Sector Conditions

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

Further Growth in the Biopharmaceutical Market

The global pharmaceutical market grew by around 7% in 2022. Revenue generated with biopharmaceuticals increased by around 4% year over year to €365 billion, somewhat slower than the average of previous years. This was partly due to lower sales of coronavirus vaccines and antibody-based COVID-19 therapeutics. Biopharma accounted for 37% of the total pharmaceutical market, compared with 38% in 2021.

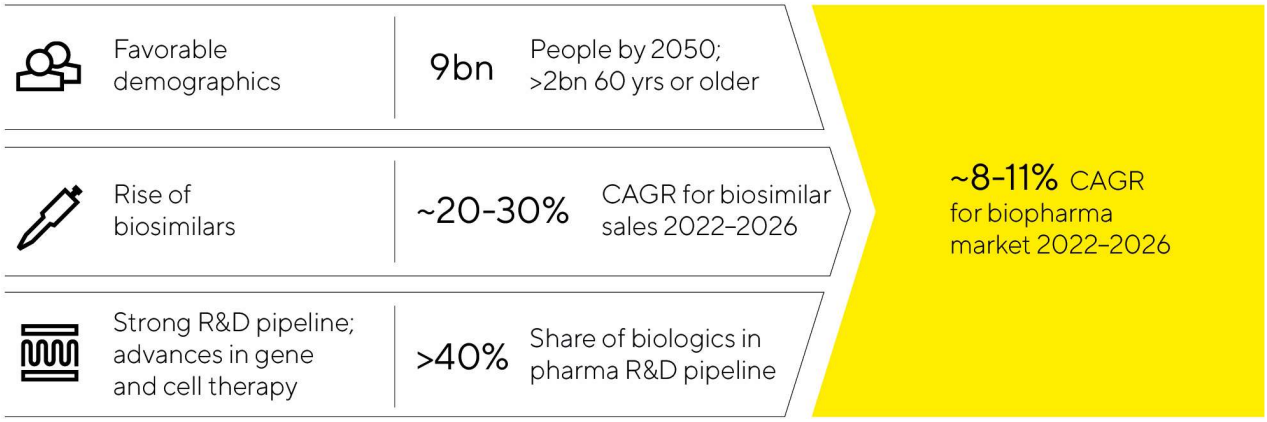
The leading manufacturers of products for the development and production of biopharmaceuticals recorded further growth in 2022, although the reported growth rates were lower, as expected, given the exceptionally high base of comparison in 2021. In particular, expected revenue from pandemic-related business was reduced significantly during the year. All leading bioprocess technology suppliers also invested heavily in capacity expansions in 2022, some of which were completed and brought on stream. This helped normalize lead times for certain product categories, some of which had increased significantly in 2021 due to strained supply chains and capacity bottlenecks.

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 globally increasing demand for drugs and the extension of the range of indications for already approved medications and their further market penetration. The approval process for new drugs requires clinical trials to be conducted, and the coronavirus pandemic meant that some of these had to be interrupted or could not be resumed. However, a resulting delay in the approval of new drugs for non-coronavirus-related indications has not been apparent to date, and the number of new biopharmaceutical approvals by the U.S. Food and Drug Administration (FDA) remained high in 2022, at 31 (2021: 30).

The growing significance and acceptance of biologics is reflected not only in their increasing share of sales revenue of the global pharmaceutical market but also in the development activities of the pharmaceutical industry. For example, biopharmaceutical compounds account for more than 40% of the R&D pipeline. 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 this context, the pharmaceutical industry is increasingly focusing on advanced therapies, such as cell and gene therapeutics or biotechnologically processed tissue products. In 2022, more than 2,000 clinical trials with such treatment approaches were conducted, meaning that this area offers significant growth potential over the medium to long term. 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, the generic versions of reference biologics that have lost their patent protection, are also playing an increasingly important role in the biotechnology market. According to market studies, their sales volume in 2022 remained modest at an estimated €19 billion, but the market 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 of biosimilars and market launches. Particularly in the USA, where development has been comparatively slow due to regulatory, patent law-related, and marketing hurdles, market penetration is expected to accelerate significantly in the next few years. A compound annual growth rate of around 20% to 30% is expected globally through 2026.

Attractive Market Environment with Good Growth Prospects



Laboratory Market Continues to Grow

The global laboratory market had a total value of around €69 billion in the reporting year and, according to estimates by various market observers, is growing at an average annual rate of around 4% to 5% over the long term. Market growth is related, among other things, to the levels of research and development spending in the individual end markets, which is partly linked to economic development.

Labs in the pharmaceutical and biopharma industries are the leading customer groups 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 and in laboratory equipment needed to perform this drug discovery. The focus is on the automation of process workflows and innovative analytical instruments that are equipped with enhanced or novel functionalities. Products from the field of bioanalytics, for example, have above-average growth rates within the laboratory market, and demand in the life science sector is generally growing faster than in other industries. According to EvaluatePharma, research spending in this particular sector remained at the previous year's high level of around €210 billion in 2022. In contrast, the funding environment for small and medium-sized biotech companies deteriorated after high inflows in the previous two years, but this has not yet had a negative impact on demand from leading laboratory equipment suppliers.

Research and quality-assurance labs in the chemical and food industry are another 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 generally robust in 2022 according to several leading laboratory product manufacturers, despite a gloomy economic outlook.

Academic and public-sector research institutions also use laboratory instruments and consumables manufactured by Sartorius Stedim Biotech. 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 Institutes of Health (NIH) is the leading government agency for biomedical research and also the world's largest research funding agency. The NIH's budget has increased steadily over the past nine years, rising again by about 4.9% to $45 billion in 2022. The proposed budget for 2023 also includes a further increase. The NIH is also slated to receive an additional approximately $12 billion over the next five years to prepare for future pandemics, meaning the scientific funding environment remains positive. The European Union has likewise continuously scaled up its research spending in past budget cycles. Around €95.5 billion of

research and innovation funding is to be provided in the period from 2021 to 2027, an increase of 19% compared with the previous program. In recent years, China has sharply increased government R&D funding, a trend that has fueled dynamic growth in the local laboratory market. Many manufacturers of laboratory products recorded robust demand from academic and public research institutions in the reporting year.

Competitive Environment

The competitive environment of Sartorius Stedim Biotech is characterized by relatively high entry barriers arising in part from the biopharmaceutical industry's strong degree of regulation and its technological complexity. 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.

The principal competitors of Sartorius Stedim Biotech in the bioprocess area are certain business units of Merck KGaA, Danaher Corporation, and Thermo Fisher Scientific Inc. Thermo Fisher and Merck are also key players in the laboratory field. In addition, the company faces competition from smaller players in individual segments.

Sources: 19th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production, April 2022; Evaluate Pharma: World Preview 2022, Outlook to 2028, October 2022; SDi: Global Assessment Report 2022, June 2022; www.fda.gov

