Sector Conditions

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

Strong Growth in the Biopharmaceutical Market

The global pharma market performed significantly better in the reporting year than in previous years, expanding by around 14% according to EvaluatePharma. This was especially due to strong growth in the biopharmaceutical segment, which rose overproportionately by around 29% to €350 billion in 2021. The reason for this growth was significant additional revenue with coronavirus vaccines and Covid-19 therapeutics estimated at more than €80 billion, which also led to an increase in the biopharma share of the total pharma market from 30% to 34%.

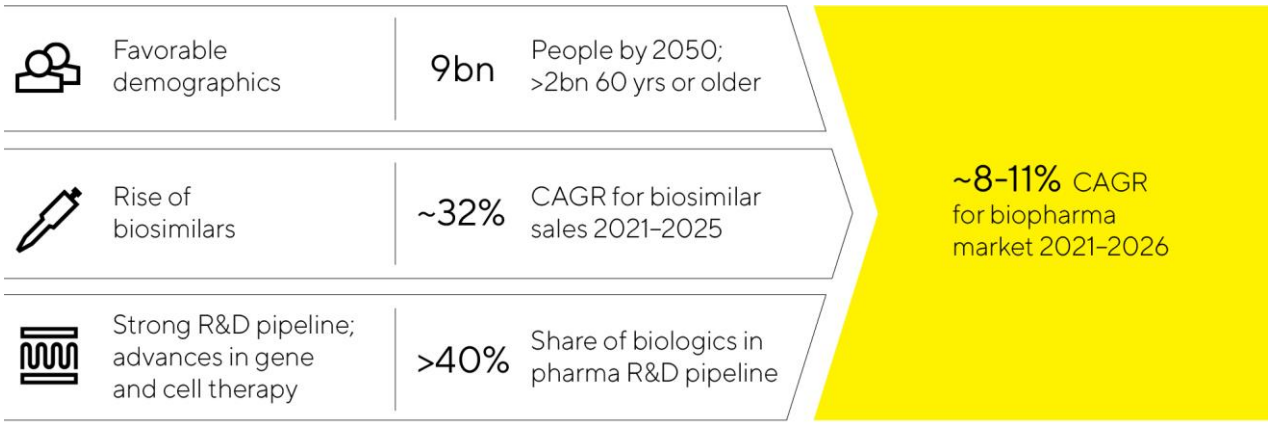
The pharma and biotech industries played a key role in helping to cope with the coronavirus pandemic in the reporting year by developing vaccines and therapeutics. After many vaccine candidates had progressed through the various development stages and initial compounds had been approved at record speed in 2020, more than 40 vaccines and medications have meanwhile received market approval in at least one country. The development activities were accompanied by a considerable expansion of production capacity, with the result that several billion vaccine doses were produced and more than 3.5 billion people were fully vaccinated in 2021. Demand associated with research activities and advancing commercial production led to very positive business performance by suppliers of bioprocess technology, which also benefited from a continuing strong non-pandemic core business. High demand for technologies for the development and production of biopharmaceuticals, coupled with an at times tense situation regarding the availability of some preliminary products, services, and logistics capacity led to longer lead times in some cases. All the leading biopharma suppliers invested heavily in capacity expansion in the face of strong growth and order intake, and these investments are expected to normalize delivery times in the future.

The measures to combat the pandemic also had a dampening effect on certain areas of the pharma and biotech industries in the reporting year. For example, clinical trials had to be interrupted or were unable to be resumed. Around 30% of projects were at an advanced stage of development at the time they were interrupted. This could translate to delayed approval for new medications for indications not related to coronavirus. In 2021, no such effect was discernible, and the number of new approvals of products by the American Food and Drug Administration (FDA) remained at a high level at 30 (2020: 26).

The growth of the biopharma market fundamentally depends more on medium- to long-term trends than on short-term economic developments. In addition to the market launch of innovative biopharmaceuticals, significant impetus was 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 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. The pharma industry is increasingly concentrating on advanced therapies, such as cell and gene therapeutics or biotechnologically processed tissue products. At the end of 2021, there were more than 2,600 clinical trials with such treatment approaches, so this area offers significant growth potential over the mid 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 2021 was still small at an estimated €13.5 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. The market volume could more than triple in this country by 2025. A compound annual growth rate of around 32% is projected globally through 2025.

Attractive Market Environment with Good Growth Prospects



Recovery of the Laboratory Market after Prior Year Dampened by the Pandemic

The global laboratory market reached a volume of around €63 billion in the reporting year and is projected to grow at a compound annual growth rate of about 4% to 5% over the long term, according to estimates from several market observers. 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. In 2021, leading suppliers of laboratory instruments and consumables reported an above-average increase in demand after growth in the prior year had been dampened by the pandemic. In addition to the base effect, the positive trend in the reporting year was due to the easing of coronavirus containment measures, which was accompanied by increasing laboratory activities in all sectors.

Labs in the pharmaceutical and biopharma industries are the leading customer groups for laboratory instruments and consumables. Research spending of this specific sector increased by 7% to around €190 billion in the reporting year according to EvaluatePharma. 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 being placed on technologies related to 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 the assessment of leading laboratory product manufacturers, this end market also proved to be particularly fast growing and continued to benefit from high additional demand in connection with Covid-19 test capacity and the development of vaccines and therapeutics.

Research and quality-assurance labs in the chemical and food industry are another important customer group. This segment's demand for laboratory products depends in part on economic trends. Additional momentum

can also be generated in this sector by regulatory changes, such as stricter requirements for quality control tests in the food industry. Demand from industrial end markets recovered significantly in 2021 following moderate development in the prior year.

Academic and public-sector research institutions also use products 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 Institute 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 constantly grown over the last eight years. During the reporting year, it climbed again by about 3.9% to €37.5 billion. The financing environment for science has improved overall due to budget increases as part of substantial investment programs by the U.S. government. 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 laboratory market there. Many manufacturers of laboratory products reported a significant rebound in demand from academic and public research institutions in the reporting year following a weak prior year due to the pandemic.

