Fundamental information about the Group

The Group

We are a science and technology company. We are pioneers of human progress, driven by our curiosity. We are working toward a better future in a special organizational setup and are bringing together different disciplines under one roof with the three business sectors Life Science, Healthcare and Electronics.

Our Life Science business sector provides the tools, high-grade chemicals and consumables that accelerate scientific breakthroughs and enable the biopharmaceutical industry to ensure that medicines are safe and effective for a global population.

In our Healthcare business sector, we advance innovation through our research, enable life-changing therapies for serious illnesses, treat patients with cancer, cardiovascular, diabetes, thyroid disorders, and multiple sclerosis, and help people to realize their wish to have a child.

In our Electronics business sector, we are the company behind the companies, advancing digital living. Our semiconductor and display solutions are used in the manufacture of many components for electronic devices. We are thus changing the way in which information is processed and made accessible.

In addition, our specialists also explore visionary new solutions at the interfaces of our three diversified business sectors.

Ever since we were established in 1668, we have continuously reinvented ourselves and adopted a long-term mindset. This approach is rooted in responsibility, care and respect: for our work, our employees, our customers, patients, society, and our planet. We want to become the global 21st century science and technology pioneer and are committed to working towards a better future: sustainable progress for humankind.

The founding family, now in the 13th generation, is still the majority owner. This is made possible by our company structure: a corporation with general partners (Kommanditgesellschaft auf Aktien – KGaA). In a KGaA, the total capital is divided between general partners and limited partners. The founding family holds a 70.274% stake in the listed Merck Kommanditgesellschaft auf Aktien, Darmstadt, Germany (Merck KGaA, Darmstadt, Germany), as general partner via the Group's ultimate parent company, E. Merck Kommanditgesellschaft, Darmstadt, Germany. The remaining 29.726% of the share capital of Merck KGaA, Darmstadt, Germany, is traded on the regulated market of the Frankfurt Stock Exchange and other stock exchanges.

The assessment of business development and the allocation of financial resources are carried out by the entire management of the company for the Life Science, Healthcare and Electronics business sectors as well as the supporting corporate functions. In addition to the Chair of the Executive Board and CEO Belén Garijo, the Members of the Executive Board are Matthias Heinzel, CEO Life Science, Peter Guenter, CEO Healthcare, Kai Beckmann, CEO Electronics, and Helene von Roeder, Chief Financial Officer (CFO). Helene von Roeder was appointed CFO as of July 1, 2023, succeeding Marcus Kuhnert on the Executive Board of the Group.

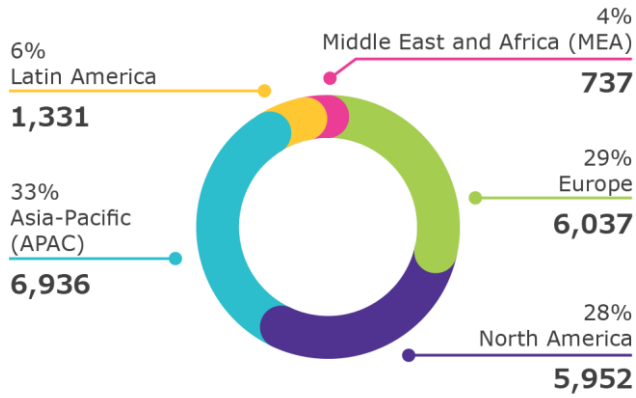
Merck KGaA, Darmstadt, Germany, holds the global rights to the company name and brand. The only exceptions are Canada and the United States. In these countries, we operate as MilliporeSigma in the Life Science business, as EMD Serono in the Healthcare business and as EMD Electronics in the Electronics business.

Apart from our three business sectors, our financial reporting presents five regions: Europe, North America, Asia-Pacific, Latin America, the Middle East and Africa. As of December 31, 2023, we had 62,908 employees[1] worldwide. The figure as of December 31, 2022, was 64,232 employees[1]. We have summarized further details on our employee structure and important aspects such as Diversity, Equity, and Inclusion in the "**Non-Financial Statement**".

For fiscal 2023, we exercise the option of publishing the Statement on Corporate Governance on the Group's website in accordance with section 315d HGB in conjunction with section 289f (1) sentence 2 HGB. It is available at **https://www.emdgroup.com/en/investors/corporate-governance/reports.html**.

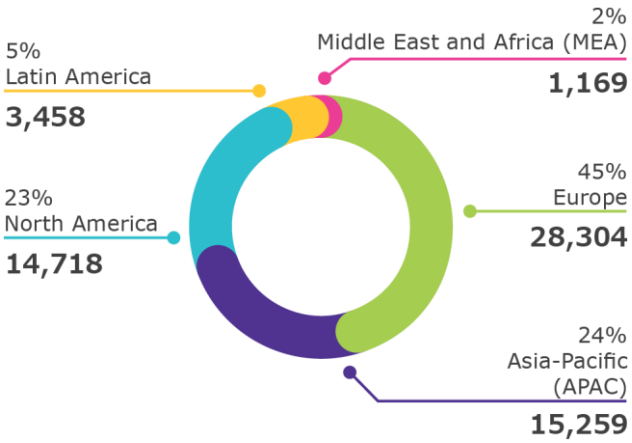
Group

Net sales by region
€ million/in % of net sales



Group

Employees by region as of December 31, 2023[1]
Number/in %



[1] Our company also employs people at sites of subsidiaries that are not fully consolidated. This number refers to people employed in fully consolidated subsidiaries.