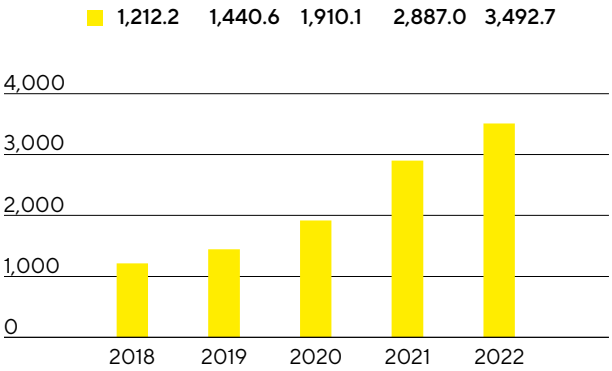
Group Business Development

Sales Revenue and Order Intake

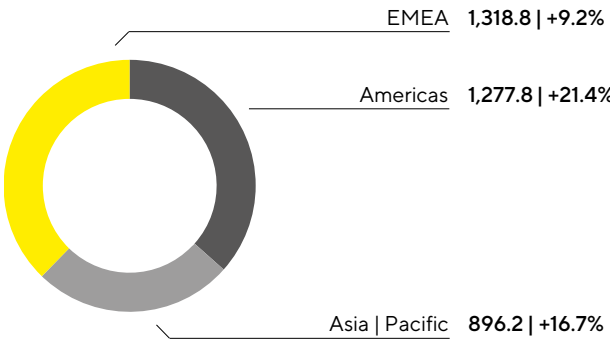
In the reporting year, sales revenue of the Sartorius Stedim Biotech Group rose 15.1% in constant currencies[1] to €3,492.7 million (reported: +21.0%). Thus, the company again grew at double-digit rates in a very challenging and volatile environment and following the exceptionally high growth rates in 2020 and 2021. This good development was primarily due to a strong organic[2] expansion of around 13.2%, driven by a high demand for innovative products and technologies for the efficient development and manufacturing of biopharmaceuticals. Recent acquisitions also developed positively and contributed 1.9 percentage points to the increase in sales. Significantly lower business with coronavirus vaccine manufacturers compared to the previous year had a dampening effect. The restrictions in China caused by the pandemic as well as the strong reduction of the business in Russia also impacted growth to a relatively minor extent.

As expected, order intake declined in 2022, after Sartorius Stedim Biotech had posted exceptionally high growth rates in the previous two years. In addition to a very good base business, there had been significant additional demand from coronavirus vaccine manufacturers and a changed ordering pattern by some customers, who had placed orders larger in size and further in advance than usual due to pandemic-related uncertainties and strained supply chains. As expected, the situation has noticeably normalized as the pandemic has subsided and supply chains have eased from mid-2022 onwards. The temporary decline in demand is due to lower production of coronavirus vaccines and the reduction of partially increased inventories at some customers. Order intake for the full year declined by 13.0% in constant currencies[1] to €3,314.8 million (reported: -9.5%). Excluding the dampening effect of the declining Covid-19-related business, order intake would have increased slightly.

Sales Revenue 2018 to 2022
€ in millions



Sales Revenue and Growth[1] by Region[3]
€ in millions unless otherwise specified



1 Constant currencies: Figures given in constant currencies eliminate the impact of changes in exchange rates by applying the same exchange rate for the current and the previous period.
2 Organic: Organic growth figures exclude the impact from changes in exchange rates and changes in the scope of consolidation.
3 Acc. to customers' location

Sartorius Stedim Biotech increased its sales revenue in 2022 in all three business regions. In EMEA, the region generating the highest share of around 38% of total revenue, sales rose by 9.2% to €1,318.8 million compared to a strong 2021 base. Accounting for around 36% of sales, the Americas region showed strong growth with an increase of 21.4% to €1,277.8 million. The Asia | Pacific region, which accounts for 26% of total sales, also posted significant double-digit growth of 16.7% to €896.2 million. (All growth rates for the regional development are in constant currencies unless otherwise stated.)

Sales Revenue and Order Intake

€ in millions	**2022**	2021	Δ in % reported	Δ in % const. fx
Sales Revenue	3,492.7	2,887.0	21.0	15.1
Order Intake	3,314.8	3,664.4	–9.5	–13.0

Development of Costs and Earnings

In 2022, cost of sales rose by 24.3% to €1,658.2 million. The respective cost of sales ratio was 47.5% compared to 46.2% in the previous year.

Selling and distribution costs rose at an underproportionate rate with respect to sales revenue by 10.1% to €446.5 million, meaning the ratio of these costs to sales revenue fell year on year to 12.8% (previous year: 14.1%). Research and development expenses rose by 19.9% to €132.4 million. The corresponding ratio of R&D expenses to sales revenue remained constant at 3.8% (previous year: 3.8%). General administrative expenses increased by 22.7% to €154.7 million, and the administrative expense ratio in 2022 was unchanged at 4.4% (previous year: 4.4%).

The balance of other operating income and expenses in 2022 was -€105.6 million (previous year: -€45.3 million), and essentially covered extraordinary items of -€46.3 million (previous year: -€26.5 million). These extraordinary items consisted primarily of expenses in connection with the most recent acquisitions as well as of expenses for various corporate projects. The realized currency hedges and valuation effects included in the balance of other operating income and expenses resulted in an expense of €41.2 million, particularly due to the development of the dollar exchange rate in 2022, following income of €8.9 million in the previous year.

EBIT increased by 15.0% to €995.2 million; the respective EBIT margin was 28.5% (previous year: 30.0%).

The financial result was €135.2 million in 2022 compared to -€218.7 million in 2021. This includes non-cash-effective income of €148.9 million predominantly from the reporting date valuation of the share-based earn-out liability in connection with the acquisition of BIA Separations which had resulted in an expense of €207.8 million in the previous year.

In 2022, tax expenses amounted to €250.5 million (previous year: €232.4 million). In relation to the reported earnings before taxes, the tax rate is 22.2% (previous year: 35.9%). However, taking into account that the above-mentioned valuation effect in the financial result has no subsequent tax impact, the tax rate amounts to 25.5% (previous year: 27.2%).

Net profit attributable to shareholders of Sartorius Stedim Biotech S.A. increased by 111.4% to €876.1 million (previous year: €414.4 million).

Statement of Profit or Loss

€ in millions	**2022**	2021	Δ in %
Sales revenue	3,492.7	2,887.0	21.0
Cost of sales	–1,658.2	–1,334.0	–24.3
Gross profit on sales	1,834.5	1,553.0	18.1
Selling and distribution costs	–446.5	–405.6	–10.1
Research and development costs	–132.4	–110.5	–19.9
General administrative expenses	–154.7	–126.1	–22.7
Other operating income and expenses	–105.6	–45.3	–133.0
Earnings before interest and taxes (EBIT)	995.2	865.4	15.0
Financial income	185.8	22.3	733.6
Financial expenses	–50.7	–241.0	79.0
Financial result	135.2	–218.7	n.m.
Profit before tax	1,130.4	646.7	74.8
Income taxes	–250.5	–232.4	–7.8
Net result	879.9	414.3	112.4
Attributable to:			
Equity holders of SSB S.A.	876.1	414.4	111.4
Non-controlling interest	3.8	–0.1	n.m.

Earnings

At the Sartorius Stedim Biotech Group, EBITDA (earnings before interest, taxes, depreciation and amortization) are used as the key profitability indicator. To provide a complete and transparent picture of the Group's profitability, also in an international comparison, earnings are adjusted for extraordinary items (underlying EBITDA). For more information about definitions, please refer to the Glossary on page 247.

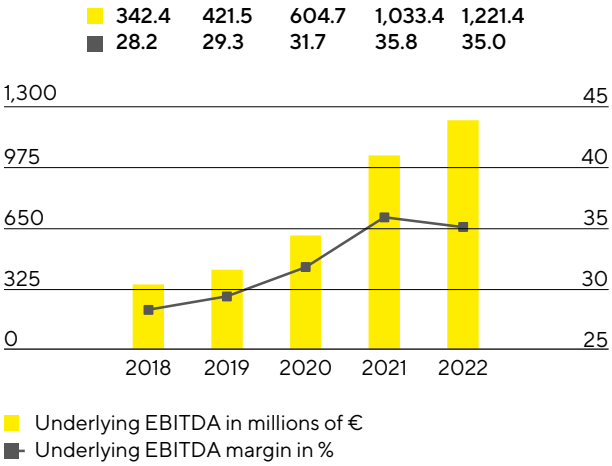
Reconciliation between EBIT and Underlying EBITDA

€ in millions	**2022**	2021
EBIT	995.2	865.4
Extraordinary items	46.3	26.5
Depreciation and amortization	179.9	141.5
Underlying EBITDA	1,221.4	1,033.4

