Report on Risks and Opportunities

In our constant pursuit of making our business resilient and generating value, risks and opportunities are an integral and indispensable part of our activities. We operate in a highly complex, global, and interconnected business environment that further necessitates a competent management of risks and opportunities. For us, risks and opportunities management are hence an imperative and a core component of our internal business planning and forecasting. We have put in place clear processes, appropriate tools, and fixed responsibilities to enable early identification of risks to derive 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 deviation from our financial and non-financial targets. Risk parameters in this context are the probability of financial (quantitative) impact (EBITDA pre/Operating Cash Flow) or non-financial (qualitative) impact (reputation/brand, Environment, Social, Governance (ESG) including Workforce and Ethics, Strategy, Operations).

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

For additional information and details regarding the non-financial topics, please refer to the **Non-Financial Statement**.

Risk and opportunity management

Group Controlling & Risk Management forms the organizational framework for risk management and reports to the Group Chief Financial Officer. Within the scope of audits, Group Internal Auditing regularly reviews the performance of risk management processes within the units on local level and, at the same time, the communication of relevant risks from the operating businesses to Group Risk Management. Furthermore, the external auditor reviews the risk early warning system during the annual audit of the financial statements.

The objective of our risk management activities is to identify, assess and manage risks in a timely manner so that appropriate measures can be implemented to mitigate their potential negative impact. Our internal risk management guidelines detail the responsibilities, objectives, and processes of risk management. The business heads, managing directors of Group subsidiaries, and the heads of Group functions are appointed as “risk owners”, who run local risk management processes. Requirements for local risk management are risk identification taking all internal and external influences into consideration (impacting financial or non-financial targets), risk analysis, risk mitigation by appropriate actions, definition of preventive measures and emergency plans if applicable, and documentation of risks and mitigation actions.

The risk owners regularly assess the risk status and report their risk portfolio to Group Risk Management. We use special risk management tools to manage and support these activities. Group Risk Management coordinates and supervises the bottom-up risk reporting, confirming the plausibility of the reported risk, evaluates the mitigation measures and the planned time frames, and determines the residual risk, which is presented as net risk in the internal risk report.

For the internal bottom-up risk reporting process, reporting is based on defined thresholds, and a variety of distribution functions are used to reflect scenarios with varied occurrence probabilities. Risks below the global reporting threshold are managed and monitored locally. The timeframe applied for internal risk reporting is five years. It can go beyond five years in special cases, e.g., for regulatory risks related to climate change. The

outlined risks and their evaluation are based on respective annual values in the reporting time frame. The assessment of the risks presented relates to December 31, 2022. There were no relevant changes after the balance sheet date that would have necessitated an amended presentation of the risk situation of the Group.

Group Risk Management uses the information reported to determine the current risk portfolio for the Group, presenting this in a report to the Executive Board, the Supervisory Board, and relevant Committees with detailed explanations twice per year. This also encompasses a quantitative aggregation of risks at 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.

The opportunity management process is integrated into our internal controlling processes and is carried out based on the Group strategy in the operating units. The business sectors analyze and assess potential market opportunities as part of the strategy and planning processes. In this context, investment opportunities are examined and prioritized primarily in terms of their potential value proposition, to ensure an effective allocation of resources. We target investment 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 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

The significance of a risk is determined based on its probability to cause potential unfavorable deviations from our financial and non-financial targets.

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 than likely

Degree of impact

Degree of impact	Explanation
> € 500 million	Critical negative impact on the net asset, financial position, and results of operations
€ 100 – 500 million	Significant negative impact on the net asset, financial position, and results of operations
€ 25 – 100 million	Moderate negative impact on the net asset, financial position, and results of operations
€ 10 – 25 million	Minor negative impact on the net asset, financial position, and results of operations
< € 10 million	Immaterial negative impact on the net asset, financial position, and results of operations

For non-financial risks (such as reputation, Environmental, Social, Governance (ESG)), we introduced a qualitative rating scale as a reference for comprehensive assessment. The evaluation range is from low to critical.

Opportunities are assessed in their respective specific business environment. General measures of the business functions are quantified during forecasting and strategic planning usually in relation to sales, EBITDA pre, and operating cash flow. Net present value, internal rate of return, the return on capital employed (ROCE), and the payback 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 projects. Similarly, scenarios are used to simulate the influence of possible fluctuations and changes in the respective parameters on results.

Internal control system for the (Group) accounting process

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

Our internal control system for financial reporting is based on the COSO framework, a globally recognized standard divided into five components: control environment, risk assessment, control activities, information and communication, as well as monitoring activities. Each of these components is regularly documented, tested and/or assessed.

