Report on Risks and Opportunities

As a global science and technology enterprise, identifying risks and opportunities is an intrinsic part of making our businesses resilient and generating value. We operate in a highly complex, global and interconnected business environment that further necessitates the competent management of risks and opportunities. Therefore, managing risks and opportunities is an imperative and a core component of our internal business planning and forecasting. We have processes, tools and responsibilities in place to enable the early identification of risks and to supply effective and efficient mitigation strategies.

In our internal risk reporting framework, we define risks as potential future events or developments that could result in unfavorable deviations from our financial and non-financial targets. Risk parameters in this context are the probability of financial (quantitative) impact (EBITDA pre/Operating Cash Flow) or non-financial (qualitative) impact (reputation/brand, Environment, Social, Governance (ESG) including workforce and ethics, strategy, operations).

Opportunities imply favorable deviations from targets. Future events and expected developments are considered in internal planning if a likely occurrence can be assumed within the planning period. The following section presents the risks and opportunities that could result in favorable and unfavorable deviations from existing plans and targets.

The following report is relevant from the perspective of both Merck KGaA, Darmstadt, Germany, and the overarching Group. For additional information and details regarding the non-financial topics, please refer to the "**Non-Financial Statement**".

Three Lines of Defense

To organize risk management and controls, we use the well-established "Three Lines of Defense Model", which was developed by the Federation of European Risk Management Associations (FERMA), the European Confederation of Institutes of Internal Auditing (ECIIA) and the Institute of Internal Auditors (IIA). The model divides our company functions for controlling risks properly and effectively into three areas, the so-called lines of defense:

The first line of defense consists of all functions that are responsible for the operational business and whose day-to-day business risks can have an impact. Risk owners (i.e. the heads of the business units, enabling Group functions and local Managing Directors) establish processes in accordance with the requirements set by the second line of defense to identify, assess, and monitor risks and to develop measures for proper risk mitigation. Results of these assessments are regularly communicated to the Executive Board.

The second line of defense includes enabling functions at both Group and local level that control and monitor the operational business (first line of defense). This includes, among other things, the design and implementation of methods and procedures for risk management and the internal control system (financial and non-financial) as well as its regular monitoring.

The third line of defense is our Internal Auditing function. As an objective and independent auditing body, it examines both the operational business (first line of defense) and the controls and monitoring functions (second line of defense) to ensure that risks are effectively identified, evaluated and controlled vis-à-vis the Executive Board and the Supervisory Board.

Both the second and third line of defense functions regularly report to the Executive Board and the Audit Committee of the Supervisory Board.

Internal control system

Internal control system for the (Group) accounting process

The objective of the internal control system for the accounting process is to implement controls that provide assurance that the financial statements are prepared in compliance with the relevant accounting laws and standards. This system covers measures designed to ensure the complete, correct, and timely reporting and presentation of information that is relevant for the preparation of the Consolidated Financial Statements and the Combined Management Report.

Our internal control system for financial reporting is based on the COSO (Committee of Sponsoring Organizations of the Treadway Commission) framework, a globally recognized standard divided into five components: control environment, risk assessment, control activities, information and communication as well as monitoring activities. Each of these components is regularly documented, tested and/or assessed. This control system aims to ensure the accuracy of the consolidated accounting process through functioning internal controls with reasonable assurance.

The Group Accounting function centrally steers the preparation of the Consolidated Financial Statements of Merck KGaA, Darmstadt, Germany, as the parent company of the Group. This Group function defines the reporting requirements that all companies of the Group must meet. At the same time, this function steers and monitors the scheduling and process-related requirements of the Consolidated Financial Statements. Our Business Services organization manages all changes to the equity holding structure and correspondingly adapts the Group's scope of consolidation. The proper elimination of intragroup transactions within the scope of the consolidation process is ensured. Group-wide accounting guidelines form the basis for the preparation of the financial statements according to International Financial Reporting Standards (IFRS), which are reported to Group Accounting; the guidelines are adapted in a timely manner to reflect changes in the financial regulatory environment and are updated in accordance with internal reporting requirements. For special issues, such as the accounting treatment of intangible assets within the scope of business combinations in accordance with IFRS 3 or defined benefit obligations, external experts are additionally involved where necessary.

The individual legal entities, including Merck KGaA, Darmstadt, Germany, have a local internal control system within a global framework. Where financial processes are handled by our Business Services organization, the internal control system of our Business Services organization is additionally applied. Both ensure that accounting complies with IFRS and with the Group accounting guidelines.

Group Accounting provides support to the local contacts and ensures a consistently high quality of reporting throughout the entire reporting process.

For Group financial reporting purposes, most of our subsidiaries use standard SAP software. Consolidation software from SAP is also used for the elimination of intragroup transactions. A detailed authorization concept ensures the segregation of duties with respect to both single-entity reporting and the Consolidated Financial Statements. The accounting process is generally designed to ensure that all units involved adhere to the principle of dual control.

The operational effectiveness of our internal financial control system is regularly tested within the scope of self-assessments by our legal entities and enabling Group functions including our Business Services organization. The quality is systematically reviewed by a dedicated global financial control and governance team. Control deficiencies are properly recorded and, wherever necessary, adequate countermeasures are taken to remediate control deficiencies in a timely manner.

The overall effectiveness of our internal financial control system with regard to accounting and compliance with financial reporting on the part of the relevant individual companies is confirmed by both the local Managing Director and the local Chief Financial Officer by signing the single-entity reporting and a separate confirmation regarding the effectiveness of the financial control system (internal financial control system sign-off letter). For the accounting treatment of balance sheet items, Group Accounting closely cooperates with Group Risk Management to correctly present potential risks in the balance sheet.

All the structures and processes described in the foregoing relate to the Group Accounting procedures and are subject to regular review by Group Internal Auditing based on an annual audit plan set out by the Executive Board.

The results of the self-assessments, quality reviews, and internal audits are dealt with by the Executive Board, the Supervisory Board and the Audit Committee. Our internal financial control system makes it possible to lower the risk of material misstatements in accounting. However, residual risk cannot be entirely ruled out as no internal control system is infallible, irrespective of its design.

Non-financial internal control system and overall evaluation*

In the context of constantly evolving external and internal requirements for the management of non-financial risks, work continued in fiscal 2023 on the development of a procedural and organizational concept as well as a roadmap for expanding non-financial risk management. An important decision was to consolidate the management of financial and non-financial risks under unified organizational leadership (with the Chief Financial Officer being responsible commencing with fiscal 2024) to increase efficiency and quality. This also includes the non-financial internal control system.

