Report on Risks and Opportunities

Risks and opportunities are inherent to entrepreneurial activity. We have put systems and processes in place to identify risks at an early stage and counteract them by taking appropriate action. Within the company, opportunity management is an integral component of our internal decision-making processes such as short- and medium-term planning and intra-year business plans.

Risk and opportunity management

Merck is part of a complex, global business world and is therefore exposed to a multitude of external and internal influences. Every business decision is therefore based on the associated risks and opportunities.

In our internal risk reporting, risks are defined as potential future events or developments that could lead to a negative deviation from our (financial) targets. In parallel, opportunities are defined as potential events or developments that imply a positive deviation from our planned (financial and non-financial) targets. Identified future events and expected developments are taken into account in internal planning, provided that it can be assumed that their occurrence is likely in the planning period. The risks and opportunities presented in the following risk and opportunities report are those potential future events or developments that could respectively lead to a negative or positive deviation from the targets covered by planning.

Risk management process

The objective of our risk management activities is to recognize, assess, and manage risks early on and to implement appropriate measures to minimize them. The responsibilities, objectives, and processes of risk management are described in our internal risk management guidelines. The business heads, managing directors of Merck subsidiaries, and the heads of Group functions are specified as employees with responsibility for risks. The group of consolidated companies for risk reporting purposes is the same as the group of consolidated companies for the Consolidated Financial Statements. Every six months, the risk owners assess their risk status and report their risk portfolio to Risk Management. We use special risk management software in the context of these activities.

Likewise, risk-mitigating measures are reported and assessed. The effectiveness of these measures and the planned implementation time frame are monitored by Group Risk Management.

The residual risk after the implementation of these measures is presented in the internal risk report as net risk.

Group Controlling & Risk Management forms the organizational framework for risk management and reports directly to the Group Chief Financial Officer. Group Risk Management uses the information reported to determine the current risk portfolio for the Merck Group, presenting this in a report to the Executive Board, the Supervisory Board, and the Finance Committee with detailed explanations twice per year. This also encompasses a probability-weighted aggregation of risks at the Group level using a Monte Carlo simulation. Furthermore, significant changes in the assessment of the risks already known and new significant risks can be reported at any time and are communicated to the Executive Board on an ad hoc basis.

For reporting risks with a potential negative impact on our EBITDA pre, a minimum threshold is set at the level of € 5 million before mitigation measures in the standard process and € 25 million in the ad hoc process. Risks below these thresholds are steered independently within the business sectors. The relevant timeframe for internal risk reporting is five years. It can go beyond five years, e.g. for regulatory risks related to climate change. The effects of risks described in this report on risks and opportunities are presented as annual values. The assessment of the risks presented relates to December 31, 2020. There were no relevant changes after the balance sheet date that would have necessitated an amended presentation of the risk situation of the Group.

Within the scope of audits, Group Internal Auditing regularly reviews the performance of risk management processes within the units and, at the same time, the communication of relevant risks from the operating businesses to Group Risk Management.

Opportunity management process

The risk management system described concentrates on business risks, and not on opportunities at the same time. The opportunity management process is integrated into our internal controlling processes and carried out in the operating units on the basis of the Group strategy. The businesses analyze and assess potential market opportunities as part of strategy and planning processes. In this context, investment opportunities are examined and prioritized primarily in terms of their potential value proposition in order to ensure an effective allocation of resources. We specifically invest in growth markets to leverage the opportunities of dynamic development and customer proximity at a local level.

If the occurrence of the identified opportunities is rated as likely, they are incorporated into the business plans and the short-term forecasts. Trends going beyond this, or events that could lead to a positive development in the net assets, financial position, and results of operations, are presented in the following report as opportunities. These could have a positive effect on our medium-term prospects.

Risk and opportunity assessment

Risks

The significance of risks is calculated on the basis of their potential negative impact on the forecast financial targets in conjunction with the probability of occurrence of the respective risk. In line with these two factors, risks are classified as ”high”, “medium”, or “low”.

The underlying scales for measuring these factors are shown below:

Probability of success

Probability of success	Explanation
< 20%	Unlikely
20 – 50%	Possible
51 – 80%	Likely
> 80%	Very likely

Degree of Impact

Degree of impact	Explanation
> 50 million €	Critical negative impact on the net asset, financial position, and results of operations
20 – 50 million €	Substantial negative impact on the net asset, financial position, and results of operations
5 – < 20 million €	Moderate negative impact on the net asset, financial position, and results of operations
< 5 million €	Immaterial negative impact on the net asset, financial position, and results of operations

The combination of the two factors results in the risk matrix below, which shows the individual risks and their significance to the Group.

Risk matrix

Impact / Probability of occurence	< 20%	20 – 50%	51 – 80%	> 80%
> 50 million €	Medium	Medium	High	High
20 – 50 million €	Medium	Medium	Medium	High
5 – < 20 million €	Low	Medium	Medium	Medium
< 5 million €	Low	Low	Low	Low

Opportunities

Opportunities are assessed in their respective specific business environment. General measures of the business functions are quantified during operational planning, usually in relation to sales, EBITDA pre, and cash flow. Net present value, internal rate of return, the return on capital employed (ROCE), and the amortization period of the investment are primarily used to assess and prioritize investment opportunities. We use these indicators to assess the opportunities arising from the investment opportunities. Similarly, scenarios are frequently set up to simulate the influence of possible fluctuations and changes in the respective parameters on results. There is no overarching, systematic classification of the probability of occurrence and impact of opportunities.