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

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

Sources: BioPlan: 18th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production, April 2021; IQVIA Institute: Global Medicine Spending and Usage Trends, April 2021; Evaluate Pharma: World Preview 2021, Outlook to 2026, July 2021; SDi: Global Assessment Report 2020, June 2021; www.fda.gov

Group Business Development

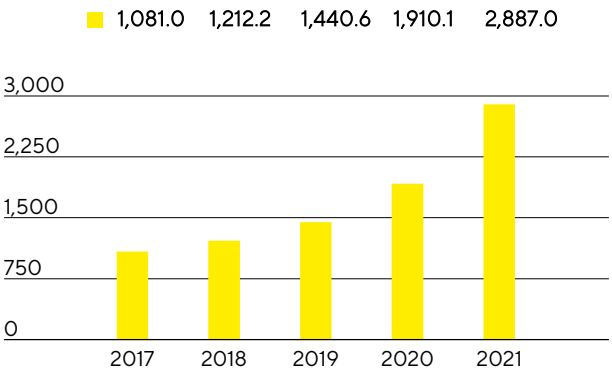
Sales Revenue and Order Intake

In the reporting year, Sartorius Stedim Biotech grew at an exceptionally dynamic rate of 52.6% to €2,887.0 million in constant currencies (reported: +51.1%) and again significantly more strongly than in the already robust previous year when growth had attained 34.6%. The forecast, that at the beginning of the year had projected a currency-adjusted increase in consolidated sales revenue by 20% to 26%, and had last been raised in July 2021 to a growth rate of about 48%, was thus again slightly exceeded. The major part of this growth was attributable to strong organic expansion of the core business. In particular, business with manufacturers of biopharmaceutical medications performed very well. Beyond this, pandemic-related demand, predominantly due to coronavirus vaccine production being established and ramped up by some customers, added around 18 percentage points to sales revenue growth, while acquisitions contributed a good 4 percentage points. The overall development was supported by expanded production capacities at several sites and overall stable, yet strained, supply chains.

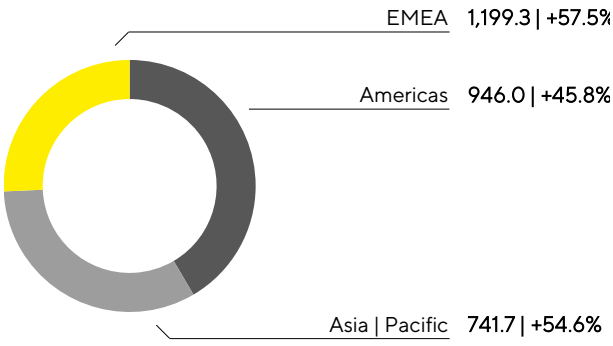
Order intake rose by 55.6% to €3,664.4 million in constant currencies (reported: +53.9%) and thus even slightly more strongly than consolidated sales revenue. Around 13 percentage points of this gain were attributed to pandemic effects and close to 7 percentage points to acquisitions. While order intake was significantly above sales revenue up into the third quarter, also because some customers in the current situation placed their orders further in advance than usual, the ratio of order intake to sales revenue normalized during the second half of the year and was at the level of the company's long-term average toward the end of the year.

Sartorius Stedim Biotech increased its sales revenue in 2021 in all three business regions. EMEA, the region generating the highest share of around 41% to total revenue, saw an especially steep increase, with sales soaring 57.5% to €1,199.3 million, bolstered by especially robust business with vaccine manufacturers. Accounting for around 33% of division sales, the Americas region reported growth of 45.8% to €946.0 million. The Asia | Pacific region also showed very strong growth, with sales up 54.6% to €741.7 million, contributing a share of 26% to total revenue. All growth rates are in constant currencies, unless otherwise stated.

Sales Revenue 2017 to 2021
€ in millions



Sales Revenue and Growth[1] by Region[2]
€ in millions unless otherwise specified



1 In constant currencies
2 Acc. to customers' location

Sales Revenue and Order Intake

€ in millions	2021	2020	Δ in % reported	Δ in % const. fx
Sales Revenue	2,887.0	1,910.1	51.1	52.6
Order Intake	3,664.4	2,381.0	53.9	55.6

Development of Costs and Earnings

In the reporting year, the cost of sales rose by 47.1% to €1,334.0 million, and the cost of sales ratio decreased from 47.5% in the previous year to 46.2%. The further cost items developed at a considerably underproportionate rate with respect to sales revenue due to economies of scale and to a partially deferred cost development due to the pandemic. Selling and distribution costs thus rose by 37.0% to €405.6 million so the ratio of these costs to sales revenue decreased year over year by 1.4 percentage points from 15.5% to 14.1%. Expenses for research and development rose by 30.8% to €110.5 million. The corresponding ratio of R&D expenses to sales revenue was 3.8% (previous year: 4.4%). Regarding general administrative expenses, Sartorius Stedim Biotech reported an increase of 32.1% to €126.1 million, and the administrative expense ratio in 2021 was 4.4% (previous year: 5.0%).

The balance of other operating income and expenses was -€45.3 million in fiscal 2021 compared to the prior year figure of -€55.6 million and essentially covered extraordinary items of €26.5 million relative to €32.7 million in 2020. These extraordinary items consisted primarily of expenses in connection with the most recent acquisitions as well as of expenses for various cross-divisional projects and rebranding.

EBIT increased clearly overproportinately in relation to sales by 83.5% to €865.4 million. The respective EBIT margin rose very strongly from 24.7% a year ago to 30.0% in the reporting year.

The financial result was -€218.7 million in 2021 relative to -€11.0 million a year earlier. This figure includes an expense item of €207.8 million from the reporting date valuation of the share-based earn-out liability in connection with the acquisition of BIA Separations; this liability essentially resulted from the increase in the respective share price and the good business performance.

In the reporting year, tax expenses of €232.4 million were above the prior-year total of €122.1 million. The tax rate was 35.4% after 26.5% in the previous year. It should be noted that the valuation effect in the financial result mentioned above will not result in any subsequent tax impact. If this valuation effect would have had a tax impact, this would have yielded a tax rate of 27.2%.

Net profit attributable to shareholders of Sartorius Stedim Biotech S.A. increased by 23.4% to €414.4 million (previous year: €335.9 million).