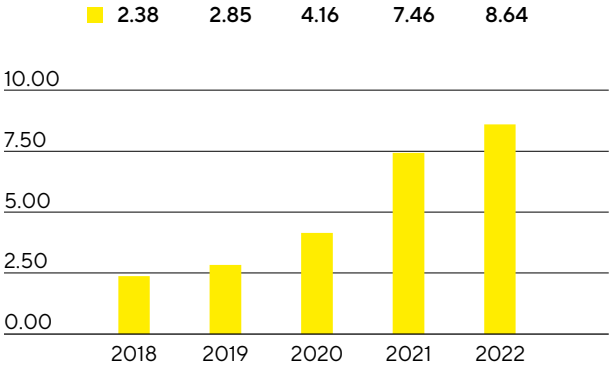
In fiscal 2022, Sartorius Stedim Biotech strongly increased its earnings and achieved high profit margins despite a significant rise in inflation rates. Underlying EBITDA rose by 18.2% to €1,221.4 million. The corresponding margin of 35.0% almost reached the high level of the prior-year period of 35.8%. The 2021 margin had been positively influenced by a partially delayed cost development, for example as a result of deferred new hires in relation to sales revenue growth because of the pandemic and low business travel activity. As planned, these cost positions normalized in 2022 and had a dampening effect on profitability. Price effects on the procurement and customer sides largely offset each other.

The underlying net result after non-controlling interest for the Group rose from €687.8 million in 2021 to €796.6 million in fiscal 2022. This figure is the basis for calculating the profit to be appropriated and is computed by adjusting for extraordinary items, eliminating amortization of €60.7 million (previous year: €48.6 million), and is based on the normalized financial result and a normalized tax rate (see Glossary). Underlying earnings per share increased by 15.8% from €7.46 a year earlier to €8.64.

Underlying EBITDA[1] and Margin



Underlying Earnings per Share[2]
in €



1 Adjusted for extraordinary items
2 Adjusted for extraordinary items, amortization acc. to IFRS 3 and fair value adjustments of hedging instruments, as well as the corresponding tax effects for each of these items.

€ in millions	2022	2021
EBIT (operating result)	**995.2**	**865.4**
Extraordinary items	46.3	26.5
Amortization	IFRS 3	60.7	48.6
Normalized financial result[1]	**–20.6**	**–11.2**
Normalized income tax (26%)[2]	–281.2	–241.6
Underlying net result	**800.4**	**687.7**
Non-controlling interest	–3.8	0.1
Underlying net result after non-controlling interest	**796.6**	**687.8**
Underlying earnings per share (in €)	8.64	7.46

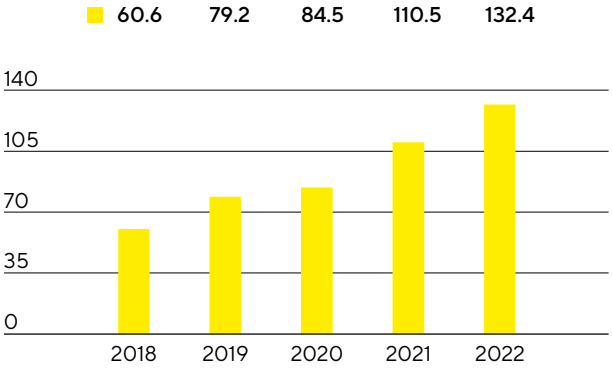
1 Financial result excluding fair value adjustments of hedging instruments and currency effects relating to financing activities and change in valuation of earn-out liability.
2 Normalized income tax based on the underlying profit before taxes and amortization.

See Glossary on page 247 for the definitions of the totals listed above.

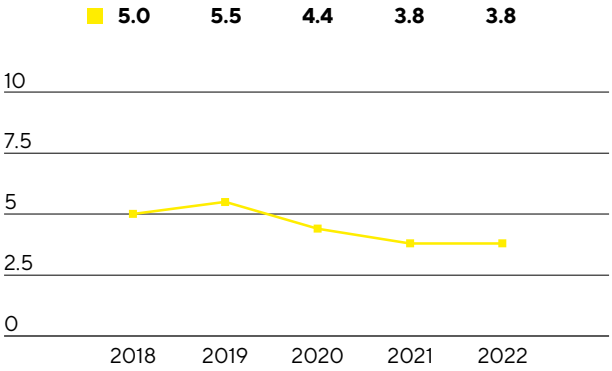
Research and Development

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 2022, the Group spent €132.4 million on R&D, corresponding to an increase of 19.9% over the previous year's investment of €110.5 million. The ratio of R&D costs to sales revenue remained constant at 3.8%. The gross capital expenditure ratio of 5.6% was above the prior-year ratio of 5.1%; this ratio is even more meaningful for the assessment of innovation-related expenses and includes capitalized development costs of €63.1 million (previous year: €37.0 million) that were disclosed in the statement of financial position.

Research & Development Costs
€ in millions



Research & Development Ratio
in % of sales revenue



To protect know-how, Sartorius Stedim Biotech pursues a targeted intellectual and industrial property rights policy. The company systematically monitors compliance with these rights and reviews 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 2022 totaled 171 compared with 71 in the previous year. As a result of the applications submitted in the past years, the company was issued 267 patents and trademarks (previous year: 234). As of the balance sheet date, there was a total of 4,067 patents and trademarks in the portfolio (previous year: 3,316).

	2022	2021
Number of patent and trademark applications	171	71
Registered patents and trademarks	267	234

Capital Expenditures

Against the backdrop of strong growth, Sartorius Stedim Biotech invested considerably in building up new capacities in all regions in 2022. In addition to significantly expanding production capacities, the investment program aims to further diversify the production network and make it more flexible. In line with the company's expansion plans, some expansion projects were completed in 2022 and have contributed to meet the strong demand. Further projects will be completed in 2023.

At €430.6 million, capital expenditures in 2022 were higher than the previous year's figure of €324.0 million, as planned. The corresponding CAPEX ratio was 12.3% (previous year: 11.2%).

The company's largest investment projects in the reporting year included the expansion of membrane manufacturing capacities and new laboratory space for product development in Göttingen, Germany.

At its site in Yauco, Puerto Rico, Sartorius Stedim Biotech is expanding its clean room capacity for the manufacture of separation and fluid management products. In addition, a production facility for cell culture media will be established here for the first time, which is scheduled to come on stream in 2023.

In the reporting year, the company also made substantial investments in additional clean room space for the production of sterile disposables at its site in Aubagne, France.

In the Asia-Pacific region, Sartorius Stedim Biotech invested heavily in Songdo, South Korea, in addition to China. After acquiring the necessary plots of land, the company began construction of a plant for cell culture media production and sterile consumables processing. In addition, the company plans to build a technology center for consulting customers and product demonstrations as well as laboratory space at the new site, which is located in the middle of a biopharma park.

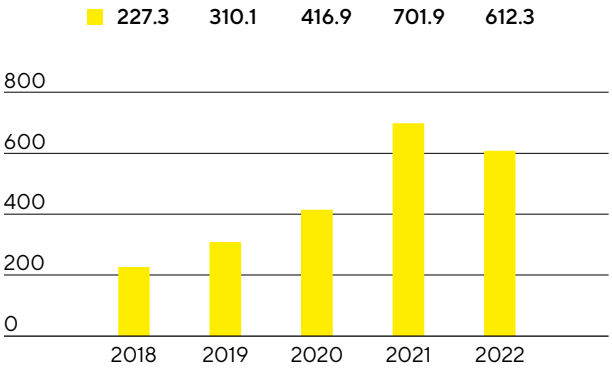
Production capacities were also expanded at other locations. For example, the company carried out expansion projects at other sites in Germany, as well as in Great Britain and Slovenia.

Net Worth and Financial Position

Cash Flow

Cash flow from operating activities amounted to €612.3 million in 2022, compared with €701.9 million in the previous year, a decrease of 12.8%. Higher earnings were offset by cash outflows in connection with the growth-related increase in working capital. Inventories were in particular built up to safeguard supply security in view of the continuing tensions in some supply chains. Recently, however, the focus has shifted back to optimizing inventories, as the supply chain situation for many product groups has improved significantly and shortages in these areas have become unlikely.