For fiscal 2023, the Group Legal & Compliance function provides the organizational framework for the non-financial internal control system. In line with the risk situation of the Group and to ensure regulatory compliance, non-financial topics such as sustainability, cyber security and supply chain are core areas of the internal control system. We base this on international standards, such as the framework for the governance of Group Cyber Security, which includes organizational, process-related, and technical measures for information security. The existing process of Cyber Security Risk Management is designed pursuant to ISO 27005:2018. In comparison with the previous year, a monthly Group Security Forum has been established, where new risks from the risk register are reported, and actions are tracked.

Additionally, the non-financial internal control system aligns with the sustainability strategy and ongoing projects for implementing sustainability reporting (e.g. CSRD). The goal is to continuously improve regulatory compliance pursuant to CSRD requirements through the implementation of organization-wide measures and controls.

The aim of our internal control system as the entirety of all systematically defined controls is therefore to prevent and reduce the probability of potential risks occurring as well as actively steer risks in business processes. Thereby, it helps to ensure the compliance of the company’s activities with laws and regulations. The entire internal control system and the applied methods are continuously developed further. The responsibility for the effectiveness of the internal control system and the further development of the non-financial key metrics lies with the respective responsible senior leaders or risk and process owners.

Relevant representatives from the business sectors and the enabling Group functions reported to the Executive Board through the implemented control system in 2023. In this context, areas where potential for improvement and optimization had been identified and relevant ongoing projects were also presented to the Executive Board. Finally, the individual Group functions and business sectors issued an assessment to the Executive Board regarding the appropriateness and effectiveness of the control system, considering the recommended improvement opportunities, where applicable. Based on this as well as the review of the non-financial internal control system, and reporting by Internal Auditing, as of December 31, 2023, the Executive Board was not aware of any indications with regard to material issues that the system is not appropriate or effective.

Given the multi-layered process landscape and the high speed of change regarding the catalog of requirements for non-financial information, the degree of development of the non-financial internal control system does not yet match that of the (Group) accounting-related internal control system. Based on risk-based assessments of the financial and non-financial internal control system, compliance and risk management and reporting by Internal Auditing, as of December 31, 2023 the Executive Board was not aware of any indications with regard to material issues that this system is not appropriate or effective.

* The contents of this chapter or section are voluntary and therefore not audited. However, our auditor has read the text critically.

Risk and opportunity management

Group Controlling & Risk Management provides the organizational framework for risk management and reports to the Group Chief Financial Officer. We have established a holistic risk management system aimed at safeguarding the long-term achievement of our Group's goals and addressing risks to ensure our continued existence and future success. Within the scope of audits, Group Internal Auditing regularly reviews the performance of risk management processes within the units on local level and, at the same time, the communication of relevant risks from the operating businesses to Group Risk Management. Additionally, the external auditor examines the risk early warning system in accordance with section 317 (4) of the German Commercial Code (HGB) as part of the year-end audit of Merck KGaA, Darmstadt, Germany.

Our risk management activities aim to continuously and promptly identify, assess and manage risks so that appropriate measures can be implemented to mitigate their potential negative impact. The responsibilities, objectives, and procedures of risk management are outlined in our internal group standard for risk management. The designated risk owners, including business heads, managing directors of Group subsidiaries, and the heads of enabling Group functions, are responsible for overseeing and running local risk management processes. These processes encompass various requirements, such as identifying risks considering internal and external factors (impacting both financial and non-financial targets), analyzing risks, implementing appropriate mitigation actions, establishing preventive measures and contingency plans if applicable, and documenting risks and mitigation efforts.

The risk owners continuously assess the status of risks and report their risk portfolio to Group Risk Management twice a year. To facilitate and support these activities, we employ dedicated risk management tools. Group Risk Management coordinates and supervises the bottom-up risk reporting process. This includes validating the plausibility of the reported risks, assessing the effectiveness of mitigation measures and time frames, and determining the residual risk. The net risk is then presented in the internal risk report.

For the internal bottom-up risk reporting process, reporting is based on defined thresholds, and a variety of distribution functions are used to reflect scenarios with varied occurrence probabilities. Risks below the global reporting threshold are managed and monitored at a local level. The timeframe applied for internal risk and opportunity reporting is five years. It may extend beyond this timeframe in specific cases, such as for regulatory risks related to climate change. The outlined risks and their evaluation are based on respective annual values within the reporting period. The assessment of the risks presented relates to December 31, 2023. No significant changes occurred after the balance sheet date that would necessitate an amended presentation of the Group’s risk situation.

Group Risk Management analyzes the reported information to determine the current risk portfolio of the Group. This assessment is presented in a comprehensive report, accompanied by detailed explanations, to the Executive Board, the Supervisory Board, and relevant committees twice a year. This also encompasses a quantitative aggregation of risks at Group level, using a Monte Carlo simulation. Moreover, any notable changes in the assessment of existing risks or the identification of new significant risks can be reported at any time and promptly communicated to the Executive Board.

Our internal controlling processes incorporate the opportunity management process, which is aligned with the Group’s strategy within the operating units. As part of the strategy and planning processes, the business sectors analyze and evaluate possible business-related opportunities. In this context, investment opportunities are carefully examined and prioritized primarily in terms of their potential value proposition, ensuring optimal resource allocation. We target investment in growth markets to leverage the opportunities of dynamic development and customer proximity at a local level.

Identified opportunities that are deemed likely to occur are integrated into the business plans and forecasts. Additionally, trends and events that have the potential to positively impact EBITDA pre or Operating Cash Flow. These opportunities have the potential to have a positive effect on our medium-term prospects.

Risk and opportunity assessment

The significance of a risk is evaluated based on its potential unfavorable deviation from our financial and non-financial targets in conjunction with the probability of occurrence of the respective risk.