Statement of Profit or Loss

€ in millions	2021	2020[1]	Δ in %
Sales revenue	2,887.0	1,910.1	51.1
Cost of sales	–1,334.0	–906.8	–47.1
Gross profit on sales	1,553.0	1,003.3	54.8
Selling and distribution costs	–405.6	–296.0	–37.0
Research and development costs	–110.5	–84.5	–30.8
General administrative expenses	–126.1	–95.5	–32.1
Other operating income and expenses	–45.3	–55.6	18.5
Earnings before interest and taxes (EBIT)	865.4	471.7	83.5
Financial income	22.3	27.0	–17.5
Financial expenses	–241.0	–38.0	–533.6
Financial result	–218.7	–11.0	–1,884.6
Profit before tax	646.7	460.7	40.4
Income taxes	–232.4	–122.1	–90.4
Net result	414.3	338.6	22.4
Attributable to:			
Equity holders of SSB S.A.	414.4	335.9	23.4
Non-controlling interest	–0.1	2.7	–103.9

1 The figures for the reporting period 2020 were restated due to the finalization of the purchase price allocation for the acquisitions of BIA Separations and WaterSep BioSeparations.

Earnings

At the Sartorius Stedim Biotech Group, earnings before interest, taxes, depreciation and amortization (EBITDA) are used as the key profitability measure. To provide a complete and transparent picture of the Group's profitability, also in an international comparison, we report earnings adjusted for extraordinary items (underlying EBITDA). For more information about definitions, please refer to the Glossary on page 270. The underlying presentation is reconciled with the EBITDA key indicator (see Glossary) as follows:

Reconciliation between EBIT and Underlying EBITDA

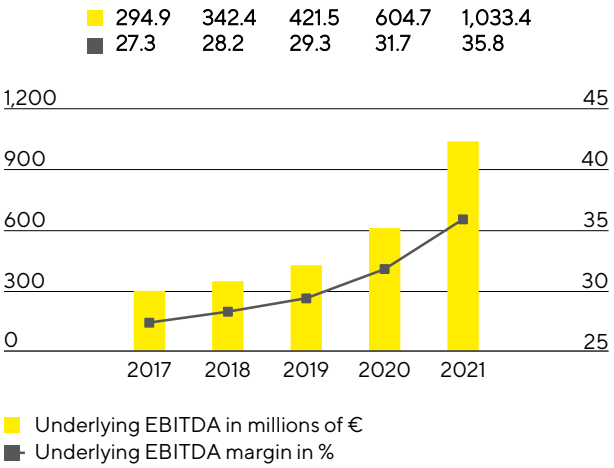
€ in millions	2021	2020[1]
EBIT	865.4	471.7
Extraordinary items	26.5	32.7
Depreciation and amortization	141.5	100.3
Underlying EBITDA	1,033.4	604.7

1 The figures for the reporting period 2020 were restated due to the finalization of the purchase price allocation for the acquisitions of BIA Separations and WaterSep BioSeparations.

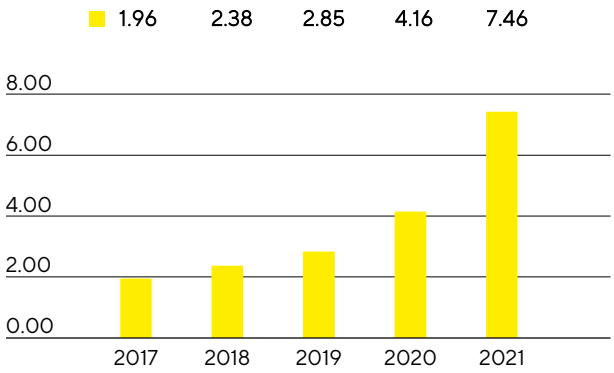
In fiscal 2021, Sartorius Stedim Biotech strongly increased its earnings. Underlying EBITDA thus showed a significantly overproportionate increase in relation to sales revenue, by 70.9% to €1,033.4 million. The respective underlying EBITDA margin climbed to 35.8% (2020: 31.7%). It was therefore clearly above the Group's forecast, which had been set at around 32.0% at the beginning of the reporting year, and in line with the guidance that had last been raised in July 2021 to around 36.0%. Besides being attributable to economies of scale, this considerable increase was influenced by partially deferred cost development, for example as a result of the low travel activity because of the pandemic and deferred new hires in relation to sales growth. This trend subsided due to the intensified buildup of the workforce in the second half of the reporting year, as well as to rising costs in logistics and purchasing. Currency effects as well as the most recent acquisitions did not have any material impact on the company's margin development.

The underlying net result after non-controlling interest for the Group rose steeply from €383.8 million a year ago to €687.8 million in fiscal 2021. This figure is the basis for calculating the profit to be appropriated and is computed by adjusting for extraordinary items, eliminating non-cash amortization of €48.6 million (previous year: €25.7 million), and is based on the normalized financial result and a normalized tax rate (see Glossary). Underlying earnings per share surged by 79.2% from €4.16 a year earlier to €7.46.

Underlying EBITDA[1] and Margin



Underlying Earnings per Share[2]
in €



1 Adjusted for extraordinary items
2 Adjusted for extraordinary items, non-cash 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	2021	2020[1]
EBIT (operating result)	**865.4**	**471.7**
Extraordinary items	26.5	32.7
Amortization	IFRS 3	48.6	25.7
Normalized financial result [2]	**–11.2**	**–7.8**
Normalized income tax (26%) [3]	–241.6	–135.8
Underlying net result	**687.7**	**386.5**
Non-controlling interest	0.1	–2.7
Underlying net result after non-controlling interest	**687.8**	**383.8**
Underlying earnings per share (in €)	7.46	4.16

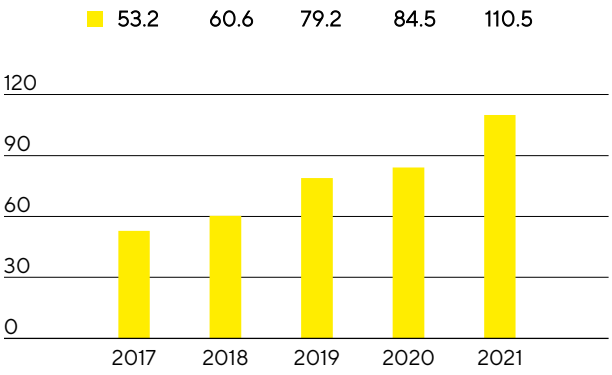
1 The figures for the reporting period 2020 were restated due to the finalization of the purchase price allocation for the acquisitions of BIA Separations and WaterSep BioSeparations.
2 Financial result excluding fair value adjustments of hedging instruments and currency effects relating to financing activities and change in valuation of earn-out liability.
3 Normalized income tax based on the underlying profit before taxes and non-cash amortization.