Net Cash Flow from Operating Activities
€ in millions



Due to high demand, Sartorius Stedim Biotech has been driving the expansion of its production capacities full speed ahead. Cash outflows from investing activities increased in the reporting period by 36.6% to €442.0 million. Because of expenses of €515.6 million in connection with the most recent acquisitions, cash flow from investing activities and acquisitions rose to -€957.5 million compared with -€465.2 million in the previous year.

Primarily driven by the financing of the most recent acquisitions, cash flow from financing activities amounted to €220.7 million in 2022 relative to -€77.7 million in the previous year. This also included dividend payments for the 2021 financial year of €117.7 million (previous year: €63.8 million).

Cash Flow Statement

€ in millions	**2022**	2021[1]
Cash flow from operating activities	612.3	701.9
Cash flow from investing activities and acquisitions	–957.5	–465.2
Cash flow from financing activities	220.7	–77.7
Cash and cash equivalents	107.1	223.6
Gross debt	1,135.7	625.5
Net debt	1,028.6	401.9

1 Interest received are reported under cash flows from operating activities since fiscal 2022. Prior year figures were restated accordingly.

Consolidated Statement of Financial Position

The balance sheet total of the Sartorius Stedim Biotech Group was €5,065.4 million as of the end of fiscal 2022 and thus €1,114.3 million higher than the prior-year level. This increase is largely due to the rise in non-current assets by €898.7 million to €3,394.2 million, predominantly driven by the recent acquisitions and by the continuation of the extensive investment program. In addition, current assets rose by €215.5 million year on year to €1,671.2 million, mainly as a result of the increase in working capital and, in particular, the buildup of inventories as a risk provision to ensure supply security in the event of interrupted supply chains. Working capital amounted to €1,663.5 million as of December 31, 2022 (previous year: €1,316.8 million).

Key Working Capital Figures

in days		**2022**	2021
Days inventories outstanding			
Inventories | sales revenue[1]	x 360	105	97
Days sales outstanding			
Trade receivables | sales revenue[1]	x 360	41	44
Days payables outstanding			
Trade payables | sales revenue[1]	x 360	50	58
Net working capital days			
Net working capital[2] | sales revenue[1]	x 360	96	83

1 Including pro forma sales of recent acquisitions
2 Sum of inventories and trade receivables less the trade payables

Equity grew by €781.0 million to €2,514.2 million as of year-end. The equity ratio – defined as the quotient of equity to the balance sheet total - was 49.6% (previous year: 43.9%).

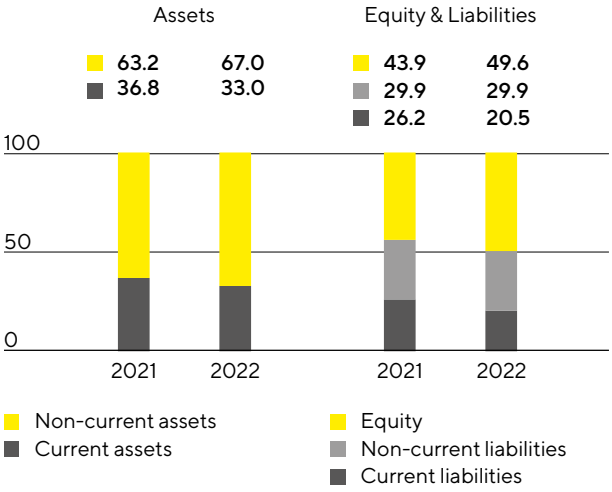
In the reporting year, current and non-current liabilities for the Sartorius Stedim Biotech Group of €2,551.2 million exceeded the previous year's figure of €2,217.9 million. The increase resulted, among other things, from the financing of recent acquisitions and the build-up of working capital.

Overall, gross debt, which is comprised of liabilities to banks and loans from the parent company Sartorius AG as well as of lease liabilities, rose to €1,135.7 million as of December 31, 2022, compared with €625.5 million for the year ended December 31, 2021. The increase is essentially due to a new loan agreement signed with Sartorius AG, mainly to serve the financing of the Albumedix acquisition. Net debt, defined as gross debt less cash and cash equivalents, was €1,028.6 million compared to €401.9 million a year ago.

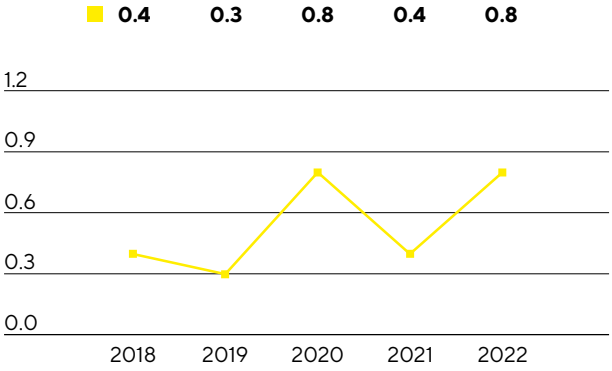
Calculation of Net Debt

€ in millions	**2022**	2021
Non-current		
Loans and borrowings	1,020.6	521.1
Lease liabilities	91.1	64.0
Current		
Loans and borrowings	4.5	25.5
Lease liabilities	19.5	14.9
Gross debt	1,135.7	625.5
Cash and cash equivalents	107.1	223.6
Net debt	1,028.6	401.9

Balance Sheet Structure
in %



Ratio of Net Debt[1] to Underlying EBITDA[2]



1 The net debt excludes the liability for the remaining purchase price for acquisitions; 2022: €245.1 million, 2021: €518.7 million, 2020: €127.8 million, 2019: €72.5 million, 2018: €8.7 million
2 EBITDA includes underlying pro forma EBITDA contributed by acquisitions for this period.

In relation to the debt financing capacity of the Sartorius Stedim Biotech Group, the ratio of net debt to underlying EBITDA is a key metric. It is defined as the quotient of net debt and underlying EBITDA over the past 12 months, including the pro forma amount contributed by acquisitions for this period. As of December 31, 2022, the ratio rose to 0.8 (previous year: 0.4) mainly driven by the financing of the extensive investments and the acquisitions made in the reporting year.

Impact of War in Ukraine

Since the beginning of Russia's attack on Ukraine, Sartorius Stedim Biotech has suspended all business activities in Russia that are not related to humanitarian medical products. This has been done in compliance with all applicable sanctions and in line with the practice of other companies in the pharmaceutical and healthcare sectors. In 2021, Russia had accounted for a good 2% of Group sales. In fiscal 2022, sales were significantly below this level and a further decline is expected in 2023.

Further explanations on the impact of the war in Ukraine on Sartorius Stedim Biotech can be found on pages 44 and 134 et seq.

Financing | Treasury

Sartorius Stedim Biotech covers its operational and strategic financing needs through a combination of operating cash flows and the taking out 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 €1,005 million provided by the parent company Sartorius AG. In 2022, Sartorius Stedim Biotech signed a new loan agreement with its parent company Sartorius AG mainly to refinance the acquisition of Albumedix.

In addition, the Group has diverse bilateral credit lines of approximately €77 million in total.