Life Science

We are a leading global provider of products and services for a wide range of customers, including research labs, biotech and pharmaceutical companies, diagnostic labs, and the industrial sector.

Across our Life Science business sector, we collaborate with the global scientific community to deliver innovations and to this end, we offer a broad and deep product portfolio as well as global Contract Testing Development Manufacturing Organization (CTDMO) services ranging from process development to commercialization. In 2023, we continued to execute our strategy as a diversified life science company to strengthen our three business units, Process Solutions, Life Science Services, and Science & Lab Solutions. Our R&D teams in the three business units have launched more than 8,500 products to respond to growth trends, including those launched through our "faucet program" for antibodies, reference materials and nanomaterials.

In 2023, Life Science generated 44% of Group sales and 45% of EBITDA pre (excluding Corporate and Other). In recent years, we have steadily expanded our presence in growth markets. Europe and North America generated 70% of Life Science's sales in 2023; Asia-Pacific and Latin America accounted for 29% of sales.

Process Solutions

The Process Solutions business unit continued to focus on delivering its product offering for the pharmaceutical development and manufacture of filtration devices, chromatography resins, single-use assemblies and systems, processing chemicals, and excipients.

Life Science Services

The Life Science Services business unit offers traditional and novel modalities, including monoclonal antibodies, high-potency active pharmaceutical ingredients (HPAPIs) and antibody-drug conjugates as well as viral and gene therapies, including mRNA. In addition to manufacturing, Life Science Services includes sales and marketing, research and development and supply chain operations. Our integrated CTDMO services support clients from preclinical phases to commercial production.

Science & Lab Solutions

The Science & Lab Solutions business unit serves customers in the pharmaceutical, biotech industries and other industries in production, testing and research, as well as public authorities and research institutions. We provide customers with access to a broad portfolio including reagents, consumables, devices, instruments, software, and services for scientific discovery in addition to lab water instruments, consumables and services, microbiology and biomonitoring products, test assays, analytical reagents, and flow cytometry kits and instruments.

In March, we opened a lateral flow assay development lab in St. Louis, Missouri, USA, an innovative space where customers collaborate with our technical experts to troubleshoot point-of-care testing.

Investments to expand capabilities and production

- We have started building a new € 30 million expansion in Allentown, Pennsylvania, USA, which will join the existing facility to create a two-building "distribution campus".
- In May, we announced an investment of € 35 million in biosafety testing facilities at our Glasgow and Stirling sites in Scotland. Biosafety testing is a step in the drug development and manufacturing process to ensure that drugs are safe, effective and compliant with regulatory requirements. Through the expansion, we plan to create nearly 500 new jobs, bringing our Life Science workforce to over 1,200 employees across the two sites.

- The investment includes a new facility in Glasgow, which will house molecular biology and sequencing services. Testing capacity in current buildings will be expanded to include biosafety testing, analytical development and viral clearance suites. The latest investment follows our recent testing expansions in Rockville, Maryland, USA, and Shanghai, China. With its BioReliance® testing services portfolio, Life Science performs more than 20,000 studies annually in the United Kingdom for more than 400 customers globally. BioReliance® contract testing services and the recently formed Millipore® CTDMO Services are part of the Life Science Services business unit.
- Also in May, we signed a non-binding memorandum of understanding with the Korean Ministry of Trade, Industry and Energy and Daejeon City, Korea, for a new Asia-Pacific bioprocessing center aimed at supporting the region's healthcare ecosystem. The planned bioprocessing facility would support commercial manufacturing for biotech and pharmaceutical customers in this region.
- In June, we announced the expansion of production capacity for highly purified reagents at the site in Nantong, China, a major transportation hub in the Yangtze River Delta region. The approximate € 70 million investment will enable large-scale manufacturing of high-purity reagents for quality control and testing for biopharma customers.
- In July, Life Science announced a € 23 million expansion of its facility in Lenexa, Kansas, USA, adding lab space and production capacity to manufacture cell culture media. Cell culture media is used in processes as varied as vaccine manufacturing, gene therapy and monoclonal antibody manufacturing. The company's strategic investments to expand capacity in existing production facilities in the Lenexa, Kansas, USA, and Nantong, China, sites with dry powder media manufacturing lines will increase both local and global production capacity.
- Since September, CTDMO can offer integrated services for all critical stages of mRNA development, manufacturing and commercialization, including products and testing, with the opening of two new GMP-grade mRNA drug substance manufacturing sites in Darmstadt and Hamburg, Germany. The new sites are part of the company's ongoing € 1 billion investment to advance mRNA technologies and build its global mRNA network and capabilities in addition to key acquisitions such as AmpTec and Exelead. With this € 28 million investment, we can provide mRNA services at different scales and applications from preclinical to commercial.
- In November, we completed the second phase of our new € 29 million Biologics Testing Center in Shanghai, China, expanding our first biosafety laboratories, which we inaugurated in 2022, in this market. This expansion enables us to provide local access to a broad range of testing for cell line characterization and lot release, from preclinical development to commercialization.

Sustainable packaging solutions*

Four years after its inception in 2019, the SMASH Packaging plan has entered its next generation, called SMASH 2.0. So far, more than 100 packaging improvement projects have been completed or are underway, removing tens of thousands of metric tons of CO_2 without sacrificing safety, quality, or performance. Key achievements include avoiding more than 300 metric tons of packaging and achieving a 23% reduction of expanded polystyrene (EPS), also known as Styrofoam. 72.5% of the paper-based materials sourced directly for packing and shipping products therefore aligns with the so-called zero deforestation standards.