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, Darmstadt, Germany, as the parent company of the Group. This Group function defines the reporting requirements that all Group 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 within a global framework. 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 operational effectiveness of our internal control system is regularly tested in the format of self-assessments by our legal entities, group functions, and shared services. The quality is systematically reviewed by a dedicated global financial control and governance team. Control deficiencies are properly recorded and, wherever necessary, adequate countermeasures are taken to remediate control deficiencies in a timely manner.

The overall effectiveness of our internal 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 and a separate confirmation regarding the effectiveness of the financial control system (internal control system sign-off letter). For the accounting treatment of balance sheet items, Group Accounting closely cooperates with Group Risk Management to correctly present potential risks in the balance sheet.

All structures and processes described above related to the Group Accounting procedures 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. The internal control system within the Group makes it possible to lower the risk of material misstatements in accounting to a minimum. However, residual risk cannot be entirely ruled out as no internal control system is infallible, irrespective of its design.

The Internal Control System of the Group as the entirety of all controls shall avoid and reduce the probability of potential risks occurring as well as actively steer risks in business processes. Thereby, it contributes to ensure the compliance of the company's activities with laws and regulations. The Internal Control System in its entirety and the applied methods are continuously developed further. The responsibility for the effectiveness of the Internal Control System and the further development of the non-financial key metrics lies with the respective responsible senior leaders/risk and process owners.

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 towards increasingly restrictive requirements in terms of drug pricing, reimbursement, and the expansion of rebate groups is continuing. Specifically, in the United States, a pricing reform on prescription drugs is part of the agenda of the current administration. These requirements can negatively influence the profitability of our products, as can market referencing between countries, and the success of market launches. Foreseeable effects are considered as far as possible in the business sector's plans. Close communication with health and regulatory authorities serves as a preventive measure to avert such risks.

Remaining risks beyond the current plans resulting from restrictive regulatory requirements are likely with a potential moderate to significant impact.

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

We must adhere to a multitude of regulatory requirements regarding the manufacturing, testing, and marketing of many of our products. Specifically, in the European Union, we are subject to the EU chemicals regulation REACH. Similar regulations are emerging globally in relevant markets, particularly in Asia. These regulations demand comprehensive tests for chemicals. Moreover, the use of chemicals in production and final products could be restricted, which would negatively impact the ability to manufacture and market certain products. With the EU Chemicals Strategy for Sustainability, an initiative of the European Green Deal, we expect increasing demands concerning the substitution of specific hazardous substances. We are constantly pursuing research and development in substance characterization and the possible substitution of critical substances so as to mitigate this risk. Nevertheless, it is classified as a possible risk with a potential significant impact on the net assets, financial position, and results of operations.

Risk of negative political and macroeconomic developments

The ongoing general trend of de-globalization and reshoring critical supplies might further increase the establishment of trade barriers. Additionally, the increased threat from armed conflicts and the rising tensions between the United States and China could lead to further sanctions. These risks can have a negative impact on our supply chains and sales in certain countries and regions. Such risks are considered as much as possible in the business plans of the affected countries and regions, and are mitigated through product, industry, and regional diversification as well as measures to ensure resilience of supply chains and networks. In addition, strategic geopolitical risk management is in place at the Group and sector levels in order not to lose sight of the global context and to prepare the Group holistically for possible risks.

The rise in inflation in the course of 2022 across some of our major markets could negatively impact our business. The current inflation dynamics are driven by a combination of supply disruptions, hefty fiscal spending, and special factors. Persistently high inflation could increase our operating expenses (e.g., raw materials, utilities, and logistics) as well as capital expenditures and lead to an increase in central bank rates, which would affect our refinancing costs.

Potential negative macroeconomic developments can also impact our business. We see an increasing risk for a global recession driven by current economic and political developments. In addition, the spread of the corona virus is associated with risks in global developments, likewise with the potential for negative effects on our businesses. To minimize these impacts, corresponding measures have been initiated.

The net risk of negative geo-political and macroeconomic developments is seen as possible and might have significant to critical effects on the net assets, financial position, and results of operations.

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 presented by our fully integrated CDMO and Contract Testing Services

The newly formed business unit, Life Science Services, fully integrates our Contract Development and Manufacturing Organization (CDMO) and contract testing services, strengthening our portfolio offerings and value chain to better serve the evolving needs of our global customers. Our CDMO service business covers traditional modalities such as monoclonal antibodies (mAbs) and high-potency active pharmaceutical ingredients (HP-APIs) and novel modalities such as antibody drug conjugates (ADCs) and viral and gene therapies (VGTs). This also includes our mRNA offerings.