See Glossary for the definitions of the totals listed above.

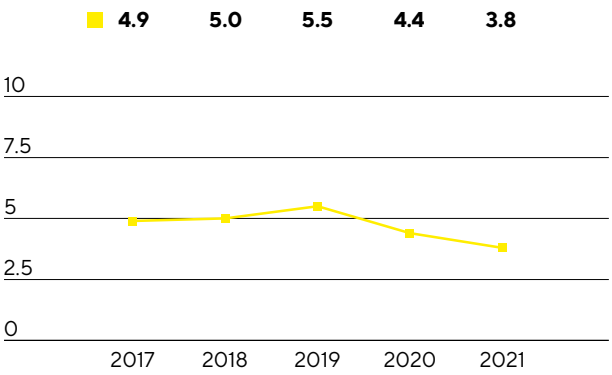
Research and Development

Sartorius Stedim Biotech continuously expands its product portfolio by investing in both the new and further development of its products, as well as in the integration of new technologies through alliances. In 2021, the Group spent €110.5 million on R&D, corresponding to an increase of 30.8% over the previous year's investment of €84.5 million. The ratio of R&D costs to sales revenue decreased to 3.8% compared to 4.4% a year earlier. The gross capital expenditure ratio at 5.1% was also below the prior-year ratio of 6.0%; this ratio is even more meaningful for assessment of innovation-related expenses and includes capitalized development costs of €37.0 million (previous year: €29.7 million) that were disclosed in the statement of financial position.

Research & Development Costs
€ in millions



Research & Development Ratio
in % of sales revenue



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

The number of applications for intellectual property rights filed in 2021 totaled 71 compared with 127 in the previous year. As a result of the applications submitted in the past years, we were issued 234 patents and trademarks (previous year: 339). As of the balance sheet date, we had a total of 3,316 patents and trademarks in our portfolio (previous year: 3,044).

	2021	2020
Number of patent and trademark applications	71	127
Registered patents and trademarks	234	339

Capital Expenditures

Against a backdrop of exceptionally strong organic growth, Sartorius Stedim Biotech invested considerably in building up new capacities in all regions in the reporting year. In this context, expansion projects already planned were moved ahead of schedule, accelerated and extended. In addition to significantly expanding production capacities, the investment program aims to further diversify and increase the flexibility of the company's production network. Several construction projects were already completed in 2021 and contributed to meeting high demand. In the current reporting year, the company plans to complete a number of additional projects.

In 2021, capital expenditures of €324.0 million were significantly higher than the prior-year figure of €159.2 million, as planned. The ratio of capital expenditures to sales revenue was 11.2% (2020: 8.3%) and thus below the forecasted figure of about 12% adjusted at mid-year due to strong sales growth.

Investments were made, among others, in Göttingen, Germany, where capacities for membrane manufacturing are being expanded and new laboratory space for product development is under construction.

At the site in Yauco, Puerto Rico, Sartorius Stedim Biotech is extending cleanroom capacity for manufacturing technologies for the Separation and Fluid Management areas. In addition, a production facility for cell culture media is being set up here for the first time and is scheduled to go into operation next year.

Extensive investments were made in the Asia|Pacific region, such as in Beijing, China, where additional cleanroom space was created for the production of filters and single-use bags, as well as a quality control laboratory. In Songdo, South Korea, Sartorius Stedim Biotech is planning to build a plant for manufacturing cell culture media and assembling sterile consumables. Moreover, a technology center for product demonstrations for customers and consultations as well as laboratory facilities are scheduled to be built at this new site that is located in the center of a biopharma hub.

Due to strong growth in demand and order intake, production capacities were also expanded in the reporting year at additional sites. For instance, expansion projects were conducted in France, Israel, Slovenia, Tunisia, and the U.K. Beyond these sites, a new Customer Interaction Center used for product demonstrations and factory acceptance testing was opened in each of the countries in China, the USA, and Germany to strengthen customer proximity and regional presence.

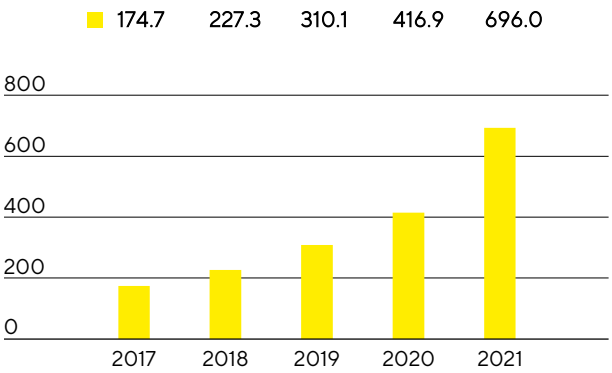
In addition, investments were made in the digital infrastructure of the Group. Thus, Group-wide implementation of a new CRM system was completed.

Net Worth and Financial Position

Cash Flow

In the reporting year, Sartorius Stedim Biotech significantly increased its cash flow from operating activities. This figure amounted to €696.0 million relative to €416.9 million a year ago, which equates to a rise of 66.9%. The development is essentially due to growth in earnings, whereas growth-driven buildup of working capital had a dampening effect. The sale of trade receivables within the scope of a factoring program resulted in an inflow of €35.0 million (inflows in the previous year: €76.2 million).

Net Cash Flow from Operating Activities
€ in millions



Due to exceptionally high demand, Sartorius Stedim Biotech has been driving the expansion of its production capacities full speed ahead. In particular, the company's investment program covers ahead-of-schedule expansion of sites in Germany and Puerto Rico. Cash outflows from investing activities more than doubled in the reporting period by 115% to €323.6 million. Because of acquisition-related expenses of €141.7 million in connection with the most recent purchases of the companies Xell and CellGenix, cash flow from investing activities and acquisitions was -€465.2 million. The prior-year figure of -€621.1 million essentially included cash outflows related to the acquisition of the life science businesses from Danaher as well as of BIA Separations.

Primarily driven by increased dividend disbursements, cash flow from financing activities amounted to -€71.7 million in the reporting year relative to €234.1 million in fiscal 2021 in which Sartorius Stedim Biotech had financed the acquisitions mentioned above.