Digitalization

In March, Life Science launched its open-source code library for Palantir Foundry on GitHub®. Our source code, "Foundry DevTools", was published under an open-source license in collaboration with Palantir. We have been partnering with Palantir since 2017 to build our data and analytics capabilities and contribute to the digital product portfolios of our Life Science, Healthcare and Electronics business sectors. The source code is freely accessible to all Foundry developers worldwide.

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Healthcare

In Healthcare, we operate as a global specialty innovator in the Neurology & Immunology and Oncology franchises as well as in the therapeutic areas of fertility and cardiovascular, metabolic and endocrinological disorders. The Healthcare business sector discovers, develops, manufactures, and markets pharmaceutical and biological prescription drugs to treat cancer, multiple sclerosis (MS), infertility, and growth disorders as well as certain cardiovascular and metabolic diseases. Our R&D pipeline is focused on strengthening our position in the fields of oncology, neurology and immunology.

In 2023, Healthcare generated 38% of Group sales and 41% of EBITDA pre (excluding Corporate and Other). Europe and North America generated 53% of Healthcare's net sales in 2023. In recent years, we have steadily expanded our presence in growth markets. In 2023, Asia-Pacific and Latin America accounted for 40% of sales.

Oncology

Erbitux® (cetuximab) remains our best-selling cancer drug with € 1 billion in sales in 2023. The drug is a standard of care for patients with epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer (mCRC) as well as both recurrent and/or metastatic and locally advanced squamous cell carcinoma of the head and neck (SCCHN). With more than 200 active clinical trials involving Erbitux®, including more than 15 Phase III studies, we are also continuously advancing our broad-based lifecycle management strategy.

We have made progress in changing the standard of care globally for patients with locally advanced or metastatic urothelial carcinoma (UC) as we continue to obtain additional regulatory approvals and reimbursement decisions for our anti-PD-L1 antibody Bavencio® (avelumab) (for further details see "**Research and Development**"). Bavencio® is approved as a first-line maintenance treatment for advanced UC in 71 countries. It has become a standard of care in the treatment of this disease based on the results of the JAVELIN Bladder 100 trial, the only Phase III study of an immunotherapy to demonstrate a significant overall survival benefit in the first-line maintenance setting.

Through our subsidiary Ares Trading SA, we regained exclusive worldwide rights to develop, manufacture and commercialize Bavencio® from Pfizer as of June 30, 2023.

Bavencio® is also approved in the first-line treatment of advanced renal cell carcinoma in combination with axitinib and it is a standard of care as a monotherapy in metastatic Merkel cell carcinoma (MCC), a rare form of skin cancer.

In September 2023, we received U.S. Food and Drug Administration approval of a supplemental Biologics Licensing Application for Bavencio®, converting the MCC indication from accelerated approval into full approval approximately four years earlier than anticipated. As a result, Bavencio® is the first MCC treatment to receive full approval in the U.S. market.

In 2023, we also continued to expand the availability of Tepmetko® (tepotinib), our oral MET inhibitor designed to inhibit the oncogenic MET receptor signaling caused by MET (gene) alterations, with additional regulatory approvals. Tepmetko® is now available in 43 markets globally.

In the therapeutic area of SCCHN, we advanced our global Phase III development program for xevinapant, an IAP (inhibitor of apoptosis protein) inhibitor in 2023, with enrollment completed in the TrilynX study. The recruitment of patients in the XRay Vision study is ongoing (for further details see "**Research and Development**").

In fiscal 2023, we also continued to advance our efforts in novel medicines. For the first antibody-drug conjugate (ADC) developed in our labs, the anti-CEACAM5 ADC M9140, we completed the dose-finding portion of our Phase I study (for further details see "**Research and Development**").

Beyond our ADC platform, we are also evaluating small-molecule DNA damage response (DDR) inhibitors as this therapeutic class has the potential for better outcomes in patients with cancer.

Within our DDR portfolio, we continue to advance the development of our potent and selective inhibitor of ataxia telangiectasia and Rad3-related (ATR), tuvusertib (M1774). We initiated the Phase Ib/IIa DDRiver NSCLC 322 study of tuvusertib in combination with cemiplimab in participants with non-squamous non-small cell lung cancer (NSCLC) (for further details see "**Research and Development**").

Neurology & Immunology

In Neurology & Immunology, we aim to provide transformative treatment solutions to support people living with neurological and immune-mediated conditions while significantly improving quality of life for them and their caregivers. With over two decades of experience in MS, our current portfolio includes two approved products for the treatment of relapsing MS (RMS) – Rebif® (interferon beta-1a) and Mavenclad® (cladribine tablets).

Rebif®, a disease-modifying drug, has been a standard treatment in RMS for over 20 years with more than 1.9 million patient-years of therapy since approval.

Mavenclad®, a short-course oral therapy for the treatment of adults with various forms of highly active RMS, reached blockbuster status in fiscal 2023 with total net sales of more than US$ 1 billion, and is approved in 95 countries worldwide, including those of the European Union, Switzerland, Australia, Canada, and the United States.

With evobrutinib, we had originally aimed to commercialize a first-in-class Bruton's tyrosine kinase (BTK) inhibitor for RMS. In December, we shared the outcome from the EVOLUTION clinical trials, which showed that the investigational drug did not meet its primary endpoint of annualized relapse rate for up to 156 weeks compared to oral teriflunomide.