We continually invest in the expansion of our portfolio and production capabilities to provide highly-specialized solutions for manufacturing traditional and novel therapies. For example, we strengthened our viral vector manufacturing capabilities with the launch of the production platforms VirusExpress® Lentiviral in 2020 and VirusExpress® 293 Adeno-Associated Virus (AAV) in 2022. This makes us one of the first CDMOs and technology-developers to provide a full viral vector manufacturing offering. We are committed to accelerating the manufacture of cell and gene therapies with the goal of getting these lifesaving treatments to patients faster. These proven, scalable platforms increase dose yields and reduce process development times. More details on our capacity expansions are included in the following sections of this report.

We also expanded our manufacturing capabilities for HP-APIs and ADCs in the United States, positioning us as one of the largest single-digit nanogram occupational exposure limit CDMO providers in the world. This will allow the continuous manufacturing of increasingly potent agents at an industrial scale for therapies with the potential to treat cancer. ADCs are an emerging class of medicines designed for the high-specificity targeting and destruction of cancer cells, while preserving healthy cells. Only 13 ADCs are currently approved worldwide. The ADC industry is experiencing strong growth and is expected to reach

€ 13 billion market value by 2030. Additionally, we strengthened our CDMO services across the mRNA value chain with the acquisition of Exelead in 2022. Exelead specializes in complex injectable formulations, including Lipid Nanoparticle-based drug delivery technology, which is key in mRNA therapeutics for use in many other indications. We plan to invest more than € 500 million in the technology scale-up of Exelead over the next ten years. This will further enable us to capture the significant potential of the fast-growing market for mRNA therapies by providing leading CDMO services to our customers.

Opportunities in Bioprocessing

In Life Science, our bioprocessing business within the Process Solutions business sector is an important growth driver. In 2022, we advanced our bioprocessing capabilities with the acquisition of the MAST® (Modular Automated Sampling Technology) Platform. This leading automated, antiseptic bioreactor sampling system provides real-time process information and cuts process development time by half, improving efficiency and lowering costs. This makes us the first company to offer a fully integrated ecosystem for advanced process technologies. The technology, coupled with the software to analyze and manage data, allows us to offer unique and integrated solutions to help customers optimize their bioprocesses and moves us closer toward our vision of connected and continuous bioprocessing to increase speed and lower costs. The MAST® Platform is part of our BioContinuum™ Platform.

In addition, we announced a collaboration with Agilent Technologies to fill an industry gap in Process Analytical Technologies (PAT) for downstream processing. By combining our advanced bioprocess portfolio with Agilent's leading analytical solutions, we are able to offer integrated capabilities for enhanced downstream process monitoring and control, bringing us one step closer to making the facility of the future a reality. Furthermore, in December 2022, we announced the acquisition of Massachusetts-based Erbi Biosystems, a developer of the two milliliter (mL) micro-bioreactor platform technology known as the Breez™. The deal strengthens our upstream portfolio in therapeutic proteins by enabling scalable cell-based perfusion bioreactor processes from 2 ml to 2,000 L with rapid lab-scale process development. At the same time it also offers future development opportunities in novel modality applications.

Opportunities from leveraging the e-commerce and distribution platform

In the Life Science business sector, our dedication to the customer experience extends from the lab to our primary e-commerce platform, sigmaaldrich.com, which connects scientists in nearly every country around the world with the products, publications, and technical expertise needed to advance their discovery, research, and development further and faster. Our efforts include innovative approaches across the globe, bolstering sigmaaldrich.com and our e-commerce expertise to continually improve the customer experience and leverage the platform as a scalable growth driver for the business.

Opportunities in the semiconductor industry

We have huge long-term growth opportunities in the semiconductor market due to the significantly accelerating global demand for innovative semiconductor materials. This demand is driven by exponential data growth and highly impactful technology trends such as the Internet of Things (IoT) and 5G. We are working on nearly all of these new technology inflection points of the semiconductor roadmap together with our customers. Our capacity investments are synchronized with our customers' expansion plans, and we continue to tackle industry challenges as well as supply reliability. Our semiconductor business has a very broad and unique portfolio that is not dependent on a single product or technology. It consists of different, independent technologies: Thin Film, Patterning, Planarization, as well as Specialty Gases and Delivery System & Services (DS&S). With this portfolio, we supply products for all essential production steps of wafer processing to support our customers with their advanced needs integral to realizing next-generation chips: patterning, deposition, planarization, etching, cleaning, doping and packaging. Moreover, we are developing new dielectric platforms in cooperation with our key customers for 3D NAND applications. We also continue to see significant potential in our DS&S business to provide our largest customers with turnkey solutions for the delivery of bulk gases in the manufacturing process. As the electronics industry continues to announce major capacity expansions over the next few years, our DS&S business is well poised to benefit from this with their portfolio of gas and chemical cabinets.