The underlying scales for measuring these factors are shown below:

Probability of occurrence

Probability of occurrence	Explanation
< 1%	Highly improbable
1 – 5%	Improbable
5 – 20%	Possible
20 – 50%	Likely
> 50%	More likely than not

Degree of impact

Degree of impact	Explanation
> € 500 million	Critical negative impact on EBITDA pre and/or Operating Cash Flow
€ 100 – 500 million	Significant negative impact on EBITDA pre and/or Operating Cash Flow
€ 25 – 100 million	Moderate negative impact on EBITDA pre and/or Operating Cash Flow
€ 10 – 25 million	Minor negative impact on EBITDA pre and/or Operating Cash Flow
< € 10 million	Immaterial negative impact on EBITDA pre and/or Operating Cash Flow

To enable a thorough evaluation of both financial and non-financial risks, a qualitative rating scale is available to evaluate the indirect financial impact. The use of this scale is mandatory for the assessment of non-quantifiable and qualitative risks such as Environmental, Social, and Governance (ESG), reputational, strategic, and operational risks as well as for material risks that also require a qualitative evaluation. The scale categorizes the risks as low, moderate, significant, or critical and provides a comprehensive reference for assessment.

Opportunities are assessed within their respective business environment. During short-term and strategic planning, general measures of business functions are quantified, typically in relation to EBITDA pre (earnings before interest, taxes, depreciation, and amortization), and operating cash flow. In addition, we identify and leverage opportunities as part of our regular business operations and through our daily observation of internal processes and markets.

Investment opportunities are primarily evaluated and prioritized using metrics such as net present value, internal rate of return, return on capital employed (ROCE), and the payback period of the investment. These indicators are used to assess the potential of investment projects and prioritize them accordingly. Similarly, scenarios are used to simulate the impact of possible fluctuations and changes in the respective parameters on results.

Business-related risks and opportunities

Political and regulatory risks and opportunities

As a global corporate group, we face political and regulatory changes in a large number of countries and markets.

Risk of more restrictive regulatory requirements regarding drug pricing and reimbursement as well as pricing-related opportunities

Our business is affected by numerous regulations that are continuously changing – and could even become more stringent. For example, in the Healthcare business sector, the known trend towards increasingly restrictive requirements in terms of drug pricing, reimbursement, and the expansion of rebate groups is continuing. With globally rising healthcare expenditures, both in absolute amounts and relative to GDP, healthcare budgets around the globe face increasing pressure. Specifically, in the United States, a pricing reform on prescription drugs is part of the agenda of the current administration. These requirements can negatively influence the profitability of our products, as can market referencing between countries, and the success of market launches. Foreseeable effects are considered as far as possible in the business sector's plans. Close communication with health and regulatory authorities serves as a preventive measure to avert such risks. The remaining risks beyond the current plans resulting from restrictive regulatory requirements are possible to likely with a moderate to significant impact. While we consider the possibility of resulting price cuts in our forecasts, there is also an opportunity that price pressure from healthcare systems worldwide is less pronounced than expected or materializes at a later point in time versus the base assumption. Additionally, as a global specialty innovator that pursues a focused leadership approach in attractive therapeutic areas, we are positioned to benefit from attractive pricing schemes for demonstrated major therapeutic improvements.

Risk of stricter regulations for the manufacturing, testing, and marketing of products

We must adhere to a multitude of regulatory requirements regarding the manufacturing, testing and marketing of many of our products. Specifically, in the European Union, we are subject to the EU chemicals regulation REACH. Similar regulations are emerging globally in relevant markets, particularly in Asia. These regulations demand comprehensive tests for chemicals. Moreover, the use of chemicals, such as per- and polyfluorinated alkyl substances (PFAS), in production and final products could be restricted, which would negatively impact the ability to manufacture and market certain products. With the EU Chemicals Strategy for Sustainability, an initiative of the European Green Deal, we expect increasing demands concerning the substitution of specific hazardous substances. We are constantly pursuing research and development (R&D) in substance characterization and the possible substitution of critical substances so as to mitigate this risk. Nevertheless, risks of stricter regulations are classified as possible to likely with moderate to significant impacts.

Risk of negative political and macroeconomic developments

The current political and macroeconomic situation, characterized by high uncertainty and volatile global developments, is a strategic factor for us as potential negative developments can also impact our businesses. The ongoing general trend of bloc building and reshoring of critical supplies and processes is leading to a further increase in the establishment of trade barriers and the general weaponization of trade to assert interests. While the global economy continues to gradually recover from the aftermath of the Covid-19 pandemic and Russia's invasion of Ukraine, the increased threat from armed conflicts including the resurgent conflict in the Middle East as well as the tensions between the United States and China could lead to further sanctions and economic measures that harm global trade and affect bilateral and multilateral relationships. For example, multiple countries have already implemented measures to restrict the export and transfer of technology to China, particularly in relation to advanced chips that could be utilized for AI, quantum computing and military applications.

These risks can have a negative impact on our supply chains and sales in our key countries and regions. Such risks are considered as fully as possible in the business plans of the affected countries and regions, and are mitigated through product, industry and regional diversification as well as measures to ensure resilience of supply chains and networks. For instance, in the Electronics business sector, a strong local presence in China enables us to remain competitive in the country while our global footprint could provide opportunities to capture

the demand shifting from Asia to other geographies (i.e. the United States and Europe). Also, given the considerable investments of several countries in the domestic chip industry (e.g. the U.S. Chips Act, EU Chips acts) to establish local supply of this critical component. Besides that, strategic geopolitical risk management is in place at the Group and business sector levels to continuously monitor and assess the global developments and to prepare us holistically for foreseeable risks.

Global economic growth is projected to slow down with growing regional divergences. Weak economic growth or even a recession could lead to less government spending or other cost-containment policies. Global inflation declined gradually in 2023, but remained significantly above target levels, keeping costs at an elevated level which could negatively impact our business. Persistently high inflation could increase our operating expenses (e.g. raw materials, operating costs and logistics) as well as capital expenditures. It could also prompt central banks to increase interest rates further and curb fiscal policy for some economies. In the course of 2022 and 2023, the European Central Bank as well as the U.S. Federal Reserve increased key interest rates significantly, which may affect our refinancing costs. Financial markets remain volatile, which could have numerous potential impacts.

The net risks of negative geopolitical and macroeconomic developments are seen as possible and might have significant to critical effects. However, our assumptions on geopolitical developments exclude extreme scenarios with severe escalation of tensions. The materialization of such scenarios would jeopardize entire industries and the balance of geopolitical and economic structures, posing a substantial challenge for us, as for any other company.

Further details on the macroeconomic development can be found under "**Macroeconomic and Sector-Specific Environment**".

Market risks and opportunities

We compete with numerous companies in the pharmaceutical, chemical, and life science sectors. Rising competitive pressure can have a significant impact on the quantities that can be sold and prices attainable for our products.