Fertility

Our Fertility franchise is a global market leader in fertility drugs and treatments.

Infertility is an increasing challenge globally due to demographic changes and lifestyle adjustments such as delayed childbearing. Based on the latest data from WHO, one in six people worldwide is affected by infertility.

According to the latest data, more than five million babies have been born worldwide with the help of Gonal-f®, a therapeutic within our Fertility portfolio. It contains the active ingredient follitropin alfa (r-hFSH alfa), which is a recombinant form of the natural hormone FSH and is available in a convenient and ready-to-use pre-filled injection pen. Treatment with Gonal-f® can result in increased follicles, oocytes, and embryos compared to urinary gonadotropins, thereby improving the chances of pregnancy and live birth.

To support and meet the needs of a variety of patients, in addition to Gonal-f®, we offer another key product called Pergoveris®. It is a product that combines recombinant human follicle-stimulating hormone (r-hFSH) and recombinant human luteinizing hormone (r-hLH). This represents another treatment option for women with severe FSH and LH deficiency. Pergoveris® is also available in a ready-to-use liquid version in a pre-filled injection pen, eliminating the need for mixing.

In September 2023, we announced our new employee "Fertility Benefit" program. The new offer is available to our employees in a number of countries and to their partners, regardless of their marital status. Apart from financial assistance, we offer employees facing fertility issues additional information services related to fertility disorders.

Cardiovascular, Metabolism & Endocrinology

Cardiovascular, Metabolism & Endocrinology (CM&E), which includes the medicines Glucophage®, Euthyrox®, Concor®, and Saizen®, is the largest franchise of the Healthcare business sector in terms of sales.

Concor®/Concor Cor®, containing bisoprolol, is a beta-blocker for treating hypertension and cardiovascular diseases such as coronary heart disease and chronic heart failure. In addition to Concor®/Concor Cor®, the Concor® family includes fixed-dose combinations such as Concor Plus®/Lodoz® (bisoprolol with hydrochlorothiazide).

Euthyrox®, with the active ingredient levothyroxine, is a leading medicine for the treatment of hypothyroidism, a disease with high prevalence but still low diagnosis rates in most emerging markets.

Glucophage®, containing the active ingredient metformin, is a drug for first-line treatment of type 2 diabetes and is available in more than 100 countries. In recent financial years, Glucophage® has been approved by further health authorities for use in prediabetes when intensive lifestyle changes failed.

Saizen®, containing the active ingredient somatropin, is our main endocrinology product and is indicated for the treatment of multiple growth hormone disorders in children and adults. Saizen® can be delivered with the Easypod® electromechanical injection device, the only growth hormone injection device able to wirelessly transfer data such as injection times, dates and doses to the web-based software system Growzen® Connect. Aluetta® (the Saizen® pen) is now available in 67 countries with the objective of expanding the reach of Saizen®, offering additional options for healthcare practitioners and patients and expanding our devices portfolio.

In endocrinology, we build evidence in the digital health space and leverage technology to provide new solutions for patient engagement, partnership with healthcare practitioners and better payer value proposition.

Minimizing the ecological footprint of our operations*

We are continuously taking action to further reduce the negative ecological impact of our operations on our planet with a holistic approach that includes our locations, products, logistics and patients. A portfolio-related activity to reduce the ecological footprint of our operations is the partnership we entered in May with Novo Nordisk, Eli Lilly and Sanofi to pioneer the world's first cross-industry solution for recycling materials from injection pens after use by patients.

Denmark was chosen because of the existing recycling infrastructure in the country. Today, the four companies involved in this partnership account for around six million injection pens used in Denmark annually. The ambitious target for the first 12 months is for 25% of all injection pens distributed by the four companies in Denmark to be recycled, amounting to more than 25 metric tons of plastic.

Electronics

We are a major supplier of materials and solutions for the semiconductor and display industries. We have a portfolio of materials, systems and services as well as R&D and a global production network close to our customers. We have built our portfolio to cater to the continued digitalization and the unabated growth of data. The demand for increasingly sophisticated semiconductor chips and displays will continue to rise, not least thanks to developments such as Artificial Intelligence (AI), 5G (fifth-generation mobile networks) and autonomous driving. In recent years, we have developed into a relevant player in the global electronic materials market. In addition, we offer decorative and functional solutions for surfaces of all kinds.

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In 2021, we started our “Level Up” growth program and are continuing to invest significantly more than € 3 billion in innovation and capacity expansion. Despite difficult market conditions in 2023, we plan to continue our “Level Up” growth program and will adjust the timeframe of our investments in line with market demand.

The Electronics business sector consists of three business units: Semiconductor Solutions, Display Solutions and Surface Solutions. Three cross-functional boards support the business units: Technology Leadership Board, Supply Chain Leadership Board, and Commercial Leadership Board. They define cross-sector standards, steer portfolio management, drive forward the exchange on good practice, and promote transparency.

Electronics accounted for 18% of Group sales in 2023, and its share of EBITDA pre (excluding Corporate and Other) was 15%. In 2023, Asia-Pacific generated 67% of Electronics’ net sales, Europe and North America accounted for 30% of sales.

Semiconductor Solutions

Semiconductor Solutions is the largest business unit in terms of sales within Electronics. It comprises our product and service offering for the semiconductor industry. We are developing materials and solutions to make the next generation of devices – we help make chips smaller, faster, more powerful and more sustainable.