Cash Flow Statement

€ in millions	2021	2020[1]
Cash flow from operating activities	696.0	416.9
Cash flow from investing activities and acquisitions	–465.2	–621.1
Cash flow from financing activities	–71.7	234.1
Cash and cash equivalents	223.6	59.8
Gross debt	625.5	587.1
Net debt	401.9	527.3

1 The figures for the reporting period 2020 were restated due to the finalization of the purchase price allocation for the acquisitions of BIA Separations and WaterSep BioSeparations.

Consolidated Statement of Financial Position

The balance sheet total of the Sartorius Stedim Biotech Group was €3,951.1 million as of the end of fiscal 2021 and thus €1,094.4 million higher than the prior-year level. This rise reflects the increase in property, plant and equipment as a result of continuous investing activities as well as the growth-driven buildup of working capital, among other things. Non-current assets thus rose by €512.7 million to €2,495.5 million; current assets increased by €581.7 million to €1,455.6 million.

Key Working Capital Figures

in days		2021	2020[3]
Days inventories outstanding			
Inventories | sales revenue[1]	x 360	97	86
Days sales outstanding			
Trade receivables | sales revenue[1]	x 360	44	47
Days payables outstanding			
Trade payables | sales revenue[1]	x 360	58	56
Net working capital days			
Net working capital[2] | sales revenue[1]	x 360	83	77

1 Including pro forma sales of recent acquisitions
2 Sum of inventories and trade receivables less the trade payables
3 The figures for the reporting period 2020 were restated due to the finalization of the purchase price allocation for the acquisitions of BIA Separations and WaterSep BioSeparations.

Equity grew by €272.2 million to €1,733.2 million as of year-end. The equity ratio was 43.9% (previous year: 51.1%). In the reporting year, current and non-current liabilities for the Sartorius Stedim Biotech Group of €2,217.9 million were higher than the previous year's figure of €1,395.7 million, which was due to growth.

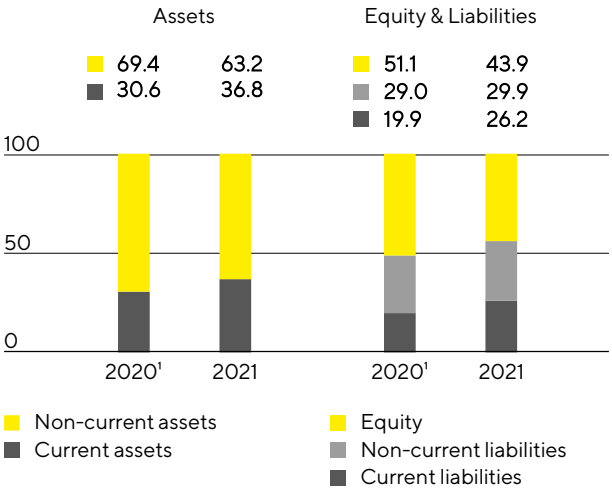
Overall, gross debt, which is comprised of liabilities to banks and loans from Sartorius AG as well as of lease liabilities, rose slightly to €625.5 million as of December 31, 2021, compared with €587.1 million for the year ended December 31, 2020. Due to significantly increased credit balances at banks, net debt, defined as gross debt less cash and cash equivalents, was €401.9 million relative to €527.3 million a year ago.

Calculation of Net Debt

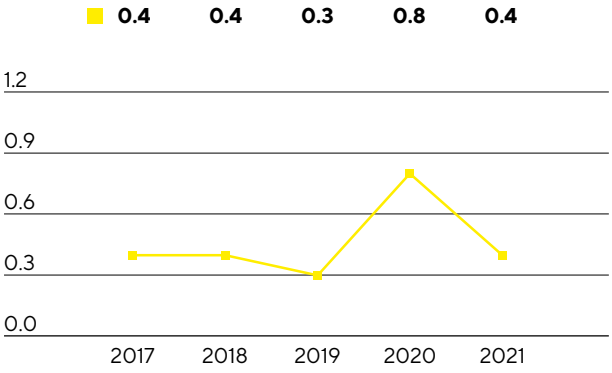
€ in millions	2021	2020[1]
Non-current		
Loans and borrowings	521.1	515.7
Lease liabilities	64.0	47.5
Current		
Loans and borrowings	25.5	13.1
Lease liabilities	14.9	10.9
Gross debt	625.5	587.1
Cash and cash equivalents	223.6	59.8
Net debt	401.9	527.3

1 The figures for the reporting period 2020 were restated due to the finalization of the purchase price allocation for the acquisitions of BIA Separations and WaterSep BioSeparations.

Balance Sheet Structure
in %



Ratio of Net Debt[2] to Underlying EBITDA[3]



1 The figures for the reporting period 2020 were restated due to the finalization of the purchase price allocation for the acquisitions of BIA Separations and WaterSep BioSeparations
2 The net debt excludes the liability for the remaining purchase price for acquisitions; 2021: €518.7 million, 2020: €127.8 million, 2019: €72.5 million, 2018: €8.7 million, 2017: €46.5 million.
3 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. This ratio was 0.4 as of December 31, 2021, relative to 0.8 in the prior year, predominantly as a result of the substantial increase in earnings and despite the acquisitions as well as extensive capital expenditures made in the reporting year, and was thus approximately in line with the most recent forecast (around 0.5).

Financing | Treasury

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

The major pillar of the financing mix is a credit line with a volume of up to €260 million and long-term loan agreements of €515 million provided by the parent company Sartorius AG. Furthermore, the Group has diverse bilateral credit lines of approximately €50 million in total.

