

Sector Conditions

Sartorius Stedim Biotech serves customers mainly in the biopharmaceutical industry, which makes its business particularly sensitive to the development of this industry.

Strong Growth in the Biopharmaceutical Market

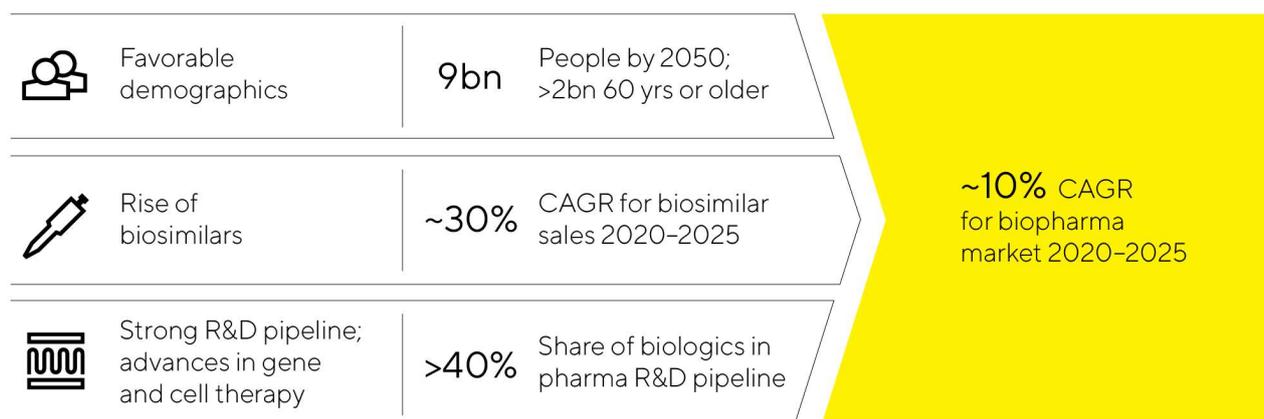
In the reporting year, the pharmaceutical and biotech industries became the focus of political and public attention in connection with the coronavirus pandemic. These industries played a key role in crisis management through their role in the development of vaccines and therapeutics. Given the large investment of resources and considerable governmental and private sector cooperation, numerous drug candidates progressed through the various phases of development at a record pace. The buildup of capacity to manufacture the clinical test material required for this as well as the need for several hundred million doses of vaccines along with their potential approval led to increasing demand for technologies for the development and production of biopharmaceuticals during the year under review. Suppliers of such technologies, who also benefited from strong development of demand independently of the pandemic, were able to increase their sales dynamically against this backdrop in 2020.

Due to its importance for healthcare, the pharmaceutical industry was exempted from many pandemic-related restrictions in the reporting year and proved robust overall despite the global recession. According to estimates by EvaluatePharma, growth was nearly at the previous year's level, around 3% to 4%. Sales of biotechnologically manufactured drugs and vaccines in particular continued to grow overproportionately by around 7% to approximately €247 billion. The increasing importance and acceptance of biopharmaceutical active ingredients is reflected not only in the growing share of sales in the global pharmaceutical market, but also in the R&D activities of the pharmaceutical industry. The share of biopharmaceutical compounds in the R&D pipeline is over 40%.

While market growth was only marginally impacted by coronavirus compared to other industries, the measures taken to fight the pandemic still substantially affected certain areas of the pharmaceutical and biotech industries. For example, over 1,000 clinical studies for non-coronavirus-related development projects had to be interrupted or could not start as planned because clinical study volunteers could only be treated in hospitals, or recruited in sufficiently large numbers, to a limited extent owing to contact restrictions and quarantine measures imposed. This development could lead to the delayed approval of new drugs. Yet in 2020, no such effect was apparent, and the number of new product approvals by the U.S. Food and Drug Administration (FDA) remained at a high level of 26.

The growth of the biopharma market fundamentally depends more on medium- to long-term trends than on short-term economic developments. In addition to the market launch of innovative biopharmaceuticals, significant impetus is provided by the world's rising demand for medications as well as the expanded range of indications for approved medications and their further market penetration. A growing number of active substances manufactured using biotech production methods is being approved for the treatment of rare illnesses that have been incurable so far. In the process, the pharmaceutical industry is increasingly concentrating on advanced therapies, such as gene and cell therapies and biotechnologically processed tissue products. At the end of 2020, there were over 1,000 clinical studies based on such treatment approaches so this field offers significant growth potential on a mid- to long-term basis. The rising number of approved biopharmaceuticals as well as an increasing variety of therapy types and substance classes coupled with growing demand for medications are the main drivers for the worldwide increase in production capacities for biopharmaceuticals.

Biosimilars, which are generic versions of biologics that have lost their patent protection, are also playing an increasingly important role in the biotechnology market. At an estimated sales volume of €14.5 billion, the biosimilars market was still quite moderate in 2020, but it is expected to grow strongly during the years to come owing to the expiration of several patents for high-selling biopharmaceuticals and an increasing number of new approvals and new launches of biosimilars. In particular in the USA, where regulatory, patent law-related and marketing hurdles have traditionally resulted in comparatively slow market penetration of biosimilars, development is forecasted to accelerate significantly in the coming years. According to data provided by the IQVIA research institute, the market volume for biosimilars could quintuple. Globally, a compound annual growth rate of around 30% is projected for this segment for the period up to 2025.



Lab Market Negatively Impacted in the First Half by the Pandemic

The global laboratory market reached a volume of around €56 billion in the reporting year and has been growing annually by 3% to 4.5% according to estimates from several market observers. Market growth is related, among other factors, to the levels of research and development spending in the individual end markets, some of which depend on cyclical trends. The coronavirus pandemic significantly dampened the rate of expansion in the lab market in 2020, with the various industries affected to varying degrees by the containment measures. Especially in the first half of the year, many labs in all sectors had to suspend or significantly reduce their activities due to the pandemic, with a correspondingly negative impact on demand for laboratory products.

Labs in the pharmaceutical and biopharma industry are the leading customers for laboratory instruments and consumables. Against the backdrop of globally rising demand for medications, the industry is continuously investing in research to find new active pharmaceutical ingredients, as well as in the laboratory equipment needed to perform this drug discovery. The focus is being placed on technologies related to process automation and innovative analytical instruments that are equipped with enhanced or novel functionalities. Over the past years, the sector's demand for lab products has developed overproportionately compared to that of other industries. The pharmaceutical and biotech industries were confronted in the reporting year with opposite effects related to the pandemic. For example, demand for laboratory products increased in connection with the buildup of COVID-19 testing capacities as well as with the development of vaccines and therapeutics. On the other hand, demand from many contract research organizations was severely impacted due to the interruption of non-coronavirus-related clinical trials.

Research and quality control labs in the chemical and food industry are another important customer group. This segment's demand for laboratory products depends in part on economic trends. Additional momentum can also be generated in this sector by regulatory changes, such as stricter requirements for quality control tests in the food industry. Demand from industrial end markets was overall weaker year over year due to the global recession triggered by the pandemic.

Academic and public-sector research institutions also use laboratory instruments and consumables manufactured by Sartorius. Growth in demand is related to such factors as government budgets and funding programs, all of which can vary from one country to another. In the United States, the National Institute of Health (NIH) is the leading government agency for biomedical research and the largest agency that provides research funding around the world. The NIH's budget has constantly grown over the last seven years. During the reporting year, it climbed again by about 4.1% to €36 billion. The European Union also continuously scaled up its funding programs for research and innovation in the past budget cycles, but decided in the reporting year to keep the volume of its funding program at the previous level. In recent years, China has sharply increased government R&D funding, a trend that has fueled dynamic growth in the laboratory market there. Many manufacturers of laboratory products experienced weaker year-over-year demand from academic and public research institutions, a significant proportion of which were completely closed for extended periods or could only operate at limited capacity in 2020.

Competitive environment

The addressable market is characterized by relatively high entry barriers arising in part from the biopharmaceutical industry's strong degree of regulation and its technological complexity. In addition, the supply industry has consolidated strongly in recent years owing to numerous takeovers, so that the majority of the market is served by just a few suppliers. New players, in particular, seek to capitalize on the opportunities inherent in this environment to gain a foothold in the market with carefully targeted niche products. The more established companies, meanwhile, are expanding their product range continuously. In this competitive landscape, Sartorius Stedim Biotech operates as a total solutions provider, covering the core process steps in biopharmaceutical production and preceding process development. It has leading market positions in key technologies, especially in the areas of bioreactors, filtration and the transport and storage of liquids.

Most of our competitors are multinationals based in the USA. Certain business units of Merck KGaA, Danaher Corp., and Thermo Fisher Scientific Inc. are among our main rivals in the bioprocess area; Thermo Fisher and Merck are key players in the laboratory field. We also face competition from smaller companies in individual segments. In the reporting year, Danaher took over the biopharmaceutical businesses of General Electric Co.