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 conveyance and presentation of information that is relevant for the preparation of the Consolidated Financial Statements and the combined management report.

Key tools

The internal 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 as the parent company of the Merck Group. This Group function defines the reporting requirements that all Merck subsidiaries must meet. At the same time, this function steers and monitors the scheduling and process-related requirements of the Consolidated Financial Statements. Group Accounting centrally 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 statutory financial statements of the parent company and of the subsidiaries, 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 company acquisitions or pension obligations, external experts are additionally involved where necessary.

The individual companies have a local internal control system. Where financial processes are handled by a Shared Service Center, the internal control system of the Shared Service Center is additionally applied. Both ensure that accounting complies with IFRS (International Financial Reporting Standards) 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 separation 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 effectiveness of Merck's internal control system with regard to accounting and compliance with financial reporting on the part of the individual companies is confirmed by both the local managing director and the local chief financial officer by signing the single-entity reporting. For the accounting treatment of balance sheet items, Group Accounting closely cooperates with Group Risk Management in order to correctly present potential risks in the balance sheet. All the structures and processes described are subject to regular review by Group Internal Auditing based on an annual audit plan set out by the Executive Board. The results of these audits are dealt with by the Executive Board, the Supervisory Board, and the Finance Committee. The internal control system at Merck makes it possible to lower the risk of material misstatements in accounting to a minimum. However, no internal control system can entirely rule out a residual risk, whatever its design.

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

In the Healthcare business sector, the known trend toward increasingly restrictive requirements in terms of drug pricing, reimbursement, and the expansion of high-rebate groups is continuing. 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 taken into account as far as possible in the business sector's plans. Close communication with health and regulatory authorities serves as a preventive measure to avert risks.

Remaining risks beyond the current plans resulting from restrictive regulatory requirements are classified as a medium risk owing to the possible critical negative impact.

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

Likewise, in our Life Science and Performance Materials business sectors, we must adhere to a multitude of regulatory specifications regarding the manufacturing, testing, and marketing of many of our products. Specifically in the European Union, we are subject to the European chemicals regulation REACH. It demands comprehensive tests for chemical products. Moreover, the use of chemicals in production could be restricted, which would make it impossible to continue manufacturing certain products. We are constantly pursuing research and development in substance characterization and the possible substitution of critical substances so as to reduce the occurrence of this risk, and therefore view it as unlikely. Nevertheless, it is classified as a medium risk given its critical negative impact on the net assets, financial position, and results of operations.

Risk of negative political and macroeconomic developments

The destabilization of political systems, and the possible establishment of trade barriers, sanctions, and foreign exchange policy changes, can lead to declines in sales in certain countries and regions. These risks are taken into account as much as possible in the business plans of the affected countries and regions, and mitigated through product, industry, and regional diversification.

Potential negative macroeconomic developments can also impact our business. To minimize these impacts, corresponding measures pertaining to the sales strategy have been initiated in these countries.

The spread of the Corona virus since the beginning of 2020 is associated with risks in global macroeconomic developments, likewise with the potential for negative effects on our businesses. The opportunities in connection with combating the Covid-19 pandemic are described in the "Risks and opportunities of research and development" section.

The net risk of negative political and macroeconomic developments is seen as possible and has critical negative effects on the net assets, financial position, and results of operations. We thus rate this as a medium risk.

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.

Opportunities due to new technologies in the manufacturing of displays

We see major opportunities in significant market growth of organic light-emitting diode (OLED) materials in high-quality display applications. According to industry estimates, the overall market volume for OLED materials will exceed that for liquid crystal materials as of 2022. We have been performing research and development in the area of organic light-emitting diode (OLED) technology for more than 15 years and have become one of the leading material suppliers for OLEDs. We focus on the production of ultrapure, extremely stable materials that are precisely tailored to customer requirements. To this end, we acquired the OLED patent portfolio for display applications from Konica Minolta. Comprising over 700 patent families, the portfolio will allow us to further expand our market position and advance our development pipeline.

Opportunities in liquid crystal distribution

We are pursuing a strategy of leveraging our expertise as the global market leader in liquid crystals in order to develop new fields of application for innovative liquid crystal technologies. For instance, we are pressing ahead to capture the future markets for liquid crystal windows (LCWs) and mobile antennas. LCWs are creating new architectural possibilities and solar shading that can be managed while maintaining transparency and color-neutrality. In 2020, we entered into a strategic partnership with Guardian Glass, a leading international manufacturer of float, coated, and other glass products. We intend for this partnership to boost commission sales of dynamic liquid crystal windows from our eyrise® brand, which uses our Licrivision® technology. Mobile antennas can receive signals transmitted in the high frequency range. As a result, mobile data exchange could improve significantly in a wide variety of fields of application. Since novel liquid crystal materials for antennas are currently being developed, we expect liquid crystal antennas to reach market maturity in the coming years.

