

# Report on Risks and Opportunities

As a global science and technology company, identifying risks and opportunities is an intrinsic part of making our business sectors 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 and the financial impact (EBITDA pre/free cash flow) or non-financial impact (e.g. on reputation or environmental, social and governance (ESG) aspects, among other factors).

Opportunities imply favorable deviations from our 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 [Sustainability 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, referred to as 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 functions and local management) 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 the design and implementation of methods and procedures for risk management and the internal control system (financial and non-financial) as well as their 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

The objective of the internal control system for the financial reporting 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, Annual Financial Statements of the Merck KGaA, Darmstadt, Germany, 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, and monitoring activities. Each of these components is regularly documented, reviewed 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 Reporting function centrally steers and monitors the preparation and requirements of the Consolidated Financial Statements of Merck KGaA, Darmstadt, Germany, as the parent company of the Group. This consolidation process ensures the proper elimination of intragroup transactions. Group-wide accounting guidelines defined by Group Reporting form the basis for the preparation of the financial statements. In accordance with the IFRS Accounting Standards, the guidelines are adapted in a timely manner to reflect changes in the financial regulatory environment and are updated to reflect 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 Global Enterprise Solutions, the internal control system of Global Enterprise Solutions is additionally applied. Both ensure that accounting complies with IFRS Accounting Standards and the Group accounting guidelines.

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

For Group financial reporting purposes, most of our subsidiaries use standard SAP software. SAP software is also used to prepare the Consolidated Financial Statements. 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 financial internal control system is regularly tested by our legal entities and enabling functions within the scope of self-assessments. The quality is systematically reviewed by a dedicated enabling function for internal controls and governance. Control deficiencies are properly recorded and, where necessary, adequate countermeasures are taken to remediate them in a timely manner.

In the context of constantly evolving external and internal requirements for the management of non-financial risks, we continued to develop and implement procedural and organizational measures for non-financial risk management. The non-financial risk assessment was further refined in fiscal 2025 as part of the overarching risk management approach.

The non-financial internal control system aligns with the sustainability strategy and is set up in accordance with the requirements of the Corporate Sustainability Reporting Directive (CSRD). The goal is to continuously prepare for and ensure regulatory compliance, pursuant to existing and upcoming regulatory requirements, by implementing organization-wide measures and controls.

The overall effectiveness of our internal control system with regard to accounting and the compliance of the relevant individual companies' financial reporting 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 control system. For the accounting treatment of balance sheet items, Group Reporting closely cooperates with Risk Management to reflect potential risks correctly in the balance sheet.

All the structures and processes described in the foregoing relate to the Group Reporting 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 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.

## **Risk and opportunity management**

Group 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 company 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 the subsidiaries and heads of Group functions, are responsible for overseeing and running risk management processes. These processes encompass various requirements, such as identifying risks while 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, as well as documenting risks and mitigation efforts.

The risk owners continuously assess the status of risks and report their risk portfolio to Group Risk Management twice per 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 various probabilities. Risks below the global reporting threshold are managed and monitored at a local level. The time frame applied for internal risk and opportunity reporting is five years. In 2025, the time frame was extended to 2030 in order to align with the financial planning process. It may be extended further 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, 2025. 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 per 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 business units. As part of the strategy and planning processes, the business sectors analyze and evaluate potential 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 and/or free cash flow are taken into consideration. These opportunities have the potential to have a positive effect on our medium-term prospects.

## Overall evaluation

The aim of our internal control system is to prevent and reduce potential risks and to actively steer existing risks in business processes. In this way, it helps ensure that the company's activities comply with laws and regulations. The entire internal control system and the methods applied are refined continuously. The respective senior leaders or risk and process owners are responsible for the effectiveness of the internal control system of the accounting processes and the further development of the non-financial key metrics.

Relevant aspects for evaluating the overall effectiveness of the internal control system and risk management were conducted as a single confirmation process in 2025. This process included respective confirmations by the enabling functions, the local Managing Director, the local Chief Financial Officer, and the business functions. The results of this assessment were presented to the Executive Board, taking the recommended opportunities for improvement into consideration where applicable.

The non-financial internal control system was further enhanced and its maturity increased. Based on risk-based assessments of the financial and non-financial internal control system, compliance and risk management, stakeholder confirmations, and regular general audits by Internal Auditing, as of December 31, 2025, the Executive Board was not aware of any material issues that would indicate that this system is not appropriate or effective.