Opportunities due to new technologies in the manufacturing of displays

We see opportunities in market growth of organic light-emitting diode (OLED) materials in high-quality display applications. We have been performing research and development in the area of OLED technology for more than 15 years and have become one of the leading material suppliers for OLEDs. Through our semiconductor and display knowledge, we will be able to contribute to the new generation of optimized sensors. Furthermore, we see opportunities in foldable displays, which require a broad set of materials ranging from encapsulation to the OLED stack.

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 other rival products (in the form of biosimilars and generics). In the Life Science and Electronics business sectors, risks are posed by not only cyclical business fluctuations but also changes in the technologies used or customer sourcing strategies. We use close customer relationships and in-house further developments as well as market proximity, including precise market analyses, as mitigating measures. Overall, the risks might have potential significant to critical impact.

Risks and opportunities of research and development

Innovation driven by research and development is a major element of the Group strategy, in particular 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, research and development projects can experience delays, expected budgets can be exceeded, or targets can remain unmet. In addition to inhouse research and development efforts, strategic alliances with external partners and the in- or out-licensing of programs also form part of the catalog of measures to develop innovative medicine and ensure the efficient allocation of resources.

In Healthcare, we are committed to drive the launches of Bavencio®, Tepmetko® and Mavenclad®. Bavencio® is a human anti-programmed death ligand-1 (PD-L1) antibody jointly developed under the strategic alliance concluded with Pfizer Inc. in 2014. It is currently approved for at least one indication for patients in more than 50 countries and targets different kinds and stages of carcinoma. Additional applications for Bavencio® have been submitted to regulatory authorities worldwide. Tepmetko® is a once-daily oral mesenchymal-epithelial transition (MET) inhibitor that inhibits the oncogenic MET receptor signaling caused by MET (gene) alterations. Discovered and developed by the Group in-house, Tepmetko® has a highly selective mechanism of action, with the potential to improve outcomes in aggressive tumors that have a poor prognosis and harbor these specific alterations. Tepmetko® (tepotinib) is available in a number of countries and under review by various other regulatory authorities globally. We are further investigating the potential role of tepotinib in treating patients with NSCLC and acquired resistance due to MET amplification in the Phase II INSIGHT 2 study. Mavenclad® (cladribine tablets) was approved by the European Commission in 2017 and is the first short-course oral treatment approved in Europe for the treatment of relapsing multiple sclerosis (RMS) in patients with high disease activity. It is now approved in more than 80 countries. New real-world data from the MSBase Registry demonstrate favorable efficacy outcomes for Mavenclad® versus other oral disease modifying therapies (DMTs) and lower occurrence of further relapses or disability progression.

In addition to marketing already approved medicines, we are pushing ahead with research projects in important therapeutic areas. We target the set-up of a new standard of care in squamous cell carcinoma of head and neck (LA SCCHN) through our potent oral inhibitor of apoptosis proteins (IAPi) antagonist xevinapant, which is currently being investigated in two randomized, double-blind, placebo-controlled Phase III clinical trials: the TrilynX study for patients with unresected LA SCCHN and the XRay Vision study for patients with resected LA SCCHN. Xevinapant is the only medicine in its class in late-stage clinical development and has the potential to be first-in-class. We have a worldwide in-licensing agreement with Debiopharm, Lausanne, Switzerland, for the development and commercialization of xevinapant. Furthermore, the development of our Bruton’s tyrosine kinase inhibitor (BTKi) evobrutinib with first-in-class potential in relapsing multiple sclerosis (RMS) is further

progressing in the Phase III Evolution RMS clinical trial program. Evobrutinib is an oral, highly selective BTKi offering a novel dual mechanism of action that could address MS pathobiology in a fundamentally new way.

