OPPORTUNITIES AND RISK REPORT

As an internationally-active pharmaceutical Company, STADA is part of a global business community and thus subject to a range of risks. These are necessary consequences of business activity, as the Group can only take advantage of opportunities if it is also prepared to take risks.

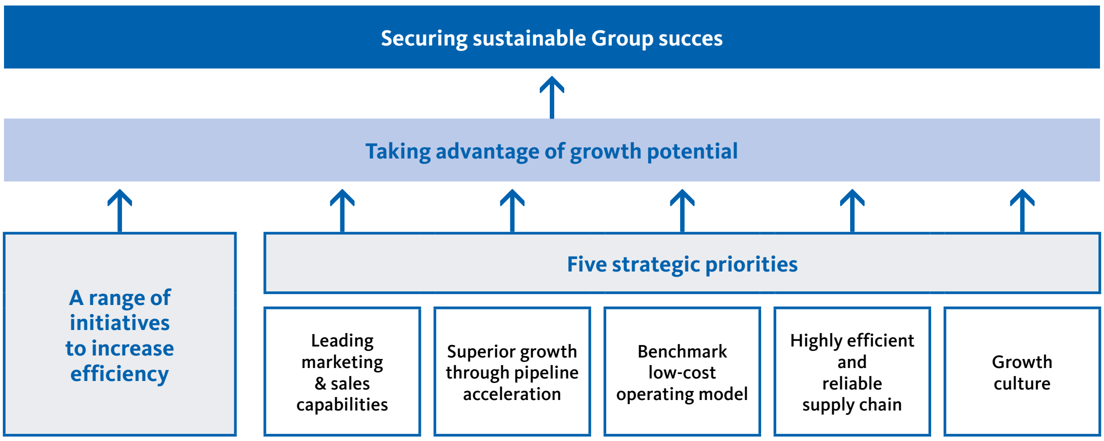
In view of the fact that the health-care and pharmaceutical sectors are relatively non-cyclical, economic cycles have only a limited impact on the Group. In addition, the dependence on negative developments or events is kept as low as possible due to the international positioning and the diversified focus on generics and branded products. Generally speaking, decades long activity in the pharmaceutical market forms a stable foundation for realistically assessing risks and for taking selected advantage of growth opportunities.

Comprehensive opportunities management to take advantage of existing growth opportunities

Opportunities management at STADA is an ongoing task. Within the scope of these efforts, the Group continuously evaluates opportunities for growth. STADA's management continuously monitors the markets and competitors in order to be able to recognize and analyze the changing requirements, trends and opportunities in the frequently fragmented markets and to align its actions accordingly. Moreover, there is a regular exchange of experiences within the individual departments which helps to identify and take advantage of additional opportunities and synergies.

Based on the continuous implementation of the numerous efficiency improvement initiatives and STADA's five strategic priorities, opportunity management serves to optimally exploit growth potential.

A range of initiatives to increase efficiency and five strategic priorities of the STADA Group for the optimal utilization of growth potential



Risk Management

STADA also defines risk management as an ongoing task of entrepreneurial activities. The risk strategy is applied in all business segments of the STADA Group and is closely linked with STADA's corporate strategy, forming the basis of the Executive Board's continuous risk management system. This system is then integrated into the value-based management and existing organizational structure of the Group. STADA's risk management system is based on the international risk management standard COSO II Enterprise Risk Management – Integrated Framework (2004).

The objective of the risk management system is to ensure that all risks are identified and assessed throughout the Group as early as possible so that they can be managed and minimized with targeted measures in the Group. At the same time, it is important to fully comply with all relevant regulatory requirements for such a system. The company-wide standard and integrated approach to risk management is intended to ensure the efficiency of Group-wide risk management and make it possible to aggregate risks and provide transparent reporting.

STADA's risk strategy is substantiated by risk policy principles. This is to ensure that all risks are fully identified, presented transparently and comparably and are assessed. It obligates those responsible for risks to proactively manage and monitor the risks. The risk policy principles are defined in the risk management guide, which also sets out binding methodical and organizational standards for the approach to risks.

The **fundamental components of the Group-wide risk management system** which calls for quarterly regular reporting are:

1. the **Risk Management & Database department**, which is vertically and horizontally integrated in the Company and is responsible for the planning and further development of the risk management system (including the Group-wide establishment of the risk management software "CRISAM" from calpana), as well as the methods and procedures used to identify and assess risks and support the local risk managers;

2. the local **risk officers** who identify and assess risks (including measures) and document and update them in the risk management system and who are integrated in all corporate units and subsidiaries throughout the Group.