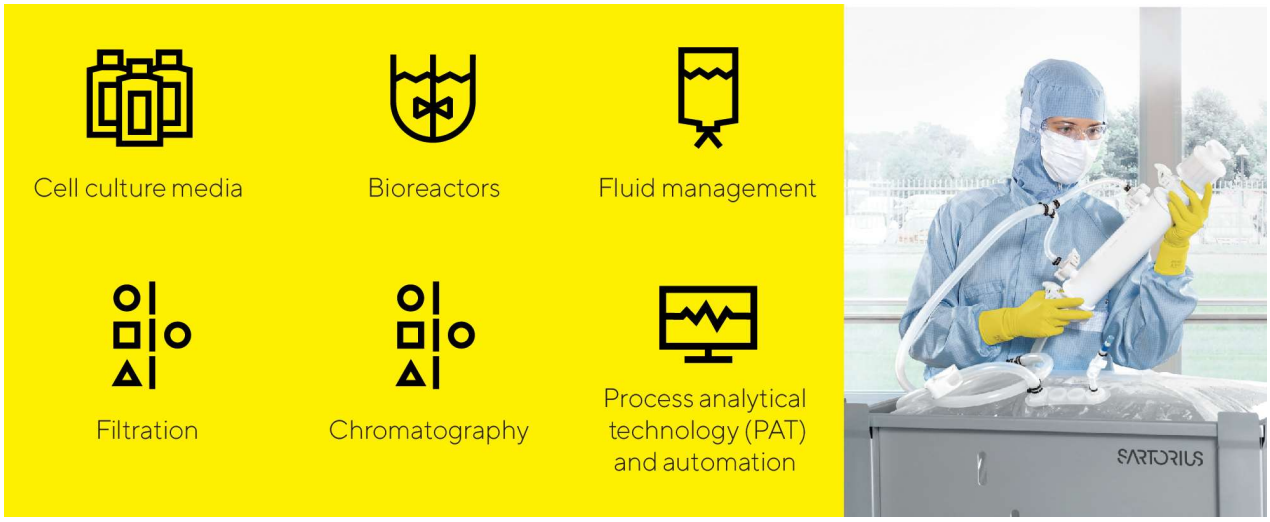
The above-mentioned financing comprises instruments with both fixed and variable interest.

As of December 31, 2022, the total volume of all available credit lines was €337 million. Of this amount, Sartorius Stedim Biotech had utilized €3 million, leaving available credit of €334 million at the end of 2022. This ensures that all Group entities have sufficient funds to successfully finance their business operations and new capital expenditures.

The company uses 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 2022, foreign exchange contracts amounted to €396 million on a reported basis, with a market value of -€2.5 million.

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.



Sartorius Stedim Biotech expanded its product portfolio by making two acquisitions in 2022:

- By acquiring the business from Novasep in February 2022, Sartorius Stedim Biotech added a complementary offering to its chromatography portfolio. The acquired portfolio includes chromatography systems primarily suited for small biomolecules, such as oligonucleotides, peptides, and insulin, as well as innovative systems for the continuous production of biopharmaceuticals.

- The acquisition of Albumedix, a leading provider of solutions based on recombinant human albumin, completed at the end of September 2022, added an important component to portfolio in the production of innovative biopharmaceuticals, especially for modalities such as cell therapies, viral therapies, and vaccines.

During 2022, Sartorius Stedim Biotech launched a scalable and ready-to-use disposable membrane for separating monoclonal antibodies as an alternative to classical resin-based column chromatography for the affinity purification step. Furthermore, the company introduced a computer-based application for optimizing cell culture development that enables substantial time and cost savings. The application is part of a cloud-based software ecosystem for analyzing and managing data along the biopharma value chain and makes it possible to maximize insights from in vitro experiments by using simulations in virtual bioreactors.

Sales Activities

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

Even after the gradual lifting of pandemic-related travel and contact restrictions in many parts of the company's business regions, sales representatives continued to interact directly with many customers using

digital communication tools. Videoconferencing and augmented reality also continue to be used for such direct interactions, for example, when demonstrating products, conducting training sessions, and bringing systems into service. One focus aimed at strengthening the sales force is on expanding the company's international presence. A further focus is on the ongoing enhancement of sales effectiveness, for example, by specialized training for employees. A further focus is on the ongoing enhancement of sales effectiveness, for example, by specialized training for employees.

Product Development

Development activities at Sartorius Stedim Biotech essentially focus on technology areas such as membranes, which are the core component of the 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.

The largest product development site is located in Göttingen, Germany, where a new product development building is scheduled to begin operations in the first quarter of 2023. Further important activities take place in France, India, the USA, and the UK, as well as in Sweden, Israel, Slovenia, and other locations in Germany.

Production and Supply Chain Management

Sartorius Stedim Biotech has a very well-developed global production network that was expanded at many sites in 2022. The largest production facilities are located in Germany, France and Puerto Rico. Beyond these locations, the company also manufactures in the U.K., Switzerland, Tunisia, India, the United States, China, Israel, and in Slovenia. Recent acquisitions have added sites in France and the UK.

The supply chain situation remained challenging in 2022, but it has eased somewhat overall compared with the previous year. Delivery times for most products have normalized, and the availability of electronic components and some chemical raw materials also improved over the course of the year. The prices of many primary products used by Sartorius Stedim Biotech did increase, however, in some cases significantly.

With regard to its energy supply, the company has taken extensive measures in Germany in order to become as independent as possible from the availability of gas, if necessary.

Sartorius Stedim Biotech has expanded production capacity in all business regions, such as China, Tunisia, and Puerto Rico. Additional production employees were hired for this purpose.

To meet the growing demand for consumables in China, the expansion of the clean room in Beijing was brought into operation in 2022. This significantly expanded the local production capacity for sterile disposable bags. In addition to bags, the company has recently started producing other types of filters in the expanded clean rooms.

Following the opening of a significantly expanded application, validation, and service center for biopharma customers at the Shanghai site in 2021, the company opened new application centers in Yantai, China, and Bangalore, India, in the reporting year. These enable customers to test complex systems at a Sartorius Stedim Biotech site first before they 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 is a decisive success factor in determining the future development of a company's shareholder value.

The point of risk management is not to always eliminate every risk possible; rather, the company's approach is to intentionally take a certain measure of risk in business activities in order to be successful in unlocking opportunities. 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.

At Sartorius Stedim Biotech, identification and management of opportunities and risks is a cross-functional component of Group management. In this context, Sartorius Stedim Biotech's risk management is integrated into the Sartorius Group organization. The risk management organization reflects a global functional organization in which individuals heading a functional area are each responsible for their own management of opportunities and risks. The Finance & Controlling department ensures a regular reporting process and is responsible for the further development of the Group's risk management system as a whole (Central Risk Management function).

Managing Opportunities

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 is one of the key roles of the relevant managers and initially takes place at the local rather than the central level. Particularly the market-facing functions, such as strategic marketing and product management in the individual divisions, play a leading role in this respect. These areas are supported by the central Business Development unit with market monitoring, data analysis and the implementation of strategic projects.

As a partner to the biopharmaceutical industries, Sartorius Stedim Biotech operates in future-oriented and high-growth sectors. 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 Sectors" on pages 25 and 59, respectively.

Based on own assessments, the company is ranked as one of the global market leaders in many subsegments and product areas. We believe the high quality of the products, the strong brand recognition and established customer relationships give Sartorius Stedim Biotech a good chance to stabilize and continue extending 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 21.

Risk Management

Organization

Overall responsibility for an effective risk management system lies with the Audit Committee. Coordinating and developing this system and combined risk reporting are the responsibilities of the the Finance department, while the particular functional areas are responsible for identifying and reporting individual risks, as well as for assessing their potential impact and for taking the appropriate countermeasures.

The Audit Committee monitors the effectiveness of the risk management system, 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. The results and findings of these audits are discussed in the Board and Audit Committee meetings. Any adjustments to the risk management system are implemented by Central Risk Management.

Insurance

Sartorius Stedim Biotech has taken out insurance policies to cover a large number 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 insurers, the Group considers particularly the credit rating of these entities, as well as the target to achieve a high degree of diversification to mitigate the related risks.

Risk Management System and Risk Reporting

The risk management system of the Sartorius Group is documented in a Risk Management Handbook that applies throughout the entire Group and includes definitions of the framework, the structural organization, processes, risk reporting and monitoring, and controlling of the effectiveness of the risk management system. This Handbook is based as a whole on the ISO 31000 "Risk Management - Guidelines" standard and the COSO standard (COSO = Committee of Sponsoring Organizations of the Treadway Commission). 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 Group’s strong growth over the past years and the rising demands of customers and regulators meanwhile require that the guidelines and rules are adapted continuously.