Sustainable long-term growth will be driven by new pipeline entrants in DNA damage biology, novel ADC and enpatoran (TLR 7/8) that underline an exciting and less risk-correlated approach in oncology and neuroinflammation. With enpatoran and M1231, a MUC1/EGFR bi-specific ADC, we have two additional assets in our portfolio with first-in-class potential. Enpatoran is a small molecule for targeted inhibition of the important lupus mediator TLR7/8, aiming for improved efficacy with low infection risk. For enpatoran, we are currently in a Phase II study in CLE (cutaneous lupus erythematosus) and SLE (systemic lupus erythematosus). M1231 is considered as next generation ADC for patients with solid tumors aiming for effective delivery of potent chemotherapy payload with reduced on- and off-target toxicity. In September 2022, we announced a collaboration agreement with licensing option with Nerviano Medical Sciences S.r.l. (NMS) for the next-generation highly selective and brain-penetrant PARP1 (poly (ADP-ribose) polymerase) inhibitor, NMS-293. NMS-293 is in early clinical development for the treatment of patients with breast cancer (BRCA)-mutated tumors as a single agent and in combination with temozolomide in recurrent glioblastoma. It has strong potential in combination with a wide variety of DNA-damaging agents, including systemic or targeted chemotherapy (ADCs) or with DNA damage response inhibitors, in numerous tumor types. In December 2022, we announced a research collaboration and commercial license agreement with Mersana Therapeutics, Inc to develop novel immunostimulatory ADC. The collaboration is focused on discovering novel STING-agonist ADCs for up to two targets leveraging Mersana's proprietary Immunosynthen platform to conjugate proprietary antibodies from our company. The STING pathway is a fundamental means of generating innate immune response that can lead to anti-tumor activity and immunological memory.

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. There is the risk that regulatory authorities either do not grant or delay approval or grant only restricted approval. The risk that undesirable side effects of a pharmaceutical product could remain undetected until after approval or registration could result in a restriction of approval or withdrawal from the market. Well-advanced programs in our pipeline and those of our partners result in potential new approvals. Missing targets in this area may have significant to critical 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 evaluated with probabilities ranging from improbable to likely.

For more detailed description on our R&D activities worldwide, please refer to the section "**Research and Development**" in "**Fundamental Information about the Group**" in the annual report.

Opportunities presented by activities to boost innovative strength

We see the rise of bioconvergence, which we define as a multidisciplinary approach that harnesses the synergies across digital and material science, as well as biotechnology. It will improve the speed and impact of scientific discovery. Fostering innovation at the intersection of our business sectors will allow us to benefit from our unique positioning at the sweet spot of converging technologies, unlocking organic growth opportunities and enabling pioneering solutions for customers and patients. Examples of innovation at the intersection of our business sectors include an automated design-make-test-analyze platform powered with state-of-the-art AI and lab automation, new treatment possibilities via enhanced mRNA LNP delivery platforms, and the deployment of digital twins in smart manufacturing.

Digital technologies and data will enable the development of personalized solutions of the future, accelerate our R&D pipelines, and ultimately improve patient and customer outcomes. In this context, developing and adhering to rigorous ethical standards is of utmost importance for all our activities. Therefore, we created our 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. In addition, we established the Code of Digital Ethics, which serves as a basis for ethical risk assessment in existing ventures as well as the design of ethic checkpoints for nascent digital solutions throughout the company.

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 our three business sectors, especially in the "Big 3" growth drivers: Process Solutions and Life Science Services in Life Science, new innovative Healthcare products, and Semiconductor Solutions in Electronics.

In Life Science, we opened a new commercial facility in Martillac, France, to expand our production capacity for mAbs and other recombinant proteins as part our global Millipore® Contract Testing, Development, and Manufacturing Organization (CTDMO) Services. Leveraging state-of-the-art technology and a proven quality system allows our clients to streamline and accelerate the commercialization process by eliminating the need for tech transfer and scale-up between clinical and commercial stages. Our Millipore® CTDMO Services network includes facilities throughout Europe, the United States and Asia covering pre-clinical to commercial phases, including testing. Investments into our global network also include the recently announced € 290 million investment in a new facility to support the increasing demand for biosafety testing and analytical development services at our site in Rockland, Maryland, USA. This is the largest testing investment in company history.

In addition, we opened a € 59 million facility in Verona, Wisconsin, USA, which positions us as one of the leading, global CDMOs of HP-APIs used in novel cancer therapies, including ADCs. We also opened a viral clearance lab as part of the first building phase of our new € 29 million biologics testing center in Shanghai, China.

We further invested more than € 230 million to strengthen our manufacturing capabilities for single-use assemblies critical to the manufacture of Covid-19 vaccines and other life-saving therapies at our sites in Molsheim, France, and Wuxi, China. In addition, we invested € 440 million in the production capacity expansion for single-use membranes and filtration at our site in Cork, Ireland. We also started construction of a lateral flow membrane production facility at our U.S. site in Sheboygan, Wisconsin, USA, supported by a € 121 million contract award from the U.S. Department of Defense, on behalf of the U.S. Department of Health and Human Services. Lateral flow membranes are a key component in rapid diagnostic test kits for a variety of applications, including Covid-19 testing.