Opportunities in the semiconductor industry

We see huge opportunities arising from our innovative Directed Self Assembly (DSA) technique for advanced lithography processing in Semiconductor Solutions. As semiconductor manufacturers continue to advance their device technologies, the image processing steps are becoming increasingly complex and the production of high-performance products is becoming more cost intensive. Our novel DSA platform and recent material advancements enable improved wafer performance and reduce the cost of ownership (COO) for the customer. This has helped Merck to secure its leading position as the "process of record" (POR) with several key semiconductor customers. Adoption of this disruptive lithography platform is expected to completely change how semiconductor manufacturing is conducted and could lead to a market leadership position for advanced lithography over the next few years. Furthermore, we are developing new dielectric platforms in cooperation with our key customers for 3D NAND applications. There has been a change in 3D NAND device architecture and some of our customers are moving from floating gate to replacement gate technology. Therefore, we are currently working with those customers on this new device architecture.

Opportunities from leveraging the e-commerce and distribution platform

With the acquisition of Sigma-Aldrich in 2015, we gained access to the leading e-commerce platform in life science, **www.sigmaaldrich.com**. With this distribution platform, our customers continue to benefit from a portfolio of more than 300,000 products, including highly respected brands. We are further expanding this platform to continuously increase the number of products available through e-commerce. Increasing speed and convenience during our customers' ordering processes as well as offering support through individualized product recommendations can lead to higher sales volumes and the winning of new customers. Consequently, this distribution channel can lead to an above-average development of sales in the medium term.

Risks and opportunities of research and development

For us, innovation is a major element of the Group strategy. Research and development projects can experience delays, expected budgets can be exceeded, or targets can remain unmet. Research and development activities are of special importance to the Healthcare business sector. In the course of portfolio management, we regularly evaluate and, if necessary, refocus research areas and all R&D pipeline projects. Alliances with external partners and the out-licensing of programs also form part of the catalog of measures for the efficient allocation of resources. The conclusion and continuation of these partnerships and externalizations plays an important role. A deviation from the strategic targets defined in this area could have a critical negative impact on net assets, financial position, and results of operations. The occurrence of a risk of this magnitude is considered unlikely, which means that this is a medium risk.

The global strategic alliance with GlaxoSmithKline plc., United Kingdom, (GSK) for the joint development and marketing of the bintrafusp alfa (M7824) immunotherapy developed by Merck is one example of an opportunity for research and development in the Healthcare business sector. This year, the Japanese Ministry of Health, Labor and Welfare granted fast-track status to bintrafusp alfa as a potential treatment for biliary tract cancer (BTC) as part of its SAKIGAKE strategy. In addition, we are currently exploring bintrafusp alfa in multiple non-correlated clinical studies. This innovative immunotherapy shows potential for new options for several hard-to-treat cancers. Despite the latest findings and the discontinuation of the INTR@PID Lung 037 study on the first-line treatment of patients with stage IV non-small cell lung cancer (NSCLC) that have high expression of PD-L1, we remain committed to investigating bintrafusp alfa in other indications. The findings from the INTR@PID Lung 037 study may be applied in other studies.

The strategic alliance concluded with Pfizer Inc. in 2014 enabled us to jointly develop Bavencio®. Following approvals for patients with metastatic Merkel cell carcinoma and those with locally advanced or metastatic urothelial carcinoma in 2017, the United States Food and Drug Administration (FDA) and the European Commission issued approvals for Bavencio® (avelumab) plus Inlyta® (axitinib) for the first-line treatment of patients with advanced renal cell carcinoma last year. This year, the FDA approved Bavencio® for the maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy. After the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion, Bavencio® has been approved recently as monotherapy for the first-line maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC) who are progression-free following platinum-based chemotherapy. Additional applications for Bavencio® have been submitted to regulatory authorities worldwide.

Mavenclad® was approved by the European Commission in 2017. It is the first short-course oral treatment approved in Europe for the treatment of relapsing multiple sclerosis in patients with high disease activity. With the approvals in a number of additional countries in 2018 and 2019, including the United States and Switzerland, Mavenclad® is now approved in around 80 countries.

In March, the Japanese Ministry of Health, Labor and Welfare approved the oncology drug tepotinib for the treatment of patients with inoperable, advanced or recurrent non-small cell lung cancer (NSCLC) with METex14 skipping alterations. In addition, the FDA has accepted the filing of the application for tepotinib for the treatment of adult patients with metastatic NSCLC and granted priority review.

This year, Erbitux was approved by the National Medical Products Administration (NMPA) of China for the first-line treatment of patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck in combination with platinum-based treatment with fluorouracil. This represents another step in our focus on acting as a global innovator for specialty products, including bringing innovative medicines to markets with high unmet medical needs.

In addition to marketing already approved medicines, we are pushing ahead with research projects in other important therapeutic areas. The portfolio of projects is evaluated on a regular basis. This may also lead to in-licensing or out-licensing, or further strategic alliances.

Investments made in 2020, e.g. to expand biotech development in Switzerland, are intended to accelerate scientific progress and the further development of our innovative clinical pipeline worldwide. The expenses currently being incurred, especially in our Healthcare research and development, are already reflected in the current plans. The same applies to sales of products for approved indications in the respective markets (e.g. Bavencio® and Mavenclad®). Further approvals may result in an increased sales potential.

Risks due to increased competition and customer technology changes

In the Healthcare business sector, both our biopharmaceutical products and classic pharmaceutical business are exposed to increased competition from rival products (in the form of biosimilars and generics). In the Life Science and Performance Materials business sectors, risks are posed by not only cyclical business fluctuations but also changes in the technologies used or customer sourcing strategies, particularly with respect to liquid crystals. We use close customer relationships and in-house further developments as well as market proximity, including precise market analyses, as mitigating measures. Overall, owing to its possible occurrence with a critical negative impact, the market risk is classified as a medium risk.