Risks and Opportunities in Life Science

The portfolio of our Process Solutions business unit encompasses a broad range of pharmaceutical development and manufacturing solutions, including filtration devices, chromatography resins, single-use assemblies and systems as well as processing chemicals and excipients. We have strategically positioned ourselves to capture numerous opportunities from the industry's shift towards biologics, coupled with the growing demand for bioproduction driven by many drug candidates and more regulatory approvals. In addition, we are well-prepared to benefit from our customers' investments in expanding bioreactor capacity. Our commitment to innovation and our customer-focused approach positions us to advance the field of biomanufacturing.

The growing use of biologics is creating a need for more efficient and higher-yield manufacturing processes. This represents an opportunity for us to enable continuous and intensified processing through our ongoing innovation in single-use technologies and advancements in bioproduction.

Consequently, faster market growth driven by the aforementioned industry shifts can lead to a more positive development compared with our latest plan.

Our Life Science Services business unit fully integrates Contract Testing, Development, and Manufacturing Organization (CTDMO) services to meet the evolving needs of our global customers across all stages of drug development, from preclinical to commercialization. Our CTDMO services cover a wide range of modalities, including monoclonal antibodies (mAbs), high-potency active pharmaceutical ingredients (HP-APIs), antibody-drug conjugates (ADCs), viral and gene therapies (VGTs), and end-to-end mRNA offerings. We continually invest in expanding our portfolio and production capabilities to offer specialized solutions for both traditional and innovative therapies. This positions us to capitilize on the potential of the growing biopharmaceutical market by providing leading CTDMO services to our customers. Through quicker establishment of model modalities on the market in combination with our broad and integrated portfolio, we can increase the potential beyond the assumptions reflected in our plan.

Our Science & Lab Solutions business unit serves customers in the pharmaceutical and biotech industries and other industries in production, testing and research, as well as public authorities and research institutions. Despite current headwinds – a complex macroeconomic environment, and softer market demand, especially in the United States and China – the business unit is well-positioned to deliver long-term, profitable growth. We aim to offer our customers a streamlined experience and a comprehensive portfolio of offerings to facilitate their research and analytical processes. This includes several customer solutions in the area of innovative digitalization and automation. A faster recovery from the aforementioned macroeconomic adverse development as well as greater commercial success of our innovative digital and automation solutions could imply an increased potential compared to our latest plans.

Further details on the industry, market developments and associated risks, such as the challenging market environment in the life science industry, can be found under "**Risks due to increased competition and customer technology changes as well as related opportunities**" and "**Macroeconomic and Sector-Specific Environment**".

Risks and opportunities in the semiconductor industry

Our Semiconductor Solutions business unit leverages a broad portfolio of independent technologies. This enables us to supply products for all essential production steps of wafer processing, helping our customers to achieve their technology roadmaps.

The underlying semiconductor industry is cyclical by nature. The current downturn has been exacerbated by a post-Covid-19 pandemic recession. The economic weakening has led to a temporary weakness of the traditional industry growth drivers such as PCs, smartphones and traditional data centers, while the new growth drivers such as AI and automotive are still too small to compensate for these effects. The multi-layered macro-economic effects and poor transparency throughout the supply chain cause a certain degree of uncertainty when estimating the timing and shape of the industry recovery. However, it may also imply upsides compared with our plan if the industry recovers faster and stronger than expected. The semiconductor cyclical correction risk is considered as likely with a significant impact.

Irrespective of the current turbulent macroeconomic situation, the positive medium- and long-term growth prospects of our markets remain unchanged. We see long-term growth opportunities in the semiconductor market due to the significantly accelerating global demand for innovative semiconductor materials with potential growth upside beyond the assumptions reflected in our plan, driven by a faster market adaptation and penetration. This demand is driven by exponential data growth and highly impactful technology trends such as autonomous driving, electric vehicles, Internet of Things (IoT) and 5G. We will benefit from the high material requirement of these AI chips and are working with our customers on almost all of these groundbreaking technological innovations in the semiconductor sector. That is why we are investing in our highly attractive growth markets and purposefully expanding production capacities with a smart localization of our footprint to further boost customer proximity and ensure supply stability. Having the right capacity in the right place to bring new products and higher volumes to our customers enables us to stay flexible about the timing of the market upswing and can serve as a competitive advantage.

The aforementioned trends and the continued announcements of major capacity expansions in the industry in the coming years also benefit our DS&S business. With this portfolio of gas and chemical cabinets and the potential to provide our largest customers with turnkey solutions for the delivery of bulk gases in the manufacturing process, we are well positioned to capture upcoming opportunities.

Risks due to increased competition and customer technology changes as well as related opportunities

In the Healthcare business sector, both our biopharmaceutical products and classic pharmaceutical business are exposed to increased competition from other rival products, especially in the form of biosimilars and generics but also in innovative R&D. We compete with other pharmaceutical companies in various therapeutic indications and rely on high quality data to successfully market our products. For this reason, we closely observe our competitive landscape and make assumptions with regard to future competitor entries that pose competition to our products. Due to the uncertainty that is inherent to clinical trials, there is the possibility that competitor trials fail to meet primary endpoints in their studies or deliver inferior data than we initially anticipated. If there

are no new competing products or if our competitors deliver less promising data, this could represent opportunities for us in therapeutic areas in which we are active.

In the Life Science and Electronics business sectors, risks are posed by not only cyclical business fluctuations but also changes in the technologies used or customer sourcing strategies. We use close customer relationships and in-house further developments as well as market proximity, including precise market analyses, as mitigating measures. Overall, the occurrence of these risks is possible to likely and could have a significant impact.

Further details on the industry and market development can be found under "**Macroeconomic and Sector-Specific Environment**", e.g. on the market challenging environment in the life science industry.

Risks and opportunities of research and development

Innovation driven by R&D is a major element of the Group strategy – including fostering innovation at the intersection of our business sectors – and is particularly important in the Healthcare business sector. In regular portfolio management reviews, we continually evaluate and, if necessary, realign research areas and R&D pipeline projects to focus our investments in areas where patient needs are served best. Nevertheless, R&D projects can experience delays, expected budgets can be exceeded, or targets can remain unmet. Sometimes, development projects are discontinued after high levels of investment at a late phase of clinical development. Decisions – such as those relating to the transition to the next clinical phase – are taken with a view to balance risks and opportunities.