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 with respect to their assessment, probability of occurrence and measures to be taken to eliminate such risks or to mitigate their impact. As a matter of policy, assessment of risks is governed by the remaining net risk, i.e., after any risk-mitigating action has been taken. In addition, as soon as these risks reach defined size criteria, they are reported to the central risk management system. Central Risk Management aggregates the reported risks reports and informs the Audit Committee regularly on the Group's risk situation. This information includes

a comparison of the risk portfolio with the risk-bearing capacity of the Group determined on the basis of the rolling liquidity planning. An urgent reporting procedure is in place to ensure that when a new or emerging significant risk to the Group's net worth, financial position and profitability is identified, the Audit Committee receives all of the necessary details without delay.

In order to provide a logical structure, four main categories have been defined: external risks, operating risks, financial risks and compliance risks. Each main category is divided into several subcategories that are described in the following sections.

Moreover, Sartorius Stedim Biotech has defined a so-called risk matrix that categorizes the probability of occurrence and potential impact on the net profit into specific 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

These two elements are combined to form the following matrix that indicates the importance of the individual 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

In principle, the ability to foresee and mitigate the direct and indirect effects of risks entailed by life in general is limited. Such risks include natural catastrophes, pandemics, armed conflicts or force majeure, and their associated damage to commercially significant and critical infrastructure. Measures are taken proactively, whenever feasible, to ensure that the company can respond appropriately and at short notice or is insured against any damage entailed by such risks.

The effects of the coronavirus pandemic also had a significant impact on Sartorius Stedim Biotech's business development. Overall, as one of the leading bioprocess technology providers, the Group was able to contribute to overcoming the pandemic by supplying products for the production of coronavirus vaccines and test methods. However, the sales generated in this context remained significantly below the level of the previous year. At the same time, the temporary lockdown in China had a slightly dampening effect on business. Pandemic-related travel and contact restrictions largely expired in the year under review and therefore had less of an impact than in previous years. It is currently assumed that the additional business in connection with the coronavirus pandemic will no longer have any significant impact on the Group's business development in the future. The situation in the supply chains was still challenging in 2022, but it has eased somewhat overall compared to the previous year.

The war in Ukraine, which has been ongoing since February 2022, had no significant direct impact on the Group as a whole in the financial year. The share of the affected countries in Group sales totaled a good 2% in 2021. Since the beginning of the war, Sartorius Stedim Biotech has suspended all business activities in Russia that are not related to humanitarian medical products. This is done in compliance with the sanctions in force and in line with the practice of other companies in the pharmaceutical and health sector. In the 2022 financial year, however, sales were significantly below the level of the previous year, and a further decline is expected for 2023.

Sartorius Stedim Biotech does not own any non-current assets in Russia, Belarus and Ukraine that are significant from a Group perspective. The default risks in connection with trade receivables in Russia are limited due to an insignificant volume of receivables as of the reporting date, as well as intensive receivables management and changed payment terms (e.g., deliveries against prepayment).

While the direct effects of the war on the economic situation of the Sartorius Stedim Biotech Group were limited overall, there were noticeable indirect effects. Although the company does not have any major suppliers in the affected countries, it has seen increased logistics and energy expenses as well as an increase in procurement costs for components and raw materials. Furthermore, some countries, particularly Germany, are highly dependent on Russian natural gas, so that in the event of a gas shortage, there is a risk of massive effects, including production outages, at the Group's own locations and at important suppliers.

These risks have been reduced with a variety of measures since the beginning of the crisis. Extensive price increases were introduced to compensate for the higher procurement costs. The German Group locations have been able to make themselves largely independent of the Russian gas supply, for example, by creating the technical prerequisites for a conversion to oil. With regard to suppliers with energy-intensive production processes, safety stocks have been increased significantly.

Overall, the direct and indirect effects of the Ukraine war on the Group's business development are currently not significant. Since the conflict is ongoing and the further development of the dispute and the indirect effects cannot be reliably estimated, there is a relatively high level of uncertainty in this context.

The Group's largest sites in Germany and France do not face any major risks from natural catastrophes, while, for example, the production plants in Puerto Rico and in Fremont, California, are exposed to the risk of severe hurricanes or earthquakes and could be impacted accordingly. By applying the highest possible safety standards to the buildings and explicitly considering this risk in the warehousing and international production network strategies Sartorius Stedim Biotech is reducing the related exposure.

In the past fiscal year, hurricane Fiona caused significant damage in the Caribbean and Canada. The Group had to temporarily halt production at the site in Yauco, Puerto Rico, but there were no lasting adverse effects to the ability to deliver and full production was resumed within a few days.

Furthermore, political developments, such as changes in foreign trade policy of various countries, can have an impact on the Group's business.

Since the Group companies operate globally and have international interdependencies, punitive tariffs and trade conflicts can have negative effects on our business activities. To reduce any possible impacts, various measures are currently being reviewed, such as an extension of our supplier network.

Overall, the importance of geopolitical risks for the Group's business activities has increased significantly in recent years. Developments in this regard are being observed and measures to reduce risks are being initiated as early as possible.

Business Cycle Risks

Owing to the concentration of its business activities in the life science sector, the effect of general economic developments on Sartorius Stedim Biotech is lower than average. The Group focuses on the biopharmaceutical industry, which is largely independent of economic cycles.

Operational Risks and Opportunities

The Group's supply chain extends from procurement to production to sales and distribution. Problems within this workflow can have consequential effects, including delays in deliveries. The supply chain management system ensures analyzing and controlling of all operations throughout our value-added chain and thereby largely minimizes the associated risks. On the other hand, the strongly international alignment of the organization opens up a whole series of opportunities. The various risks and opportunities encountered within the Group's supply chain are explained in detail below.

Procurement Risks and Opportunities

The company purchases a wide range of raw materials, components, parts and services from suppliers and is consequently exposed to the risks of unexpected delivery bottlenecks and|or price increases.

In the field of supplier management, powerful tools and robust processes have been implemented in recent years to manage risks and ensure supply continuity. Important measures to reduce potential supply bottlenecks include maintaining safety stock levels and identifying alternative materials and suppliers. In addition, the Group regularly conducts supplier reviews and carefully monitors the delivery status and inventory coverage of critical raw materials.

The Group actively mitigates procurement risks arising from the current raw material shortages in the market. By concluding binding purchase agreements with suppliers and/or by seeking alternatives within the supplier network, their impact can be reduced and continuous supply largely secured.

In addition, Sartorius Stedim Biotech identifies and evaluates the supplier base with regard to compliance with sustainability standards. In the event of deviations, the process provides for a large number of measures that are coordinated with the suppliers concerned.

Opportunities can arise in the area of procurement when the Group's growth leads to an increase in order quantities and thereby strengthens its position with suppliers.

Production Risks and Opportunities

Based on the core technology expertise, the Group manufactures a significant proportion of products that involve a high level of vertical integration (e.g., filters). 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. Where products are manufactured internally, the Group bears 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.

These risks are reduced by planning production capacities carefully, using versatile machines and semi-automated individual workstations in conjunction with flextime work schedules, and continuously monitoring production processes. Moreover, a global manufacturing network enables the Group to compensate partially for capacity bottlenecks by shifting production to other regional plants and to limit our dependency on individual local manufacturing sites. Furthermore, policies for business interruption insurance have been taken out to compensate for any possible losses due to production downtimes.

Some production processes use highly flammable or explosive materials. The improper handling of such materials can result in significant damage to property and business interruptions. The Group has taken all necessary organizational and structural measures at the affected locations to mitigate this risk as much as possible.