Sources: BioPlan: 17th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production, April 2020; Daedal Research: Global Biologics Market: Size, Trends & Forecasts, December 2020; IQVIA Institute: Global Medicine Spending and Usage Trends, March 2020; IQVIA Institute: Fokus Biosimilars, May 2020; Evaluate Pharma: World Preview 2020, Outlook to 2026, July 2020; SDi: Global Assessment Report 2018, February 2018; www.fda.gov

Group Business Development

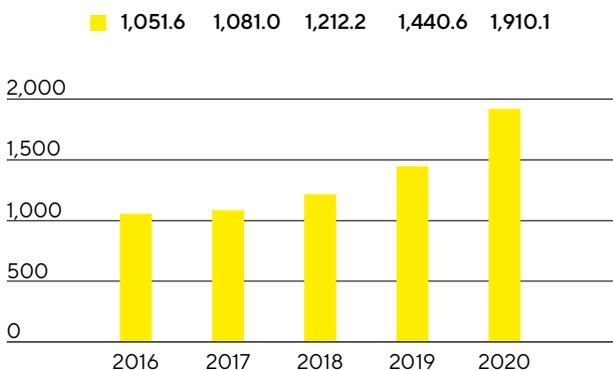
Sales Revenue and Order Intake

In the reporting year, Sartorius Stedim Biotech grew at an exceptionally dynamic rate of 34.6% to €1,910.1million in constant currencies (reported: +32.6%). As a result, the Group exceeded the forecast given at the beginning of the year, which had projected an increase in consolidated sales revenue by 11% to 14% and had last been raised upon release of its nine-month figures, with this latter forecast projecting consolidated sales revenue to increase at the upper end of, or slightly above, the range of 26% to 30%. In addition to vigorous development of its core business, the Group’s strong organic growth was fueled by pandemic-related effects of a good 12 percentage points of which the majority was attributable to additional sales in connection with the increase in production capacities for coronavirus vaccines and Covid-19 therapeutics and the remaining part to inventory buildup on the side of some customers. Initial consolidation of the most recent acquisitions contributed close to 6 percentage points.

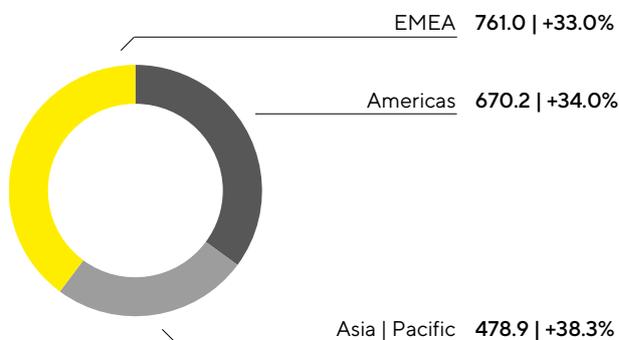
Order intake was influenced more strongly by the pandemic than consolidated sales revenue and rose significantly by 56.7% to €2,381.0million in constant currencies (reported: +54.3%), with pandemic effects accounting for close to 19 percentage points.

In 2020, Sartorius Stedim Biotech increased its sales revenue by double digits yet again in all business geographies. EMEA, the region generating the highest revenue for the Group, recorded a sharp increase of 33.0% to €761.0million. As this gain was especially strong in comparison to the very solid prior-year development, the region’s share of revenue slightly rose to 40% of total sales. Organic growth in this region benefited from additional demand in connection with the development and production of coronavirus vaccines and Covid-19 therapeutics. This also applied to the Americas region, which represented around 35% of Group’s revenue. Following a strong-prior year, sales in this region surged by 34.0% to €670.2million, partially driven by the latest acquisitions. Business in the Asia | Pacific region, which accounted for around 25% of the company’s total sales, also saw exceptionally strong growth with revenue up by 38.3% to €478.9million. This rise was fueled in part by dynamic project business, particularly in the first half. All growth rates are in constant currencies, unless otherwise stated.

Sales Revenue 2016 to 2020
€ in millions



Sales Revenue and Growth¹ by Region²
€ in millions unless otherwise specified



1 In constant currencies
2 Acc. to customers' location

Sales Revenue and Order Intake

€ in millions	2020	2019	Δ in % reported	Δ in % const. fx
Sales Revenue	1,910.1	1,440.6	32.6	34.6
Order Intake	2,381.0	1,543.5	54.3	56.7

Development of Costs and Earnings

In the reporting year, the cost of sales increased by 31.1% to €907.4 million. At 47.5%, the cost of sales ratio was slightly below the previous year's level of 48.1%.

The further cost items developed underproportionately with respect to sales revenue due to economies of scale and partly to the pandemic. Selling and distribution costs rose by 23.0% to €296.0 million so the ratio of these costs to sales revenue decreased by more than 1 percentage point to 15.5% in 2020 (previous year: 16.7%). Expenses for research and development increased year over year by 6.6% to €84.5 million. The ratio of R&D expenses to sales revenue was 4.4%, below the prior-year level of 5.5%. Concerning general administrative expenses, Sartorius Stedim Biotech reported an increase of 25.3% to €95.5 million. In relation to sales revenue, general administrative expenses decreased slightly from 5.3% in the previous year to 5.0% in 2020.

The balance of other operating income and expenses was -€54.9 million compared to the prior-year figure of -€20.3 million and essentially covered extraordinary items of -€32.0 million relative to €16.8 million in the year before. These extraordinary items consisted primarily of expenses in connection with the most recent acquisitions as well as of expenses incurred for various corporate projects and the rebranding.

EBIT rose clearly overproportionately in relation to sales by 42.2% to €471.8 million. The respective margin increased to 24.7% (previous year: 23.0%).

The financial result was €10.8 million in 2020 relative to -€14.4 million in 2019. This figure includes income of €31.6 million from the reporting date valuation of the share-based earn-out payments in connection with the acquisition of BIA Separations.

In the reporting year, tax expenses of €122.1 million were higher than the prior-year total of €81.4 million. The company's tax rate was 25.3% compared with 25.6% in the year before. It should be noted that the valuation effect mentioned above will not result in any subsequent tax impact for the reporting year. Adjustment would yield a tax rate of 27.1%.

Net profit attributable to shareholders of Sartorius Stedim Biotech S.A. increased at a significantly overproportionate rate in relation to sales revenue, by 52.6% to €357.8 million (previous year: €234.5 million).

Statement of Profit or Loss

€ in millions	2020	2019	Δ in %
Sales revenue	1,910.1	1,440.6	32.6
Cost of sales	-907.4	-692.3	-31.1
Gross profit on sales	1,002.7	748.3	34.0
Selling and distribution costs	-296.0	-240.7	-23.0
Research and development costs	-84.5	-79.2	-6.6
General administrative expenses	-95.5	-76.2	-25.3
Other operating income and expenses	-54.9	-20.3	-170.0
Earnings before interest and taxes (EBIT)	471.8	331.8	42.2
Financial income	48.9	6.9	611.5
Financial expenses	-38.0	-21.3	-78.6
Financial result	10.8	-14.4	175.0
Profit before tax	482.6	317.4	52.0
Income taxes	-122.1	-81.4	-50.0
Net result	360.5	236.0	52.7
Attributable to:			
Equity holders of SSB S.A.	357.8	234.5	52.6
Non-controlling interest	2.7	1.5	73.7

Earnings

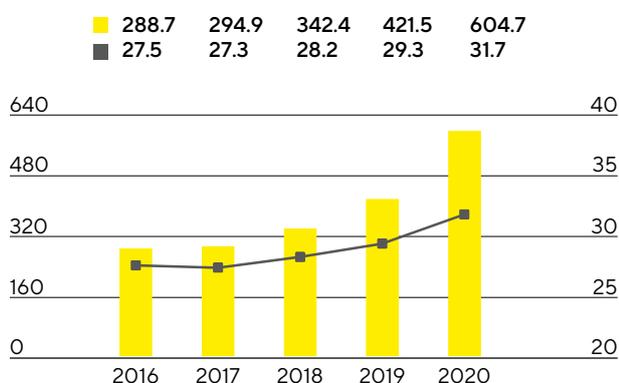
At the Sartorius Stedim Biotech Group, earnings before interest, taxes, depreciation and amortization (EBITDA) are used as the key profitability measure. To provide a complete and transparent picture of the Group's profitability, also in an international comparison, we report earnings adjusted for extraordinary items (underlying EBITDA). For more information about definitions, please refer to the Glossary on page 246. The underlying presentation is reconciled with the EBITDA key indicator (see Glossary) as follows:

Reconciliation between EBIT and Underlying EBITDA

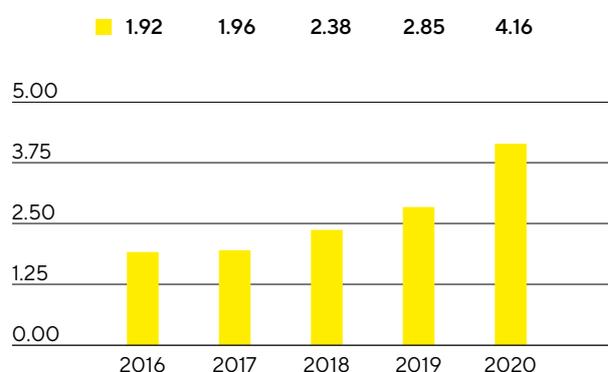
€ in millions	2020	2019
EBIT	471.8	331.8
Extraordinary items	32.0	16.8
Depreciation and amortization	100.9	72.8
Underlying EBITDA	604.7	421.5

In fiscal 2020, Sartorius Stedim Biotech strongly increased its earnings. Underlying EBITDA thus showed a significantly overproportionate increase in relation to sales revenue, by 43.5% to €604.7 million. The respective underlying EBITDA margin climbed to 31.7% (2019: 29.3%) and was therefore in line the Group's forecast, which had been specified at 29.5% at the beginning of the reporting year and had been raised upon release of the nine month figures in the same year to around 32.0%. Considerable economies of scale played a primary role in this substantial increase in profitability, yet the underproportionate development of costs in some areas also added to this effect. The most recent acquisitions had a neutral effect on the earnings margin, while currency headwinds had a somewhat dilutive impact.