In addition to in-house R&D efforts, strategic alliances with external partners and the in- and out-licensing of programs also form part of the catalog of measures to develop innovative medicine and ensure the efficient allocation of resources. Strategic alliances with partners as well as in- and out-licensing transactions always follow a stringent selection process along clear strategic and financial decision criteria. An example of such in-licensing deals is the recently announced partnership with Jiangsu Hengrui Pharmaceuticals Co. Ltd. for a next-generation selective PARP1 (poly (ADP-ribose) polymerase 1) inhibitor and ADC (antibody drug conjugate) which represents a strong strategic fit leveraging our internal DNA damage response expertise and in-house ADC capabilities. This agreement provides the opportunity to advance more therapeutic options for patients with difficult-to-treat cancers. However, in general, there is a possibility that we may not be able to identify a sufficient number of in-licensing assets on financially acceptable terms.

The aforementioned development opportunities are associated with different types of risks. There is the risk that regulatory authorities either do not grant or delay approval or grant only restricted approval. The risk that undesirable side effects of a pharmaceutical product could remain undetected until after approval or registration could result in a restriction of approval or withdrawal from the market. Furthermore, we cannot guarantee that all the assets we are currently developing will achieve the desired commercial success. The failure to meet targets in this area could have significant effects, for example due to lower net sales or the non-occurrence of milestone payments from collaboration agreements. These risks are evaluated with probabilities ranging from possible to likely.

Moreover, in Electronics, we will also continue to invest heavily in R&D in leading-edge material solutions. The aim is to seize growth opportunities arising from the increasing global demand for innovative semiconductors. Promising opportunities for innovation are constantly arising throughout our Semiconductor Solutions business. We work closely with our customers to exploit these. Technology inflection points bring opportunities to our material solutions and the chance to differentiate from competition. We are further developing new dielectric platforms in cooperation with our key customers for 3D NAND applications.

In addition, we see opportunities in organic light-emitting diode (OLED) materials in high-quality display applications. We have been conducting R&D in the area of OLED technology for more than 15 years and have grown into a well-positioned material supplier for OLEDs. Through our semiconductor and display knowledge, we will be able to contribute to the new display devices including foldable displays and Augmented Reality/ Virtual Reality applications, which require a broad set of materials.

More detailed descriptions on our R&D activities worldwide can be found under "**Research and Development**" in "**Fundamental Information about the Group**".

Risks and opportunities related to the quality and availability of products

Opportunities arising from capacity expansion

We make targeted investments worldwide to expand our regional capacities and drive sustainable growth in all three of our business sectors.

During the Covid-19 pandemic, supply chains experienced unprecedented disruption, with customers placing greater emphasis on supply security. In Life Science, we responded to this trend by actively diversifying our global presence by moving to a production network in the region and for the region to increase resiliency and meet the local needs of customers in North America, Europe and Asia-Pacific.

In fiscal 2023, we announced several new investments to expand capacity and product capabilities at facilities around the world. These include investments in biosafety testing, the expansion of our production for highly purified reagents and expanded lab space and production capability to manufacture cell culture media. Having the right capacity in the right place to ensure supply security, to bring new products to the market and to serve higher customer demand offers us the opportunity to capture higher market shares and can serve as a competitive advantage. However, market dynamics naturally influence our expansion activities as well as utilization. We therefore regularly review our expansion plans and adapt them accordingly.

Risks arising from project execution

In today's dynamic business environment, we prioritize innovation and growth. Projects are essential for achieving our strategic objectives, driving expansion, and promoting sustainable development. To effectively support further business growth and enhance efficiency, we continuously invest in projects, such as IT systems, distribution centers, office buildings and other projects. However, project execution involves significant capital expenditures, making effective project management crucial to avoid delays and higher spending. Inadequate planning, execution errors, and ineffective change management can lead to inefficiencies and disruptions, resulting in increased costs and lower sales.

In a rapidly evolving market, there is also a risk of missing out on market growth and development by delaying or deferring investments. To mitigate this risk, we actively monitor industry trends, conduct market research, and maintain a flexible project portfolio. By aligning our investment decisions with market dynamics, we aim to capture opportunities and minimize the risk of being left behind. This is particularly important in industries like semiconductors, where market cycles present substantial risks.

To proactively address project execution risks, we apply well-established project planning and internal control practices, collaborate closely with stakeholders, and conduct regular project reviews through teams and steering committees. This approach enables us to detect risks early on and implement corrective actions or discontinue projects that are unlikely to succeed. Through comprehensive planning, accurate cost estimations and re-evaluations, we monitor costs and ensure efficient resource allocation. Effective project governance and prioritization further contribute to desired project outcomes.

By employing these strategies, we mitigate project execution risks, ensuring successful project delivery, improved efficiency, and alignment with our strategic objectives. Overall, the possible risks could have a moderate to significant impact.

Risk of a temporary ban on products/production facilities or of non-registration of products due to non-compliance with quality standards

We are required to comply with the highest standards of quality in the manufacturing of pharmaceutical products (Good Manufacturing Practice or official pharmacopoeia). In this regard, we are subject to the supervision of the regulatory authorities. Conditions imposed by national regulatory authorities could result in a temporary ban on products/production facilities and possibly affect new registrations with the respective authority. We make the utmost effort to ensure compliance with regulations, regularly perform own internal audits, and carry out external inspections. Thanks to these quality assurance processes, the occurrence of a risk with a significant impact is improbable to possible; however, it cannot be entirely ruled out and depends on the product concerned and the severity of the objection.

Risks of production availability

Further risks include operational failures due to fire or force majeure, for example natural disasters such as floods, droughts or earthquakes, which could lead to a substantial interruption or restriction of business activities. As far as possible and economically viable, the Group limits its damage risks with insurance coverage, the nature and extent of which is constantly adapted to current requirements. Likewise, we are exposed to risks of production outages and the related supply bottlenecks that can be triggered by technical problems in production facilities with very high-capacity utilization. Furthermore, there are risks of supply bottlenecks due to a lack or disappearance of capacity. We work towards continual mitigation of such risks by making regular investments, setting up alternative sourcing options and maintaining sufficient inventory levels.

Although the occurrence of these risks is considered improbable, an individual event could have a critical negative effect.

Risks of dependency on suppliers and opportunities from supply reliability

Like many other market players in other industries, we have been exposed in the recent past to unprecedented events such as the Covid-19 pandemic and other geopolitical events. Throughout these challenging times, we have been able to avoid any major supply disruptions for our customers. A significant part of this success is rooted in our efforts to build resilient supply chains over the years with our strategic suppliers and reduce the probability of these risks. These strong and esteemed relationships have enabled us to respond to the changes in a difficult environment and adapt to the new circumstances quickly.