## 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. This evaluation focuses on the most likely risk scenarios.

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 free cash flow
€ 100 – < 500 million	Significant negative impact on EBITDA pre and/or free cash flow
€ 25 – < 100 million	Moderate negative impact on EBITDA pre and/or free cash flow
€ 10 – < 25 million	Minor negative impact on EBITDA pre and/or free cash flow
< € 10 million	Immaterial negative impact on EBITDA pre and/or free 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 used scale includes dimensions such as ESG, reputational, strategic, and/or operational aspects and is mandatory for the assessment of non-quantifiable and qualitative risks. The scale categorizes the risks' impact as minor, moderate, significant, or critical and provides a comprehensive reference for assessment.

Opportunities are assessed within their respective business environment. General measures of business functions are quantified during short-term and strategic planning, typically in relation to EBITDA pre (earnings before interest, taxes, depreciation, and amortization) and free 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, and the payback period of the investment. These indicators are used to assess the potential of investment projects and to prioritize them accordingly. Similarly, scenarios are used to simulate the impact of potential fluctuations and changes in the respective parameters on results.

## Business-related risks and opportunities

### Political and regulatory risks and opportunities

As a global company, 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. In the field of healthcare, for example, the known trend toward increasingly restrictive requirements in terms of drug pricing, reimbursement and the expansion of rebate groups is continuing. With rising healthcare expenditures worldwide, both in absolute amounts and relative to GDP, healthcare budgets around the world face increasing pressure. These developments 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 Healthcare 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 improbable to likely with up to a significant impact. Additionally, an event with minor impact is more likely than not to occur. While we consider the possibility of price cuts in our forecasts, there is also an opportunity in the event 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 adhere to a multitude of regulatory requirements regarding the manufacturing, testing and marketing of our products. In the European Union specifically, we are subject to the EU chemicals regulation REACH. Other regulations are also emerging globally in relevant markets, especially in Asia. 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 such as the substitution of specific hazardous substances or comprehensive testing for chemicals. We are constantly pursuing research and development (R&D) in substance characterization and the possible substitution of substances of concern to mitigate this risk. Further regulatory requirements could potentially lead to additional efforts and/or costs. Nevertheless, risks of stricter regulations are classified as improbable to likely with minor to moderate impacts.

#### **Risk of negative political and macroeconomic developments**

Throughout 2025, we have operated in an environment shaped by increased geopolitical fragmentation, shifts in global power dynamics and evolving regulatory priorities across major economies such as the United States, the European Union, China, and a range of emerging markets including India, Brazil and the wider BRICS group. Each region is advancing its own industrial and economic policies, resulting in new patterns of trade, investment and regulatory oversight that directly affect our operations.

Military conflict and regional instability remain significant factors. The ongoing war between Russia and Ukraine continues to influence energy markets and supply chains in Europe. In the Middle East, persistent conflicts present ongoing risks for trade flows and operational stability. In Asia, heightened tensions in the Taiwan Strait and the South China Sea, combined with evolving U.S.-China relations, present further uncertainties for technology and manufacturing networks critical to our business.

At the same time, the regulatory environment is evolving. The expansion of U.S., EU and Chinese export controls, particularly on advanced semiconductors, biotechnology and dual-use goods, has introduced additional compliance complexity and procurement risks. New and overlapping data privacy laws – such as the EU AI Act, U.S. executive orders and China’s cross-border data requirements – require careful management of information and technology flows. Chemical regulation, including the EU’s PFAS (per- and polyfluoroalkyl substances) restriction initiative and diverse state-level regulations in the United States, has implications for product pipelines and supply continuity, especially in the healthcare and life science sectors.

Governments in core markets are reviewing their healthcare budgets, tax regimes and public procurement policies, which increases volatility in demand, pricing and margin expectations. Investment screening is becoming more stringent in the United States, the EU, China, and India, especially for biotech and advanced technology sectors, resulting in longer lead times and additional requirements for cross-border transactions.

Talent acquisition and mobility are also affected. Global shortages of scientific and technical talent, combined with tighter immigration regulations and changing workforce policies, continue to influence recruitment costs, project timelines and compliance exposure.

Economic nationalism and the drive for greater supply chain localization are reshaping procurement strategies across the industry. Domestic content mandates, industrial subsidies and the emphasis on regional production are contributing to higher input costs and greater planning complexity for our global operations. In addition, the risk landscape now includes hybrid threats, such as disinformation campaigns and cyber intrusions, which require ongoing monitoring and rapid response to maintain business continuity and stakeholder trust.