The underlying net result after non-controlling interest for the Group rose significantly from €263.0 million a year ago to €383.8 million in fiscal 2020. This figure is the basis for calculating the profit to be appropriated and is computed by adjusting for extraordinary items, eliminating non-cash amortization of €26.3 million (previous year: €13.9 million), and is based on the normalized financial result and a normalized tax rate (see Glossary). Underlying earnings per share surged by 45.9% from €2.85 a year earlier to €4.16.

Underlying EBITDA¹ and Margin

■ Underlying EBITDA in millions of €
 ■ Underlying EBITDA margin in %

Underlying Earnings per Share¹
in €

¹ Adjusted for extraordinary items

€ in millions	2020	2019
EBIT (operating result)	471.8	331.8
Extraordinary items	32.0	16.8
Amortization IFRS 3	26.3	13.9
Normalized financial result¹	-7.8	-5.1
Normalized income tax (26%) ²	-135.8	-92.9
Underlying net result	386.4	264.5
Non-controlling interest	-2.7	-1.5
Underlying net result after non-controlling interest	383.8	263.0
Underlying earnings per share (in €)	4.16	2.85

¹ Financial result excluding fair value adjustments of hedging instruments and currency effects relating to financing activities and change in valuation of earn-out liability

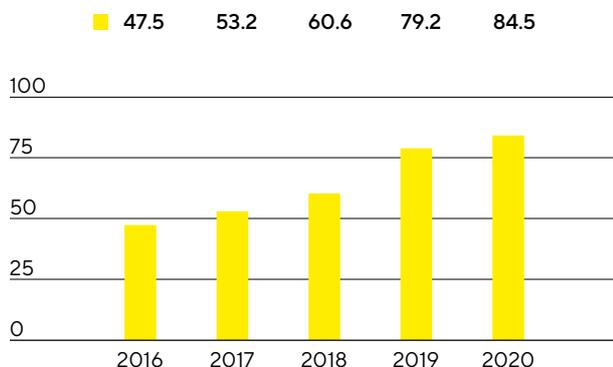
² Normalized income tax based on the underlying profit before taxes and non-cash amortization

See Glossary for the definitions of the totals listed above.

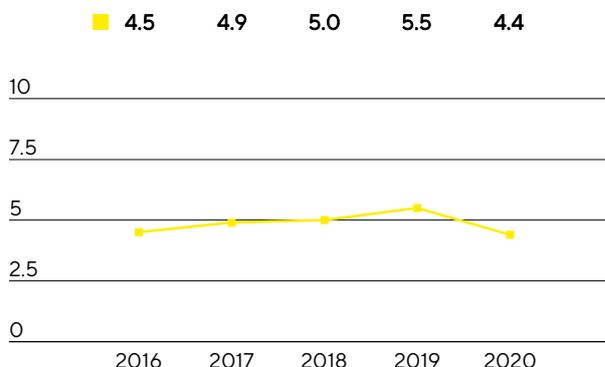
Research and Development

Sartorius Stedim Biotech continuously expands its product portfolio by investing in both the new and further development of its products, as well as in the integration of new technologies through alliances. In 2020, the Group spent €84.5 million on R&D, corresponding to an increase of 6.6% over the previous year's investment of €79.2 million. The ratio of R&D costs to sales revenue decreased by almost one percentage point to 4.4% compared to 5.5% a year earlier. The gross capital expenditure ratio at 6.0% was also below the prior-year ratio of 7.3%; this ratio is even more meaningful for assessment of innovation-related expenses and includes capitalized development costs of €29.7 million (previous year: €25.9 million) that were disclosed in the statement of financial position.

Research & Development Costs
€ in millions



Research & Development Ratio
in % of sales revenue



To protect our know-how, we pursue a targeted intellectual and industrial property rights policy. We systematically monitor compliance with these rights and review from a cost|benefit viewpoint whether it is necessary to continue to maintain individual rights.

The number of applications for intellectual property rights filed in 2020 totaled 127 compared with 108 in the previous year. As a result of the applications submitted in the past years, we were issued 339 patents and trademarks (previous year: 222). As of the balance sheet date, we had a total of 3,044 patents and trademarks in our portfolio (previous year: 2,453).

	2020	2019
Number of patent and trademark applications	127	108
Registered patents and trademarks	339	222

Capital Expenditures

Against the backdrop of strong organic growth, Sartorius Stedim Biotech made above-average investments in new capacity over the past years. Several large expansion projects were completed in 2019. In the reporting year, the company further ramped up its production capacities at many sites due to exceptionally high demand. For this reason, capital expenditures of €159.2 million in 2020 were higher than originally planned (2019: €136.0 million). However, due to strong sales revenue growth the ratio of capital expenditures to sales revenue was 8.3% and therefore within the range of our guidance (previous year: 9.4%).

In Göttingen, Germany, laboratory areas for product development are currently being extended following large-scale expansion of production capacity at this location in previous years. At the site in Yauco, Puerto Rico, Sartorius Stedim Biotech invested in production capacities for membranes. In 2019, manufacturing capacity for filters and aseptic bags had already been doubled when operations were started up at the expanded production facilities. Due to strong growth in demand and order intake, bioprocessing capacities were also expanded in the reporting year at some additional sites. For instance, expansion projects were conducted in France, Germany, Israel, the U.K. and Tunisia.

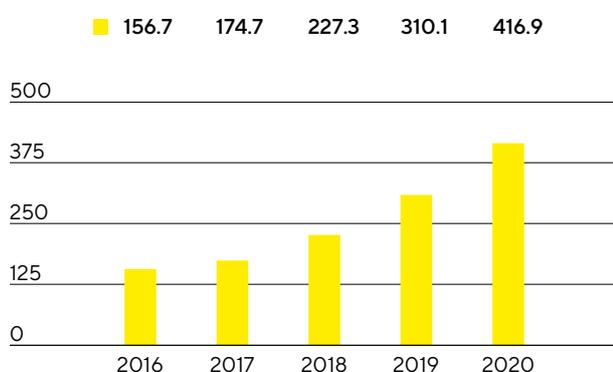
Beyond these expansion projects, investments were made in the digital infrastructure of the Group. Among other things, Sartorius Stedim Biotech invested in computerized systems used in manufacturing to optimize processes and improve production output.

Net Worth and Financial Position

Cash Flow

In the reporting year, Sartorius Stedim Biotech significantly increased its cash flow from operating activities again. This figure was €416.9million relative to €310.1million a year ago, which equates to a rise of 34.4%. The development is essentially due to growth in earnings; in addition, the sale of about €76.2million in trade receivables within the scope of a factoring program (previous year: €27.5million) had a positive effect. By contrast, growth-driven buildup of working capital had a dampening impact.

Net Cash Flow from Operating Activities € in millions



Cash outflows from investing activities increased by 10.7% to -€150.5million. These investments were for expansion of production capacities at numerous locations, including Yauco and Göttingen.

Due to expenditures of -€470.6million in connection with the most recent acquisitions, cash flow from investing activities and acquisitions|divestitures stood at -€621.1million relative to -€184.4million in the previous year.

Cash flow from financing activities of €234.1million (previous year: -€122.2million) was mostly attributed to financing of the acquisitions.

Cash Flow Statement

Summary

€ in millions	2020	2019 ¹
Cash flow from operating activities	416.9	310.1
Cash flow from investing activities and acquisitions	-621.1	-184.4
Cash flow from financing activities	234.1	-122.2
Cash and cash equivalents	59.8	28.2
Gross debt	586.8	138.6
Net debt	527.0	110.4

¹ The figures for the reporting period 2019 were restated due to the finalization of the purchase price allocation for the acquisition of Biological Industries.

Consolidated Statement of Financial Position

The balance sheet total of the Sartorius Stedim Biotech Group increased by €1,224.0million to €3,069.3million between year-end 2019 and the reporting date on December 31, 2020. This increase is predominantly attributable to the acquisitions. In addition to the extensive investment program continued in the reporting year, these acquisitions essentially had an impact on the increase in non-current assets as well, which grew by €985.0million to €2,194.1million.

Current assets rose by €239.0million to €875.2million, mainly because of the growth-driven buildup in working capital and the higher cash and cash equivalents increased in light of the pandemic to allow for risk aspects.

Key Working Capital Figures

in days		2020	2019
Days inventories outstanding			
Inventories sales revenue ¹	x 360	87	81
Days sales outstanding			
Trade receivables sales revenue ¹	x 360	47	55
Days payables outstanding			
Trade payables sales revenue ¹	x 360	56	49
Net working capital days			
Net working capital ² sales revenue ¹	x 360	78	87

¹ Including pro forma sales of recent acquisitions

² Sum of inventories and trade receivables less the trade payables

Equity of the Sartorius Stedim Biotech Group grew by €294.0million to €1,482.9million as of the reporting date. At 48.3%, the equity ratio remained at a comfortable level, even after closing of the acquisitions (previous year: 64.4%).

