

Opportunity and Risk Report

Principles

Every business activity entails opportunities and risks, which have to be managed. The skill with which this is done goes a long way in determining the future development of a company's shareholder value. The central element in risk managements is systematic identification and realization of opportunities, as well as avoidance of risks that could jeopardize the success of the company.

In managing risks and opportunities, Sartorius Stedim Biotech aims to identify and use business opportunities systematically, as well as to recognize and evaluate risks at an early stage and take measures to counter them where possible. It is not the task of risk management to eliminate all risks: rather, our approach is to intentionally take a certain measure of risk in our business activities in order to be successful in unlocking opportunities. However, in this endeavor, it is important to keep risks contained within acceptable limits and to control them carefully. Through appropriate guidelines, we ensure that risk assessments are taken into account in the decision-making processes from the very beginning.

Sartorius Stedim Biotech has no single organizational unit tasked with identifying and managing opportunities and risks. Instead, it prefers to make this a cross-functional component of Group management. In this context, Sartorius Stedim Biotech's risk management is integrated into the Sartorius Group organization. Our risk management organization reflects a global functional matrix organization in which individuals heading a functional area are each responsible for their own management of opportunities and risks. The Finance & Controlling department is responsible for the organization of the respective reporting process, including the further development of the Group's risk management system.

Managing Opportunities

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

As part of strategy reviews, the members of the Executive Committee regularly meet with the managers having operational responsibility and with the Business Development unit to discuss short-, medium- and long-term opportunity potential for the various business areas. The subsequent steps of prioritizing the opportunities and evaluating them from a business management perspective, deriving strategic measures and allocating resources proceed in accordance with a standardized decision-making process that applies throughout the Group. 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. The status of opportunity management as a permanent fixture of the corporate management system means that it also features in the discussions and decision-making processes of top-level management.

Key areas of opportunity are presented below. Where appropriate, reference is made to the relevant section of the Group Management Report in order to avoid repetition. Most of the risks we describe in the section on specific risks represent opportunities, should events develop in the opposite, positive direction. For this reason, we discuss these opportunities in the section on specific risks and opportunities at the end of this chapter.

Areas of Opportunity

As a supplier for the pharmaceutical and laboratory 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 Sector" on pages 22 et seq. and pages 63 et seq., respectively.

Our assessments rank the company as one of the global market leaders in many subsegments and product areas. We believe the high quality of our products, our strong brand recognition and our established customer relationships give Sartorius Stedim Biotech strong opportunities to continue extending our market leadership. The corresponding strategies and the growth opportunities and initiatives based on them are discussed in the section on the strategy of the Group, which begins on page 20.

Strict management of processes and costs provides opportunities to further increase our profitability. Key target areas in this respect include continued enhancements of our procurement chain and ongoing efforts to optimize production, which we present on page 32.

Other opportunities are discussed in the context of the presentation of specific risks and opportunities beginning on page 55.

Risk Management

Just as for opportunity management, 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 Finance & Controlling department, while the particular functional areas are responsible for identifying and reporting 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. Furthermore, while carrying out their statutory audit mandate for the annual financial statements and consolidated financial statements, the independent auditors examine whether the early warning system in place is capable of prompt identification of risks that could jeopardize the future of the company.

Risk Management System and Risk Reporting

At the heart of the risk management system is the Sartorius Group Risk Management Handbook, which applies throughout the entire Group organization. The Handbook, which includes definitions of the framework, the structural organization, processes, risk reporting and monitoring and control of the effectiveness of the risk management system, is based on the internationally recognized COSO standard. There are also a number of other sources that contain stipulations for the handling of risks, including the articles of association and rules of procedure of the Group companies and other internal guidelines.

The Group-wide risk reporting system forms the cornerstone of internal risk communication. The object is to make it possible to address risks in a structured, continuous manner and to document them in accordance with the relevant statutory and regulatory requirements. 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.

A key element of our internal communication of risks is Group-wide risk reporting. The objective of this is to enable structured, continuous tracking of risks and to document them in compliance with legal and regulatory requirements.

The prescribed reporting process in the risk categories subsequently described establishes the rules for the ongoing review of and information on risk situations. Those responsible for functional areas at the Group subsidiaries periodically review and assess their respective 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. In addition, as soon as these risks reach defined size criteria, they are reported to the central risk management system. Appropriate insurance policies are taken out to reduce any remaining risk situations, where feasible. New organizational units joining the consolidated Group companies are successively integrated into our risk reporting process.