3. **Review and coordination** by the Risk Management & Database department with the locally responsible risk officers on current issues and on the identified risk situation in the individual divisions in the Group (especially with regard to risk aggregates);

4. The Company-specific **risk management guide**, which defines the risk management terms, risk policy and the risk management system including the risk management process and responsibilities.

5. **Risk reporting** at Group and individual-company level.

STADA's Group-wide risk management covers STADA Arzneimittel AG and its Group companies as well as companies in which STADA holds a stake of at least 50%, even if they are not consolidated. Insofar as risks to the Group arise at subsidiaries in which STADA holds a stake of less than 50%, these risks are also recorded in the Group's risk management system.

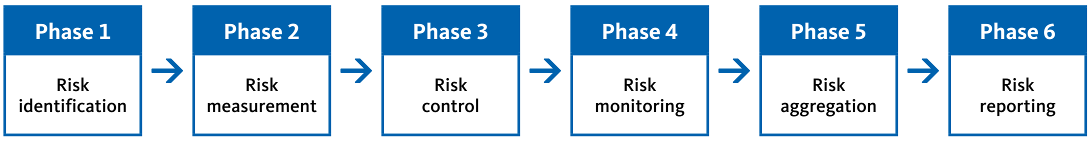
The risk management system does not provide for a segregated identification of opportunities. The identification and evaluation of opportunities takes place in the respective business environments. A comprehensive, systematic classification regarding the probability and effects of the opportunities is not performed.

At STADA, the **risk management process** comprises the phases of risk identification, risk measurement, risk control, risk monitoring, risk aggregation and risk reporting. With the introduction of the new risk management software CRISAM at the end of the third quarter of 2020, the general risk management process has not changed.

In preparation for meeting the expanded requirements of the revised auditing standard IDW PS 340 n.F., which took effect in 2021, the assessment of individual risks was extended to include a gross assessment, i.e. an assessment of individual risks before taking into account implemented and effective control and monitoring instruments, and the recording of measures was revised when the new CRISAM risk management software was introduced at the end of the third quarter of 2020. These expansions ensure that the increased requirements of IDW PS 340 n.F. are met in the recording of risks and measures from 2021.

The introduction of these innovations has not led to any changes in the general flow of the continuous risk management process outlined below.

Risk management process of the STADA Group



The ongoing risk management process begins with risk identification (phase 1), in which all individual risks that could have significant negative impacts on STADA's business model are systematically recorded. Identification of individual risks is carried out, on the one hand, through decentralized self-assessments and, on the other hand, through centralized inquiries.

Risk measurement is carried out following risk identification (phase 2). This occurs on the basis of probability and potential impact; the evaluation should consider potential direct damage as well as indirect results caused by individual risks if they arise. Objective criteria or historical data are used in the evaluation to as great an extent as possible.

As part of risk control (phase 3), suitable measures for risk avoidance, reduction, transferring and/or compensation are identified. The measures identified can relate to the cause (preventative) as well as to the effect (reactive).

The Risk Management and Database department ensures, through the ongoing risk monitoring (phase 4), that newly arising individual risks and changes in individual risks and any corresponding need for adjustment in risk management are checked for plausibility at an early stage and can be included in ad hoc reports.

Before preparing the risk reporting, the Risk Management & Database department summarizes the individual risks within a risk aggregate in the risk aggregation (phase 5) that have an identical or similar cause of risk in order to increase transparency.

In the risk reporting (phase 6), the department creates recipient-oriented risk reports on the identified individual risks for the management and Supervisory Board. Significant individual risks and risk aggregates indicated are jointly discussed by the Executive Board and the Supervisory Board and if required, further measures to counter risks are addressed. In the case of new significant individual risks or risk aggregates, the Executive Board and the Supervisory Board are also immediately informed through ad-hoc reporting, including outside of the quarterly risk reporting.

Internal Audit conducts regular company internal and independent system audits with a focus on effectiveness, appropriateness and economic efficiency of the STADA risk management system established by the Executive Board. As part of the monitoring of the Executive Board, the Supervisory Board also looks at the effectiveness of the risk management system. In the scope of auditing the annual financial statements, STADA's auditor also reviews and evaluates whether the early risk detection system which is integrated into the risk management system is generally suitable to recognize risks that may jeopardize the continued existence of the Company at an early stage.