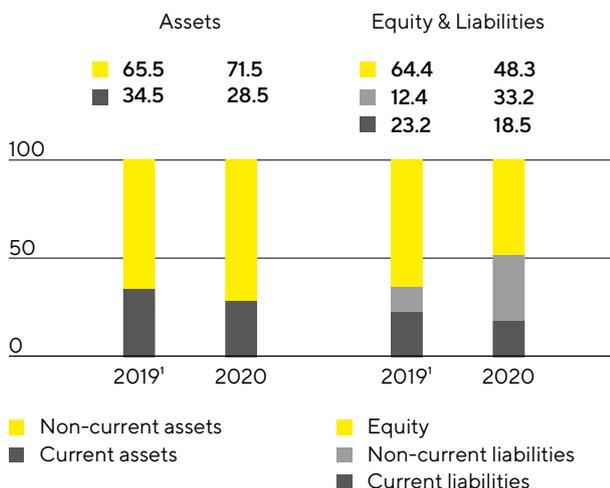
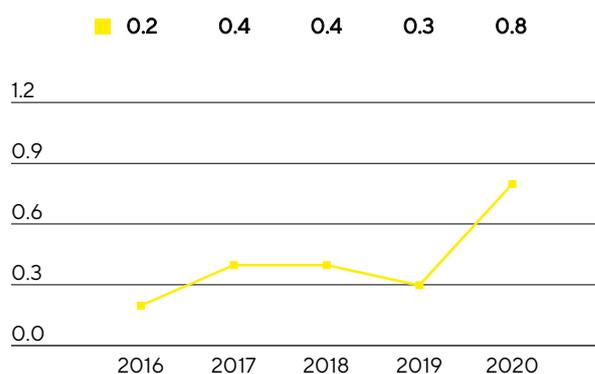
Current and non-current liabilities rose to €1,586.4million, up from €656.5million in the previous year, predominantly driven by the acquisitions previously mentioned as well as additionally to the buildup in working capital.

Overall, gross debt, which is comprised of liabilities to banks and loans from Sartorius AG as well as of lease liabilities, increased to €586.8million as of December 31, 2020, compared with €138.6million for the year ended December 31, 2019. The year-over-year increase is essentially attributable to the financing of the most recent acquisitions. Net debt, defined as gross debt less cash and cash equivalents, was €527.0million relative to €110.4million a year ago.

Calculation of Net Debt

€ in millions	2020	2019 ¹
Non-current		
Loans and borrowings	515.7	40.0
Lease liabilities	47.3	44.1
Current		
Loans and borrowings	13.1	43.5
Lease liabilities	10.7	11.0
Gross debt	586.8	138.6
Cash and cash equivalents	59.8	28.2
Net debt	527.0	110.4

¹ The figures for the reporting period 2019 were restated due to the finalization of the purchase price allocation for the acquisition of Biological Industries.

Balance Sheet Structure
in %**Ratio of Net Debt² to Underlying EBITDA³**

¹ The figures for the reporting period 2019 were restated due to the finalization of the purchase price allocation for the acquisition of Biological Industries.

² The net debt excludes the liability for the remaining purchase price for acquisitions; 2020: €305.3 million, 2019: €72.5 million, 2018: €8.7 million, 2017: €46.5 million, 2016: €49.6 million.

³ EBITDA includes underlying pro forma EBITDA of acquisitions completed in 2020.

Regarding the debt financing potential of the Sartorius Stedim Biotech Group, the ratio of net debt to underlying EBITDA represents a key management indicator. As of December 31, 2020, this ratio stood at 0.8, as expected, and was thus due to the financing of the recent acquisitions above previous year's level of 0.3.

Financing | Treasury

Sartorius Stedim Biotech covers its operational and strategic financing needs through a combination of operating cash flows and the assumption of short-, medium- and long-term financial liabilities.

The major pillar of the financing mix is a credit line with a volume of up to €260 million and long-term loan agreements of €515 million provided by the parent company Sartorius AG. Furthermore, the Group has diverse bilateral credit lines of approximately €41 million in total.

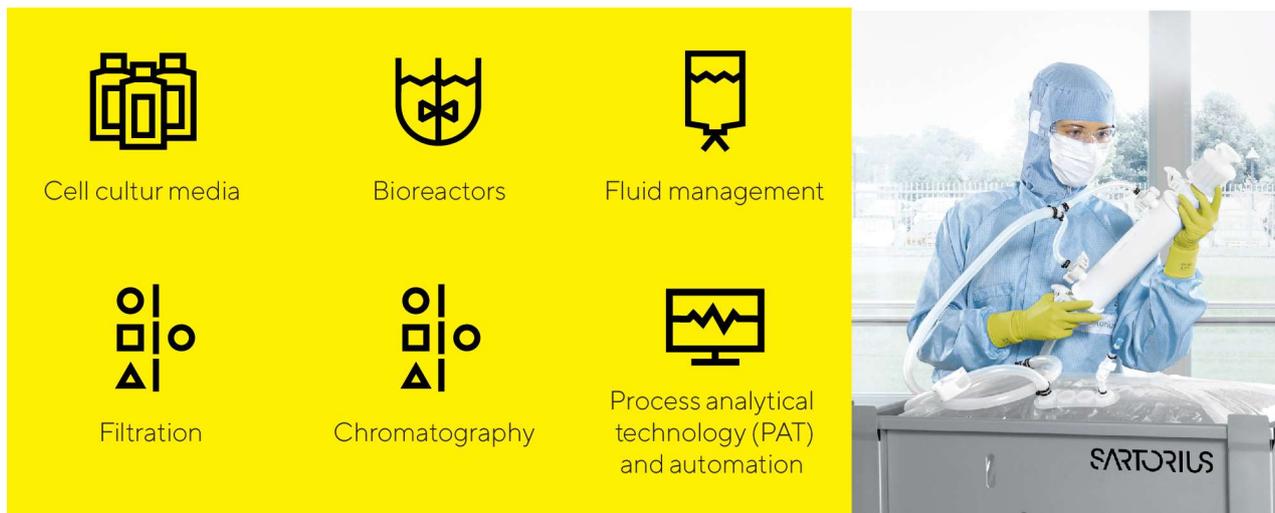
The above-mentioned financing comprises instruments with both fixed and variable interest.

As of December 31, 2020, the total volume of all available credit lines was €301million. Of this amount, Sartorius Stedim Biotech had utilized on €7million, leaving available credit of €294million at the end of 2020. This ensures that all Group entities have sufficient funds to successfully finance their business operations and new capital expenditures.

We use hedging transactions to counteract the fluctuations in foreign-exchange rates to which the Group is exposed on account of its worldwide business operations. At the end of 2020, foreign-exchange contracts amounted to €182million on a reported basis, with a market value of €10.1million.

Products and Sales

Sartorius Stedim Biotech markets products and services for the entire added-value chain in biopharmaceutical production and preceding process development. The portfolio includes cell lines, cell culture media, bioreactors, a wide range of products for separation, purification and concentration, and products and systems for storage and transportation of intermediate and finished biological products.



The product portfolio of Sartorius Stedim Biotech was significantly broadened by the acquisition of selected life science businesses from Danaher Corporation. Among the new technologies and products added are chromatography systems and resins that are used in essential steps for the purification of biopharmaceuticals. Sartorius Stedim Biotech's offering for these process steps formerly centered on innovative membrane-based solutions until this acquisition and now has been expanded by complementary reusable and single-use technologies for the field of established column chromatography. Beyond this, the portfolio lineup in downstream processing has been strengthened by further acquired product groups in the areas of tangential flow filtration systems and flow kits. Overall, the expanded portfolio covers all purification strategies from small-volume lab-scale to commercial-scale production, which makes the offering more relevant from the customer's point of view and significantly strengthens the positioning of Sartorius Stedim Biotech.

Also resulting from the acquisition of selected Danaher life science businesses was the integration of the SoloHill business covering microcarrier technology and particle validation standards used in cell cultures and other bioprocesses.

The Sartorius Stedim Biotech portfolio for customers in the fast-growing field of advanced cell and gene therapies was expanded by the acquisition of BIA Separations in November 2020. The company develops and manufactures products for purification and analysis of large biomolecules, such as viruses, plasmids and mRNA, which are already used in production of the first commercialized advanced gene therapeutics. BIA Separations' innovative technology has been specially optimized for purification of advanced therapeutics, providing higher product yields and quality compared to alternative solutions and reduces the time customers need for installation and use.

Through the acquisition of the U.S.-based purification expert WaterSep in December 2020, Sartorius Stedim Biotech added single-use and reusable hollow-fiber membrane devices as well as presterilized assemblies for upstream and downstream applications to its current offering for cell and gene therapy applications, cell harvesting and various solutions for intensified bioprocessing.

During the reporting year, the portfolio was also strengthened by the further development of established product lines. For instance, our third-generation bioreactor system enables fast product development and seamless scale-up to commercial production, significantly accelerating timelines up to the clinical phase. The bioreactor, along with its data-controlled software and comprehensive array of analytical tools, is operated by a new automation platform offering higher productivity, enhanced usability, more flexibility and lower costs.

Sartorius Stedim Biotech also updated its software for multivariate data analysis of biopharmaceutical production processes. This software collects, evaluates and controls quality-critical parameters, enabling customers to optimize, stabilize and lower costs while increasing productivity and product quality.

Likewise in the area of process analytics, Sartorius Stedim Biotech introduced a sensor that can be used in automated micro- and mini-bioreactor systems as well as in scalable bioreactors. In combination with an analytical instrument, the sensor simultaneously monitors a number of parameters that can be used for computer modeling to simulate production processes. The knowledge gained by these simulated production runs help the customer to scale up processes faster and more efficiently all the way to commercial-scale manufacturing.

Sales Activities

Sartorius Stedim Biotech markets its product portfolio directly. Sales activities for key accounts are coordinated and supported by global key account management.