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 and estimated as involving €2.5million or higher, the Audit Committee receives all of the necessary details without undue delay.

Risk Classification

The first level of risk management relates to the four main risk categories defined by Sartorius Stedim Biotech: external risks, operating risks, financial risks and corporate governance risks.

The second level consists of additional subcategories that we classify within these main categories, such as supply chain risks, sales and distribution risks, and quality risks.

We categorize risks according to the scale of their implications too, and also perform a specific evaluation in which all risks are assigned the value of their maximum impact at the time of risk analysis. In other words, we record the maximum risks without considering the probability of occurrence or the effects of risk mitigation measures.

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

Probability of occurrence	
Low	< 5%
Medium	5%– 20%
High	> 20%

Significance

in thousands of €	Impact on Earnings*	Impact on Assets*
Of limited significance	< 1,000	< 5,000
Significant	> 1,000	> 5,000

Explanation of Principal Risks and Opportunities

General and Macroeconomic Risks and Opportunities

General Risks

In principle, our ability to foresee and mitigate the direct and indirect effects of risks entailed by life in general is limited, but we proactively take measures, whenever feasible, to ensure that we can respond appropriately and at short notice or are insured against any damage entailed by such risks that include, for instance, natural catastrophes and their associated damage to commercially significant and critical infrastructure.

Business Cycle Risks

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

Supply Chain Risks and Opportunities

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

Procurement Risks and Opportunities

We purchase a wide range of raw materials, components, parts and services from suppliers and are consequently exposed to the risks of unexpected delivery bottlenecks and/or price increases, as well as obligatory minimum purchase quantities that may result in claims for compensation if we do not reach such quantities.

Over the past years, we have implemented powerful tools and robust processes in our Materials Management unit to manage risks and critical materials. These means enable us to meet the needs of our customers with respect to delivery reliability and transparency. This can represent a competitive advantage.

We moreover conduct regular supplier reviews and also use early warning systems. In addition, we always maintain reserve inventories for strategic raw materials and work with alternative suppliers where possible.

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

Increased globalization of our supplier pool holds the prospect of purchasing on more favorable terms, moreover, and there is also a possibility of our expanded purchasing activities in the international markets leading us to identify suppliers with special product and technical expertise that could eventually enhance our own competitive edge.

Production Risks and Opportunities

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

Beyond this, we work closely together with our customers to gain a better understanding of their needs and to schedule our production capacities optimally.

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 individual production sites can concentrate on specific manufacturing technologies, gaining added efficiency as a result. Our international manufacturing network also makes it possible to capitalize on the cost advantages offered by individual sites. Furthermore, continuous improvements in production, such as simplifying processes and increasing levels of automation, help drive manufacturing efficiency even higher.

Sales and Distribution Risks and Opportunities

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 our focus on less price-sensitive sales markets, such as products for 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. Our business relationships, most of which are established for the long term, and our global presence provide opportunities, moreover, and our ongoing project to strengthen direct sales also promises to enhance our sales prospects.

Quality Risks and Opportunities

Our customers use Sartorius Stedim Biotech products in a wide range of critical production processes, including the manufacture of pharmaceuticals, foods and chemicals, and in research and development laboratories. The main risk encountered in these areas is non-compliance with agreed quality criteria, which can lead to losses for our customers, or their customers, for which we may be made liable through compensation claims. 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 continuous improvement processes, moreover, and are optimized as requirements evolve. Our successful completion of a host of annual audits by customers and our certification under ISO 9001 and ISO 13485 together document the high level of quality achieved in Sartorius Stedim Biotech products and processes. Irrespective of these measures, we also maintain significant insurance coverage against product liability risks. Sartorius Stedim Biotech has established a traceability system that enables us to recall an entire production batch immediately, if necessary, and minimize any adverse consequences in the event of defects being discovered in a product.

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, so we actually regard this first and foremost not as a risk, but as an opportunity that opens up new market prospects. Also, challenging quality demands represent a considerable barrier to entry for potential new competitors and provide stimulus for further technical innovation to which we actively respond.