Our response to this risk landscape is rooted in regional diversification, supply chain resilience and proactive risk management. We are expanding our dual sourcing strategies, strengthening strategic inventories and maintaining close engagement with regulatory authorities and industry associations. Compliance processes are being automated and regularly reviewed, and scenario planning is used to anticipate and adapt to evolving developments across military, regulatory, economic, and reputational domains.

Extreme escalation scenarios are not part of current baseline planning. However, we continue to strengthen our resilience and compliance measures to mitigate potential disruptions and to adapt to the changing geopolitical and macroeconomic environment.

The net risks of negative geopolitical and macroeconomic developments are considered possible to likely and could have minor to significant effects. However, our assumptions on geopolitical developments exclude scenarios with severe escalation of tension. The materialization of such scenarios would jeopardize entire industries and the balance of political 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

### Risks and opportunities in the life science industry

The Science & Lab Solutions business unit serves customers across the pharmaceutical and biotechnology industries, government agencies, scientific institutions, and other industries. We provide them with access to a broad portfolio that includes reagents, consumables, equipment, instruments, software, and services for research, production, and testing. Despite a complex macroeconomic environment and cautious spending among some customer segments, the business unit remains well-positioned to deliver long-term, profitable growth. We aim to provide customers with a streamlined, end-to-end experience and a comprehensive portfolio that supports their research and analytical workflows.

In 2025, we expanded our innovation capabilities and strategic partnerships to better serve evolving scientific needs. The acquisition of Hub Organoids Holding B.V., Netherlands (Hub Organoids), strengthens our position in next-generation biology by advancing access to organoid-based technologies for drug discovery and toxicology research. Our collaboration with Opentrons Labworks, Inc., USA, and the launch of the Advanced Automation Workstation (AAW) demonstrate our commitment to accessible laboratory automation and digitalized workflows. Additionally, our global distribution and collaboration agreement with Rapid Micro Biosystems, Inc., USA, expands our offering in rapid microbiological testing, enhancing quality assurance capabilities for pharmaceutical and biotech customers. For emerging biotechnology companies, the pace and scale of a sustained recovery in funding will influence R&D investment levels, presenting both opportunities for growth and risks related to market timing.

The Process Solutions business unit offers its comprehensive bioprocessing portfolio to biotechnology and pharmaceutical customers that develop and manufacture both traditional and novel therapies, including filtration devices, chromatography resins, single-use assemblies and systems, and excipients. Despite signs of market recovery, excess market capacities persist across the industry and could lead to increased competition with potential price impacts. Additionally, the trend toward multi-sourcing strategies among customers continues to shape the competitive landscape. To address and mitigate these impacts, we have strategically positioned ourselves to capture opportunities arising from the industry's shift toward biologics and the growing demand for bioproduction capacity driven by an expanding pipeline of drug candidates and regulatory approvals. Our expected acquisition of the chromatography business of JSR Corporation, Japan (JSR), and the expansion of our new filtration manufacturing facility in Blarney, Ireland, strengthen our global network, enhance our supply resilience and expand our production capacity in crucial technologies. Through our multi-year regionalization and smart pricing strategies, we are balancing volume growth with margin protection while improving proximity to our customers. Together, these initiatives reinforce our ability to meet evolving market needs and sustainably support the future 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 ongoing innovation in single-use technologies and bioproduction. We also see continued growth potential in high-innovation areas, such as novel modalities, as well as emerging technologies that define the "facility of the future". While the acceleration of pharmaceutical development could result in faster market expansion than expected, a slowdown in R&D activity may temper near-term market development. In 2025, research spending by pharma and biotech companies was lower than historical averages due to capital constraints and portfolio reprioritizations. Growth in demand is expected to normalize as funding levels stabilize, underpinned by a robust and diverse pipeline of therapies in development.

Continued pricing pressure reflects market overcapacity, rising competition and evolving customer procurement practices. Inflation uncertainty and policy measures in key markets, including China and the United States, add to this environment. We are mitigating these effects through disciplined pricing strategies and ongoing cost reduction initiatives to sustain profitable growth.