In Electronics, we plan to invest nearly € 3 billion in innovation and capacities up to the end of 2025. We will continue to heavily invest in research and development (R&D) in leading-edge material solutions and plan to spend close to € 2 billion in long-term fixed assets (capital expenditures). Through our Level Up growth program, we aim to capture the growth opportunities that come along with the significantly accelerating global demand for innovative semiconductor and display materials and invest in smart localization of our footprint to further boost customer proximity and ensure supply stability. Furthermore, we recently completed the acquisition of the chemicals business of Mecaro, a Korean supplier to the semiconductor industry to expand our portfolio in the fast-growing Semiconductor Solutions business unit. Among other things, we will further leverage our data analytics capabilities and invest even further into the safety realm.

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 audits, and carry out external inspections. Thanks to these quality assurance processes, the occurrence of a

risk with a significant impact is improbable to possible; however, it cannot be entirely ruled out. Depending on the product concerned and the severity of the objection, such a risk might have a negative impact on the net assets, financial position, and results of operations.

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. 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 work towards continual mitigation of such risks by making regular investments, setting up alternative sourcing options, and maintaining inventory levels.

Although the occurrence of these risks is considered – improbable, an individual event could have a critical negative effect on the net assets, financial position, and results of operations.

Risks of dependency on suppliers

In balanced markets, single-sourcing strategies may be chosen to bundle our company's demand and achieve price reductions. However, this strategy might result in dependency on individual suppliers for a number of goods or services. Consequently, events like discontinued/curtailed production or supply disruptions could potentially result in unavailability of such goods or services and have a critical impact on the concerned businesses. The Covid-19 pandemic represented an additional force, highlighting the potential risks of the single-source strategies. The past few years an increasing number of events, from the Covid-19 pandemic to the war in Ukraine, have shaped the risks and opportunities around single source strategies. With long-term strategic alliances, qualification and validation of alternative sources, as well as second supplier development strategies, we are able to reduce the probability of occurrence of these risks and rate them as possible.

Risks due to product-related crime

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

Risks and opportunities from the use of social media

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

Nevertheless, reputational risks could result, for instance through public dialogues in social media. We thus rate this as a potentially significant risk.

Financial risks and opportunities

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

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

Liquidity risks

To ensure continued existence, we must be able to fulfill our commitments arising from operating and financial activities at any time. Therefore, to reduce potential liquidity risks, we have a central Group-wide liquidity management system in place, and a balanced maturity profile. The maturities of our financial liabilities are aligned with our planned free cash flow. Furthermore, we have a syndicated loan facility of € 2.5 billion with a term until 2027, 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 the Group's credit rating should deteriorate. Additionally, we have a commercial paper program with a maximum volume of € 2 billion.

Counterparty risks

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

As for counterparty risks from financial transactions, we review all central positions relating to trading partners and their credit ratings daily. We manage financial risks of default by diversifying our financial positions and through the related active management of our trading partners. Significant financial transactions involving credit risk are entered into with banks and industrial companies that have a good credit rating. Moreover, our large banking syndicate – the renewed syndicated loan facility of € 2.5 billion was syndicated among 15 banks in 2022 – 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 possible risk with a moderate 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 future cash flows from sales and costs in foreign currency. We use derivatives to manage and reduce these risks and opportunities (further information can be found in the note "Derivative financial instruments" in the Notes to the Consolidated Financial Statements). Foreign exchange rate risks are rated as possible with a potential substantial effect on the net assets, financial position, and results of operations.

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 negative impact, are considered possible, and pose an immaterial 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 in the notes “Goodwill” and “Other intangible assets” in the Notes to the Consolidated Financial Statements). All relevant risks were assessed during the preparation of the Consolidated Financial Statements and were taken into consideration accordingly. We rate risks beyond this as improbable with a potential critical impact.