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 and application requirements and from exceeding planned development deadlines. Our advanced project management, intensive R&D controlling and early involvement of our customers in the development process substantially limit these R&D risks. Patents and continuous tracking of the technologies and competitors relevant to us secure our technology and marketing position.

On the other hand, the R&D sphere also offers a number of potential opportunities. Our intensive collaboration with partners that rank among the global market leaders in their own fields opens up the opportunity for us to jointly develop products with an especially high level of innovation. In areas such as membrane technology and plastics technology, as well as sensorics and bioprocess engineering, in turn, the expertise of our own specialists puts us at the very forefront of global research and development, presenting us with an opportunity to turn this technical knowledge into potential sales and an even stronger position on the market.

Customer Risks and Opportunities

Sartorius Stedim Biotech sources its key customers from the pharmaceutical, chemical and food industries and from research and educational institutions of the public sector. 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 most of its markets. Some of our competitors are larger than us, and most share our status as a globally operating company. Examples of our competitors include Merck|Millipore and Danaher|Pall. As we serve a large number of customers from highly regulated sectors like the pharmaceutical and food industries, and the technology barriers to market entry are substantially high, we regard the probability of new competitors emerging within the short term as low. Furthermore, our global presence significantly mitigates individual regional risks.

Changes in the competitive environment, for example, consolidation in the markets, can pose opportunities. Our sectors find themselves in an ongoing process of change in which Sartorius Stedim Biotech has been actively participating. We have been continuously making acquisitions in recent years to reinforce our market position and open up new potential synergies.

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. To prevent these risks, we take various measures, such as performing a standard due diligence review of important areas and carrying out comprehensive analysis of the market concerned. In addition, we involve external consultants and experts in the purchase or sales process as required. We especially focus on drafting transaction contracts so that they adequately counter such risks, especially by clauses assuring specific characteristics or by contractual warranty or guarantee provisions, as well as agreements on mechanisms for adjustment of the purchase price and on liability clauses. Immediately after an acquisition has taken place, an integration phase is initiated in which any potential risks can likewise be detected as early as possible and prevented or minimized by taking the appropriate counteractions.

Personnel Risks and Opportunities

As an innovative technology group, Sartorius Stedim Biotech employs a large number of highly qualified people.

We counter the risks of a possible scarcity of required specialists, especially those in key positions and of demographic change by offering performance-related remuneration models, targeted continuing professional development options, further attractive social benefits, continuous education and training for junior staff members within our organization and interesting people development opportunities.

The success of these measures is apparent in the low attrition rates of recent years and the many years of seniority our people accumulate on average. Employment contracts in certain cases contain a clause prohibiting any move to a direct competitor.

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

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, aside from risks associated with Group accounting, are exchange rate risks, interest rate risks and liquidity risks, all of which are described below and addressed in detail in the Notes to the Consolidated Financial Statements. Vice versa, financial risks, most notably exchange rate risks and interest rate risks, are balanced by opportunities of approximately equal magnitude.

Risks Associated with Group Accounting

Except for the general, typical risks inherent in any accounting process, no specific risks concerning Group accounting are discernible. Typical accounting errors in this connection are, for example, incorrect discretionary decisions in the measurement of assets and liabilities. The use of various common and standardized control mechanisms integrated into our accounting process ensures that such errors are recognized and corrected at an early stage.

Exchange Rate Risks and Opportunities

As we generate around half of consolidated sales revenue in foreign currencies and two-thirds of this total revenue in U.S. dollars or in currencies pegged to the U.S. dollar, we are positively or negatively impacted by currency effects, especially when converting the currencies of balance sheet items and profit or loss items, respectively. To largely compensate for the general risk resulting from the impact of individual foreign currencies, we have taken a number of measures besides hedging currencies. Our global production network thus enables us to offset the lion's share of sales revenues received in foreign currency within the Group against costs likewise incurred in foreign currency. For example, we manufacture many of our products for the North American market locally, and are not disadvantaged in competition with our U.S. rivals, insofar as this general currency risk is concerned. We continuously monitor both exchange rates and our net currency exposure – i.e. that proportion of our foreign currency sales revenue that remains after we have settled our costs, likewise in a foreign currency – and use derivative financial instruments for hedging. These instruments are primarily spot, forward and swap transactions, on the basis of current and anticipated net currency exposure and foreign currency levels. In individual cases, target redemption forwards are used to optimize exchange rates. We make it a policy to hedge up to 70% of our exposure in advance for the following 18 months. Due to the currently low exchange rates, we extended our hedges for the U.S. dollar for up to 36 months. Hedging transactions are set up by one group of staff and monitored by another, separate group.