Opportunities presented by activities to boost innovative strength

With the M Lab™ Collaboration Center in Shanghai, we opened the doors to the largest of our nine centers worldwide to date. Encompassing non-GMP (Good Manufacturing Practice) laboratory space for pilot projects and process developments, it offers customizable solutions that are tailored to the Chinese life science community to advance drug development. Pharmaceutical and biopharmaceutical manufacturers can explore ideas, learn innovative techniques and work side-by-side with our scientists and engineers. The Collaboration Center is located in Pudong, at the heart of the biomedical sciences and research community in Shanghai, meaning we have our pulse right on the finger of Asia’s rapidly growing pharmaceutical market. Other M Lab™ Collaboration Centers are located in the United States, Singapore, Japan, Korea, India, France, and Brazil.

Digital technologies are becoming increasingly important for our markets and our world of work. In 2015, we launched several strategic digital initiatives geared toward improving the efficiency of our internal processes and toward evaluating the opportunities of digitalization for our products and customers. In this context, we set up a collaborative partnership with Siemens in 2020 in order to advance our modular production and to meet customer and market requirements quicker, more efficiently and more flexibly. Developing and adhering to rigorous ethical standards is of utmost importance for all our activities. Therefore, we created the Merck Digital Ethics Advisory Panel to provide external guidance and expertise on complex ethical matters around data usage, algorithms and new digital innovations, ensuring that the company develops new digital technologies responsibly. We are also working on establishing new business outside our three business sectors, with a focus on digitalization and our innovation fields of Clean Meat, Liquid Biopsy, and Biosensing and Interfaces. In addition to collaborations with external partners such as the European Space Agency, the Accelerator program, which is being driven by our Innovation Center, is one component of our innovation strategy.

Cooperating with start-ups gives us extensive opportunities to drive innovative approaches and ideas. In 2020, we helped to advance numerous projects through various support models like our Innovation Labs and Centers and different investment programs, such as the China Seeds Fund. Among other things, we invested in SynSense, a neuromorphic computing start-up based in China and Switzerland whose AI (artificial intelligence) processors and sensors provide an unprecedented combination of ultra-low power consumption and low latency for a broad range of edge applications for smart home, smart security, autonomous driving, drones and robots.

The Industry 4.0 start-up Feelit also launched its first commercial product on the market. RetroFeel™ combines a wireless edge computing device with a printed nanotechnology sticker sensor that detects structural changes in mechanical parts and systems and is able to predict upcoming failures (predictive maintenance). This sensor solution can be used in process industries such as pharmaceuticals, food and beverage, oil and gas, as well as in semiconductor manufacturing. We take an active role in our portfolio companies and focus our investments on the early stage and the foundation of companies or spin-offs with a view to utilizing their science and technology base.

In the Life Science business sector, we strengthened our viral vector manufacturing capabilities with the launch of the VirusExpress™ lentiviral production platform. We are committed to accelerating the manufacture of cell and gene therapies with the goal of getting these lifesaving treatments to patients faster. This proven, scalable platform increases dose yields and reduces process development times.

In Life Science, we also expanded our HPAPI and ADC manufacturing capabilities in the United States with the creation of one of the largest single-digit nanogram containment production facilities for high-potent pharmaceutical ingredients (HPAPI). This will allow the continuous manufacturing at an industrial scale of increasingly potent agents for therapies with the potential to treat cancer. Antibody drug conjugates (ADCs) are an emerging class of medicines designed for the high-specificity targeting and destruction of cancer cells while preserving healthy cells. Only nine ADCs are currently approved worldwide. The ADC industry is experiencing strong growth and is expected to reach € 13 billion by 2030.

Merck also opened a new research center for electronic applications on the campus at its headquarters in Darmstadt, Germany. The building offers space for additional research and development activities, especially for next-generation materials including display materials – such as innovative liquid crystals and quantum dot pixel color converters (QDPCC) – as well as semiconductor materials such as photoresist materials, dielectrics, and directional self-alignment materials (DSA).

Opportunities provided by the CRISPR technology

As a pioneer of genome-editing innovation for 15 years, we are leveraging CRISPR technology as a core competency of our business. Around the world, our Life Science business sector holds 28 CRISPR-related patents in methods and composition, including the fundamental technology of CRISPR Cas9 for gene editing and integration in mammalian cells and paired Cas9 nickases. Two of the CRISPR-Cas9-assisted genome-editing patents were approved in the United States in 2020. This gives us the opportunity to support US scientists and researchers in their work to advance and protect gene therapy development programs. In the reporting year, we also signed agreements licensing our CRISPR technology to two companies: panCELLa, a cell therapy company based in Toronto, Canada, and Takara Bio USA, Inc., a biotechnology company based in Mountain View, California, United States. The licenses are aimed at accelerating drug discovery leading to the development of new treatments.

CRISPR technologies open up promising new avenues for medical research and potential solutions to treat some of the most difficult diseases, including cancer as well as hereditary and rare diseases. Merck recognizes that the growing potential of genome-editing technologies is accompanied by scientific, legal and societal concerns. It supports research using genome editing under careful consideration of ethical and legal standards. Among other things, it has established an independent, external Bioethics Advisory Panel to provide guidance for its research.