The relevant period for internal regular reporting to the Executive Board is the current year plus two additional years. In addition, there is an area-related internal recording and monitoring of long-term risks beyond this relevant period. The assessment of the individual risks as well as the overall risk situation of STADA in the Combined Management Report relates to December 31, 2020. There were no relevant changes after the balance-sheet date that would have necessitated an amended presentation of STADA's risk situation. There is, however, no way to fully identify and manage risks with absolute certainty.

Internal Control and Risk Management System for the Group accounting process (report in accordance with Sections 289 [4], 315 [4] HGB)

The **Group-wide Internal Control and Risk Management System with regard to the financial reporting process (ICRMS)** is a component of STADA's Group-wide risk management system and aims to ensure the accuracy and effectiveness of accounting and financial reporting. STADA ensures the reliability of the accounting processes and the correctness of the financial reporting with a variety of measures and internal controls. These include the preparation of separate and Consolidated Financial Statements and Management Reports that comply with regulations. The ICRMS is constantly developed and is an integral component of the accounting and financial reporting processes in all relevant legal units and central functions. The system contains principles, processes and preventative and disclosing controls.

It includes, among other things:

- Uniform accounting, measurement and account assignment specifications for the entire Group that are continuously examined, updated and regularly communicated,
- Supplementary processes instructions, Group-internal reporting formats as well as IT-based coordination processes for Group-internal balances,
- Processes that ensure the completeness of financial reporting,
- Processes for functional separation, the dual-control principle within the context of the preparation of financial statements and for authorization and access regulations for relevant IT accounting systems,
- External experts, who are consulted when necessary, for example for purchase price allocation in accordance with IFRS 3.

The primary control functions for the significant accounting processes are carried out by the respective plausibility tests integrated in the programs. Outside the software-supported systems, manual plausibility tests and verification of the completeness and accuracy of data and calculations are carried out at all Group levels. The vast majority of the separate financial statements of Group companies (included in STADA's Consolidated Financial Statements) are generally subject to review by the auditor once a year.

Responsibility for the introduction and the functionality of the ICRMS rests with the Executive Board of STADA Arzneimittel AG, which assesses its appropriateness and effectiveness at least once every financial year. Its appropriateness and effectiveness are also regularly examined across the Group by Internal Auditing.

Furthermore, the Audit Committee of the STADA Supervisory Board regularly monitors the accounting process and the effectiveness of the control system, the risk management system and the internal auditing system as well as the audit on the basis of Section 107 (3) AktG. The ICRMS for the accounting process cannot, however, offer any absolute security that false statements are not made in accounting.

Evaluation of risk categories

The evaluation of individual risks is generally conducted for individual segments in the form of net risks, i.e. the individual risks are evaluated under consideration of implemented and effective management and control instruments. If no segment is explicitly referenced, the described risks affect both the Branded Products and Generics segments. As already described under "Risk management process," the introduction of the CRISAM risk management software at the end of the third quarter of 2020 created the possibility of also performing a gross assessment when evaluating individual risks. In addition, measures recording was also revised. The risk reporting system remained unchanged in 2020. An adjustment will be made in the current financial year 2021.

Within the risk management process described above, at STADA individual risks are evaluated on the basis of the probability of occurrence and a potentially negative impact on the forecast financial targets in relation to adjusted EBITDA.

The underlying scale for the classification of the probability of occurrence and the potential impact is presented in the following diagram:

Scale for the classification of risk categories	low	moderate	high
Probability	>0% to ≤30%	>30% to ≤70%	>70% to 100%
Impact over 36 months	up to ≤€5 million	>€5 million to ≤€10 million	>€10 million

Note on the probability category "moderate" and "high": In general, all individual risks with a probability of occurrence greater than 50% were checked for circumstances requiring recognition as a liability and corresponding provisions were formed.

The combination of these two factors leads to the risk matrix presented below in which the risk categories of the combined individual risks as well as aggregated risks are classified and presented according to their importance for the Group:

Risk matrix

Probability \ Impact	low	moderate	high
high	moderate	high	high
moderate	low	moderate	high
low	low	low	moderate

STADA classifies the identified risks in the risk reporting in accordance with the risk categories presented below. The chart shows all relevant risk categories in accordance with the STADA evaluation scheme. Individual risks and aggregate risks that were classified as “high” as of the balance-sheet date December 31, 2020 are to be considered particularly relevant.