Interest Rate Risks and Opportunities

We have concluded fixed interest agreements for a smaller portion of our outstanding loans to eliminate the risk posed by variable interest payments. The majority of the financial instruments outstanding on the reporting date are subject to variable interest based on the market rate. More than half of these are currently covered by interest rate swaps, so interest rate risks and opportunities apply only to the remainder. We monitor interest rate trends and our interest rate exposure constantly and have the facility to arrange additional hedging transactions where we consider it necessary and economically advisable to do so for individual loans.

Liquidity Risks and Opportunities

Sartorius Stedim Biotech Group's liquidity is managed centrally in order to minimize liquidity risks and optimize liquidity allocation within the organization. For this purpose, various long- and short-term financial instruments are utilized. Regarding the maturities of our loans, we make it a policy to take a risk-averse approach.

In addition to a 300 MEUR credit line provided by Sartorius AG that can be accessed and repaid at short notice, we have a number of bilateral working capital credit lines for individual Group companies in place. Furthermore, we use cash pooling agreements between selected Group companies as the primary tool to manage liquidity within the Group.

Regulatory Risks

Our role as a supplier to the biopharmaceutical industry and health care providers means that Sartorius Stedim Biotech can also be affected by underlying developments in these areas. The possibility of the regulatory authorities (FDA, EMA) adopting a more restrictive approach to the approval of new medications remains the principal source of risk in this context. 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 established an environmental management system that encompasses, and is integrated into, all divisions and covers a whole series of environmentally relevant regulations to minimize environmental risks. This management system has been certified for compliance with ISO 14001 at a number of the company's relatively large manufacturing sites. The respective company organizational units ensure at the particular sites that the laws and regulations relating to environmental protection are observed and that further technical possibilities for limiting environmental risks are identified on an ongoing basis.

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

IT Risks and Opportunities

Besides the risks already described, the Sartorius Stedim Biotech Group is exposed to potential risks in the area of IT as a result of its pronounced dependence on these systems, since their error-free operation is essential for the smooth functioning of the company's business processes. IT security risks are reduced by continuously enhancing and implementing IT security guidelines and policies. These rules and measures are based on the requirements of ISO 27001 and the standards of the German Federal Office for Information Security (BSI Standards). Furthermore, our company's existing IT applications and IT systems are checked for potential risks in regular external and internal IT audits, and appropriate measures are taken to minimize any risks identified. Continuous alignment of our IT strategy and business strategy, tracking of new technical developments and the use of advanced hardware and software minimize the risk inherent in the operation of our IT system environment. A new ERP system has been successively rolled out to the Group sites around the world. This ERP system has been implemented in Germany and North America, as well as in 2016 in France, Belgium and Tunisia. In conducting this IT project, one focus was made on controlling the risks involved, such as by maintaining a precautionary backup system. The implementation of the new system brings with it a whole series of opportunities, especially in relation to efficiency gains and the standardization and harmonization of business processes worldwide.

Process Risks

Process 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.

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 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 necessary.

Assessment of the Overall Risk Situation and Risk Outlook

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

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

Risk Category	Probability of Occurrence	Significance
General and macroeconomic risks		
Business cycle risks	Medium	Significant
General risks	Low	Significant
Supply chain risks		
Procurement risks	Low	Of limited significance
Production risks	Low	Significant
Sales and distribution risks	Medium	Significant
Quality risks	Low	Significant
R&D risks	Low	Significant
Customer risks	Low	Of limited significance
Competitive risks	Low	Of limited significance
Acquisition risks	Low	Significant
Personnel risks	Low	Of limited significance
Financial risks		
Risks associated with Group accounting	Low	Of limited significance
Exchange rate risks	Medium	Significant
Interest rate risks	Medium	Significant
Liquidity risks	Low	Significant
Regulatory risks	Low	Of limited significance
Environmental risks	Low	Of limited significance
IT risks	Low	Significant
Process risks	Low	Of limited significance

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.