For example, the promise of our Healthcare business sector to reliably serve our patients is a top priority for us and requires a strong and resilient supply chain. In 2023, we proved that we could continue to reliably supply our patients with highly needed drugs while competitors in Fertility and Endocrinology ran out of stock. This stock-out situation faced by competitors could continue in the near future and would provide us with opportunities to gain additional market share by serving patient demand.

However, part of our supply chain remains vulnerable to certain events. Therefore, we continue to invest in the improvement of our supply chain, by for example, avoiding single-source situations wherever possible and economically sensible, and by increasing stock levels for essential materials in close collaboration with our suppliers. Through these measures we keep our dependencies on individual partnerships as low as possible within the highly regulatory environment we operate in. Overall, the likely risks might have a moderate to significant impact.

Risks due to product-related crime

As a leading global science and technology company and manufacturer of innovative products of the highest quality, we are exposed to various security- and crime-related risks. Due to the complexity of international trade and global supply chains, our products are at risk of being counterfeited, stolen, illegally diverted and misused. If left unaddressed, this would not only lead to financial loss, reputational damage and business disruption, but also compromise patient and customer safety. Consequently, we have implemented technical, operational and procedural measures aimed at protecting the integrity of our products and supply chains, while also ensuring that new threats are identified and managed appropriately.

Overall, the threat resulting from product-related crime is likely with a moderate impact.

Risks from the use of social media

We and our employees are active on numerous social media platforms. The consistent and legally compliant use of such platforms and their content is important in terms of increasing awareness of our brand, among other things. We take all necessary precautions and have implemented processes to ensure awareness regarding the proper handling of social media as well as actively manage and control our publications and communication.

Nevertheless, reputational risks could result, for instance through public dialogues on social media. On the qualitative rating scale, we thus rate this risk as significant.

Financial risks and opportunities

As we operate internationally, and due to our presence in the capital markets, we are exposed to various financial risks and opportunities. Above all, these are liquidity and counterparty risks, financial market risks and opportunities, and risks of fluctuations in the market values of operational tangible and intangible assets as well as risks and opportunities from pension obligations.

In the area of financial risks and opportunities, we use an active management strategy to reduce the effects of fluctuations in exchange and interest rates. The management of financial risks and opportunities by using derivatives is regulated through extensive guidelines. Speculation is prohibited, and derivative transactions are subject to constant risk controls. The strict separation of functions between trading, settlement, and control functions is ensured.

Liquidity risks

To ensure continued existence, we must be able to fulfill our commitments arising from operating and financial activities at any time. Therefore, to reduce potential liquidity risks, we have a central Group-wide liquidity management system in place, and a balanced maturity profile. The maturities of our financial liabilities are aligned with our planned free cash flow. Furthermore, we have a syndicated loan facility of € 2.5 billion with a term until 2028, which ensures continuing solvency if any liquidity bottlenecks occur. As our loan agreements do not contain any financial covenants, these agreed lines of credit can be accessed even if our credit rating should deteriorate. Additionally, we have a commercial paper program with a maximum volume of € 2.5 billion.

Counterparty risks

Counterparty risks arise from the potential default by a partner in connection with financial investments, loans, and financing commitments on the one hand and receivables in operating business on the other.

As for counterparty risks from financial transactions, we review all central positions relating to trading partners and their credit ratings daily. We manage financial risks of default by diversifying our financial positions and through the related active management of our trading partners. Significant financial transactions involving credit risk are entered into with banks and industrial companies that have a good credit rating. Moreover, our large banking syndicate – the renewed syndicated loan facility of € 2.5 billion was syndicated among 15 banks in 2023 – reduces possible losses in the event of default.

The solvency and operational development of trading partners are regularly reviewed as part of the management of operational counterparty risks. Sovereign risks are also analyzed. The volume of receivables of each customer is capped in line with their credit ratings. Risk-mitigating measures, such as credit insurance, are utilized as appropriate. Nevertheless, defaults by isolated trading partners, even those with outstanding credit ratings, cannot be entirely ruled out, although rated as unlikely.

Counterparty risks are classified as possible risks and might have moderate effects.

Financial market risks and opportunities

As a result of our international business activities and global corporate structure, we are exposed to risks and opportunities from fluctuations in exchange rates. These result from financial transactions, operating receivables, and liabilities as well as future cash flows from sales and costs in foreign currency. We use derivatives to manage and reduce these risks and opportunities (further information can be found under "**Derivative financial instruments**" in the "**Notes to the Consolidated Financial Statements**"). Foreign exchange rate risks are rated as possible with a significant effect on EBITDA pre or operating cash flow.

Variable interest and current financial liabilities are exposed to the risks and opportunities of interest rate fluctuations. Interest rate risks have a negative impact, are considered possible, and pose a minor negative risk overall.

Risks of impairment of balance sheet items

The carrying amounts of individual balance sheet items are subject to the risk of changing market and business conditions and thus to changes in fair values as well. Necessary impairments could have a significant negative non-cash impact on earnings and affect the accounting ratios. This applies specifically to the high level of intangible assets including goodwill, which mainly derive from the purchase price allocations made in connection with past acquisitions (further information can be found under "**Goodwill**" and "**Other intangible assets**" in the "**Notes to the Consolidated Financial Statements**"). This qualitative risk might have a significant effect on reputation.