Risk category	Risk subcategories (individual risk or aggregate risk)	Probability of occurrence	Net impact
Industry risks	Market position (competitors)	moderate	high
	Marketing (market penetration)	high	high
Regulatory risks	Health policy (price change)	high	high
Economic risks	No relevant risks	no relevant risks	no relevant risks
Product portfolio risks	Licenses & approvals (Prescription Status)	moderate	high
	Licenses & approvals (Prescription Status)	moderate	high
Legal risks	No relevant risks	no relevant risks	no relevant risks
Corporate strategy risks	No relevant risks	no relevant risks	no relevant risks
Performance-related risks	Production & purchasing (supply interruption)	moderate	high
Personnel risks	No relevant risks	no relevant risks	no relevant risks
Compliance risks	No relevant risks	no relevant risks	no relevant risks
Risks in relation to information technology	No relevant risks	no relevant risks	no relevant risks
Financial risks	Taxes (audits)	moderate	high
Other risks	Pandemic	moderate	high

As a supplement to the tabular presentation and regardless of the degree of evaluation, the current main risk categories for the STADA business model, based on the general risk reporting from Risk Management as of December 31, 2020 are explained in detail below.

Business-related risks

Risks that could have a significant influence on the net assets, financial position and results of operations of the STADA Group are described below. Risks, which are not yet known or have been assessed as insignificant, could also influence the net assets, financial position and results of operations.

Industry risks, regulatory and economic risks

a) Industry risks

According to the STADA evaluation scale, these are relevant risks.

STADA is subject to constantly changing market conditions in the individual national markets. In terms of competition, the risks exist on the basis of strong competition in particular in terms of pricing, range of products and services as well as supply and discount conditions of existing and new competitors. In terms of demand, there is also the risk of a potential increase in purchasing power of individual customer groups such as doctors, pharmacists, patients, health insurance organizations, buying groups, pharmacy chains, wholesalers or mail-order companies. Such developments could weaken STADA’s competitive position, for example through the (partial) loss of newly planned tenders or through a (partial) loss of previously won tenders, and consequently result in a loss in sales or earnings. However, STADA principally takes advantage of opportunities arising in individual markets or individual products or product groups and is also willing to accept, if necessary, temporary losses, for example, in national markets with major potential for growth or to maintain or expand its market position. Overall, STADA tries to counteract industry risks through a diversification of brands and products.

Since the beginning of the conflict between Russia and Ukraine in 2014, business development of STADA has been impaired in both the Russian and Ukrainian markets. In financial year 2020, too, the partial reluctance to buy remained noticeable. As a result of the continued lack of momentum in the development of real income, the buying power of the Russian population remained limited in 2020, and pressure on the pricing thus remained accordingly.

In the MENA region, the ongoing politically uncertain situation in the reporting year continued to have a negative impact on export business in this region. It is currently unclear how the situation in this regionwill develop and, as a result, the remaining export business could continue to be negatively impacted.

In connection with the exit of the United Kingdom from the EU, there is the risk that it could cause a shifting of market share toward local competitors in the self-payer area.

If these crises continue, this could have further negative impacts on the results of operations and financial position of the STADA Group.

b) Regulatory risks

According to the STADA evaluation scale, this is a relevant risk.

The national markets in which STADA is active are characterized by a large number of regulations. The changing, lifting or passing of new regulations could have significant economic and strategic impacts on STADA and the economic success of individual products or investments. Regulations at a national or supranational level are highly significant if, for example, they affect the market structure, pricing, reimbursement or approvals of pharmaceutical products. This can mean that as a result of national regulations, the prices of pharmaceutical products are regulated directly (for example through statutory price reductions) or indirectly (for example through reference prices, mandatory discounts, terms concerning discounts, reduction or exclusion of cost reimbursement). Furthermore, direct costs for the fulfillment of requirements (e.g. during approval) or increased indirect costs (e.g. through evasive action by competitors or consumers) can be incurred. This can reduce the profitability of products affected in the markets and prevent the market launch of a product in individual cases. STADA assumes that the extent of price regulation and pricing pressure will remain, primarily in the Generics segment. STADA counters these risks, among other things, through a targeted expansion of the product portfolio in less regulated areas.