Semiconductor Solutions supplies products for major production steps in wafer processing, including doping, patterning, deposition, planarization, etching, and cleaning. It also supplies delivery equipment for semiconductor manufacturing. Specialty cleans, photoresists, and conductive pastes for semiconductor packaging complement the portfolio. Intermolecular is our center for complex material solutions in Electronics, located in San Jose, California, USA. There, we explore, test, and develop combinations of different materials for next-generation electronics.

Our Semiconductor Solutions business unit consists of the following business fields: Formulations, Thin Films, Specialty Gases and Delivery Systems & Services.

- The Formulations business field comprises the Patterning and Planarization production steps. This includes lithography products for surface treatment such as photoresists and the associated auxiliaries, anti-reflective coatings and materials for directed self-assembly (DSA). The Planarization business comprises CMP materials (chemical-mechanical planarization).
- The Thin Films business field supplies solutions and productions for our customers in the fields of dielectrics (organosilanes and spin-on dielectrics) and metallics product offerings. Many of our materials are used for leading edge nodes, which is the enabler of advanced chips for generative AI.
- The Specialty Gases business field provides high-purity gases for semiconductor manufacturing. These gases are crucial for precise deposition, doping, etching, and cleaning during wafer fabrication. With a strong commitment to meeting the semiconductor industry’s stringent requirements, our Specialty Gases business supports the industry in the development of advanced electronic devices.
- The Delivery Systems & Services (DS&S) business field, with its systems business, develops and installs reliable delivery equipment to ensure the safe and responsible handling of specialty chemicals and gases for semiconductor manufacturing. At many sites of the industry, production facilities and delivery systems are operated and maintained by our MEGASYS® Total Gas and Chemical Services employees.

In 2023, the semiconductor market was impacted by a cyclical downturn, mainly due to advance spending on consumer electronics (PCs, smartphones, game consoles) in previous years due to the Covid-19 pandemic. The situation was amplified by inflation and high interest rates during the fiscal year. These developments prompted consumers to postpone purchases of electronic devices.

Semiconductor manufacturers continue to invest at a high level. This is also evidenced by the strong growth of our equipment business (part of DS&S) in 2023 despite the currently weak semiconductor market. In view of the expected long-term increase in demand, we continue to expand global production capacity for our specialty gas, liquid chemical and slurry delivery systems.

In fiscal 2023, we integrated the chemical business of Mecaro Co. Ltd., which we acquired in 2022, into our Semiconductor Solutions business. We also strengthened our business in thin films technology and our footprint in Korea. In February 2023, we broke ground for a new integrated facility in Kaohsiung, Taiwan. Here we will produce a comprehensive portfolio of semiconductor materials in one single site.

In April 2023, we announced our plans to expand manufacturing capacities at our site in Hometown, Pennsylvania, USA, thus increasing domestic production capacity for electronics components. The roughly € 300 million investment in the Hometown site is intended to further develop our largest integrated specialty gases facility. In June 2023, we commissioned a new production facility for DS&S in Chandler, Arizona, USA.

Display Solutions

Our Display Solutions business unit includes the businesses with liquid crystals (LC), display patterning materials (materials for surface treatment), organic light-emitting diodes (OLED), photoresists, reactive mesogens, smart antenna (LC-based antennas), and liquid crystal glazing (LC-based windows). We support our customers in developing novel display technologies for TV, IT, mobile devices, automotive, gaming, and other applications. Together with our customers we are working in the field of AR/VR to expand the application scenarios of LC & OLED materials and enhance the user experience in small and micro-sized displays. We are working very closely with leading panel makers to develop next-generation products with LCD (liquid crystal display) technology for the electronics market.

While lockdowns and working from home pulled forward demand for TVs and IT devices during the Covid-19 pandemic, this trend has meanwhile reversed. The industry saw a significant reduction in demand during 2023, resulting in a decline in customer factory utilization.

The Covid-19 pandemic has accelerated the shift of the liquid crystals industry towards China and increased competition. In 2023, we maintained our position as manufacturer of innovative LC materials with our XtraBright™ products, winning new projects for large-area displays as well as high-resolution mobile devices. Our OLED and photoresist materials are used in multiple free-form display products. In addition, we are actively working with customers on both LC-on-silicon (LCoS) and OLED-on-silicon solutions for AR/VR displays.

With our OLED materials, we are also supporting our customers in making sustainable OLED structures, which are important for new OLED applications such as IT screens. In 2023, we developed deuterated materials for next-generation OLED displays. They have the potential to more than double the lifetime of OLED stacks without compromising on efficiency and voltage, enabling displays with higher brightness.

Real estate investors use our product eyrise® s350 solar shading (sun protection at the touch of a button) to deliver on ESG (environment, social, governance) objectives. For example, a large real estate investor in Switzerland has already installed eyrise® on all facades of its flagship project in the center of Zurich. More commercial projects are currently in installation.

Surface Solutions

In our Surface Solutions business, we provide our customers with solutions that help them to create functional and decorative surfaces of all kinds. We focus on markets for automotive coatings, cosmetics, and, to a smaller extent, industrial applications. With our portfolio of active ingredients, we enable cosmetics manufacturers to enrich their skin care products with moisturizing, protecting and anti-aging effects. Moreover, our functional solutions serve many innovative applications, from dirt-repellent and easy-care surfaces to laser markings of plastic parts and cables.

Despite the current challenging economic environment, Surface Solutions is continuing to implement its strategic transformation. We continued to invest in digitalizing and modernizing our production plants around the globe while adjusting our capacities to the changing demands in our different markets.