Our Life Science Services business unit fully integrates testing services in addition to its services as a contract development and manufacturing organization to support customers across all stages of drug development, from preclinical to commercialization. We enable customers to advance complex therapies for patients worldwide both efficiently and reliably. While continued pressure on biotech funding presents near-term uncertainty, we mitigate this risk through a diversified client portfolio, operational excellence and ongoing investments in specialized capabilities and quality systems that strengthen our position in a dynamic and growing market. Opportunities also arise from our strong U.S. footprint, which enables pharmaceutical companies to access our domestic manufacturing and testing capacity quickly, without the need for lengthy new investments amid a shifting geopolitical landscape.

The market risks for the Life Science business sector are assessed as possible to likely with minor to moderate impact.

Further details on the industry, market developments and associated risks 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 differentiated, complementary technologies. This enables us to supply products for every key step in wafer processing, helping our customers to achieve their technology roadmaps. With the acquisition of Unity-SC SAS, France (Unity-SC), we are expanding our portfolio beyond front-end offerings and now also actively participate in high-end packaging.

The semiconductor industry remains cyclical and the positive recovery in 2025 has been uneven across individual segments. The growth experienced so far has been driven primarily by artificial intelligence (AI), data centers and high-bandwidth memory. At the same time, mature, replacement-led end markets such as PCs and smartphones, as well as demand outside AI in broader server and automotive applications, remained modest. The multilayered macroeconomic effects and lack of full transparency throughout the global supply chain cause a certain degree of uncertainty when estimating the future trajectory of the semiconductor industry. This uncertainty is reinforced by the current dynamic around the trade conflict between the United States and China, as well as tensions in the Taiwan Strait and potential price pressure from Chinese competitors. External and internal assumptions on the shape of the industry recovery and the future escalation of the trade conflict (e.g. further trade restrictions and tariffs) can deviate either positively or negatively. Such deviations present both an inherent opportunity and a risk to our base plan.

Irrespective of the current macroeconomic situation, the positive medium- and long-term growth prospects of our markets remain unchanged. Structural growth is supported by the increasing adoption of AI and the resulting demand for computing performance, which is driving higher materials intensity – particularly in advanced logic and memory devices.

We are also investing in our highly attractive growth markets and selectively expanding production capacities, thus strategically localizing our footprint to further boost customer proximity and strengthen supply resilience. Having the right capacity in the right locations enables us to deliver new products and required volumes efficiently, serving as a key competitive advantage.

The market risks for our Semiconductor Solutions business unit are assessed as possible to likely with up to significant impact.

## **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, 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 respective assumptions. 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 to what 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 not only by cyclical business fluctuations but also changes in the technologies used or customer sourcing strategies. As mitigating measures, we use close customer relationships and internal development capabilities as well as proximity to the market, including precise market analyses.

The risks due to increased competition and customer technology changes are assessed as being possible to more likely than not with up to a significant impact.

Further details on the industry and market development can be found under [Macroeconomic and Sector-Specific Environment](#).

## **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 balancing 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. In general, however, forecasting the exact number of transactions per year is challenging and, furthermore, 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 of regulatory authorities not granting approval, delaying approval or granting 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. Failure to meet targets in this area could have significant effects due to lower net sales or the non-occurrence of milestone payments from collaboration agreements, for example.

In Electronics, we will continue to invest in R&D with a strong focus on 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 emerging throughout our Semiconductor Solutions business unit, and we work closely with our customers to exploit these. Technology inflection points bring new opportunities to our material solutions and the chance to differentiate ourselves.

The pace of innovation in the semiconductor industry remains high, with system design, high-performance packaging and front-end chip manufacturing all increasing in importance. Demand for advancements in 3D advanced packaging, metrology and process control is accelerating. The acquisition of Unity-SC positions us to capture these innovation shifts and respond effectively to changing market needs.

Beyond semiconductor materials, we see opportunities in display devices, especially augmented reality applications, which require a broad set of new materials. The increasing convergence of optical and semiconductor technologies enables us to leverage existing competencies in these fields and benefit from growing demand.

The risks of research and development are evaluated with probabilities ranging from possible to more likely than not with a moderate to significant impact. 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.