Exact forecasts concerning potential changes in national or supranational regulations as well as their effects on STADA's business activities are not possible since the introduction and scope of such regulations depend on the political process of the country in question or on court decisions, the consequences are influenced to a large degree by the reactions of the market participants affected. Changes in the regulatory environment in STADA's main markets by sales volume are continuously analyzed. Depending on the extent of state regulation, it could become necessary to adjust the business model in individual markets.

Based on the conflict between Ukraine and Russia, regulatory obstacles for the import of products produced in Russia have occurred that have led to delays in delivery and thus to bottlenecks. Should these obstacles continue to occur in the future, this could have additional negative effects on the results of operations and financial position of the STADA Group.

c) Economic risks

According to the STADA evaluation scale, these are not relevant risks.

STADA's business success is, to a certain extent, dependent on economic influences, because an economic downturn often results in a reduction in purchasing power in the affected market. A reduction in purchasing power can particularly cause a reluctance to buy in the area of Branded Products, which is primarily a self-pay market. Furthermore, an economic downturn could intensify the already dominant cost pressure in individual national health care systems and thus significantly increase the speed and scope of regional regulatory measures to contain costs. For STADA, this could result in significant disadvantages with reimbursable pharmaceutical products or in state-required price reductions and the elimination of reimbursability for individual products. In general, STADA is continuously working to counteract potential risks through performance increases or cost reductions.

In the referendum on June 23, 2016, the majority of voters in the United Kingdom voted in favor of the United Kingdom leaving the EU ("Brexit"). Following lengthy negotiations, the EU and the United Kingdom were able to agree on a trade and cooperation agreement which was signed on December 30, 2020. The agreement took effect on January 1, 2021, subject to ratification by the European Parliament. This is still pending.

So far, the British economy has shown itself to be robust in relation to the effects of the "Brexit". However, there is a risk that negative consequences of the new agreement will only emerge with time. There is also a risk that the impact of the Covid-19 pandemic on the UK economy will further intensify these negative effects. This could lead to an economic downturn that would increase cost pressure in the health-care system and, consequently, result in price cutting measures. Furthermore, in the event of an economic downturn, there is a risk of a general reluctance to purchase on the part of consumers in the self-payer area.

Product portfolio risks

According to the STADA evaluation scale, these are relevant risks.

The continuous expansion of the product portfolio plays an essential role for the competitive position and business success at STADA. Associated with this is the risk that products to be added to the product portfolio either cannot be launched on the market, are launched belatedly or only launched at higher development and production costs than originally assumed due to unexpected events or faulty implementation. Reasons for this can include additional requirements of approval authorities, direct government price controls or additional approvals for reimbursement via the relevant national health system. The risks of development and approval processes for new products are continuously identified and evaluated.

Furthermore, in the Generics segment in particular, a significant factor in the development and approval of each product is the meticulous observance of relevant legislation such as commercial property rights. This involves the risk that an individual regulation is violated despite careful investigation of the legal situation and the introduction of a new product is delayed or even hindered. This also applies retrospectively for products already introduced to the market. There is also the risk that, despite intensive investigation, potential side effects or quality defects in products are not uncovered until after approval or that new scientific findings and evaluations lead to a market recall and corresponding legal proceedings.

Legal risks

According to the STADA evaluation scale, these are not relevant risks.

STADA's business activities are subject to risks resulting from existing or potential future legal disputes. In the Generics segment, in particular, STADA's business activities are associated with an increased risk of legal disputes regarding commercial property rights (particularly patents and supplementary protection certificates), product liability, warranty obligations, breaches of duty of care as well as the allegations of violations of Company or trade confidentiality. As a consequence of these legal disputes, in particular in the cases of such processes in the USA, damage claims, legal fees, a complete or temporary ban on the marketing of products or costs for recalls may be incurred, irrespective of whether a damage claim ultimately exists. In order to protect trade and business secrets, which are to be treated with confidentiality, STADA makes use of confidentiality agreements with employees, external alliance partners, service providers or other contractual partners.

Furthermore, it may be difficult for STADA to enforce its own claims under the law of a country where STADA undertakes business at affordable costs and without any materially adverse effects on business in this country. If, contrary to expectations, it turns out that this is not a case in a country, this can have significant negative impacts on the Group as a whole.

If there is a serious risk of future damage claims, STADA creates case-specific provisions for potential damage claims. However, STADA currently does not expect any negative effects on the net assets, financial position and results of operations from pending proceedings.