Strategy*

Strategy fundamentals and ambition

We are curious minds dedicated to human progress. We believe that scientific exploration and responsible entrepreneurship are key to technological advances that benefit us all. Our values – courage, achievement, responsibility, respect, integrity, and transparency – guide us in every step we take and in every decision we make. Our company has a firm foundation with convictions and principles that the Merck family has lived by for generations. We always take them into consideration when discussing and deciding on our enterprise strategy.

Compared to last year, we face greater challenges as the increasingly complex global situation has also impacted some of our end markets. This poses challenges for the global economy and society. With a history of more than 355 years and a truly global footprint today, we have established a solid, resilient foundation that continues to bolster our confidence in our ambition for the future – to become the global 21st century science and technology pioneer. To achieve this, we continue to focus on our key growth drivers: Process Solutions, Life Science Services, Science & Lab Solutions, and Semiconductor Solutions as well as developing specialty drugs in our Healthcare business. Our must-win battles include building an organization with comprehensive data expertise and strengthening our ability to innovate. For instance, in our “Data & Digital” initiatives, we focus on identifying, prioritizing, and implementing technical capabilities across our businesses to promote future growth.

Through our multi-industry business model, we serve attractive global markets with secular growth trends as a trusted partner to advance human progress. Our diversified portfolio benefits from key megatrends. In Life Science, this includes a growing market for complex and novel modalities. In Healthcare, we develop and commercialize specialty pharmaceuticals in the Oncology and Neurology & Immunology franchises. These include the medicines Erbitux® (cancer), Bavencio® (cancer) and Mavenclad® (multiple sclerosis). In addition, we are conducting clinical trials with late-stage xevinapant (head and neck cancer) and further drug candidates in oncology, neurology and immunology in earlier stages of clinical development. With our comprehensive portfolio of semiconductor materials, we expect to benefit in the medium and long term from continuously increasing demand for chips due to the exponential growth of data volumes as well as the further implementation of artificial intelligence (AI) and the Internet of Things (IoT).

We strive to make a positive impact in our communities and on the planet while assessing and considering the ESG (environmental, social, governance) impact of our growth ambition. Since the launch of our sustainability strategy, we have achieved essential milestones in integrating sustainability as a foundational element of our overall governance and decision-making frameworks. We are diligently striving to achieve human progress for more than one billion people through sustainable science and technology by 2030. Fully integrating sustainability into our value chains by 2030 is at the forefront of our priorities. In addition, we are committed to achieving climate neutrality and minimizing resource consumption by 2040.

Active portfolio management is an integral part of our strategy. This has enabled us to transform over the last decades and our evolution into a global science and technology pioneer. In this sense, inorganic growth is a relevant element to accelerate strategic plans and to leverage business opportunities in our attractive end markets. Strengthening our key growth businesses remains the highest priority for which mergers and acquisitions (M&A) could serve as appropriate tools.

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Business strategies

Life Science

Our Life Science business sector is a global leader in the approximately € 230 billion life sciences industry. We continue to consistently deliver long-term profitable growth despite near-term headwinds, including a decline in Covid-19-pandemic-related demand, destocking by key customers and softening of funding for early-stage biotech companies. Our long-term market growth outlook remains unchanged at approximately 5% to 7% C AGR, fueled by increasing demand for commercial medicines and the essential nature of R&D across customer segments. We are well-positioned to weather challenging market conditions and emerge as an even more integral partner to our customers.

Our strategy builds on the transformation we began last year, with a sharpened focus on differentiating both our core and high-growth portfolios and capitalizing on the unique capabilities of our company. We are doing this by leveraging our distinctive breadth of offerings to customers in academia, the biopharmaceutical industry and the industrial sector, including food & beverage, to advance leading edge science. We aspire to comprehensively address customers' scientific needs and serve as a partner across products and services with a focus on enabling novel modalities. We amplify customer value by proactively addressing future customer needs to create lasting differentiation beyond the breadth and performance of our offerings. Our multichannel commercial approach, e-commerce platform and focus on sustainability set us apart. We enhance competitiveness by pursuing operational and commercial excellence and building future-oriented capabilities and ways of working.

This course we have set directs our focus and resources to pursuing opportunities that financially and technologically "move the needle" while deprioritizing those that may distract from our focused ambition to continue to be a global science & technology leader. For example, our Process Solutions business unit is optimizing its go-to-market approaches to address shifting customer behaviors, including expanding access to Process Solutions products via sigmaaldrich.com, our e-commerce platform. Our growing Life Science Services Contract Testing and Development Manufacturing Organization (CTDMO) business is building an end-to-end offering for novel modalities with a focus on anti-drug conjugates (ADCs), mRNA and viral vectors, where customers are seeking greater technical expertise and collaboration.

The diverse customer and portfolio base of our Science and Lab Solutions business provides a stable foundation while continuing to build positions in higher-growth segments. Our Integrated Supply Chain Organization's evolution to become more agile, resilient, and customer-centric is an essential foundation for continued profitable growth. To this end, we have implemented new processes to more closely connect our sales and production plans, using digital tools to align with customers on lead times and other supply expectations, standardizing operations across sites and regionalizing our network – especially in Asia-Pacific (APAC) – to meet local needs and balance risk. We have also embedded sustainability criteria in R&D and operations, providing customers with an expanded range of greener alternatives and data, such as product carbon footprints, to help reach their sustainability goals.

Our strategy reflects our purpose – to impact life and health with science – and allows us to deliver customer and shareholder value now and into the future. We are prepared to address short-term challenges and emerge from the post-Covid-19-pandemic era with deeper customer relationships, high-value innovations and a more resilient and cost-effective operating network.