The way the company interacts with customers changed significantly during the reporting year due to the pandemic-related travel and contact restrictions. In addition, Sartorius Stedim Biotech had to meet substantially higher demand and short timelines in development projects in connection with coronavirus vaccines and Covid-19 therapeutics. The company overcame these challenges by increased usage of videoconferencing and other digital communication tools, among other measures. For instance, Sartorius Stedim Biotech uses a special augmented reality device, a headset equipped with cameras and a microphone, which enables customers to view objects through “the eyes of the wearer” and to project holograms into the environment as needed. This permits real-time interaction over long distances and can be employed for giving product demonstrations, advising customers and providing repair instructions to name a few examples.

In the reporting year, Sartorius Stedim Biotech additionally entered into a partnership with a leading provider of consulting services in life science manufacturing. As a certified service and training partner, this company performs installation services, configures data connectors, develops multivariate models, provides customer-specific training courses and delivers online configurations, among other services. Through this alliance, Sartorius Stedim Biotech can keep pace with growing demand for software solutions and extend its reach.

Product Development

Development activities at Sartorius Stedim Biotech essentially focus on technology areas such as membranes, which are the core component of our filter products; various technology platforms such as single-use containers for fluid management in biopharmaceutical processes and sensors; and control technologies for processes such as fermentation and cell cultivation. Additional focal areas entail developments in materials and components that include plastics, elastomers and intelligent polymers; expanded data analysis; and cell line development.

Our largest site for product development is Göttingen, Germany. Further key sites are in France, Germany, India, the USA, U.K., and Sweden. Through acquisitions, sites in Israel and Slovenia have been added since 2019.

Production and Supply Chain Management

Sartorius Stedim Biotech has a very well developed global production network that was expanded at many sites in the reporting year. The largest production facilities are located in France, Germany and Puerto Rico. Beyond these locations, the company also manufactures in the United Kingdom, Switzerland, Tunisia, India, the United States, China, and, since the acquisition of BIA Separations at the end of 2020, in Slovenia as well. The latter site in Ajdovščina will serve as Sartorius Stedim Biotech's center of competence for purification of cell and gene therapeutics in the future.

Moreover, by acquiring selected life science businesses from Danaher, Sartorius Stedim Biotech gained new sites in the U.K., France and the USA.

During the lockdown due to the coronavirus pandemic in the spring and fall, Sartorius Stedim Biotech was able to keep its production operations up and running. Despite the restrictions in worldwide logistics, the company's supply chains proved to be mostly stable.

Sartorius Stedim Biotech expanded its production due to additional demand related to coronavirus vaccines and Covid-19 therapeutics as well as the buildup in inventories by some customers. On top of this, the company hired additional production staff since the beginning of the pandemic and introduced an expanded shift system at a few sites to manufacture around the clock seven days a week.

At the end of 2020, Sartorius Stedim Biotech started up operations at a new Customer Interaction Center (CIC) in Marlborough, Massachusetts, USA, for biopharmaceutical customers. The CIC enables customers to test complex systems at our site first before these are delivered to and set up at their plant facilities.

Sustainability

Sustainability information for the Sartorius Stedim Biotech Group is not reported. In accordance with the provisions of Article L.225-102-1 IV of the French commercial code, Sartorius Stedim Biotech is exempted from presenting this information, because it is included in the non-financial statement established and published by the controlling company, Sartorius AG, as per applicable German regulations.

Opportunity and Risk Report

Principles

Every business activity entails opportunities and risks, which have to be managed. The skill with which this is done goes a long way in determining the future development of a company's shareholder value.

It is not the task of risk management to eliminate all risks: rather, our approach is to intentionally take a certain measure of risk in our business activities in order to be successful in unlocking opportunities. However, in this endeavor, it is important to keep risks contained within acceptable limits and to control them carefully. Through appropriate guidelines, we ensure that risk assessments are taken into account in the decision-making processes from the very beginning.

Sartorius Stedim Biotech has decided to make the identification and the management of risks and opportunities a cross-functional component of Group management. In this context, Sartorius Stedim Biotech's risk management is integrated into the Sartorius Group organization. Our risk management organization reflects a global functional matrix organization in which individuals heading a functional area are each responsible for their own management of opportunities and risks. The Finance & Controlling department is responsible for the organization of the respective reporting process, including the further development of the Group's risk management system.

Managing Opportunities

Our opportunity management centers on the analysis of target markets and sector environments, as well as the assessment of trends, both of which give strong indications as to future business opportunities. The identification of the potential for development in this context is one of the key roles of the relevant managers and initially takes place at the local rather than the central level. The market-facing functions, such as marketing and product management in the individual divisions, play a leading role in this respect. The central Business Development unit supports these areas with market monitoring, data analysis and the implementation of strategic projects.

As part of strategy reviews, the members of the Board of Directors regularly meet with the managers that have operational responsibility to discuss short-, medium- and long-term opportunity potential for the various business areas. If the opportunities are short-term in nature, they are considered in annual budget planning. Medium- and longer-term opportunities are tracked systematically as part of strategic planning.

As a supplier for the pharmaceutical industry, Sartorius Stedim Biotech operates in a future-oriented and high-growth sector. The significant opportunities generated by the various market and technology trends are described in detail in the sections entitled "Sector Conditions" and "Outlook for the Sector" on pages 26 et seq. and pages 59 et seq., respectively.

Our assessments rank the company as one of the global market leaders in many subsegments and product areas. We believe the high quality of our products, our strong brand recognition and our established customer relationships give Sartorius Stedim Biotech strong opportunities to continue extending our market leadership. The corresponding strategies and the growth opportunities and initiatives based on them are discussed in the section on the strategy of the Group, which begins on page 22.

Risk Management

Organization

The overall responsibility for the maintenance of an effective risk management system ensuring comprehensive and consistent management of all material risks rests with the Audit Committee. The Finance & Controlling Department is responsible for coordinating and developing this system and for consolidated risk reporting, while the particular functional areas are responsible for identifying, analyzing and reporting individual risks. This includes the assessment of their potential impact and the decision-making on taking the appropriate countermeasures.

The Audit Committee monitors the effectiveness of the risk management system. Furthermore, while carrying out their statutory audit mandate for the annual financial statements and consolidated financial statements, the independent auditors examine whether the early warning system in place is capable of prompt identification of risks that could jeopardize the future of the company. Finally, the Internal Audit Department regularly reviews the risk management process and system.

Insurance

We have taken out insurance policies to cover a wide range of risks where possible and economically advisable. These insurance policies include coverage against product liability, property damage, business interruption, transport, material and pecuniary damages and other risks, and provide comprehensive coverage for legal costs. An independent department working in conjunction with an external insurance broker regularly reviews the nature and extent of our insurance protection and makes any adjustments as necessary.

When choosing our insurers, we particularly consider the credit rating of these entities as potential contractual partners, as well as aim to achieve a high degree of diversity in order to mitigate the related risks.

Risk Management System and Risk Reporting

Sartorius has implemented a global guideline (Risk Management Handbook), which includes definitions of the framework, structural organization, processes, risk reporting, and monitoring and controls of the effectiveness of the risk management system. The handbook is based on ISO 31000 "Risk Management - Guidelines" and the COSO (Committee of Sponsoring Organizations of the Treadway Commission) standard. There are also a number of other sources that contain stipulations for handling risks, including the articles of association and rules of procedure of the Group companies, and other internal guidelines.

The prescribed reporting process in the risk categories subsequently described establishes the rules for the ongoing review of and information on risk situations. If any specific risks are discernible, these are documented within a specific risk management software with respect to their assessment, probability of occurrence and measures to be taken to eliminate such risks or to mitigate their impact.

We have an urgent reporting procedure in place to ensure that when a new or emerging significant risk to our net worth, financial position and profitability is identified, the audit committee receives all of the necessary details without undue delay.

To classify risks appropriately, we have defined four main categories: external risks, operating risks, financial risks and compliance risks. Each main category is divided into several subcategories that are described in the following sections.

Furthermore we have defined a so-called risk matrix, that allocates the probability of occurrence and the potential impact to certain classes as follows:

Probability of Occurrence

Remote	< 10%
Possible	10% - 50%
Probable	50% - 75%
Very likely	> 75%

Significance

in millions of €	Impact on Earnings
Insignificant	< 10
Moderate	10 - 50
Significant	50 - 100
Critical	> 100

The combination of both elements leads to the following matrix that describes the overall significance of the respective risks for the Group:

> 75%	low	medium	high	high
50 - 75%	low	medium	medium	high
10 - 50%	low	medium	medium	medium
< 10%	low	low	medium	medium
Probability Impact	< €10 million	€10 - 50 million	€50 - 100 million	> €100 million

External Risks

General Risks

The main risks in this area are those arising from natural catastrophes, especially the hurricane risk in Puerto Rico, pandemic crises like the coronavirus and political developments in the United Kingdom or in the USA. In principle, our ability to foresee and mitigate the direct and indirect effects of risks entailed by life in general is limited, but we proactively take measures, whenever feasible, to ensure that we can respond appropriately and at short notice or are insured against any damage entailed by such risks that include, for instance, natural catastrophes and their associated damage to commercially significant and critical infrastructure.

Many countries reacted to the pandemic with extensive lockdowns and, accordingly, severe restrictions to economic activity. The result was a global recession that is still ongoing, albeit with very different characteristics in the various industries. For Sartorius Stedim Biotech there was in some cases significant increases in demand in connection with the development of coronavirus vaccines, therapeutics and test procedures as well as an increase in inventories on the part of some customers. The corresponding production capacities were expanded at numerous SSB locations. The changed requirements for interaction with customers were met, among other things, through the increased use of video conferences and other digital communication tools, e.g. in the area of augmented reality. Various task forces in the different functional areas and regions also ensured that the constantly changing framework conditions could be responded to immediately and appropriately. In particular, the supply chains have proven to be largely stable despite the restrictions in global logistics.