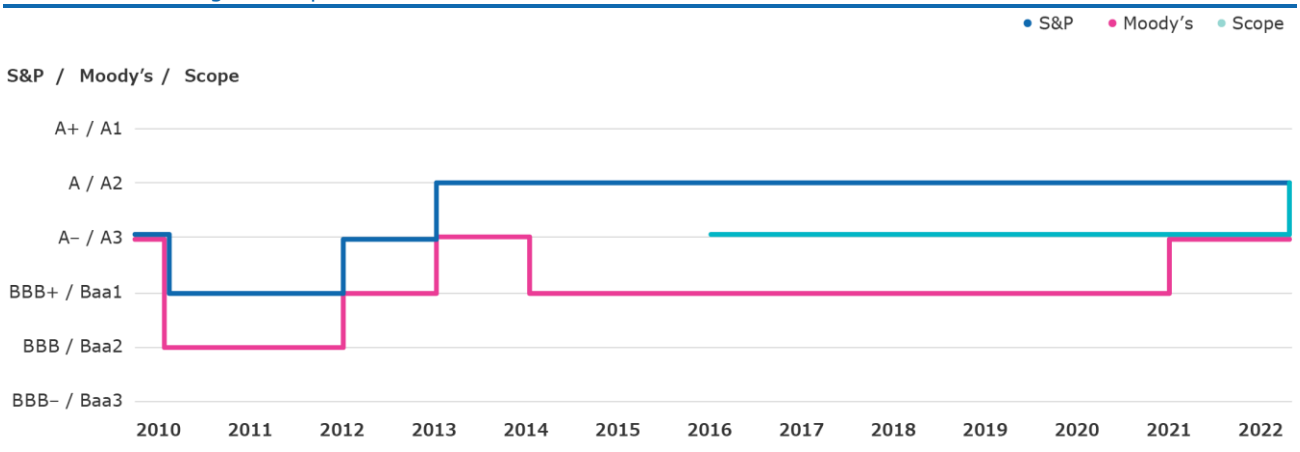
Risks and opportunities from pension obligations

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 possible risk due to pension obligations could have moderate effects on the net assets, financial position, and results of operations.

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 the Group. 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 A3 with a stable outlook, and Scope a rating of A with a stable outlook. In line with market procedures, our financing conditions are closely tied to our rating. The better the rating, the more favorably we can generally raise funds on the capital market or from banks.

Overview of Rating Development



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

Successfully acquiring and subsequently integrating new businesses entails risks. These are primarily centered around the uncertainty of reaching business targets and synergy goals, as well as staying within the planned integration budget. Divestments, on the other hand, could lead to liabilities and additional expenses related to potential indemnifications and commitments guaranteed in the sale transaction. We leverage our solid acquisition track record to reduce the probability of any transaction-associated risks, by integrating lessons learned from past transactions, strong due diligence, and closely managed integration processes. Given the current situation, there are no major risks.

Tax risks

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

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

The Group's tax function regularly and systematically assesses the relevant tax risks. Appropriate standards are put in place to identify tax risks at an early stage in order to review, assess and mitigate them effectively and efficiently. Mitigation measures are coordinated by the tax department with the subsidiaries. Risks in addition to those already considered in the balance sheet are classified as improbable to possible with potential moderate to substantial impact on the net asset, financial position, and results of operations.

For information on the accounting and measurement policies for income taxes, please refer to the section "**Income tax**" in "**Notes to the Consolidated Financial Statements**" in the annual report.

Legal risks

Generally, we strive to minimize and control our legal risks. To this end, we have taken the necessary precautions to identify threats and defend our rights where necessary.

Nevertheless, we are still exposed to risks from litigations or legal proceedings. In particular, these include risks in the areas of product liability, competition and antitrust law, pharmaceutical law, patent law, trademark law, data protection law, tax law, and environmental protection. As a research-based company, we have a valuable portfolio of industrial property rights, patents, and brands that could become the target of attacks and infringements. The outcome of future proceedings or those currently pending is difficult to foresee.

For instance, we are currently involved in litigation with Merck & Co. Inc., Kenilworth, NJ, United States (outside the United States and Canada: Merck Sharp & Dohme Corp. (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 substantial to critical impact on our business and earnings.

Despite extensive precautionary measures, non-compliance with laws and regulations leading to related consequences can never be completely excluded.

In our opinion, the lawsuits described below constitute the most significant legal risks. This should not be seen as an exhaustive list of all legal disputes currently ongoing.

Risks due to antitrust and other government proceedings

Raptiva®: In December 2011, the federal state of São Paulo, Brazil, sued us 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®. We have taken appropriate accounting measures for these issues, which relate to various legal cases. Risks in excess of this with a negative effect on the net assets, financial position, and results of operations cannot be ruled out, but are considered possible with minor impact.

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

Paroxetine: In the United Kingdom, the Group was subject to antitrust investigations by the British Competition and Market Authority in connection with the generics business that was divested in 2007. In March 2013, the authorities informed us of the assumption that a settlement agreement entered into in 2002 between Generics (UK) Ltd., United Kingdom, and several subsidiaries of GlaxoSmithKline plc, United Kingdom, in connection with the antidepressant drug paroxetine, violated British and European competition law and set a fine. They stated that our company was liable as the then owner of Generics (UK) Ltd. and because it was involved in the negotiations for the settlement agreement. The investigations into Generics (UK) Ltd. started in 2011, without this being known to us. After the European Court of Justice confirmed in January 2020 that such settlement agreements can violate European competition law, the Competition Appeal Tribunal confirmed in May 2021 the low single-digit million euro fine that the Group paid in September 2021. British National Health Services subsequently asserted claims for damages on account of the anti-competitive settlement agreements in 2002. The Group and the National Health Service for England and Wales agreed on a settlement payment in December 2022. The payment was made in January 2023. The previous provision in a low double-digit million euro amount was reversed almost in full.