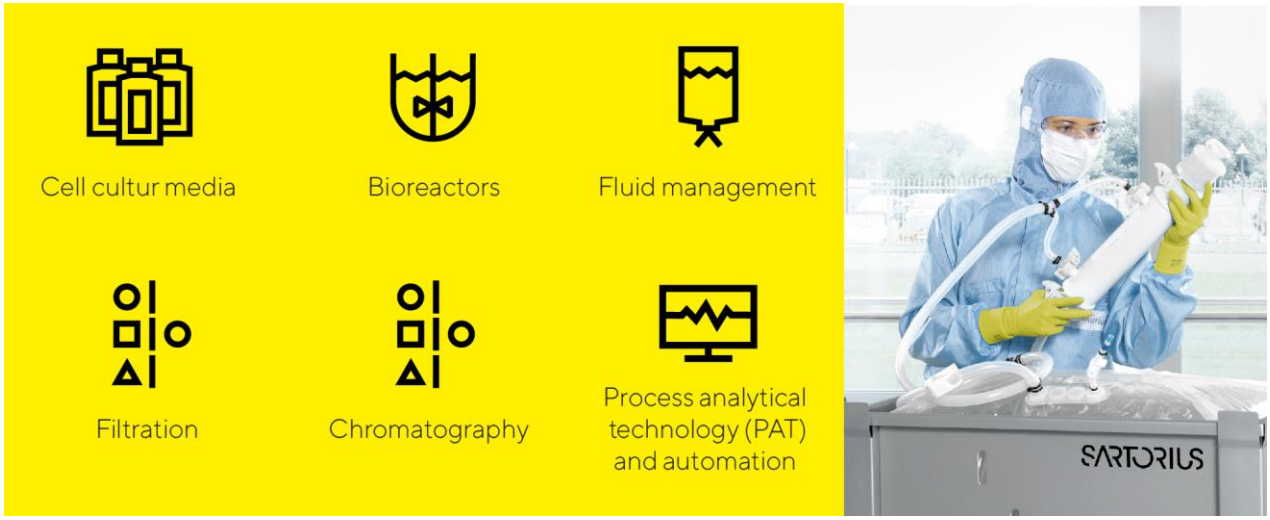
The above-mentioned financing comprises instruments with both fixed and variable interest.

As of December 31, 2021, the total volume of all available credit lines was €310 million. Of this amount, Sartorius Stedim Biotech had utilized on €25 million, leaving available credit of €285 million at the end of 2021. This ensures that all Group entities have sufficient funds to successfully finance their business operations and new capital expenditures.

We use hedging transactions to counteract the fluctuations in foreign-exchange rates to which the Group is exposed on account of its worldwide business operations. At the end of 2021, foreign-exchange contracts amounted to €404 million on a reported basis, with a market value of -€7.1 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 for manufacturing cell and gene therapeutics by two acquisitions:

- CellGenix produces critically essential cell culture components, such as growth factors, cytokines and media in GMP quality, for manufacturing cell and gene therapy products
- The cell culture specialist Xell develops and produces media and feed supplements for cell cultures, especially for manufacturing viral vectors that are used in gene therapeutics and vaccines

Beyond these acquisitions, Sartorius Stedim Biotech has been collaborating with Waters Corporation since the reporting year. As part of this collaboration, a Waters bioprocess analyzer based on mass spectroscopy will be combined with the Sartorius multi-parallel bioreactor system, enabling specific analytical steps during drug discovery and cell line development to be performed directly in the production environment, i.e., at-line measurements, so these steps do not have to be outsourced to external laboratories for sample testing, the usual procedure until now. This solution greatly accelerates the timeline for process development for the benefit of users.

In addition, Sartorius Stedim Biotech launched on the market new software versions for design of experiments (DoE) and for multivariate data analysis, which accelerate development and optimization of processes and enhance evaluation of complex datasets generated across the biopharmaceutical production process, respectively.

Sales Activities

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

In the reporting year, many direct customer contacts were enabled through the use of digital communication tools, even after pandemic-mandated travel and distancing restrictions were eased. Videoconferencing and augmented reality continue to be increasingly used for direct interaction, such as for product demonstration, training and commissioning. To strengthen its sales organization, Sartorius Stedim Biotech is concentrating on expanding its international presence, especially by more recruitment. 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 our filter products; various technology platforms such as single-use containers for fluid management in biopharmaceutical processes and sensors; and control technologies for processes such as fermentation and cell cultivation. Additional focal areas entail developments in materials and components that include plastics, elastomers and intelligent polymers; expanded data analysis; and cell line development.

Our largest site for product development is in Göttingen, Germany. Further key activities take place in France, Germany, India, the USA, the U.K., and Sweden, as well as in Israel and Slovenia.

Production and Supply Chain Management

Sartorius Stedim Biotech has a very well-developed global production network that was expanded at many sites in the reporting year. The largest production facilities are located in 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. Additional sites in Germany have been added by the most recent acquisitions.

Despite the restrictions in worldwide logistics as a result of the coronavirus pandemic, the company's supply chains proved to be strained, yet mostly stable. A few preliminary products, raw materials, components and services took longer to deliver or their availability was temporarily limited. This was reflected in some cases by correspondingly extended delivery times for our own products.

Sartorius Stedim Biotech expanded its production in all regions due to high demand in its core business and to additional customer needs related to coronavirus vaccines and Covid-19 therapeutics. On top of this, the company increasingly hired additional production staff and has been manufacturing at a few sites around the clock seven days a week.

Sartorius Stedim Biotech started up operations at a new Customer Interaction Center (CIC) in China for biopharmaceutical customers. The CIC enables customers to test complex systems at our site first before these are delivered to and set up at their plant facilities. A significantly expanded application, validation and service center was opened at the company site in Shanghai, and a customer test laboratory in Havant, U.K. Production facilities were also expanded in Israel and Slovenia.

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, our approach is to intentionally take a certain measure of risk in our 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. Our 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 cross-divisional Finance & Controlling department is responsible for the organization of the respective reporting process, including the further development of the Group's risk management system.

Managing Opportunities

Our opportunity management centers on the analysis of target markets and sector environments, as well as the assessment of trends, both of which give strong indications as to future business opportunities. The identification of the potential for development 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.

We regularly review the Group's strategy and revise it as necessary. As part of strategy reviews, the members of the Executive Board regularly discuss short-, medium- and long-term opportunity potential for the various business areas with the managers having operational responsibility. If the opportunities are short-term in nature, they are considered in annual budget planning. Medium- and longer-term opportunities are tracked systematically as part of strategic planning.

As a partner to the biopharmaceutical industries, Sartorius Stedim Biotech operates in a 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 57, respectively.

Our assessments rank the company as one of the global market leaders in many subsegments and product areas. We believe the high quality of our products, our strong brand recognition and our established customer relationships give Sartorius Stedim Biotech a good chance to stabilize and continue extending our market leadership. The corresponding strategies and the growth opportunities and initiatives based on them are discussed in the section on the strategy of the Group, which begins on page 21.