In all measures taken, the health of the employees was and still is in the foreground; in addition, maintaining the ability to deliver is of essential importance, as our products are used in the development and manufacture of vaccines and drugs to combat the pandemic. Since the coronavirus pandemic is ongoing, negative consequences for the future cannot be ruled out. Since many of the vaccine and therapeutic producers are among our customers, we are currently not assuming any negative effects for the year 2021 as a whole. However, it should be noted that these developments are at the expense of other customer projects and that the pandemic-related postponement of studies for other indications also entails risks for our business development.

On the basis of our best knowledge our largest sites in Germany and France do not face major risks from natural catastrophes, while e.g. our production plants in Puerto Rico and Fremont are exposed to the risk of severe hurricanes or earthquakes. We control this risk by applying high security standards to the buildings and explicitly consider this risk in our warehousing and production network strategy.

Political developments, such as the referendum on the United Kingdom's leaving the European Union ("Brexit") or changes in foreign policy of certain countries (e.g. China or the United States), can have an impact on the Group's business. Such developments may involve changes to the tax system or customs duties, delays in deliveries caused by trade restrictions, as well as impacts on the exchange rate of the euro to the British pound or the U.S. dollar (for more on the subject of exchange rates, see the section below on Exchange Rate Risks).

In the U.K., we run various manufacturing and sales entities with a significant business volume. Any development that has a negative impact on the trading between the U.K. and other countries could therefore lead to a corresponding decrease in the Group's earnings. Further developments are being closely observed and numerous measures like safety stocks have already been implemented.

Our group companies operate globally and have international ties, which is why punitive tariffs and trade disputes can have negative effects on our business activities. Various measures, such as the extension of our supplier network, are currently being examined to reduce possible effects.

Business Cycle Risks

The nature of our various business areas means that Sartorius Stedim Biotech as a whole is insulated to a certain extent from the full force of wider cyclical effects. If economic developments prove more positive than expected, this, in turn, can additionally stimulate stronger growth.

Operational Risks and Opportunities

Our supply chain extends from procurement to production to sales and distribution. Problems within this workflow can have consequential effects, including delays in deliveries. The global supply chain management system we have instituted throughout our process chains largely minimizes the associated risks by analyzing and controlling all of the operations involved. The strongly international alignment of our organization opens up a whole series of opportunities too. The various risks and opportunities encountered within our supply chain are explained in detail below.

Procurement Risks and Opportunities

We purchase a wide range of raw materials, components, parts and services from suppliers and are consequently exposed to the risks of unexpected delivery bottlenecks and | or price increases.

Over the past years, we have implemented powerful tools and robust processes in our Materials Management and Procurement units to manage risks and critical materials. These means enable us to meet the needs of our customers with respect to delivery reliability and transparency. Important measures to reduce potential supply bottlenecks are to maintain security stock and to define alternative suppliers when feasible. We moreover conduct regular supplier reviews and carefully monitor the delivery status and inventory range of critical raw materials.

Risks from raw material prices play a rather subordinate role in our business. On the one hand, the proportion of raw materials in our production costs is comparatively low. On the other hand, we purchase a wide range of materials from a large network with alternative sources of supply.

Opportunities can arise in the area of procurement when our growth enables us to increase order quantities and thereby strengthen our position with our suppliers, such as by receiving price discounts or preferential treatment as a "preferred customer." In addition, we maintain a list of preferred suppliers in order to enter into long-term business relationships with key suppliers to our mutual benefit.

Production Risks and Opportunities

Manufacturing a large proportion of our products ourselves, we bear the associated risks of capacity bottlenecks or overcapacity, production downtimes, excessive reject rates and high levels of tied-up working capital, as well as dependency on individual manufacturing sites.

Based on our core technology expertise, we manufacture products that involve a high level of vertical integration. Other products, such as reusable fermenters and bioreactors, are manufactured in collaboration with suppliers so that some of the production risks are transferred to external third parties.

We contain and reduce the risks relating to capacities by careful production planning, using versatile machines, semi-automated individual workstations and flextime work schedules, and by continuously monitoring production processes. Moreover, our global manufacturing network enables us to partially compensate for any capacity bottlenecks by shifting production to other regional plants and consequently reducing our dependency on individual local production plants. Furthermore, we have taken out policies for business interruption insurance to compensate for any possible losses due to production downtimes.

In certain production areas we are using easily flammable or explosive materials. Improper handling of those materials can lead to significant damage to property and business interruptions. We have implemented all necessary organizational and constructional measures in order to reduce these risks to the extent possible.

We consider it an opportunity that our investments in infrastructure and production resources have given us high flexibility in our manufacturing operations and that we are capable of meeting our customers' requirements and regulatory standards with respect to business continuity concepts. In addition, this approach ensures that our individual production sites can concentrate on specific manufacturing technologies and makes it possible to capitalize on the cost advantages offered by individual sites. Furthermore, continuous improvements in production, such as simplifying processes and increasing levels of automation, help drive manufacturing efficiency even higher.

Sales and Distribution Risks and Opportunities

The potential risks entailed to the variety of channels to sell and distribute our products around the world are unexpected changes in the demand structure, growing price pressure and non-compliance with supply agreements concluded with customers. We employ targeted market analyses to identify emerging demand trends in individual segments early on so that we have time to respond appropriately. Our technical innovations and the fact that a wide range of our products are used in validated production processes in the biopharmaceutical industry reduce our exposure to the risk of growing price pressure. We have reduced our risk exposure in the area of logistics in recent years by setting up and using central warehouses to optimize distribution logistics.

Opportunities arise in the area of sales and distribution when the increasing breadth of our product range puts us in a position to sell new products to existing customers. Our business relationships, most of which are established for the long term, and our global presence provide further opportunities. After all, we are continuously expanding our product range through acquisitions. After the acquisitions in the year under review, we are offering our customers new technologies in the field of downstream processing.

Sartorius Stedim Biotech sources its key customers from the pharmaceutical and chemical industries. These customers are usually relatively large organizations that have been in existence for some time and have strong credit ratings. Accordingly, the Group has had low to zero credit losses over the past years, and its overall credit risk continues to be at a very low level. Most of our business areas have a highly diversified customer base, so the Group as a whole is not dependent on individual key accounts to any significant degree.

Competitive Risks and Opportunities

Sartorius Stedim Biotech has a leading competitive position in most of its markets. Some of our competitors are larger than us, and most share our status as a globally operating company. As we serve a large number of

customers from highly regulated sectors like the pharmaceutical and food industries, and, the technology barriers to market entry are substantially high, we regard the probability of new competitors emerging within the short term as low.

The fact that many of our products are used in validated bioprocesses reduces the risk of losing significant market share within a short timeframe. At the same time, it is also more difficult for us to quickly force out the competition that serves customers in this area.

Changes in the competitive environment, for example, a further consolidation in the markets, can pose opportunities. We have been continuously making acquisitions in recent years to reinforce our market position and open up new potential synergies.

Quality Risks and Opportunities

The main risk encountered in this area is non-compliance with agreed quality criteria, which can lead to losses for our customers, or their customers, for which we may be made liable through compensation claims. Our customers use Sartorius Stedim Biotech products in a wide range of critical production processes, including the manufacture of pharmaceuticals, foods and chemicals, and in research and development laboratories.

We employ rigorous quality checks and advanced production methods and processes, such as classified cleanroom technology, to ensure that our products satisfy the most stringent quality standards and high regulatory requirements. These manufacturing methods and processes are subject to constant review under our continuous improvement processes, moreover, and are optimized as requirements evolve. We have implemented process controls with regard to critical or essential product properties in order to ensure compliance with the relevant specifications. Our successful completion of a host of annual audits by customers and implementation of quality systems compliant with ISO 9001 and, where applicable, with ISO 13485 document the high level of quality achieved in Sartorius products and processes. Irrespective of these measures, we also maintain significant insurance coverage against product liability risks. Sartorius Stedim Biotech has established a traceability system that enables us to locate and – if necessary - recall an entire production batch immediately and minimize any adverse consequences in the event of defects being discovered in a product. Furthermore, we have installed a complaints management system that ensures an efficient analysis of customer reports and the initiation of appropriate measures.

In the sectors we address, quality requirements are growing more and more stringent all the time, not least as a result of increasing requirements on protection of medical patients and on product safety by regulatory authorities. Increasing and changing requirements typically entail the risk that a new requirement might be overlooked or be difficult to achieve, but we regard this first and foremost as an opportunity that opens up new market prospects. The reason is that challenging quality demands represent a considerable barrier to entry for potential new competitors and provide stimulus for further technical innovation to which we actively respond. Moreover, we actively seek to draw up new requirements through our work on professional committees, membership in industry associations and standards committees, and are able to identify emerging requirements at an early stage and prepare ourselves accordingly.

R&D Risks and Opportunities

Main risks in this area may arise from development results that diverge from market needs and application requirements, and from exceeding planned development deadlines, since we devote a considerable share of our resources to research and development.

Our advanced project management, intensive R&D controlling and early involvement of our customers in the development process substantially limit these R&D risks. We ensure that product developments are always reviewed very promptly with regard to how well they meet the customers' needs so products can be adapted accordingly as needed. Patents and continuous tracking of the technologies and competitors relevant to us secure our technology and marketing position.