Operational risks

a) Corporate strategy risks

According to the STADA evaluation scale, these are not relevant risks.

STADA's corporate strategy is mainly focused on growth and internationalization in the pharmaceutical market in the Generics and Branded Products segments. STADA's growth strategy is associated with the risk that companies, products or other assets acquired in the past or in the future may only be able to be integrated with high integration costs or that intended synergy effects cannot be achieved at the desired level. Furthermore, acquired companies or products may not achieve the expected results on the market, as markets or market segments, which STADA focuses on, may develop differently than expected. STADA reduces these risks by means of careful analyses. Nevertheless, it cannot be ruled out that each of the situations mentioned above could lead to an impairment requirement on intangible assets or that expected results in individual markets cannot be achieved.

b) Performance-related risks

According to the STADA evaluation scale, these are relevant risks.

The Group's own production facilities (including product development and logistics) are subject to the risk of defective or inefficient planning and production processes as well as to production faults or breakdowns as a result of this or external influence. As hazardous substances are regularly used within these processes, such faults can also damage employees' and third parties' health or result in environmental damage. This could have a materially adverse effect on costs, competitiveness, supply availability and the associated expectations regarding units sold, sales and earnings as well as the image with clients.

Furthermore, STADA's ability to deliver can also be negatively influenced by the the supplier's inability to deliver, as the change in a supplier is generally associated with delays. STADA restricts this risk by partially using more than one resource supply (dual sourcing).

A further negative influencing factor on the ability to deliver is the increasing volume volatility in individual national markets in the Generics segment which regularly arise in the environment of tenders from state institutions or public health insurance organizations. Although STADA undertakes every effort to avoid delivery bottlenecks or an unintentional increase in inventories, this cannot be ruled out in consideration of the comprehensive portfolio.

STADA is dependent on global developments with respect to purchase prices for active ingredients or auxiliary materials required as well as on the prices negotiated with contract manufacturers in the case of products produced by these companies; these prices may fluctuate significantly, also depending on the product. To limit the risk of market-related margin losses due to reduced selling prices, STADA partly makes use of instruments towards suppliers that involve them in the market price risk such as retroactive negotiations or the agreement of special procurement prices for special sales volumes, in the context of tenders, for example. However, it cannot be ruled out that procurement cost increases and/or supply shortages in the case of individual products will have materially adverse effects on the Group's sales and/or profit margins.

c) Personnel risks

According to the STADA evaluation scale, these are not relevant risks.

STADA depends to a large extent on the commitment, motivation and abilities of its employees. The loss of specialists and managers as well as a prolonged search for reappointments in key positions could have significant adverse effects on the development of the Group. STADA's continued success also depends on its ability, in competition with other companies, to attract and keep qualified employees in the future for the long-term regardless of demographic challenges. Country, industry and business- specific fluctuation risks must be proactively identified and addressed specifically to maintain and achieve success and critical skills and competencies within the Company. STADA counters these risks through global employee development and succession processes through which the potential of employees is systematically identified and promoted. These processes support both young professionals and experienced highly qualified employees in their professional development and to help STADA to develop, promote and retain performance-critical skills in the Company.

d) Compliance risks

According to the STADA evaluation scale, these are not relevant risks.

It is STADA's expressed goal that all business activities are carried out exclusively within the framework of the respective laws and internal guidelines. STADA has therefore implemented a Group-wide compliance system, in which all employees are regularly informed about existing compliance guidelines at STADA, adapted to their individual area of responsibility. STADA believes that the compliance system is sufficient provision for the compliance with and observance of national and international regulations. Training courses and compliance guidelines cannot, however, fully guarantee that employees do not accidentally, negligently or deliberately breach laws or internal guidelines. Such breaches can disturb internal business processes and negatively influence the financial position.

e) Risks in relation to information technology

According to the STADA evaluation scale, these are not relevant risks.

STADA's strategic goals can only be achieved through optimal alignment and appropriate support using a variety of IT systems and processes. Therefore, the Group has to make continuous investments to appropriately adapt these complex and high-performing systems to changing business processes.

Global IT applications form the basis for the delivery of products to the global customers of the STADA Group as agreed upon. Inefficiencies in the IT processes in the Group, the failure of business-critical IT applications as well as the failure of a data center could have a direct impact on STADA's supply availability.