Risks and opportunities from pension obligations

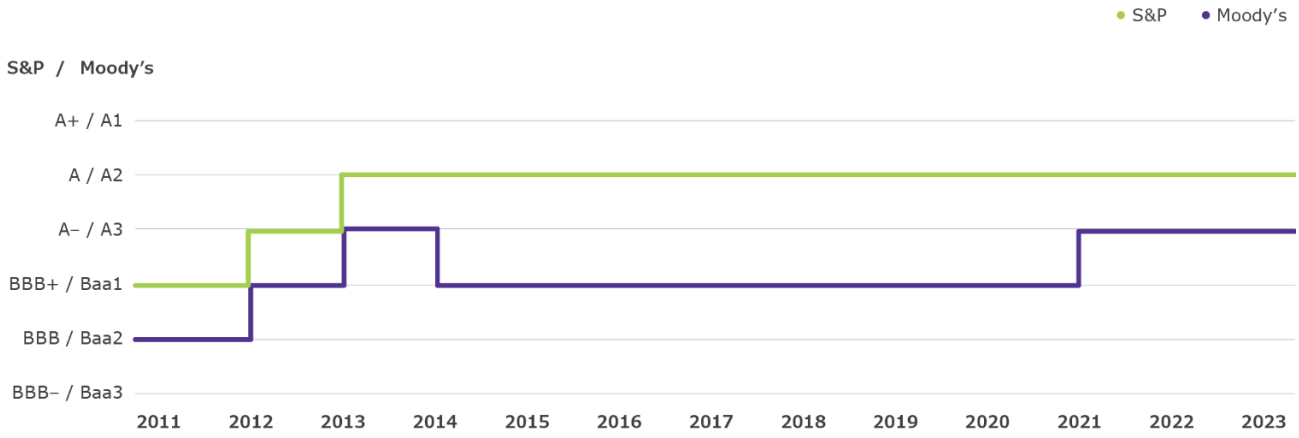
We have commitments in connection with pension obligations. The present value of defined benefit obligations can be significantly increased or reduced by changes in the relevant valuation parameters, for example the interest rate or future salary increases. Pension obligations are regularly assessed as part of annual actuarial reports. The obligations are covered by the pension provisions reported in the balance sheet based on the assumptions as of the balance sheet date. Some of these obligations are funded by plan assets (further information can be found under "**Provisions for pensions and other post-employment benefits**" in the "**Notes to the Consolidated Financial Statements**").

To the extent that pension obligations are covered by plan assets consisting of interest-bearing securities, shares, real estate, and other financial assets, decreasing or negative returns on these assets can adversely affect the fair value of plan assets and thus result in further additions to pension provisions. By contrast, rising returns increase the value of plan assets, thereby resulting in excess cover of plan liabilities. We increase the opportunities of fluctuations in the market value of plan assets on the one hand and reduce the risks on the other by using a diversified investment strategy. The possible risk due to pension obligations could have minor effects.

Assessment by independent rating agencies

The capital market uses the assessments published by rating agencies to help lenders assess the risks of financial instruments used by the Group. We are currently rated by Standard & Poor's and Moody's. Standard & Poor's has issued a long-term credit rating of A with a stable outlook and Moody's a rating of A3 with a stable outlook. In line with market procedures, our financing conditions are closely tied to our rating. The better the rating, the more favorably we can generally raise funds on the capital market or from banks.

Overview of Rating Development



Risks due to the divestment, acquisition and integration of companies and businesses

Successfully acquiring and subsequently integrating new businesses entails risks. These are primarily centered around the uncertainty of achieving business targets and synergy goals as well as remaining within the planned integration budget. Divestments, on the other hand, could lead to liabilities and additional expenses related to potential indemnifications and commitments guaranteed in the sale transaction. We leverage our solid acquisition track record to reduce the probability of any transaction-associated risks by integrating lessons learned from past transactions, strong due diligence, and closely managed integration processes. Currently, we are not aware of any significant risks in this area.

Tax risks

The Group and its subsidiaries operate worldwide and are consequently subject to different national tax laws and regulations. National tax audits of our entities are conducted on an ongoing basis by the tax authorities of the respective countries in which we operate. Tax risks originate particularly from the changes in national tax laws and regulations, and case laws and interpretations by national tax authorities as well as from significant transactions such as acquisitions, divestments and reorganizations.

Findings of the national audit authorities of the various countries may lead to higher tax expenses and payments and may also have an impact on the amount of tax receivables, and tax liabilities as well as on deferred tax assets and liabilities.

The Group's tax function regularly and systematically assesses the relevant tax risks. Appropriate standards are put in place to identify tax risks at an early stage in order to review, assess and mitigate them effectively and efficiently. Group Tax coordinates mitigation measures with the subsidiaries. Risks in addition to those already accounted for in the balance sheet are classified as improbable to possible with moderate to significant impact.

Information on the accounting and measurement policies for income taxes can be found under "**Income tax**" in the "**Notes to the Consolidated Financial Statements**".

Legal risks

Generally, we strive to minimize and control our legal risks. To this end, we have taken the necessary precautions to identify threats and defend our rights where necessary. Nevertheless, we are still exposed to risks from litigations or legal proceedings. In particular, these include risks in the areas of product liability, competition and antitrust law, pharmaceutical law, patent law, trademark law, data protection law, tax law, and environmental protection. As a research-based company, we have a valuable portfolio of industrial property rights, patents, and brands that could become the target of attacks and infringements. The outcome of future proceedings or those currently pending is difficult to foresee. For instance, we are currently involved in litigation with Merck & Co. Inc., Rahway, New Jersey (USA) (outside the United States and Canada: MSD), against whom we have filed lawsuits in various countries. This company has also sued us in the United States for trademark infringement, among other things.

Due to long statutes of limitations or in some cases the absence thereof, it is not possible to rule out that we will face third-party claims arising from the same issue despite the conclusion of legal proceedings. Court or official rulings or settlements that we consider as "highly improbable" to "more likely than not" could lead to expenses with a significant to critical impact on our business and earnings. Despite extensive precautionary measures, non-compliance with laws and regulations leading to related consequences can never be completely excluded. In our opinion, the lawsuits described below constitute the most significant legal risks. This should not be seen as an exhaustive list of all legal disputes currently ongoing.

Risks in connection with a settlement agreement concluded by the divested Generics group

Citalopram: In connection with the generics business that was divested in 2007, the Group was accused of breaching EU antitrust law through agreements entered into by its former subsidiary Generics (UK) Ltd., United Kingdom, relating to the antidepressant Citalopram patented by Lundbeck A/S, Denmark. The European Commission imposed a fine in June 2013. Appeals against the decision were unsuccessful. Following the payment of the fine of around € 18 million, British health authorities brought legal claims for damages against the Group and other companies in a mid-triple-digit million-euro amount in fiscal 2023 due to alleged infringements of competition law. In addition, there were further claimants from various other jurisdictions who have not yet quantified their claims. In response to the latest developments in the proceedings, the provision was adjusted as of December 31, 2023, and is now recognized in a high single-digit million-euro amount. A cash outflow within the next twelve months is considered possible.