Healthcare

Despite external volatility in recent years, the pharmaceutical industry has proven its resilience and remains attractive with solid growth expectations. Global megatrends such as growing and aging populations as well as better access to healthcare continue to drive the need for our products. At the same time, the macroeconomic and geopolitical environment has become more uncertain. Our mixed portfolio and our diverse geographic footprint build a resilient foundation to meet these demands and respond appropriately to the dynamics of our markets, paving the way for the future success of our Healthcare business.

Following our successes over the past years, we continue to drive pipeline projects with the aim of bringing groundbreaking medicines to patients, maximizing our existing portfolio and continuing our expansion in growth markets. We are resolute in our ambition to become a global specialty innovator with a high-growth future in oncology as well as neurology and immunology. This ambition is built on a firm foundation and continues to foster sustainable and profitable growth in the Cardiovascular, Metabolism & Endocrinology franchise while further strengthening our leadership position in fertility. We pursue this ambition with a focused leadership approach, concentrating investments on decorrelated opportunities in our pipeline and across therapeutic areas, regions and payer types.

The first pillar of our strategy is to reinforce and expand our global footprint, bringing the innovation of our pipeline to patients and growing our presence in the United States and in China, for example. Driven by well-known demographic trends, the expected absolute global pharma market growth contribution will remain highest in established markets, while the emerging markets are expected to grow faster than developed markets in relative terms as a result of rapidly developing pharma infrastructure. With our diversified portfolio of specialty and mature product businesses, we are benefiting from these trends. While our solid base within established markets (France, Germany, Italy, Japan, Spain, the United Kingdom, and the United States) enables us to achieve growth with our specialty portfolio, the emerging markets will be a large growth driver for many of our established products in the future. Managing the balance between delivering innovative new medicines with first-in-class and/or best-in class potential while leveraging our strengths in other markets and ensuring the profitable growth of the existing business will be one of the strategic imperatives.

The second pillar of our strategy is the focus on specialty medicine franchises. Here, we expect the oncology, neurology and immunology markets to remain highly attractive in terms of size, growth prospects and profitability. Within each specialty franchise, our approach is to develop deep internal expertise and insight, from internal research to commercialization, through external talent searches and strategic partnerships. In order to optimize the holistic value and focus of our pipeline, we continuously monitor and assess the potential of our pipeline candidates, based on clinical data, strategic fit and financial criteria, to determine the best way forward.

The third strategic pillar is innovation. We aim to develop potential first-in-class and best-in-class therapies. We have streamlined our pipeline and expanded our innovation capabilities with strong investigational drug candidates and technologies. In order to maximize the output of our R&D investments and to ensure long-term sustainability, we are focusing our expertise on specific franchises. Further, we increase our intake of external innovation, in line with industry practice, to meet our ambition of launching a new product every 18 months. We are investing in assets with the most promising value generation outlook as well as digital technologies and novel modalities such as antibody-drug conjugates to drive pipeline growth.

Electronics

We are an innovation leader within the electronics industry, targeting the most critical materials segments of the semiconductor wafer processing as well as OLED and LC display panels. Our diversified portfolio proves to be resilient in a dynamic market environment. We partner with leading experts around the world to enable the next generation of electronic devices, innovating with leading-edge customers and being a local partner for their global presence.

The long-term growth prospects of the industry remain very attractive, despite the current downcycle. We believe in the long-term growth drivers of digitalization and its visualization, fueled by an exponential increase in data volumes. Semiconductors will thus continue to be a critical component in many industries. The main accelerator in the industry is and will remain AI. Although the number of AI chips is still small, the high growth rates and the high value of these chips as well as the required materials will fuel the growth of the semiconductor industry. This trend will be supported by technologies such as 5G networks, autonomous driving, electric vehicles, and IoT. We will benefit from the high material requirements of these AI chips in terms of value and volume.

In the short term, AI alone cannot offset the current market decline in the electronics industry, which results from weak demand after the Covid-19 pandemic and associated excess inventory along the value chain. However, in the medium and long term, the fundamental growth drivers, such as AI, are expected to accelerate the market development through the next decade. To produce ever more powerful and energy-efficient chips, innovation in novel materials will be even more essential.

To benefit from the strong electronics industry growth, we are continuously expanding our capacities and our capabilities. We are continuing to invest significantly more than € 3 billion in innovation and capacities, which are aligned with the customers and regions we serve. These investments are an essential part of our ongoing Level Up growth program, which we kicked off at the end of 2021. The investments are made in lockstep with the capacity expansions of our customers in order to support their growth and new fabs with a reliable supply of innovative materials and systems. We will continue to invest in our geographic proximity to our customers while boosting R&D and innovation. Electronics also seeks to exploit attractive external growth opportunities through acquisitions.

Our ability to systematically use data and digital methods across the entire value chain differentiates in the market, enabling us to meet and exceed the increasing requirements regarding quality, speed and reliability. Furthermore, we are accelerating important initiatives to transform the industry towards sustainability and investing even further in safety.

After substantial investments in improving our processes and expanding our production capacities in Surface Solutions, we remain confident of successfully implementing our strategic transformation within that business.