In fiscal 2025, we strengthened our Life Science business through several strategic expansions and acquisitions that enhance our production capabilities, supply resilience and innovation potential – and we will continue to do so. These include the expected acquisition of the chromatography business of JSR, which will broaden our purification offering and strengthen our downstream processing portfolio, the expansion of our filtration manufacturing facility in Blarney, Ireland, which increases production capacity for critical bioprocessing products, and the acquisition of Hub Organoids, which advances our expertise in next-generation biology and organoid-based technologies. For our Electronics business sector, we also invested in the new precursor R&D site in Sheboygan, Wisconsin, USA, and new manufacturing capacities in Jade Park, Taiwan.

Having the right capacity in the right place secures a more reliable and effective supply chain and helps meet growing customer demand in key markets. These initiatives create opportunities to strengthen our competitive position, while also requiring careful management of utilization, integration and evolving market dynamics. We therefore review our expansion and investment plans regularly to ensure alignment with long-term growth objectives and industry needs.

### **Risks arising from project execution**

In today's dynamic business environment, we prioritize innovation and growth. Projects are essential for achieving our strategic objectives, including driving innovation, expansion and promoting sustainable development. To effectively support further business growth and enhance efficiency, we continuously invest in production facilities and equipment, IT systems, distribution centers, office buildings, and other projects. However, project execution involves significant capital expenditures, making effective project management critical to avoid delays and higher costs. 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, delaying or deferring investments poses a risk of missing out on market opportunities and development. 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 economic sectors such as the semiconductor industry, where market cycles present substantial risks. Overall, the risks are possible to likely and could have a moderate impact.

To proactively address project execution risks, we apply well-established project planning, effective oversight and internal control practices, while collaborating closely with stakeholders and conducting 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.

### **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 or production facilities and potentially affect new registrations with the respective authority. We make the utmost effort to ensure compliance with regulations by regularly performing our own internal audits and carrying out external inspections. Due to these quality assurance processes, the occurrence of a risk with a moderate impact is highly improbable to possible.

### **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 loss of capacity. We work toward the continual mitigation of such risks by making regular investments, setting up alternative sourcing options and maintaining sufficient inventory levels.

The occurrence of these risks with up to significant impact is considered improbable to likely, while a highly improbable individual extreme event could have up to a critical negative effect and a more likely than not event could have a moderate impact.

### **Supply chain integrity**

In 2025, we successfully navigated a complex landscape of challenges, including ongoing geopolitical tensions, supply chain disruptions due to natural disasters, and evolving regulatory environments. Our commitment to building resilient supply chains has been pivotal in ensuring uninterrupted service across all business sectors.

In Life Science, our supply resilience activities have enabled us to monitor several potential impact events closely, ensuring that we remain responsive to challenges rooted in geopolitical factors and regulatory changes. Our proactive engagement with suppliers has been crucial in maintaining service continuity and adapting to evolving circumstances.

In the Healthcare business sector, we effectively managed the supply of our medicines, ensuring that patients have access to essential therapies. Through proactive measures such as diversifying sourcing options and maintaining close relationships with suppliers, we fortified our supply reliability.

In Electronics, we avoided major disruptions due to our strong supplier relationships and ongoing efforts to enhance resilience. Our focus on diversifying sourcing and strengthening partnerships has positioned us to navigate these challenges effectively.

We acknowledge that certain vulnerabilities persist and are therefore committed to investing in our supply chain resilience across all business sectors. Overall, the improbable to likely risks could have a minor to significant impact.

### **Risks due to product-related crime**

As a leading global science and technology company and manufacturer of innovative products, we face various security and crime-related risks due to the complexities of international trade and global supply chains. Our products are vulnerable to counterfeiting, theft, illegal diversion, and misuse. If unaddressed, these risks could lead to financial loss, reputational damage and business disruption and could even compromise patient safety. To mitigate these threats, we have implemented technical, operational and procedural measures to protect our product integrity and supply chains while ensuring that emerging threats are managed effectively.

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 for increasing awareness of our brand, among other things. We take all necessary precautions and have implemented processes to ensure awareness of the proper handling of social media as well as actively managing and controlling our publications and communication.

Nevertheless, reputational risks could result from public dialogues on social media, for example. On the qualitative rating scale, we thus rate this possible risk with up to critical impact.

## 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 include liquidity and counterparty risks, financial market risks and opportunities, 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 segregation of functions between trading, settlement and control 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 2029, 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 at our disposal. The occurrence of liquidity risk is assessed as highly improbable and with only immaterial impact.

### 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 as well as receivables in operating business on the other hand.

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 loan facility of € 2.5 billion was syndicated among 15 banks – 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 implemented, as appropriate. Nevertheless, defaults by isolated trading partners, even those with outstanding credit ratings, cannot be entirely ruled out.