Product liability risks

Operating in the chemical and pharmaceutical industries, we are exposed to product liability risks. Product liability risks can lead to considerable claims for damages, costs to avert damages, and potentially loss of reputation. In view of this, we have taken out standard liability insurance to mitigate such risks. However, it could be that the insurance coverage available is insufficient for individual cases. Although the occurrence of product liability claims in excess of the existing insurance coverage is considered improbable, individual cases could still have a critical effect.

Human resources risks

Our future growth is highly dependent on our innovative strength. Therefore, the expertise and engagement of employees in all business sectors in which we operate are crucial to our success. The markets relevant to the company are characterized by intense competition to recruit qualified specialists and talents, and by the challenge of being perceived by the public as an attractive employer. Fluctuation risks specific to countries and industries have to be identified ahead of time and specifically addressed in order to keep the skills and expertise critical to success and business within the company.

Recruiting as well as retaining specialists and talent are therefore key priorities for the company and are managed through the targeted use of, for instance, employer branding initiatives, global talent, and succession management processes as well as competitive compensation packages. Nevertheless, employee-related risks that affect business activities are possible; even though their impact is difficult to assess we evaluated a potential impact on the qualitative rating scale as moderate.

Information technology risks

We use a variety of IT systems and processes to optimally support our globalization. Trends in information technology offer various opportunities but also harbor risks.

Risks due to cybercrime and the failure of business-critical applications

Increasing international networking and the related possibility of IT system abuse are resulting in cybercrime risks for us, such as the failure of central IT systems, the loss of the data integrity or the disclosure of confidential data from R&D as well as business activities, the manipulation of IT systems in process control, or an increased burden or adverse impact on IT systems as a result of virus attacks.

We maintain and operate an information protection management system based on ISO 27001. Our governance framework contains organizational, process-related, and technical information security countermeasures based on recognized international standards. In addition, we employ harmonized electronic and physical security controls (e.g. access control and security monitoring) to bolster our ability to handle sensitive data, such as trade secrets.

Cyber Security is part of our Group Corporate Security Office. In addition, we have a Group Chief Information Security Officer and a network of Information Security Officers within the business sectors, each supported by dedicated networks. The individual sectors hold risk ownership and act as our first line of cyber security defense. Our Global Cyber Security function acts as a second line of defense and has responsibilities regarding cyber security risk governance and oversight. Our third line of defense consists of internal audits.

Globally used IT applications form the basis for the contractual delivery of products and solutions. The failure of business-critical IT applications could therefore have a direct influence on our ability to deliver and on the quality of our products. This also applies to the failure of a data center. To achieve the required service quality, we use a quality management system certified to ISO 9001 that also applies to the provision of IT. In addition, to reduce the risk of failure, we operate several redundantly designed data centers. Furthermore, insurance solutions for cybercrime offenses are in place at Group level.

Likewise, complications with the changeover of IT systems could negatively impact the earnings situation. Close monitoring of critical IT projects serves to mitigate this risk.

Despite the mitigation measures applied and functional continuity plans, the effects of cybercrime or the failure of business-critical IT applications and their influence on EBITDA pre and operating cash flow are considered to be possible and with a significant impact.

Environmental, climate-related, and safety risks

Risks arising from environment, climate as well as plant and equipment

As a company with global production operations, we are exposed to risks of possible damage to personnel, goods and our reputation. These include physical risks stemming from exposure to droughts, storms, and floods. Mitigation measures such as audits, consultations and trainings on environmental protection, occupational health and safety minimize these risks to people as well as the environment. In order to ensure the continuity of plant and equipment, we monitor these risks both at our own sites as well as at suppliers and contract manufacturers. By adhering to high technical standards, our rules of conduct, and all legal requirements in environmental protection as well as occupational health and safety, we ensure the preservation of goods and assets.

We have taken sufficient appropriate accounting measures for the environmental risks known to us. We monitor regulatory risks in connection with the transition to a low-carbon economy, which could materialize in the mid- and long-term through rising carbon prices through emissions trading systems, taxes or energy legislation. We mitigate those risks with our energy and CO_2 management measures. Mainly, we classify these as possible risks with moderate impacts. However, a critical impact on EBITDA pre or operating cash flow cannot fully be ruled out.

Risks due to climate change

In 2022, we performed a qualitative climate risk and vulnerability assessment to identify transitional and physical climate-related risks that are material to our activities. In 2023, in accordance with TCFD recommendations, we conducted a quantitative climate scenario analysis to identify climate-related risks and opportunities. Consequently, we conducted an evaluation in relation to impacts of transition risks and the exposure related to physical hazards.

During this assessment, we utilized two climate pathways (1.5°C and 4°C) considering different time horizons (2030 and 2050) to identify climate-related risks and opportunities. Based on our findings, we determined the potential effects of physical risks on our key sites and evaluated the impact of transitional risks on our business.

In line with our ongoing dedication to risk mitigation, we continuously develop innovative and sustainable approaches. As a result, we foresee no significant deviations from our expectations regarding impacts on EBITDA pre or operating cash flow.

For further details on climate-related risks, please see “**Increased uncertainty due to climate risks**” in the “**Notes to the Consolidated Financial Statements**”.

Overall view of the risk and opportunity situation and management assessment

The most significant individual risks or risk clusters have been outlined in this report, with business- and market-related risks being the most significant alongside IT and legal risks. Of particular significance are the still ongoing global macroeconomic and geopolitical developments, increasing existing risks related to more restrictive regulatory requirements regarding drug pricing and reimbursement, the demand for our products, business interruptions at our production sites, lack of availability of good quality materials or services, and risks related to R&D.

By implementing risk mitigation measures such as continually improving management actions (organizational responsibilities and process improvements), utilizing existing insurance coverage, and taking accounting precautions, we have successfully taken counteraction, particularly against significant individual risks.

The overall risk of the Group, which is derived from the probability-weighted aggregation of the identified risks, leads to the assessment that an existence-threatening risk-scenario, for which coverage and financing of the losses are questionable, is improbable. We are convinced that we will also successfully manage the aforementioned challenges in the future and benefit from diversification through our different products and markets.

Based on our assessment, we believe that the most promising opportunities arise from business-related opportunities. The activities described hold significant opportunities for us in the medium to long term, beyond the forecast period. We actively pursue the opportunities that arise and specify their expected effects in the forecast development of EBITDA pre and operating cash flow. Additionally, we proactively seek out new opportunities, assess their feasibility, and drive them forward where appropriate. If opportunities arise in addition to the forecast developments, or these occur more quickly than anticipated, this could have positive effects on our EBITDA pre or operating cash flow.