Opportunities in connection with combating the Covid-19 pandemic

As a science and technology company, we have helped to combat the global challenges resulting from Covid-19 in various ways. In Life Science, we are working with more than 50 vaccine developers around the world and supporting more than 35 testing solutions and more than 20 projects involving monoclonal antibodies, plasma products, and antiviral drugs. We are collaborating with numerous researchers and institutions to assist them with process development of and the production process for potential Covid-19 vaccine candidates, as well as development and preparations for the mass production of SARS-CoV-2 diagnostic tests. To meet the unprecedented demand in our Life Science business sector, we expand our production capability with

investments in the US, Singapore and Germany. These investments will strengthen our manufacturing footprint to meet demand for key-life saving products. Additionally, we acquired AmpTec, a leading Hamburg, Germany-based, mRNA contract development and manufacturing organization (CDMO) to strengthen our capabilities across the mRNA manufacturing chain. Combining our expertise in lipids manufacturing with AmpTec's PCR-based technology will allow us to offer customers innovative technologies, products and services to help advance life-enhancing therapeutics and vaccines for Covid-19.

In the Healthcare business sector, the FDA cleared the investigational new drug application (IND) for M5049 for the treatment of patients with Covid-19 pneumonia. M5049 is a potentially first-in-class small molecule that blocks the activation of the toll-like receptors TLR7 and TLR8. A Phase II randomized, controlled clinical study evaluating the safety and efficacy of M5049 in this patient population began in late July. The results of the study are expected by the second quarter of 2021.

Opportunities arising from the further integration of Sustainability in the Corporate Strategy

In 2020, we integrated sustainability more strongly in the corporate strategy, setting three goals in the areas of science & technology, value chain and climate & environment. By considering the goals of the sustainability strategy when making business decisions, Merck contributes to achieving the United Nations Sustainable Development Goals. Additionally, the company is planning to also link the long-term variable compensation of the Executive Board from 2022 onward with the progress made toward achieving the company's sustainability goals.

Risks of discontinuing development projects and regulatory approval of developed medicines

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 minimizing risk. We are currently not aware of any risks beyond general development risks that could significantly affect the net assets, financial position, and results of operations.

Furthermore, there is the risk that regulatory authorities either do not grant or delay approval or grant only restricted approval. Additionally, there is the risk that undesirable side effects of a pharmaceutical product could remain undetected until after approval or registration, which could result in a restriction of approval or withdrawal from the market. Well-advanced programs in our pipeline and those of our partners result in potential new approvals; on the other hand, missing targets in this area may have critical negative effects on our financial position and operating result, for example due to lower net sales or the non-occurrence of milestone payments from collaboration agreements. These risks are considered to be medium overall, with probabilities ranging from unlikely to possible.

Risks and opportunities related to the quality and availability of products

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 our own internal inspections, and carry out external audits. Thanks to these quality assurance processes, the occurrence of a risk with a critical negative impact is unlikely; however, it cannot be entirely ruled out. Depending on the product concerned and the severity of the objection, such a risk can have a moderate negative impact on the net assets, financial position, and results of operations. Therefore, we rate this as a medium risk.

Risks of production availability

Further risks include operational failures due to fire or force majeure, for example natural disasters such as floods or earthquakes, which could lead to a substantial interruption or restriction of business activities. Insofar as it is 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 are working to continuously mitigate the risks by making regular investments, setting up alternative sourcing options, and maintaining inventory levels.

Although the occurrence of these risks is considered unlikely, an individual event could have a critical negative effect on the net assets, financial position, and results of operations, and they are therefore classified as a medium risk.

Risks of dependency on suppliers

Quality controls along the entire value chain reduce the risks related to product quality and availability. This starts with the qualification of our suppliers. Quality controls also include comprehensive quality requirements for raw materials, purchased semi-finished products, and plants. We are dependent on individual suppliers for a number of precursor products, packaging materials, and finished goods. In the event that one of these suppliers curtails or discontinues production, or supply is disrupted, this could potentially have a critical impact on the business concerned. With long-term strategic alliances for precursor products critical to supply and price as well as alternative sourcing strategies, we reduce the probability of occurrence of these risks and rate them as unlikely. Overall, these are classified as medium risks.

Product liability risks

Companies in the chemical and pharmaceutical industries are particularly exposed to product liability risks. Product liability risks can lead to considerable claims for damages, loss of reputation, and costs to avert damages. We have taken out the liability insurance that is standard in the industry for 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 unlikely, individual cases could still have a critical negative effect on the net assets, financial position, and results of operations. We therefore rate a potential product liability risk as a medium risk.

Risks due to product-related crime and espionage

Owing to our portfolio, we are exposed to a number of sector-specific crime risks. This relates primarily to products, including among other things, counterfeiting, illegal channeling, and misuse, as well as all types of property crime, including attempts at these crimes. Crime phenomena such as cybercrime and espionage could equally affect our innovations or innovation abilities as such.

To combat product-related crime, an internal coordination network covering all functions and businesses, the Merck Anti-Counterfeiting Operational Network was set up several years ago. In addition, security measures are in use to protect products against counterfeiting. Innovative technical security solutions and defined preventive approaches are used to ward off dangers relating to cybercrime and espionage. Measures to prevent risks and to prosecute identified offenses are conducted in all the relevant crime areas in close and trustworthy cooperation with the responsible authorities. The impact of these risks on business operations depends on the respective individual case, product-specific factors, the value chain, and regional aspects in particular. Our Corporate Security department is responsible for the overall coordination of all measures in this area. Overall, the threat resulting from crime in general is seen as being possible and is classified as a medium risk.