Minor counterparty risks are classified as unlikely to likely and could have minor to moderate effects.

### Financial market risks and opportunities

As a result of our international business activities, 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 expenses in foreign currency. We use derivatives to manage 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 likely with a significant effect on EBITDA pre and free 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 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 possible qualitative risk could 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, such as the interest rate or future salary increases. Pension obligations are 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 by using a diversified investment strategy on the other hand. The possible risk due to pension obligations could have minor effects.

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

The successful acquisition and integration of new businesses inherently involve risks, due primarily to the uncertainty of meeting business objectives and synergy targets as well as adhering to the planned integration budget (e.g. the integration of SpringWorks Therapeutics, Inc., USA, with its highly innovative product pipeline for the treatment of rare diseases). Conversely, divestments (e.g. the Surface Solutions business unit) may result in liabilities and additional expenses arising from potential indemnifications and commitments assumed in the sale transaction or from separation costs exceeding expectations. We mitigate transaction-related risks by leveraging our robust track record, conducting rigorous due diligence and employing representations and warranties insurance in our merger and acquisition transactions. Furthermore, we ensure seamless integration through strategic planning and execution, facilitating the alignment of the acquired entities with our organizational goals. At present, only moderate negative impacts are likely.

## 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 us. 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 has issued 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



## Tax risks

Merck KGaA, Darmstadt, Germany, 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 as well as case laws and interpretations by national tax authorities and from significant transactions such as acquisitions, divestments and reorganizations.

Findings of the national tax 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, tax liabilities and deferred tax assets and liabilities.

Our Group 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 a 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

Our Legal, Compliance and Data Privacy team plays a crucial role in safeguarding our business integrity and ensuring adherence to legal standards. We are committed to fostering a culture of compliance and risk awareness across the organization. By aligning our strategies with our overarching goals, we empower our teams to make informed decisions while navigating the complexities of the regulatory landscape. Our proactive approach not only helps mitigate potential legal risks but also supports our mission to drive innovation and deliver value to our stakeholders.

We strive to minimize and control our legal risks by taking the necessary precautions to identify threats and defend our rights where necessary. However, we remain exposed to risks from litigation and legal proceedings, particularly in such areas as product liability, competition and antitrust law, pharmaceutical law, patent law, trademark law, insider law, data protection law and tax law, as well as environmental protection.

As a research-based company, we possess a valuable portfolio of industrial property rights, patents and trademarks that may be vulnerable to infringements. The outcome of current or future proceedings is difficult to predict. For example, we are currently involved in litigation with Merck & Co. Inc., Rahway, New Jersey, USA (known as MSD outside the United States and Canada), with lawsuits filed in various countries. This company has also initiated a trademark infringement lawsuit against us in the United States.

Due to long statutes of limitations, or their absence in some cases, we cannot rule out facing third-party claims related to the same issue even after legal proceedings have concluded. Court or official rulings or settlements deemed unlikely to possible could result in moderate to significant expenses impacting our business and earnings. Despite extensive precautionary measures, the risk of non-compliance with laws and regulations and the consequences thereof can never be completely excluded.

## Product liability risks

We face product liability risks that can lead to substantial claims for damages and defense costs. To mitigate these risks, we have obtained liability insurance. However, it is possible that the insurance coverage may be insufficient in certain cases. Although the instances of product liability claims exceeding existing insurance coverage are deemed highly improbable to improbable, individual cases could still have a critical impact on our operations.

## Human resources risks

The company's future growth relies significantly on its innovative strength, making employee expertise and engagement essential for its success in all business sectors. The market for qualified specialists and talented young staff is characterized by fierce competition, while the company is also faced with the challenge of being viewed as an attractive employer. To retain critical skills and expertise, it is important to proactively identify and address country- and industry-specific fluctuation risks.

We prioritize recruiting and retaining specialists and talent through strategies such as employer branding initiatives, global talent management, succession planning, and competitive compensation packages. However, there are potential employee-related risks that could affect business activities, which are assessed as possible with a moderate impact on a qualitative rating scale.

## 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 IT applications

Increasing international networking and the related possibility of IT system abuse are resulting in cybercrime risks for us. Such risks include the failure of central IT systems, the loss of data integrity or the disclosure of confidential data from R&D or business activities, the manipulation of IT systems in process control, and 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.