Citalopram: In connection with the generics business that was divested in 2007, the Group was accused of breaching EU antitrust law through agreements entered into by its former subsidiary Generics (UK) Ltd., United Kingdom, relating to the antidepressant Citalopram patented by Lundbeck A/S, Denmark. The European Commission imposed a fine in June 2013. Our company filed a lawsuit against the Commission’s decision with the European Court (EC) in August 2013. The lawsuit was rejected in 2016. Our company subsequently filed an appeal against this decision with the European Court of Justice, which confirmed the first instance ruling in March 2021. Although the fine of € 18 million was paid in 2013, additional potential claims were considered to be probable. A provision in a mid-double-digit million euro amount was recognized for these proceedings as of December 31, 2022. A cash outflow within the next twelve months is considered possible.

Product liability risks

Operating in the chemical and pharmaceutical industry, we are particularly exposed to product liability risks. Product liability risks can lead to considerable claims for damages, costs to avert damages, and potentially loss of reputation. Considering this, we have taken out the liability insurance that is a standard within our industry to mitigate such risks. However, it could be that the insurance coverage available is insufficient for individual cases. Although the occurrence of product liability claims in excess of the existing insurance coverage is considered highly improbable, individual cases could still have a critical effect on the net assets, financial position, and results of operations.

Human resources risks

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

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

Information technology risks

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

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

Increasing international networking and the related possibility of IT system abuse are resulting in cybercrime risks for our company, such as the failure of central IT systems, the loss of the data integrity or the disclosure 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 Group maintains and operates an information protection management system based on ISO 27001. Our governance framework contains organizational, process-related, and technical information security countermeasures based on recognized international standards. In addition, we employ harmonized electronic and physical security controls (e.g., access control and security monitoring) to bolster our ability to handle sensitive data, such as trade secrets.

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

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

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

Despite the mitigation measures applied and functional continuity plans, the effects of cybercrime or the failure of business-critical IT applications and their influence on the net assets, financial position, and results of operations are considered to be possible and with potentially significant impact.

Environmental, climate-related, and safety risks and opportunities

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

As a company with global production operations, we are exposed to risks of possible damage to personnel, goods, and our reputation. Those include physical risks stemming from exposure to droughts, storms, and floods. Mitigation measures like audits, consultations, and trainings on environmental protection, occupational health and safety minimize these risks to people as well as the environment. In order to ensure the continuity of plant and equipment, we monitor these risks both at our own sites as well as at suppliers and contract manufacturers. By adhering to high technical standards, our rules of conduct, and all legal requirements in environmental protection, 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 possible risks based on which a significant impact on the financial position cannot be ruled out.

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 and technology, value chain, and climate and environment. By considering the goals of the sustainability strategy when making business decisions and actively shifting our portfolio to increase the positive sustainability impact, we contribute to achieving the United Nations Sustainable Development Goals. In 2022, we extended the targeted strategies for our business sectors. Also, we launched a sustainability scorecard for our research and development activities. Our dedication to sustainability paired with our commitment to quality, regulatory excellence, and compliance is important for us. Combining these strategic elements will ensure an effective and efficient execution of our strategy and enable us to cater to the increasing expectations of customers, patients, employees, investors, and the general public.

Overall view of the risk and opportunity situation and management assessment

The most significant individual risks or risk clusters have been named in the report above, with business- and market-related risks being the most significant alongside IT and legal risks. Most notably, the still ongoing Covid-19 pandemic and global macroeconomic and geo-political developments increase existing risks related to more restrictive regulatory requirements regarding drug pricing and reimbursement, the demand for our products, business interruptions at our production sites, lack of availability of good quality materials or services, and risks related to research and development.

Following the risk mitigation measures taken – such as the 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 an existence-threatening risk-scenario, for which coverage and financing of the losses are questionable, is highly improbable. We are convinced that we will also successfully manage the above-mentioned challenges in the future and benefit from diversification through our different products and markets. For our assessment of the appropriateness and effectiveness of the risk management system and the internal control system we refer to the Statement on Corporate Governance.

In our view, business-related opportunities offer the greatest potential. 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 operating 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 positive effects on our net assets, financial position, and results of operations.