Risks and opportunities from the use of social media

Merck and its employees are active on numerous social media channels. The consistent and legally compliant use of the channels and their content is important in terms of increasing awareness of our brand, among other things. Merck takes precautions and implements processes to ensure awareness of the proper handling of social media, controlling publication, and actively managing communication.

Nevertheless, reputational risks could result, for instance through public dialogues in social media.

Overall, we rate this as a low risk.

Financial risks and opportunities

As a corporate group that operates internationally, and due to our presence in the capital market, we are exposed to various financial risks and opportunities. Above all, these are 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.

Risk and opportunity management in relation to the use of financial instruments

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 in particular is regulated by extensive guidelines. Speculation is prohibited. Derivative transactions are subject to constant risk controls. The strict separation of functions between trading, settlement, and control functions is ensured.

Liquidity risks

In order to ensure its continued existence, a company must be able to fulfill its commitments from operating and financial activities at all times. 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 multi-currency revolving credit facility of € 2 billion with a term until 2025, 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 Merck’s credit rating should deteriorate. Additionally, we have a commercial paper program with a maximum volume of € 2 billion.

Overall, the liquidity risk is unlikely and rated as low.

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 positions relating to trading partners and their credit ratings on a daily basis. 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 multi-currency revolving credit facility of € 2 billion was syndicated by 20 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 utilized as appropriate. Nevertheless, defaults by isolated trading partners, even those with outstanding credit ratings, cannot be entirely ruled out, although rated as unlikely (further information can be found in "Credit risks" in the note "Management of financial risks" in the Notes to the Consolidated Financial Statements).

Counterparty risk is classified as a medium risk overall owing to the unlikely probability of occurrence with a potential critical negative effect.

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 forecast future cash flows from sales and costs in foreign currency. We use derivatives to manage and reduce the aforementioned risks and opportunities (further information can be found in the note "Derivative financial instruments" in the Notes to the Consolidated Financial Statements). Due to their possible occurrence with a potentially critical negative effect on the net assets, financial position, and results of operations, foreign exchange rate risks are rated as medium risk.

Variable interest and current financial liabilities are exposed to the risks and opportunities of interest rate fluctuations. These are also managed and reduced using derivatives. Interest rate risks have a potentially moderate negative impact, are considered unlikely, and pose low risks 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 in particular 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 in the note "Intangible assets" in the Notes to the Consolidated Financial Statements). All relevant risks were assessed during the preparation of the Consolidated Financial Statements and taken into account accordingly. We rate risks beyond this as unlikely with a critical negative impact. Therefore, this is seen as a medium risk.

Risks and opportunities from pension obligations

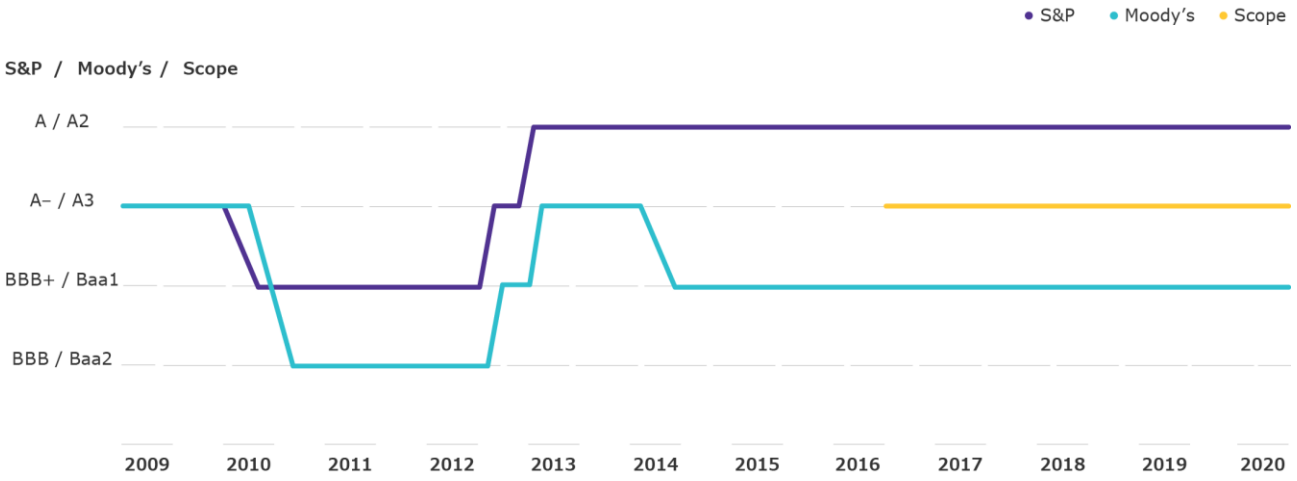
We have commitments in connection with pension obligations. The present value of defined benefit obligations can be significantly increased or reduced by changes in the relevant valuation parameters, for example the interest rate or future salary increases. Pension obligations are regularly assessed 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 in the note "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 unlikely risk due to pension obligations could have moderate negative effects on the net assets, financial position, and results of operations, and is classified as low.

