdes, Pompey, Strasbourg

**Germany** – Bielefeld, Freiburg, Göttingen, Guxhagen, Ulm

**Israel** – Beit Haemek

**Russia** – St. Petersburg

**Slovenia** – Ajdovščina

**Switzerland** – Tagelswangen

**Tunisia** – Mohamdia

**United Kingdom** – Havant, Nottingham, Stonehouse

## Medium-term planning until 2025 and 2028

In 2018, Sartorius Stedim Biotech presented its medium-term planning up to 2025, according to which sales revenue was projected at €2.8 billion with an underlying EBITDA margin of around 30%. These targets were raised twice in the following years and most recently envisaged sales revenue of around €4.4 billion with an underlying EBITDA margin of more than 35%. Against the backdrop of the weaker than expected market situation in the entire life science sector following the pandemic and the resulting temporary decline in sales and earnings, a review of the medium-term targets was announced in October 2023. The new medium-term ambition until 2028 communicated at the end of January 2024 replaces the previous planning until 2025.

Sartorius Stedim Biotech intends to continue its profitable growth course in the long term and expects to grow faster than the market. According to the new medium-term targets, the Group plans to achieve average annual growth in the low- to mid-teens percentage range over the five-year period to 2028 of which acquisitions are anticipated to contribute around a fifth. The underlying EBITDA margin is also expected to increase and reach above 35% in 2028. The margin target includes expenses of around 1 percent of Group sales revenue for measures to reduce the company's CO<sub>2</sub> emission intensity.

Forecasts have been prepared based on historical information and are consistent with accounting policies. All forecast figures are based on constant currencies, as in the past years. Management points out that the dynamics and volatilities in the industry have increased significantly in recent years. In addition, uncertainties due to the changed geopolitical situation, such as the emerging decoupling tendencies of various countries, are playing a greater role. This results in higher uncertainty when forecasting business figures.

The objectives are implemented through various growth initiatives with the following focal points:

### Expansion of the Product Portfolio

Sartorius Stedim Biotech has a broad product portfolio that is aligned with the value chain of the biopharma industry and that the company is continuously expanding. The focus is on products that offer solutions for customers' needs and make the company's offering even more attractive from the customer's perspective. Aside from its own research and development activities and strategic partnerships, acquisitions that are complementary to or extend the company's strengths appropriately will remain part of the portfolio strategy. Due to high innovation dynamics, the company considers further additions to be possible on an ongoing basis across the entire breadth of the product portfolio. When identifying suitable companies, Sartorius Stedim Biotech considers the following criteria in particular: complementarity of technologies to its existing portfolio; strong market positioning, for example, through innovative products with unique selling propositions; integration capability; appropriate valuation; and growth and profitability profile.

### Regional Growth Initiatives

Sartorius Stedim Biotech continued to expand its production capacity in the reporting year. Capital expenditures totaled approximately €473.6 million in 2023 and were used to expand sites in Germany, France, Puerto Rico, the USA, and South Korea, among other countries.

North America and Asia are the key focal areas of the regional growth strategy. The USA is the world's largest market for bioprocess equipment. Yet because it is home to the company's main competitors, Sartorius Stedim Biotech formerly had lower market share in this region than in Europe and Asia. By systematically strengthening its sales and service capacities, Sartorius Stedim Biotech has gained market share in the USA in recent years.

In Asia, one focus is on the construction of a new production facility in South Korea, which offers excellent growth prospects with its dynamically expanding biopharma market.

## Optimization of Work Processes

Sufficient production capacity and a powerful supply chain are an essential foundation of future growth. In recent years, Sartorius Stedim Biotech has substantially expanded its capacities for nearly all product groups at various Group sites in order to optimize delivery times and reliably maintain delivery capability even in the event of local transport restrictions.

Sartorius Stedim Biotech is driving forward digitalization and automation in many areas to further accelerate and enhance processes and, wherever meaningful, to standardize such processes throughout the Group.

This also includes extending the company's activities in the areas of e-commerce, digital marketing, and analytics, as well as on the topic of IT security.