Sartorius Stedim Biotech considers it an opportunity that the investments in infrastructure and production resources, among other things, have given high flexibility in manufacturing operations and that customers' requirements and regulatory standards can be fulfilled with respect to business continuity concepts. In addition, this approach ensures that the international production sites can concentrate on specific manufacturing technologies, leveraging regional cost advantages as a result. Continuous improvements in production, such as simplifying processes as well as increased automation and digitalization, also help to increase efficiency.

Sales and Distribution Risks and Opportunities

Sartorius Stedim Biotech uses a variety of channels to sell and distribute its products around the world. The potential risks entailed are unexpected changes in the demand structure, for example, driven by further consolidation in the relevant markets, growing price pressure and non-compliance with supply agreements concluded with customers. The Group employs targeted market analyses to identify emerging demand trends in individual segments early on so that appropriate responses can be initiated. Technical innovations and the fact that a large number of the Group's products are used in validated production processes in the biopharmaceutical industry reduce the exposure to the risk of growing price pressure. The risk exposure in the

area of logistics has been reduced 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 the product range puts the Group in a position to sell new products to existing customers. Moreover, business relationships, most of which are established for the long term, and the Group's global presence provide opportunities. After all, acquisitions contribute to the continuous expansion of the product range. Newly acquired technologies in the areas of cell culture media and downstream processing have recently been added to the Group's offering.

Sartorius Stedim Biotech sources its key customers from the pharmaceutical, chemical and food industries. These customers are usually relatively large organizations that have been in existence for some time and have strong credit ratings. Most 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 its core technologies and competes mainly with larger rivals sharing the status as a globally operating company. As the Group serves a large number of customers from highly regulated sectors like the pharmaceutical and food industries, and the technology barriers to market entry are fairly high, the probability of new competitors emerging within the short term is regarded as relatively low.

The fact that many of the Group's products are used in validated processes, especially those in the biopharmaceutical industry, reduces the risk of losing significant market share within a short time frame. Conversely, the hurdles faced by Sartorius Stedim Biotech in winning clients from our competitors in this industry are also higher.

Further risks could arise from changes in the competitive environment, for example, further consolidation in the markets or new competitors, for instance in China. Sartorius Stedim Biotech has been continuously making acquisitions in recent years, thus further strengthening its market position and opening up new potential synergies.

Quality Risks and Opportunities

Customers use Sartorius Stedim Biotech's products in a wide range of critical production processes, including the manufacture of medications, foods and chemicals, and in research and development laboratories. The main risk encountered in these areas is non-compliance with specified quality criteria, impacting the performance of the products, which - in worse case - can lead to losses for the Group's customers, or their customers for which the Group may be made liable through compensation claims.

The company applies rigorous quality checks and advanced production methods and processes, such as cleanroom technology, to ensure that all products satisfy the most stringent quality standards and high regulatory requirements. These manufacturing methods and processes are subject to constant review under the continual improvement processes, moreover, and are optimized as requirements evolve. Quality control tests are implemented through in-process control tests and test procedures of final products to ensure that critical or essential product properties are continuously met. A rigid product release process ensures that only products will be shipped that are in compliance with the agreed specifications.

The effectiveness of the Group's quality system is confirmed through the successful completion of regular audits by customers as much as through implementation of certified quality systems compliant with ISO 9001

and, where applicable, with ISO 13485 to document the high level of quality achieved in Sartorius Stedim Biotech's products and processes. Irrespective of these measures, significant insurance coverage against product liability risks is maintained.

In addition, a traceability system has been established that enables the Group to efficiently identify and, if required, recall an entire production batch immediately. This minimizes the consequences in the event that a defect or non-conforming item is discovered in a product and ensures compliance to regulations. A complaints management system has also been installed to deal with customer requests promptly and to ensure efficient documentation.

In the addressed sectors, 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. There is a risk that new regulations may be overlooked or be difficult to implement. For Sartorius Stedim Biotech, this also unlocks opportunities by putting up further barriers to entry for potential market players. The reason is that challenging quality demands represent a considerable barrier to entry for potential new competitors and provide stimulus for further technical innovation. Moreover, through the work on professional committees, and the membership in industry associations and standards committees, the Group actively takes part in drafting new standards and guidelines and is able to identify emerging requirements at an early stage and make the necessary preparations.

R&D Risks and Opportunities

The Group devotes a considerable share of its resources to research and development. Potential risks in this area may arise from development results that diverge from market needs or application requirements and from exceeding planned development deadlines and budgets. These risks are substantially limited through our approach into trend monitoring as well as early-stage proof-of-concept activities to de-risk the product developments, as well as project management, intensive R&D controlling and early involvement of our customers in the development process. In particular, the company ensures that proofs of concept and product designs are always reviewed promptly with regard to how well they meet customers' needs so products can be adapted accordingly as required. The continuous tracking of technology trends and competitor activities together with an early-stage patent filing ensure the Group's technology and marketing position.

Intensive collaboration with partners who are among the global market and opinion leaders in their fields enables Sartorius Stedim Biotech to jointly develop products with an especially high level of innovation. In areas such as membrane technology and plastics technology, sensorics and biopharmaceutical process engineering, the expertise of its own specialists puts the Group worldwide at the very forefront of global research and development, presenting the 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 enables Sartorius Stedim Biotech to identify promising developments at universities, start-ups and at customers' plants and to ensure all relevant IP positions are secured in advance.

Acquisition Risks and Opportunities

By nature, acquisitions provide many opportunities, such as sales growth, extension of product portfolios and development of new markets. By contrast, 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.

Sartorius Stedim Biotech takes various measures to reduce these risks. These include performing a thorough due diligence review of important areas and carrying out a comprehensive analysis of the market concerned.

In addition, the Group involves external consultants and experts in the purchase or sales process as required. A special focus is on the construction of 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. Appropriate insurance policies are taken out when necessary. 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. A Post-Merger Integration (PMI) Office has been established as an independent function to ensure the efficiency of the integration process and minimization of the associated risks.

Personnel Risks and Opportunities

As an innovative technology group, Sartorius Stedim Biotech employs a large percentage of highly qualified people. This entails the risk that Sartorius Stedim Biotech may not be able to hire sufficient numbers of highly qualified employees in the future or may lose high performers currently working for the company. The strong growth of the Group and the associated expansion of its workforce moreover pose sizable challenges for the integration and familiarization of new employees, and thus also harbor risks.

Sartorius Stedim Biotech strives to retain employees in key positions and talented individuals over the long term by offering performance-based compensation models, targeted training opportunities, attractive fringe benefits, and by highlighting interesting development prospects. In this context, the Group particularly continued to enhance staff development initiatives and management programs. The success of these measures is reflected in the low attrition rates seen in recent years. In certain cases, employment contracts contain a clause prohibiting any move to a direct competitor.

Sartorius Stedim Biotech is countering demographic change primarily by training junior employees and promoting continuous learning for every employee, accompanied by appropriate performance development processes. This, in turn, creates opportunities for the Group, as training its own employees ensures that Sartorius can meet its own demand for qualified personnel.

In order to smoothly onboard new employees and ensure an appropriate transfer of knowledge, the Group has developed and implemented specific onboarding processes for employees and managers. In addition, Sartorius Stedim Biotech uses a digital HR platform that supports secure and stable processes and enables decisions to be made on the basis of high-quality data.

IT Risks and Opportunities

The Sartorius Stedim Biotech Group's business processes are supported by a wide array of specific software applications and IT systems. A failure or significant impairment of the business-critical IT systems and the supporting technical infrastructure due to cyberattacks or other threats could significantly hamper the smooth functioning of the company's business processes and lead to manipulation or the uncontrolled loss or outflow of data.

Sartorius Stedim Biotech mitigates these risks by continuously investing in the implementation and operation of secure IT systems and applications and by continually developing and applying the concepts and security measures on the basis of the international ISO 27001 "Information security management" standard, among others. In addition, the Group incorporates the results of regular audits and vulnerability assessments by external companies specializing in IT security.