On the other hand, the R&D sphere also offers a number of potential opportunities. Our close collaboration with partners that rank among the global market leaders in their own fields opens up the opportunity for us to jointly develop products with an especially high level of innovation. In areas such as membrane technology and plastics technology, as well as sensorics and bioprocess engineering, the expertise of our own specialists puts us at the very forefront of global research and development, presenting us with an opportunity to turn this technical knowledge into potential sales and an even stronger position on the market. The combination of different innovative activities in a separate Corporate Research Department further enables us to identify and benefit from promising developments and emerging trends at universities, startups and at our customers' plants.

Acquisition Risks and Opportunities

The purchase and sale of companies or parts of companies entail a number of typical risks, such as incorrect valuation assumptions or insufficient usage of anticipated synergy effects. On the other hand, acquisitions also provide many opportunities, such as sales growth, extension of our product portfolio and development of new markets.

To prevent the risks, we take various measures, such as performing a standard due diligence review of important areas and carrying out comprehensive analysis of the market concerned. In addition, we involve external consultants and experts in the purchase or sales process as required. We especially focus on drafting transaction contracts so that they adequately counter such risks, especially by clauses assuring specific characteristics or by contractual warranty or guarantee provisions, as well as agreements on mechanisms for adjustment of the purchase price and on liability clauses.

Immediately after an acquisition has taken place, an integration phase is initiated in which any potential risks can likewise be detected as early as possible and prevented or minimized by taking the appropriate counteractions. In order to ensure an efficient integration process in the Group and to mitigate the related risks we have established a post-merger integration (PMI) office within the department of Business Process Management.

Personnel Risks and Opportunities

The main risk in this area is that we are not able to hire skilled staff needed for the planned growth of the company. As an innovative technology group, Sartorius Stedim Biotech employs a large percentage of highly qualified people. We counter the risks of a possible scarcity of required specialists, especially those in key positions, and of demographic change by offering performance-related remuneration models, targeted continuing professional development options, further attractive social benefits, continuous education and training for junior staff members within our organization, and interesting people development opportunities. The success of these measures is apparent in the low attrition rates of recent years. Moreover, employment contracts in certain cases contain a clause prohibiting any move to a direct competitor.

Opportunities for Sartorius Stedim Biotech primarily arise in that it can further qualify its staff by offering its own training courses and retain such staff over the long term, thus covering company needs for qualified personnel particularly well.

IT Risks and Opportunities

Since nearly all business processes of the Sartorius Stedim Biotech Group are supported by IT applications, systems failure or other impairment of the relevant IT systems or (cyber)attacks can considerably disrupt the smooth functioning of the companies' business processes and lead to manipulation or to uncontrolled loss or leakage of knowledge or data.

We minimize this risk by continuously investing in the setup and operation of secure IT systems and applications, and by continuously further developing and implementing our concepts and security measures based on the International Standard ISO 27001, Information Security Management System. In addition, we incorporate the results of regular audits and vulnerability assessments carried out by external companies specialized in IT security.

Protection of our data against misuse is ensured by specific authorization and authentication policies based on the assignment of rights, limited to a "need-to-know" basis for performing certain tasks, as well as a strict functional segregation. The application of such policies is reviewed at regular intervals.

We protect our systems against failure and data loss by regular data backups, recovery testing based on rolling disaster scenarios and risk-based use of redundant IT infrastructures. Multi-factor authentication solutions enable us to prevent malware threats.

We are convinced that the threat of cyberattacks is growing worldwide, both in number and intensity. This is why we are continuously extending and strengthening our activities: we are improving our efforts by further automating management of authorizations and reducing the potential for data misuse, among other measures. We inform our staff in a targeted way about possible threats and risks, involving our employees by providing them with simple but effective options for decentralized defense and reporting suspicious emails to IT for checking.

By extending our means for competent and fast response to cyberattacks including other IT security incidents, we supplement our organizational basis for running the Sartorius system and applications at the lowest possible risk across the entire landscape.

Financial Risks and Opportunities

The global nature of the Sartorius Stedim Biotech Group's operations means that its business activities are inevitably exposed to financial risks. The most significant of these are exchange rate risks, interest rate risks, liquidity risks and tax risks, all of which are described below and addressed in detail in the Notes to the Consolidated Financial Statements. Vice versa, certain financial risks, most notably exchange rate risks and interest rate risks, are balanced by opportunities of approximately equal magnitude.

Exchange Rate Risks

As a consequence of its global business activities, the Group is exposed to risks arising from foreign currency fluctuations. Since we generate around two-thirds of consolidated sales revenue in foreign currencies and, of this figure, approximately two-thirds of this total revenue in U.S. dollars or in currencies pegged to the U.S. dollar, we are positively or negatively impacted by currency effects, especially when converting the currencies of balance sheet items and profit or loss items, respectively. Besides the U.S. dollar, other key currencies are, the British pound, the Singapore dollar, the South Korean won, the Japanese yen, the Chinese renminbi and the Swiss franc.

Our global production network thus enables us to offset the lion's share of sales revenues received in foreign currency within the Group against costs likewise incurred in foreign currency. For example, we manufacture many of our products for the North American market locally, and are not disadvantaged in competition with our U.S. rivals, insofar as this general currency risk is concerned. We continuously monitor the portion of our foreign currency sales revenue that remains after we have settled our costs, so-called net exposure.

In order to evaluate and steer the remaining risk based on the expected net exposure for the next 12 months and take into consideration hedging transactions already executed, we are continuously calculating our risk exposure with a cash flow at-risk model. We use this basis to decide on whether to use additional derivative financial instruments, especially spot, forward and swap transactions, to adjust for maximum loss. Hedging transactions are set up by one group of staff and monitored by another, separate group.

Interest Rate Risks and Opportunities

The main risk in this area is posed by changes in interest rates that can lead to higher payments. The major part of the financial instruments outstanding on the reporting date is subject to variable interest based on the market rate. However, the overall debt level of the Group and the resulting interest risk is very low. We monitor interest rate trends and our interest rate exposure constantly and have the facility to arrange for hedging transactions where we consider it necessary and economically advisable to do so for individual loans. As of December 31, 2020, we did not have any interest rate derivatives in our portfolio of financial instruments.

Liquidity Risks and Opportunities

The general risk is that Sartorius Stedim Biotech will not be able to pay its creditors. In order to minimize those liquidity risks and optimize liquidity allocation within the organization the Group's liquidity is managed centrally on the Sartorius Group level by using various long- and short-term debt instruments.

Sartorius Stedim Biotech is mainly using a €300million credit line provided by Sartorius AG that can be accessed and repaid at short notice. Additionally, we have a number of bilateral working capital credit lines for individual Group companies in place and we have concluded cash pooling agreements between selected Group companies as the primary tool to manage liquidity within the Group.

Tax Risks

Sartorius Stedim Biotech is acting globally with its affiliates and consequently falls under numerous local tax laws and regulations. Changes in tax laws, jurisdiction or the interpretation of laws by the authorities in these countries can lead to additional tax expenses and payments and have an impact on tax positions in the statement of financial position and profit or loss.

We are controlling this risk by permanently monitoring and analyzing the fiscal framework with our central tax department which is supported by external experts in the concerned countries.

Compliance Risks

Regulatory Risks

Our role as a supplier to the biopharmaceutical industry and health care providers means that Sartorius Stedim Biotech can also be affected by regulatory changes in these areas. The main risk in this context is a potentially more restrictive approach by the supervisory authorities, such as the Food & Drug Administration (FDA) USA, the European Medicines Agency (EMA) and the Chinese National Medical Products Administration (NMPA) in the approval of new drugs or medical devices. Furthermore, compliance with the regulations of other relevant authorities (e.g. Environmental Protection Agency or Department of Agriculture in the USA) is important in order to control local or global regulatory risks.

Environmental Risks

The main risk in this area is to cause environmental damage, e.g. by polluting the air or the ground with hazardous substances. Sartorius Stedim Biotech has established an environmental management system to minimize these risks. This management system has been certified for compliance with ISO 14001 at a number of the company's relatively large manufacturing sites. The respective company organizational units ensure at the particular sites that the laws and regulations relating to environmental protection are observed and that further technical possibilities for limiting environmental risks are identified on an ongoing basis.

The increasing importance of sustainability considerations in many industries represents an opportunity. That is why this aspect is becoming a key element in our supplier selection process for assessing the suitability of a particular company as a business partner.

Litigation Risks

Litigation risks for Sartorius Stedim Biotech can arise from pending or forthcoming legal disputes or from administrative proceedings. All judicial or extrajudicial disputes are attended to by the company's own attorneys and legal experts, who engage external lawyers as needed.

At present, there are no pending or discernible legal disputes or proceedings that lack any cost coverage allowances in the statement of financial position or that could have a substantial negative impact on Group.

Assessment of the Overall Risk Situation and Risk Outlook

Where feasible, we adopted countermeasures and/or arranged for balance sheet measures during the reporting year to cover all discernible risks within the Sartorius Stedim Biotech Group, and those of a defined probability of occurrence, that had the potential to damage our net worth, financial situation and profitability.

In order to determine the significance of each of these risks, they have been assessed in relation to their probability of occurrence and the anticipated magnitude of their negative impact, taking into account the effects of risk management measures. The most material risks in each category are marked with an asterisk.