Assessment by independent rating agencies

The capital market uses the assessments published by rating agencies to help lenders assess the risks of a financial instrument used by Merck. We are currently rated by Standard & Poor's, Moody's, and Scope. Standard & Poor's has issued a long-term credit rating of A with a stable outlook, Moody's a rating of Baa1 with a stable outlook, and Scope a rating of A-, likewise 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.

Report on Risks and Opportunities

Overview of Rating Development



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 litigation 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., Kenilworth, NJ, United States (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 can lead to expenses with a significant 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.

Tax risks are reviewed regularly and systematically by Group Tax. Corresponding standards and guidelines are used in order to identify tax risks at an early stage as well as to review, evaluate, and correspondingly minimize them. Risk reduction measures are coordinated by Group Tax together with the subsidiaries abroad.

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 from product-related and patent law disputes

Merck is involved in a patent dispute with Biogen Inc., Massachusetts, United States ("Biogen"), in the United States. Biogen claims that the sale of Rebif® in the United States infringes on a Biogen patent. The disputed patent was granted to Biogen in the United States in 2009. Subsequently, Biogen sued Merck and other pharmaceutical companies for infringement of this patent. Merck defended itself against all allegations and brought a countersuit claiming that the patent is invalid and not infringed by our actions. In the first instance, a jury recognized the invalidity of the patent. This jury verdict was overturned by a judge in the same instance in September 2018. For the time being, the patent is thus deemed to be legally valid and to have been infringed. Merck already filed a complaint with the United States Court of Appeals for the Federal Circuit (second instance) against the first-instance ruling in October 2018. On September 28, 2020, this court overturned the verdict of the judge in the first instance, declared Biogen's patent to be invalid, and instructed the District Court to reinstate the original jury verdict. A cash outflow is considered to be unlikely based on this decision. Accordingly, the provision of € 365 million that was recognized at that point in time for potential compensation payments for damages was reversed.

In the Performance Materials business sector, Merck is involved in a legal dispute with JNC Corporation, Japan (JNC). JNC claims that by manufacturing and marketing certain liquid crystal mixtures, Merck has infringed JNC patents in China, Taiwan and Korea. Merck maintains that the above mentioned patents are invalid owing to relevant prior art. At the end of the second quarter of fiscal 2020, the actions in China and Taiwan were concluded with legally binding effect in favor of Merck. In view of these developments, the provision was reduced accordingly. In Korea however, a patent infringement action, a patent nullity action and a "correction trial" are still pending ex parte JNC. In addition, new statutory rules were implemented in Korea that could have an adverse effect on any potential amount of damage. Merck has taken appropriate accounting measures according to the remaining litigation risk in Korea. A potentially considerable impact of the legal dispute on the financial position cannot be ruled out. A cash outflow within the next 12 months is considered possible at present.

Risks due to antitrust and other government proceedings

Raptiva®: In December 2011, the federal state of São Paulo, Brazil, sued Merck for damages because of alleged collusion between various pharmaceutical companies and an association of patients suffering from psoriasis and vitiligo. This collusion is alleged to have been intended to increase sales of the medicines from the companies involved to the detriment of patients and state coffers. Moreover, patients are also suing for damages in connection with the product Raptiva®. Merck has taken appropriate accounting measures for these issues, which relate to various legal cases. Risks in excess of this with a substantial negative effect on the net assets, financial position, and results of operations cannot be ruled out, but are considered unlikely. This is rated as a medium risk.

On July 6, 2017, Merck received notice from the European Commission (EU Commission) in connection with the antitrust review proceedings for the acquisition of Sigma-Aldrich, in which the EU Commission informed Merck of its preliminary conclusion that Merck and Sigma-Aldrich allegedly transmitted incorrect and/or misleading information within the scope of the acquisition of Sigma-Aldrich. The EU Commission received registration of the merger on April 21, 2015, and granted clearance on June 15, 2015, subject to the condition that Merck and Sigma-Aldrich divest parts of the European solvents and inorganic chemicals businesses of Sigma-Aldrich in order to resolve antitrust concerns. According to the preliminary viewpoint of the EU Commission communicated in a letter dated July 6, 2017, Merck and Sigma-Aldrich withheld related important information about an innovation project. According to the EU Commission, the innovation project should have been included in the remedies package. This resulted in an administrative procedure with the EU Commission. On July 1, 2020, the EU Commission informed Merck that the parts of the procedure relating to Merck were no longer under investigation and that the procedure now related solely to the allegations against Sigma-Aldrich. Merck again countered these remaining accusations at a hearing on November 13, 2020. The administrative procedure could result in the issuance of a fine that would be open to appeal. In the second quarter of 2020, the existing provision in a mid double-digit euro amount was reduced to a low double-digit euro amount. A potential outflow of resources is considered possible for 2021.

This is currently classified as a medium risk with a probable substantial negative impact on the financial position.

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

Paroxetine: In connection with the divested generics business, Merck is subject to antitrust investigations by the British Competition and Market Authority (CMA) in the United Kingdom. In March 2013, the authorities informed Merck of the assumption that a settlement agreement entered into in 2002 between Generics (UK) Ltd. and several subsidiaries of GlaxoSmithKline plc, United Kingdom, in connection with the antidepressant drug paroxetine, violated British and European competition law. Merck, the then-owner of Generics (UK) Ltd., was allegedly involved in the negotiations for the settlement agreement and is therefore liable. The investigations into Generics (UK) Ltd. started in 2011, without this being known to Merck. On February 11, 2016, the CMA imposed a fine in this matter. Merck has taken legal action against this fine. The Appeals Tribunal has since submitted the relevant legal questions to the European Court of Justice (CJEU) for a preliminary ruling. The CJEU confirmed in January 2020 that such settlement agreements in general may breach European competition law. The proceeding will now be continued at the UK Competition Appeal Tribunal (CAT). A decision is pending. Appropriate accounting measures have been taken. A decision and an outflow of resources within the next 12 months are considered possible. A provision in a low double-digit million euro amount was recognized for these proceedings. This is currently classified as a medium risk with a moderate negative impact on the financial position.