Cybersecurity is part of our 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 cybersecurity defense. Our Corporate Cybersecurity function acts as a second line of defense and has responsibilities regarding cybersecurity 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 in accordance with 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.

The risks of cybercrime or the failure of business-critical IT applications and their influence on EBITDA pre and free cash flow are considered to be improbable to likely and with a moderate impact, while highly improbable events could lead to significant or critical impacts.

### Artificial intelligence risks

We increasingly use artificial intelligence (AI) – including generative AI and machine learning – across our Life Science, Healthcare and Electronics business sectors and the Group functions to streamline operations, accelerate R&D and improve decision-making. As we embrace innovation, we recognize that new technologies come with risks and uncertainties. We proactively manage associated risks through secure-by-design enablement (e.g. our myGPT generative AI companion), clearly defined ethical guardrails (our Group Code of Digital Ethics and the independent Digital Ethics Advisory Panel), robust data and AI quality, governance and security controls, and broad upskilling via our Group Data & Digital Academy.

Nevertheless, potential AI-related risks remain. These include model and data quality issues, bias and limited explainability, evolving regulation across various jurisdictions (e.g. the EU AI Act), and cyber security threats. If not appropriately managed, these could lead to operational, legal or reputational impacts or hinder effective scaling of AI. Our mitigation measures are designed to reduce these risks while enabling responsible adoption of AI in our business processes and product offerings. While residual risks remain, we continue to refine our controls and practices as the technology and regulatory landscape evolve. Failure to successfully adopt these

technologies into our business processes and product offerings or the inability to scale AI effectively could result in competitive disadvantages.

Based on current risk exposure and mitigations, we assess the probability on EBITDA pre and free cash flow as highly improbable; however, should risk materialize, the potential impact could be significant. We therefore maintain disciplined monitoring, regularly reviewing our AI risk and adopting a roadmap to ensure responsible scaling consistent with our vision: “Sparking Discovery, Elevating Humanity”.

## Environmental, climate-related and safety risks

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 from droughts, storms, floods, extreme heat, and wind. Mitigation measures such as audits, consultations and training on environmental protection and occupational health and safety minimize these risks to people and the environment. We monitor these risks at our sites and those of our suppliers and contract manufacturers, ensuring continuity of plant and equipment. By adhering to high technical standards, our Code of Conduct, and all legal requirements in environmental protection alongside occupational health and safety, we preserve goods and assets with comprehensive insurance policies providing further financial protection.

We continuously monitor regulatory risks associated with the transition to a low-carbon economy, which could materialize, in particular, through rising carbon prices via emissions trading systems, taxes or changes in energy legislation. We aim to mitigate these risks through comprehensive strategies, including our energy and CO<sub>2</sub> management initiatives and efforts to reduce process emissions, all of which are included in the implementation of our inaugural transition plan. Mainly, we classify these as possible to likely risks with moderate impacts. However, highly improbable cases with a significant or critical impact on EBITDA pre or free cash flow cannot be fully ruled out.

Climate resilience analysis is a vital tool for identifying and evaluating the risks and opportunities that climate change presents to our business. In 2022, we conducted a qualitative assessment of climate risks and vulnerabilities across our upstream and downstream activities and our own operations. Building on this foundation, we aligned our efforts with the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD) by undertaking quantitative climate scenario analyses, specifically focusing on upstream activities and our own operations, while excluding downstream activities. This assessment identified climate-related risks and opportunities across three potential climate pathways: a 1.5°C Paris Agreement-aligned scenario, a 2.7°C current trajectory scenario and a 4.0°C fossil-fueled development scenario, using a 2050 time horizon. All three scenarios are based on those created by the Intergovernmental Panel on Climate Change (IPCC). Our analysis encompasses both transition and physical risks and opportunities related to our business activities.

In line with our commitment to risk mitigation, we continue to develop innovative and sustainable approaches, foreseeing no relevant short-term deviations from our expectations regarding impacts on EBITDA pre or free cash flow.

For further details on climate-related risks, please see our [Climate Resilience Analysis](#).

## 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, supply chain 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 high-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 countermeasures against significant individual risks in particular.

The overall risk of the Group, which is derived from the aggregation of the identified risks applying a Monte Carlo simulation, 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 are business-related. 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 free cash flow. Additionally, we proactively seek out new opportunities, assess their feasibility and pursue them 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 and/or our free cash flow.