Safeguarding data, systems, and applications from misuse and other threats is managed via the uniform risk management system at Group level and implemented through the governance structure and IT risk management, and appropriate IT security policies and effective communication and practices. Fundamental principles such as secure configuration, user training and security awareness, network security, malware prevention, privilege management, and incident response are fundamental to the security organization and procedures.

The Group expects that the threat of cyberattacks will further increase worldwide, both in number and intensity. For this reason, the corresponding measures and activities were further expanded in the reporting year. The Group-wide IT security organization was strengthened in terms of personnel and expertise, a security control and defense team was established around the clock and additional systems and services for monitoring, detecting and defending against cyberattacks were set up.

The IT department actively provides targeted information across the Group on potential cyber threats and risks, and it engages employees by giving them simple but effective ways to defend themselves in a decentralized manner and report suspicious incidents for review.

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. Conversely, 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 in foreign exchange rates. Since around two-thirds of consolidated sales revenue are generated in foreign currencies and, in turn, approximately two-thirds of this total revenue in U.S. dollars or in currencies pegged to the U.S. dollar, the Group is positively or negatively impacted by currency effects when converting the currencies of balance sheet items and profit or loss items, respectively. Other currencies relevant to the Sartorius Stedim Biotech Group are the British pound, the Singapore dollar, the South Korean won, the Japanese yen, the Chinese renminbi and the Swiss franc.

The global production network enables the Group to offset the majority of sales revenues generated in foreign currencies against costs likewise incurred in foreign currency. For example, many products for the North American market are manufactured locally, and the Group is therefore not disadvantaged on the cost side in competing with U.S. rivals, insofar as this risk is concerned.

The risk exposure is monitored continuously with a cash flow at-risk model in order to evaluate and steer the remaining risk based on the expected net exposure for the next 12 months and taking into consideration hedging transactions already executed. This is the basis to decide on whether to employ additional derivative financial instruments, especially spot, forward and swap transactions, to adjust for maximum loss.

Interest Rate Risks and Opportunities

The Group has concluded fixed interest agreements for more than 70% of the loans outstanding so that any changes in the interest rate will not have any meaningful effects on consolidated earnings. The remaining portion of the financial instruments outstanding on the reporting date is subject to variable interest rates

based on the market rate. Interest rate trends and our interest rate exposure are monitored constantly and hedging transactions are arranged where it is considered necessary and economically advisable to do so for individual loans. As of December 31, 2022, the Group did not hold any interest rate derivatives in its 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 €300 million credit line provided by Sartorius AG that can be accessed and repaid at short notice. Additionally, there are some bilateral credit lines in place on a smaller scale for individual Group companies. Furthermore, cash pooling agreements are used between selected Group companies as the primary instrument for managing liquidity within the Group.

Tax Risks

Sartorius Stedim Biotech and its subsidiaries do business across the globe and are therefore subject to the tax laws and regimes of various countries. Changes in tax laws, rulings by the courts and interpretation of the laws by the fiscal authorities or courts in these countries can result in additional tax expenses and payments and thus also affect the corresponding tax items in the statements of financial position and profit or loss.

The central Group Tax department manages the resulting risks by continually monitoring and analyzing tax conditions along with the support of third-party consultants in the respective countries.

Compliance Risks

Regulatory Risks

As a partner of the biopharmaceutical industry and healthcare providers, Sartorius Stedim Biotech can also be affected by underlying developments in these areas. In this context, the principle source of risk is the possibility that regulatory authorities, such as the U.S. Food & Drug Administration (FDA), the European Medicines Agency (EMA), and other national or international bodies might adopt a more restrictive approach to the approval of new medications or medical devices of the Group's customers. In addition, adherence to the regulations of other relevant authorities like the Environmental Protection Agency or the Department of Agriculture in the USA is important to contain local or global regulatory risks.

Failure on the part of Sartorius Stedim Biotech's customers to adequately comply with the regulations in force at any given time could delay approval processes or even reduce the number of newly approved drugs and thus also worsen the Group's future prospects in the medium term. With regard to its own products, the Group is also subject to extensive approval, registration, and reporting obligations in numerous countries. Failure to comply with the often complex requirements could result in sales or import bans as well as penalties. The functions responsible for regulatory affairs monitor the affected markets and assess whether the Group needs to make any changes to its processes.

Environmental Risks

Sartorius Stedim Biotech procures a wide range of raw, auxiliary and operating materials, such as plastic, metal and electronic components as well as packaging. In addition, some production processes produce waste due to the use of solvents, which is subject to special rules regarding recycling or disposal. In this context, there is a risk that the relevant legal regulations are not complied with.

The Environment, Health and Safety department is responsible for observing the applicable regulations regarding the safe handling of materials, avoidance of emissions and orderly disposal routes. Sartorius Stedim Biotech has set up a cross-divisional environmental management system for managing environmental issues and mitigating risk. In addition, most of the large production sites have been certified according to ISO 14001: 2015, including France, India, Puerto Rico, and China. At these sites, corresponding organizational units have been set up to ensure compliance with relevant legal and regulatory requirements and the continuous implementation of sustainable technical innovation to improve environmental aspects in production processes. It is important to incorporate environmental topics in almost all decision-making processes as early as possible. In this way, potential environmental risks can be systematically reduced and the business can be operated in a sustainable and environmentally friendly fashion.

Environmental and sustainability aspects are playing an increasingly important role in many business processes for the Group. The aspect of environmentally sustainable business has thus become a central element of how suppliers are selected. For more information on these topics, please see the non-financial Group statement.

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 the Group.

Assessment of the Overall Risk Situation and Risk Outlook

Where feasible, countermeasures are adopted and | or risk provisions are made in the balance sheet during the reporting year to cover all discernible risks within the Sartorius Stedim Biotech Group, and those of a defined probability of occurrence, which had the potential to damage our net worth, financial situation and profitability.

For the purposes of this report, the probability of occurrence of the risks has been assessed as shown below and, in the adjacent columns, classified according to their particular significance for the entire Group. The most significant risks in each category are marked with an asterisk.

Risk Category	Probability of Occurrence	Significance
External risks		
General risks*	Probable	Moderate
Business cycle risks	Possible	Moderate
Operating risks		
Procurement risks*	Possible	Significant
Production risks	Possible	Significant
Sales and distribution risks	Possible	Moderate
Competitive risks	Possible	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	Moderate
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.

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, analyze and manage the related risks.

Control Activities
These control activities are carried out at every level of the Group to ensure efficient internal control: 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 controls 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 of the Board of Directors
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 96.

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 system, representatives from different business and functional areas regularly address issues related to the management of financial and non-financial risks (including environmental or social risk related to sustainability topics) in a quarterly reporting process. The risk typology is described on page 42. The Audit Committee of the Board of Directors and the General Management regularly hear the Head of the Controlling, who gives an overview of such financial and non-financial risks to which the company is exposed to. This organization enables management to take appropriate actions, as the CEO attends the Audit Committee as a guest.

Internal Auditing Department
Based on the annual audit plan approved by the Audit Committee of the Board of Directors, the Internal Auditing department (IA) evaluates and improves the effectiveness of the organization's governance, risk management and the internal controls 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 Head of the Legal Affairs & Compliance of the 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 and support 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.

In 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 fully complies 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 2022

The Company continues to review all policies, internal procedures and organizational measures and update them with the view of continuous improvement.

Code of Conduct and Anti-Corruption Code

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

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

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

The Company ensures that employees are familiar with the Anti-Corruption Code and the Code of Conduct by asking them to take part in an online training course every year. 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 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, these transactions 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, 2022, 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
25/02/2022	Sartorius AG	Share	Sale	Price: €336.40 Volume: 200,442

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 in 2020. The overall purchase price comprised of a payment of €234.2 million 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.

In accordance with the recommendations of the AFEP-MEDEF Code and the Autorité des Marchés Financiers Recommendation No. 2010-07 of November 3, 2010, hedging transactions of any kind on the company's shares with regard to stock options are prohibited.

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.