Risk Management

Organization

Overall responsibility for the maintenance of an effective risk management system ensuring comprehensive and consistent management of all material risks rests with the Audit Committee. Coordinating and developing this system and combined risk reporting are the responsibilities of the the Finance & Controlling 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.

Insurance

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

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

Risk Management System and Risk Reporting

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 controls of the effectiveness of the risk management system. This Handbook is based as a whole on 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 strong growth of the Group over the past years and the rising demands of customers and regulators meanwhile require that we continue to adapt our guidelines and rules.

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

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

Moreover, we have 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, our 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 or force majeure, and their associated damage to commercially significant and critical infrastructure and currency or monetary crises. Yet we proactively take measures, whenever feasible, to ensure that we can respond appropriately and at short notice or are insured against any damage entailed by such risks.

The coronavirus pandemic and the extensive measures to contain it led to a global recession in 2020. The global economy was largely able to recover from this during the reporting year, although the upturn has not extended evenly to all regions and sectors and has to some extent been curbed by supply chain problems and prices of raw materials. The pharma and biotech industry, which is almost independent of economic fluctuations, developed robustly overall in this environment. The sector also played a key role in managing the crisis as a result of its role in developing and manufacturing vaccines and therapeutics, and certain manufacturers invested significantly in building up corresponding production capacity. As one of the leading bioprocess technology providers, Sartorius Stedim Biotech benefited from this development and reported additional revenue again in the reporting year, particularly in connection with the development and production of coronavirus vaccines and test procedures.

Travel and contact restrictions due to the pandemic continue to impact direct sales in 2021. The changing requirements for interaction with customers were met, among other things, by increasing the use of video conferencing and other digital communication tools, including augmented reality. Supply chains have proven to be largely stable despite the restrictions on global logistics. However, our lead times for certain products have increased due to the fraught supply situation for some of the components and services we need to procure.

We currently expect the additional demand arising from the coronavirus pandemic to continue for some time as a result of the need for booster shots and the expansion of vaccination campaigns to countries that previously had little access to vaccines. As the coronavirus pandemic persists, negative consequences for the future cannot be ruled out. However, it should be noted that the sector's focus on vaccines and therapeutics for the coronavirus will be at the expense of other customer projects and that the pandemic-related postponement of studies for other indications also has an adverse effect on the course of our business.

Our largest sites in Germany and France do not face any major risks from natural catastrophes, while, for example, our production plants in Puerto Rico and in Fremont, California, are exposed to the risk of severe hurricanes or earthquakes and could be impacted accordingly. We endeavor to counteract this risk by applying the highest possible safety standards to the buildings and explicitly consider this risk in our warehousing and international production network strategies

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

In the U.K., the Group operates several manufacturing and sales entities accounting for a significant business volume. Any developments that have a negative impact on trade between the U.K. and other countries such as the introduction of customs duties could therefore result in a corresponding decrease in Group's earnings. To date there have been no substantial negative effects from Great Britain's exit from the European Union ("Brexit"), but further developments are being closely observed, and some measures to reduce risks have already been taken, such as maintaining safety stock.

Since our 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.

Business Cycle Risks

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

Operational Risks and Opportunities

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

Procurement Risks and Opportunities

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

Over the past years, we have implemented powerful tools and robust processes within the regular operating rhythm in our Supplier Management to manage supply risks and ensure supply continuity. Important measures in this respect are to maintain safety stock and to define alternative materials and suppliers. In addition, we conduct regular supplier reviews and carefully monitor the delivery status and inventory coverage of critical raw materials.

We actively mitigate procurement risks arising from the current raw material shortages in the market. By concluding binding purchase agreements with our suppliers and/or by seeking alternatives within our supplier network, we reduce their impact and secure continuous supply.

Opportunities can arise in the area of procurement when our growth enables us to increase order quantities and thereby strengthen our position with our suppliers, such as by receiving price discounts or preferential treatment.

Production Risks and Opportunities

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

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

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

We consider it an opportunity that our investments in infrastructure and production resources, among other things, have given us high flexibility in our manufacturing operations and that we are capable of meeting our customers' requirements and regulatory standards with respect to business continuity concepts. In addition, this approach ensures that our international production sites can concentrate on specific manufacturing technologies, leveraging regional cost advantages as a result. Continuous improvements in production, such as simplifying processes and increasing levels of automation and digitizing the core drives, manufacturing and logistics efficiency even higher.

Sales and Distribution Risks and Opportunities

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

Opportunities arise in the area of sales and distribution when the increasing breadth of our product range puts us in a position to sell new products to existing customers. Moreover, our business relationships, most of which are established for the long term, and our global presence provide opportunities. After all, we are continuously expanding our product range through acquisitions. Finally, we are continuously extending our portfolio through acquisitions. We are offering our customers newly acquired technologies in the areas of cell culture media and downstream processing.

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 of our business areas have a highly diversified customer base so the Group as a whole is not dependent on individual key accounts to any significant degree.

Competitive Risks and Opportunities

Sartorius Stedim Biotech has a leading competitive position in its core technologies and competes with mainly larger rivals sharing our status as a globally operating company. As we serve a large number of customers from highly regulated sectors like the pharmaceutical and food industries, and, the technology barriers to market entry are fairly high, we regard the probability of new competitors emerging within the short term as relatively low.

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

Changes in the competitive environment, for example, further consolidation in the markets, can pose further risks but also opportunities. 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

Our customers use Sartorius Stedim Biotech 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 our products, which - in worse case - can lead to losses for our customers, or their customers for which we may be made liable through compensation claims.

We employ rigorous quality checks and advanced production methods and processes, such as cleanroom technology, to ensure that our products satisfy the most stringent quality standards and high regulatory requirements. These manufacturing methods and processes are subject to constant review under our 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 our 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 document the high level of quality achieved in Sartorius products and processes. Irrespective of these measures, we also maintain significant insurance coverage against product liability risks.

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

In the sectors we address, quality requirements are growing more and more stringent all the time, not least as a result of increasing requirements on protection of medical patients and on product safety by regulatory authorities. 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 barrier 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 our work on professional committees, membership in industry associations and standards committees, we actively take part in drafting new standards and guidelines and are able to identify emerging requirements at an early stage and prepare ourselves accordingly.