In addition, all IT systems used in the STADA Group could principally be affected by misuse of digital technologies as a means to perpetrate new types of crime, so-called cyber-crime (e-crime), that alongside the manipulation or failure of the affected IT systems could also result in the transfer of confidential information to third parties or a revocation of pharmaceutical approval due to the deficient validation of relevant IT systems.

To reduce the risk of failure and to protect against cybercrime, STADA operates a quality management system for IT and redundantly designed data centers.

Financial risks

To the extent that it is possible, STADA counters financial risks with finance policy methods and specific risk management. The basic principles of financial policy and of financial risk management are determined or confirmed at least once annually by the Executive Board in the context of the budget process. Furthermore, transactions above a certain relevance threshold determined by the Executive Board require a prior decision on the part of the Executive Board and may also be subject to approval from the Supervisory Board. The Executive Board is also regularly informed of the nature, scope and number of current risks.

a) Liquidity risks

According to the STADA evaluation scale, these are not relevant risks.

Liquidity risks may result, for example, from the loss of existing cash items, lack of availability of credit, reduced access to financing of Nidda, or fluctuation in the operational development of business. The goal of the liquidity management is to ensure solvency and financial flexibility of the STADA Group at all times by way of maintaining a sufficient supply of liquidity reserves. In 2020, STADA financed itself with current and non-current borrowings from Nidda, promissory note loans, bonds, a revolving credit facility and factoring.

b) Currency risks

According to the STADA evaluation scale, these are not relevant risks.

Due to the international alignment of business activities, STADA is subject to risks arising from exchange rate fluctuations. These particularly result from fluctuations of the US dollar, Russian ruble, British pound , Swiss franc, Serbian dinar as well as the Ukranian hryvnia in relation to the euro. A currency risk consists of potential changes in value, especially of receivables and liabilities in a currency other than the respective functional currency or as a result of exchange rate fluctuation (transaction risk). However, STADA is only subject to this risk to a limited extent, as the Company counters currency-related risks through, in addition to natural hedges, the use of derivative financial instruments. These are used to hedge currency risks from operating activities, financial transactions and investments. In the reporting year, STADA made use of foreign-exchange futures contracts and interest/currency swaps. The maturity of futures contracts is aligned with the terms of the underlying transactions. The remaining term of the contracts is currently up to one year.

Furthermore, currency risks also exist in relation to the conversion of the balance sheet items as well as the conversion of earnings and expenses of international Group companies outside of the euro zone (translation risk). In this connection, the current political conflict between Ukraine and the Russian Federation, as well as negotiations between the United Kingdom and the EU over Brexit, could indirectly continue to have a negative influence on the earnings situation and exchange rates.

A currency sensitivity analysis on the basis of the outstanding foreign currency items as of December 31, 2020 showed that in financial year 2020, an appreciation or devaluation of the functional currency compared with the ruble by 10% with otherwise unchanged conditions would change the EBITDA by approximately €27.2 million (previous year: €2.0 million) (translation risk). At the same time, an appreciation or devaluation of the functional currency in relation to the British pound of 10% with otherwise unchanged conditions would lead to a change in EBITDA of approximately €2.2 million (previous year: €6.5 million) (translation risk).

c) Interest rate risks

According to the STADA evaluation scale, these are not relevant risks.

STADA is subject to interest rate risks from financial assets and financial debts, primarily in the euro zone and Russia. STADA calculates existing interest rate risks using sensitivity analyses, which show the effects of changes in market interest rates on interest payments, interest income and expenses as well as equity. Should the sensitivity analysis show that interest rate fluctuations could lead to significant impacts, STADA could use derivative hedging instruments to avoid the risk.

A sensitivity analysis has shown that an increase in market interest rates of 100 basis points in financial year 2020 would have led to a burden on earnings in the amount of €9.4 million (previous year: €6.2 million) and a decrease in market interest rates of 100 basis points would have led to a relief on earnings in the amount of €0.4 million (previous year: €0.4 million).

d) Default risks

According to the STADA evaluation scale, these are not relevant risks.

STADA is exposed to a default risk in its operating business or as a result of financing activities if contracting parties fail to meet their obligations. Alongside the implementation of appropriate credit management processes, such transactions are generally only concluded with counterparties of impeccable financial standing to avoid default risks in financing activities.