Risk Category	Probability of Occurrence	Significance
External risks		
General risks*	Possible	Moderate
Business cycle risks	Possible	Moderate
Operating risks		
Procurement risks*	Possible	Significant
Production risks	Possible	Significant
Sales and distribution risks	Possible	Moderate
Competitive risks	Remote	Moderate
Quality risks	Remote	Significant
Research and development risks	Possible	Significant
Acquisition risks	Possible	Significant
Personnel risks	Possible	Significant
IT risks	Possible	Significant
Financial risks		
Exchange rate risks*	Probable	Moderate
Interest rate risks	Probable	Insignificant
Liquidity risks	Remote	Moderate
Tax risks	Possible	Moderate
Compliance risks		
Regulatory risks*	Possible	Significant
Environmental risks	Remote	Moderate
Litigation risks	Possible	Moderate

After thorough analysis of the entire risk situation and according to our current review, there are no discernible risks at present that could jeopardize the continued existence of the Group.

Similarly, based on our current review, there are no discernible risks that could jeopardize the future existence of the Group. No material events of any nature occurred after the reporting date.

Internal Control Procedures

Introduction

The objectives defined by the Chairman for the internal control system of Sartorius Stedim Biotech are as follows:

- Prevent risks that would endanger the quality of the assets of Sartorius Stedim Biotech or even its existence;
- Ensure that the executive management activities, the transactions completed and the conduct of employees comply with the guidelines defined by executive management, applicable laws and regulations, the fundamental values, standards and internal rules of the business and the ethical codes and conventions of the healthcare industry;
- Ensure that accounting and financial information and management data provided to the executive management of the company accurately reflect the operations of Sartorius Stedim Biotech;
- Prevent risks arising from operations, errors or fraud, especially in the accounting and financial area.

Scope of Internal Control

The internal control system described covers the parent company and its affiliates.

Components of Internal Control

Environment for Internal Control

The core of any business is its people (their individual attributes, including integrity, ethical values and expertise) and the environment in which they operate. They are the engine that drives the organization and the foundation that supports the company.

Risk Assessment Process – Risk Mapping

The company must be aware of, and deal with, the risks it faces. It must set itself objectives and integrate them into its sales, production, marketing, financial and other activities so that the organization operates in concert. It must also establish mechanisms to identify, analyse and manage the related risks.

Control Activities

These control activities are undertaken at every level of the Group to ensure that internal control is efficient: checking the accuracy, completeness, authorization, validation and recording of transactions and ensuring that different people discharge different duties so as to reduce the risk of errors or fraud.

Information and Communication

The availability of accurate, reliable and complete information is essential both to achieve business objectives and to enable proper reporting to all parties concerned in compliance with the applicable laws and regulations.

Monitoring, Control and Management

Responsibilities and authorities must be defined and understood at all levels of a company for internal control to function effectively. Duties must be assigned in such a way that a person's work is always checked and approved by a different person. Where the size of the local unit concerned permits, responsibility for initiating, authorizing, recording and processing transactions must always be assigned to different individuals.

Unit management is responsible for maintaining internal checks and internal control at all times.

Internal Controlling Roles

Executive Management

The Chairman and Chief Executive Officer is responsible for the internal control system and management at all levels. He is also responsible for the development, operation, monitoring and management of the internal controlling systems and for providing the necessary assurances that these steps have been implemented.

Audit Committee

The Audit Committee is responsible for carrying out any necessary reviews and evaluations of the internal controlling procedures, including those relating to financial information, and also assists with the preparation of the Group's consolidated financial statements. For further information about the Audit Committee, see page 92.

Risk Management

The Sartorius Stedim Biotech Group is inevitably exposed to a wide variety of risks by the nature of its operations around the world. Accordingly, an internal risk management system has been set up to help identify, assess and manage these risks efficiently. Within this risk management system, ad hoc reports comprised of representatives of different departments regularly studies current issues of risk management. This enables the Audit Committee to provide executive management with an overview of the risk to which the company is exposed, enabling it to take appropriate action when required.

Internal Auditing Department

Based on the annual audit plan approved by the Audit Committee, the Internal Auditing Department (IA) evaluates and improves the effectiveness and suitability of risk management and the internal control system in all Sartorius Group companies. As part of the internal control system IA contributes to the compliance with internal and external rules and standards. Based on the internal audits performed during the year IA compiles major findings and respective recommendations which are presented to the Audit Committee by the Compliance Officer of Sartorius Group at least once a year or ad-hoc, if necessary.

Finance and Controlling Departments

The Finance and Controlling Departments track and monitor operations and projects to optimize the Group's profitability and cash flow, providing both internal and external stakeholders with reliable information.

These two departments define the Group's accounting rules and methods and its principle financial processes (multi-year business plan, budget, etc.) as well as reporting tools, in order to monitor the day-to-day business.

Procedures for Preparing the Group Financial Statements and Other Accounting and Financial Information

The accounts of affiliates are prepared in accordance with the Group's accounting policies. The data is then adjusted, where necessary, to produce company accounts that comply with the applicable local legal and tax

provisions. Integrated consolidation software is used both for management reporting purposes and to produce the Group financial statements.

Since 2013, the Group has decided to implement a hard-close process as of November 30 in order to anticipate and improve the annual audit.

Accounting Standards

The consolidated financial statements are prepared in accordance with IFRS accounting standards as currently adopted by the European Union. The consolidated financial statements comply with accounting rules and methods as detailed in the Notes to the Consolidated Financial Statements.

Roles of the Group's Finance and Controlling Departments

The Finance and Controlling Departments check the quality of the reporting packages submitted by affiliates, focusing primarily on the following elements: checking corporate data and consolidated adjustments entered locally, inter-company eliminations, the accounting treatment of non-recurring transactions for the reporting period, and verifying principal movements between the opening and closing balance sheets to prepare the cash flow statement.

The Finance Department also verifies the results of procedures, including currency translation, intercompany eliminations, etc.

Key points of review include the preparation and validation of the statement of changes in shareholders' equity and the cash flow statement.

Financial Information and Reporting

The Group's rules and procedures in relation to financial reporting and accounting are set out in the Accounting and Reporting Manual. Application of and compliance with these principles, rules and procedures are the direct responsibility of the finance director of each affiliate. They must ensure that information provided via the Management Information System complies fully with all applicable disclosure requirements.

Executive Management reviews the effectiveness of the internal controlling of financial reporting regularly. In particular, it verifies that transactions have been recorded consistently, in accordance with IFRS international accounting standards as applied by the Group and as set out in the Accounting and Reporting Manual, in order to ensure the pertinence of transactions and assets recognized within the times set.

Internal Control in 2020

We continue to review all of our policies, internal procedures and organizational measures and up-date them with the view of continuous improvement.

Code of Conduct and Anti-Corruption Code

Sartorius Code of Conduct defines the requirements we place on our employees with respect to responsible conduct. The code helps employees act ethically and in accordance with the law in their daily work.

Sartorius Code of Conduct covers compliance with international social and environmental standards, general rules of conduct and dealing with conflicts of interest.

Sartorius Anti-Corruption Code forms the basis for raising employee awareness about corruption risks.

We ensure that our employees are familiar with the Anti-Corruption Code and the Code of Conduct by asking them to take part in an online training course. The course teaches employees how to deal with ethically or legally problematic situations.

A complaint system ensures that employees and external third parties can report cases of damaging conduct, such as corruption, discrimination or sexual harassment. The compliance team can be contacted face-to-face, via a telephone hotline, the department's electronic mailbox or – in the case of anonymous reports – the whistleblower system. The relevant contact options are listed on the intranet and are thus available company-wide. They are also available on the company's website and can thus be accessed by external persons concerned.

Corporate Transactions

The Company complies with Regulation (EU) No. 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (the "Market Abuse Regulation") and the AFEP-MEDEF code, as amended in January 2020. Thus, transactions involving the purchase or sale of the company's securities or financial instruments are prohibited during the periods between the date on which managers, persons considered managers under the law, and any person having regular or occasional access to privileged information are aware of precise information on the course of business or prospects that, if made public, could have a significant influence on the price and the date on which the information is made public.

In addition, pursuant to Article 19 of the Market Abuse Regulation, they are also prohibited for a period of thirty calendar days prior to the date of publication of the company's annual and half-yearly financial statements.

In accordance with the Market Abuse Regulation and the recommendations of the AFEP-MEDEF code, hedging transactions of any kind on the company's shares in connection with stock options are prohibited.

In addition, transactions in the Company's shares by the persons referred to in Article L. 621-18-2 of the French Monetary and Financial Code must be reported to the Autorité des Marchés Financiers (the "AMF") in accordance with the procedures and time limits set out in Article 223-22-A et seq. of the AMF's General Regulations and Article 19 of the Market Abuse Regulation. These statements are available on the AMF website (www.amf-france.org).

During the year ended December 31, 2020, the Members of the Board and persons mentioned in Article L.621 - 18 - 2 of the French Monetary and Financial Code carried out the following transactions on the company's shares:

Date of the transaction	Details of the person discharging managerial responsibilities / person closely associated	Description of the financial instrument	Nature of the transaction	Aggregated information of price and volume
02.11.2020	Sartorius AG	Share	Sale	Price: €327.00 Volume: 405,887

The transaction was not related to the exercise of a stock option program or to a bonus or performance share grant but part of the purchase price of the acquisition of BIA Separations by Sartorius Stedim Biotech. The overall purchase price comprised of a payment of €234.2million in cash and 405,887 shares of Sartorius Stedim Biotech. The shares were transferred by the parent company Sartorius AG to the owners of the acquired company. As a consequence, Sartorius Stedim Biotech incurred a corresponding liability against Sartorius AG.

Mid-Term Prospects

The Group will continue to work on Internal Control issues, by strengthening its approach to risk mapping and risk management. This process is based on elements of the AMF Internal Control Reference Framework.