R&D Risks and Opportunities

We devote a considerable share of our 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. 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 substantially limit these R&D risks. In particular, we ensure that proof of concepts 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 the technology trends and competitor activities together with an early stage patent filing ensure our technology and marketing position.

Not least, our intensive collaboration with partners that rank among the global market and opinion leaders in their own fields opens up the opportunity for us to jointly develop products with an especially high level of innovation. In areas such as membrane technology and plastics technology, sensorics and biopharmaceutical process engineering, the expertise of our own specialists puts us worldwide at the very forefront of global research and development, presenting us with an opportunity to turn this technical knowledge into potential sales and an even stronger position on the market. The combination of different innovative activities in a separate Corporate Research Department enables us to identify promising developments at universities, startups and at our customers' plants and ensure the all relevant IP positions are secured in advance.

Acquisition Risks and Opportunities

By nature, acquisitions provide many opportunities, such as sales growth, extension of our product portfolio 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.

We take various measures to reduce these risks. These include performing a thorough due diligence review of important areas and carrying out comprehensive analysis of the market concerned. In addition, we involve external consultants and experts in the purchase or sales process as required. We especially focus on drafting transaction contracts so that they adequately counter such risks, especially by clauses assuring specific characteristics or by contractual warranty or guarantee provisions, as well as agreements on mechanisms for adjustment of the purchase price and on liability clauses. 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 was established as an independent function in the responsibility of the Group CFO 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 at 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.

We therefore aim to keep key employees for the long term by offering performance-related remuneration models, targeted continuing professional development options, attractive social benefits and interesting people development opportunities. In connection with this, we have, in particular, enhanced our staff development initiatives and management programs. The success of these measures is apparent in the low attrition rates of past years. Employment contracts in certain cases contain a clause prohibiting any move to a direct competitor.

We counter demographic change primarily by offering continuous education and training for junior staff members. This, in turn, results in opportunities for Sartorius Stedim Biotech as we can further qualify employees on our own and retain such staff over the long term, thus covering company needs for qualified personnel particularly well.

In order to ensure the seamless onboarding of the large number of new staff and also proper knowledge transfer, we have improved and expanded our initial training processes. We also use a digital HR platform, which 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 cyber-attacks 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.

We are reducing these risks by continuously investing in the implementation and operation of secure IT systems and applications and by continually developing and applying our concepts and security measures on the basis of the International ISO 27001 Standard for Information Security Management Systems, among others. In addition, we incorporate the results of regular audits and vulnerability assessments by external companies specializing in IT security.

The protection of our data, systems, and applications from misuse is managed through a unified risk management framework on a group basis, established through the governance structure and IT risk management, and implemented through applicable policies and effective communications 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 our security organization and procedures.

We continue to expect the threat of cyber-attacks to increase worldwide, both in number and intensity. That is why we have again stepped up our measures and activities this year. We have strengthened the Group-wide IT security organization in terms of personnel and expertise, established a round-the-clock security control and defense team, and set up further systems and services to monitor, detect and defend against cyber-attacks.

We actively provide targeted information across the Group on potential cyber threats and risks, and engage employees by giving them simple but effective ways to defend themselves in a decentralized manner and report suspicious incidents to IT department 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 we generate around two thirds of consolidated sales revenue 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, we are 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.

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

We continuously calculate our risk exposure 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 take into consideration hedging transactions already executed. This is the basis we use 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

We have concluded fixed interest agreements for more than 80% of our 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. We monitor interest rate trends and our interest rate exposure constantly and arrange for hedging transactions where we consider it necessary and economically advisable to do so for individual loans. As of 12/31/2021, we did not have any interest rate derivatives in our portfolio of financial instruments.

Liquidity Risks and Opportunities

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

Sartorius Stedim Biotech is mainly using a €300 million credit line provided by Sartorius AG that can be accessed and repaid at short notice. Additionally, we have a number of bilateral credit lines in place on a smaller scale for for individual Group companies. Furthermore, we use cash pooling agreements 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.

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

Compliance Risks

Regulatory Risks

Our role as a partner of the biopharmaceutical industry and healthcare providers means that 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 the Chinese National Medical Products Administration (NMPA), might adopt a more restrictive approach to the approval of new medications or medical devices of our 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.

Such a move would reduce the number of new pharmaceutical products to be marketed and would consequently downgrade future prospects for Sartorius Stedim Biotech over the medium term.

Environmental Risks

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 our companies in 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 us to incorporate environmental topics in almost all decision-making processes as early as possible. In this way, we can systematically reduce potential environmental risks and operate the business in a sustainable and environmentally friendly fashion.

Environmental and sustainability aspects are occupying an increasingly important role in many business processes for us. The aspect of environmentally sustainable business has thus become a central element of how we select suppliers. 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 Group.

Assessment of the Overall Risk Situation and Risk Outlook

Where feasible, we adopted countermeasures and|or made risk provisions 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, that had the potential to damage our net worth, financial situation and profitability.

For the purposes of this report, we have assessed the probability of occurrence of the risks as shown below and, in the adjacent columns, classify their particular significance for the entire Group.

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

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

Similarly, based on our current review, there are no discernible risks that could jeopardize the future existence of the Group.

Internal Control Procedures

Introduction

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

as follows:

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

Scope of Internal Control

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

Components of Internal Control

Environment for Internal Control

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

Risk Assessment Process – Risk Mapping

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

Control Activities

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

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

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

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

Internal Controlling Roles

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

Audit Committee
The Audit Committee is responsible for carrying out any necessary reviews and evaluations of the internal controlling procedures, including those relating to financial information, and also assists with the preparation of the Group's consolidated financial statements. For further information about the Audit Committee, see page 91.

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

Internal Auditing Department
Based on the annual audit plan approved by the Audit Committee, the Internal Auditing Department (IA) evaluates and improves the effectiveness of the organisation'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 Compliance Officer of Sartorius Group at least once a year or ad-hoc, if necessary.

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

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

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

Accounting Standards

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

Roles of the Group's Finance and Controlling Departments

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

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

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

Financial Information and Reporting

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

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

Internal Control in 2021

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

Code of Conduct and Anti-Corruption Code

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

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

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

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

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

Corporate Transactions

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

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

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

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

During the year ended December 31, 2021, the Members of the Board and persons mentioned in Article L.621 – 18 – 2 of the French Monetary and Financial Code have not carried out transactions on the company`s shares. 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.