Default risks also exist as a result of the supply of goods and services. STADA therefore strives to maintain business relations only with partners of impeccable financial standing. In addition, STADA partly uses suitable measures such as guarantees, loan insurances, or the transfer of assets to safeguard itself against default risk. Past due receivables in the operating area are continuously monitored and potential default risks are anticipated through the creation of valuation adjustments. Furthermore, there is the risk that in a difficult economic and financial environment, national health care systems delay or fail to make payments to STADA or business partners of STADA and that, as a result, directly or indirectly increased default risks arise.

e) Tax risks

According to the STADA evaluation scale, this is a relevant risk.

STADA's business activity in the individual national markets is subject to the applicable national or supranational legal tax regulations. Changes to the tax laws and their jurisdiction as well as different interpretations as part of external audit can result in risks with impacts on tax expenses, tax revenues, tax receivables and tax liabilities. The Group tax department identifies, evaluates and monitors tax risks as early as possible and systematically and initiates measures to reduce risk, where appropriate.

Furthermore, STADA takes advantage of an international network and carries out strategic Group functions centrally through STADA Arzneimittel AG. This means an overarching tax transfer-pricing model for the billing of the corresponding Group internal services is of increasing importance. Potential risks of non-recognition of these transfer prices for tax purposes, for example from retro-active tax claims of the local tax authorities against a subsidiary of the STADA Group, are limited by way of the introduction of corresponding agreement procedures and a comprehensive definition of transfer prices in the form of a Group guideline.

f) Impairment risks

According to the STADA evaluation scale, these are not relevant risks.

The valuation rates of the assets included in the Group balance sheet are subject to changes in market and business relationships and thereby to changes in fair value. As part of an annual or case-related impairment test, significant non-cash burdens on earnings and impacts on balance sheet ratios may result. This particularly applies to goodwill, which primarily results from purchase price allocations linked to previous acquisitions, and for other intangible assets. All relevant risks are considered in the context of the preparation of the Consolidated Financial Statements.

Other risks

According to the STADA evaluation scale, this is a relevant risk.

STADA as a Group and the STADA subsidiaries in the markets, like any company, are subject to additional general business risks such as unexpected disruptions in infrastructure, strikes, accidents, natural disasters, sabotage, criminal activities, terrorism, war and other unforeseeable materially adverse influences. STADA protects itself against such risks to the extent possible and financially reasonable through appropriate insurance policies. However, it cannot be ruled out that these insurances are insufficient.

Should STADA no longer meet the necessary criteria according to IFRS 10 ("Consolidated Financial Statements") for control, and consequently for consolidation of subsidiaries due to particular capital constraints or other measures – such as may arise as a result of political or military conflict – STADA would have to deconsolidate these companies. The resulting effects depend on the significance of the affected companies for STADA and could result in materially adverse effects for the Group.

The SARS-CoV-2 Corona virus, which first appeared in Wuhan (China) in December 2019, has become a Covid-19 pandemic in 2020, affecting all countries throughout the world. The pandemic and the associated restrictions have had a significant impact on the global economy and thus also on the business operations of the STADA Group. Significant sources of risk such as a slowdown in active ingredient and product deliveries, less contact with doctors and pharmacists as well as reduced consumer purchasing power could lead to product shortages and lower sales volumes with a corresponding impact on STADA's market situation and sales.

Summary evaluation of risks

The assessment of the overall risk situation is the result of the consolidated consideration of all significant individual risks on the basis of the applied risk management system.

While the assessments of individual risks changed in the reporting year due to the development of external conditions, changes in STADA's business portfolio, the effects of the Company's own counter-measures and adjustments to risk assessments, the overall risk situation for STADA – with the exception of the Covid-19 pandemic – did not change significantly overall in the reporting year compared to the previous year, despite regionally varying economic development.

STADA currently considers the Covid-19 pandemic, including the corresponding risks, to be one of the greatest challenges for its business activities. Inventories of active ingredients and finished products were increased in order to ensure the ability to deliver to customers and the Group's own production. Protective measures were also taken for STADA's employees.

In addition to the pandemic, the unchanged geopolitical situation in the CIS region and the possible consequences of the UK leaving the EU are seen as further risks.

In the event that one or more of the above-mentioned risks should materialize or newly occur in the development of business, this could have materially adverse effects on the Group's business activities. In particular, materially adverse effects on STADA's net assets, financial position and results of operations could arise as a result. From today's perspective, however, no risks are discernible which, individually or as a whole, could jeopardize the continued existence of the Group. In terms of organization, STADA has created the necessary prerequisites to be informed of possible risk situations early and to be able to take appropriate measures.