Citalopram: In connection with the divested generics business in 2007, Merck is accused of breaching EU antitrust law through agreements concluded by its former subsidiary Generics (UK) Ltd., Denmark, relating to the antidepressant Citalopram patented by Lundbeck A/S. In 2013, the EU Commission imposed a corresponding fine in a double-digit euro amount. Merck filed a lawsuit against the Commission’s decision with the European Court in August 2013. The lawsuit was rejected in 2016. Merck subsequently filed an appeal with the European Court of Justice (CJEU). In the course of these proceedings, the Advocate General of the CJEU recommended that the European Court’s verdict be confirmed. The Court announced that it will issue a ruling in March 25, 2021. In light of the disadvantageous development in this matter, additional accounting measures were taken for potential additional claims and the corresponding provision has increased by a double-digit million euro amount as a result. This is currently classified as a medium risk with a probable substantial negative impact on the financial position.

Human resources risks

Our future growth is highly dependent on our innovative strength. Therefore, the expertise and engagement of employees in all sectors in which we operate are crucial to the success of the company. The markets relevant to the company are characterized by intensive competition for qualified specialists 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 and 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 rate this as a medium risk.

Information technology risks

We use a variety of IT systems and processes in order 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 Merck, such as the failure of central IT systems, the disclosure or loss of the data integrity of confidential data from research and 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.

The Merck Group operates an information protection management system based on ISO 27001 comprising security guidelines as well as organizational and technical measures to prevent and address IT security incidents. 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 mitigating measures taken and functional continuity plans, the effects of cybercrime or the failure of business-critical IT applications and their influence on the net assets, financial position, and results of operations are considered high risks owing to likely and potentially critical negative impacts.

Environmental, climate related and safety risks

As a company with global production operations, we are exposed to risks of possible damage to people, goods, and our reputation. Those include physical risks stemming from exposure to droughts, storms and floods. Audits, consulting, and training on environmental protection, and occupational health and safety minimize these risks to people and 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 and 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 carbon management measures. We classify these as a high risk since a critical negative impact on the financial position cannot be ruled out.

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

Irrespective of the fact that acquisitions made in the past have been successfully completed, the risk of conducting acquisitions and subsequent integration exists for future transactions. This includes, among other things, the inability to meet sales volume targets, and higher integration costs than expected, as well as the failure to meet synergy goals. The divestment of companies and businesses can lead to liability vis-à-vis the buyer or additional expenses, for instance through indemnity clauses and guarantee commitments or long-term supply contracts. Through strong due diligence processes and closely managed integration processes, we seek to reduce the probability of occurrence of this risk. Therefore, we classify this as a low risk with an unlikely probability of occurrence and potentially moderate negative effects on the net assets, financial position, and results of operations.

Overall view of the risk and opportunity situation and management assessment

The most significant individual risks in the businesses have been named in the report above, with business-related risks being the most significant alongside IT and legal risks. These risks include already the risks stemming from the recent developments regarding the Covid-19 pandemic. Most notably, the pandemic increases existing risks related to more restrictive regulatory requirements regarding drug pricing and reimbursement, the demand for our products, business interruptions at our production facilities, lack of availability of good quality materials or services, risks related to research and development, and negative macroeconomic developments.

With respect to high and medium risks, certain changes have occurred, as the assessment of the individual risks has of course shifted over the fiscal year due to changing external and internal conditions while the overall risk profile remained stable. Thanks to the risk reduction measures taken – such as the consistent implementation of management action (organizational responsibility and process improvements), existing insurance coverage, and accounting precautions – we were able to take counteraction, in particular 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 we are not exposed to risks of a nature to threaten the existence of the Group as a going concern, or for which coverage and financing of the losses are questionable. We are confident that we will continue to successfully master the challenges arising from the above risks in the future as well. Our company also benefits from diversification through our different products and markets.

In our view, business-related opportunities offer the greatest potential. An important element here is the continuous expansion of our businesses. With the successful focusing and continued intensification of our research and development activities, we want to be able to continue to offer our customers innovative products and help shape markets. Moreover, we also consolidate our expertise in numerous alliances with industrial partners as well as various universities and international organizations. We are making targeted investments in future-oriented companies and start-ups via our Merck Ventures Investment Fund and our Accelerator programs. The topic of innovation is at the forefront of all our activities. Externally, this is becoming particularly apparent through our Innovation Center at Group headquarters in Darmstadt, Germany, which is to develop into a nucleus of creativity at Merck. The activities listed hold significant opportunities for us in the medium to long term, beyond the underlying forecast period.

We pursue the opportunities that arise and specify their expected effects in the forecast development of net sales, EBITDA pre, and cash flow. Furthermore, we will actively seek new opportunities, examine their implementation, 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 correspondingly positive effects on our net assets, financial position, and results of operations.