Data & Digital strategy

Going forward, we will further identify transformative technologies to serve as pivotal enablers for our growth and innovation ambition. Therefore, we will look into novel technologies beyond our core products and markets while maintaining strategic proximity to our business sectors so as to leverage our existing assets and core competencies. Our Group Science & Technology Office and our newly established Data & AI Organization are leading the implementation of our combined strategy for innovation and “data & digital”. They promote innovation within and between business areas by bringing transformative technology trends into the company and exploiting the potential of high-quality data and state-of-the-art digital capabilities. In addition, we are investing in building smart manufacturing capabilities, across our business sectors thus leveraging synergies across business sectors while also exploring digital business models as a separate growth opportunity.

Furthermore, we are deploying a company-wide harmonized data and analytics operating model and ecosystem. This enables us to derive actionable insights from data, support informed decision-making and scale related activities across the company to solve real business challenges with machine learning and AI.

Data culture is fundamental for our digital transformation. Through targeted measures to improve data literacy activities, we are strengthening the ability of our employees to identify, understand, create, model, analyze, interpret data as well as, communicate and argue with data. We foster generative AI literacy by giving employees the possibility to test AI in a secure environment. With myGPT of Merck KGaA, Darmstadt, Germany, our employees have access to an AI assistant to use when working with confidential and internal information.

Sustainability strategy

Leveraging science and technology

In our view, sustainable entrepreneurship and profitable growth go hand in hand; we can remain competitive only by creating added value for society. Through our innovative and high-quality products, we want to help meet global challenges. At the same time, these types of products secure our financial performance capability. Responsible action is an integral part of our company culture. This also includes respecting the interests of our employees, customers, investors, and society.

Safety and ethics matter just as much to us as business success. We mitigate ethical, economic, environmental, and social risks as far as possible. From the early stages of development through to disposal, we keep an eye on the entire life cycle of a product. We apply strict sustainability standards to our procurement activities. During product manufacture, it is important to us to keep the environmental impact as low as possible, which is why safe production, high environmental standards and strict quality management are of course so important to us. By supplying products that meet extensive sustainability criteria, we also help other companies to achieve their sustainability goals.

Sustainability is an essential element of our enterprise strategy. We have set ourselves three strategic sustainability goals: In 2030, we will achieve progress for more than one billion people through sustainable science and technology. By 2030, we will fully integrate sustainability into our value chains. By 2040, we will be climate neutral and reduce our resource consumption. With these goals, we are helping to achieve the UN Sustainable Development Goals (SDGs). Overall, our sustainability strategy is centered on seven focus areas within which we are realizing numerous initiatives and projects today and tomorrow, measuring our progress as we go.

Refining the sustainability strategy

In 2023, we revised our sustainability strategy, which we had communicated in 2020. In particular, we sharpened the second goal: Under the new heading “Partnering for sustainable business impact”, we want to strengthen our focus on the social aspects in our value chains and embed sustainability more comprehensively into our decision-making processes. Therefore, in addition to the existing focus area “Sustainable and transparent supply chain”, we are now also working on the new focus areas “Sustainability in our ways of working and decision-making” and “Our people and communities; providing a diverse and inclusive environment”. For the third goal, “Reducing our ecological footprint”, we modified two of our key indicators for waste and water. The two new indicators, which are valid as of 2024, use more common metrics and also include circular economy criteria.

We use 14 key indicators to record and assess our progress towards achieving our sustainability goals. Our annual Long-Term Incentive Plan (LTIP) for Executive Board members and senior executives contains a sustainability factor. We use it to measure performance over a period of three years based on selected key indicators for each of our three sustainability goals. Details on how this sustainability factor is calculated can be found in the “**Compensation Report**”. In 2023, the company tied 15% of variable employee compensation to sustainability parameters for the first time.

We are in the process of transforming the company and are integrating sustainability into the innovation process and all parts of the value chain. It is our aim to decouple the growth of our businesses from negative environmental impacts. More information on sustainability topics can be found in the “**Non-Financial Statement**”, which is also part of the management report.

Strategic finance and dividend policy

We pursue a conservative financial policy characterized by the following aspects:

Financial flexibility and a conservative funding strategy

We ensure that we meet our obligations at all times and adhere to a conservative and proactive funding strategy that involves the use of various financial instruments. Our diversified and profitable business activities form the basis for our strong and sustainable cash flow generation capacity. Moreover, we have several funding resources in place. A € 2.5 billion syndicated loan facility is in place until 2028 to cover unexpected cash needs. This credit line is a backup facility that is intended to be used in exceptional circumstances only.

We also agreed upon several bilateral loan facilities. In addition, we have a commercial paper program with a volume of € 2.5 billion at our disposal. Within the scope of this program, we can issue short-term commercial paper with a maturity of up to one year.

The bond market also represents an important source of financing. The most recent bond issue took place in June 2022 (€ 1.0 billion bond issue). The use of various instruments provides a broad financing basis and addresses different investor groups.

Maintaining long-term and reliable business relations with a core group of banks

We work mainly with a well-diversified, financially stable, and reliable group of banks. Due to our long-term business approach, bank relationships typically last for many years and are characterized by professionalism and trust. The banking group consists of banks with strong capabilities and expertise in various products and geographical regions. We regard these banks as strategic partners and involve them in important financing transactions accordingly.

Strong investment-grade rating

The rating of our creditworthiness by external rating agencies is an important indicator of financial stability. A strong investment-grade rating is an important cornerstone of our financial policy as it safeguards access to attractive financial conditions on the capital markets.

In November 2023, our ratings were confirmed by Moody’s (A3, stable outlook) and Standard & Poor’s (A, stable outlook). We discontinued our Scope rating (previously: A, stable outlook) in December 2023.

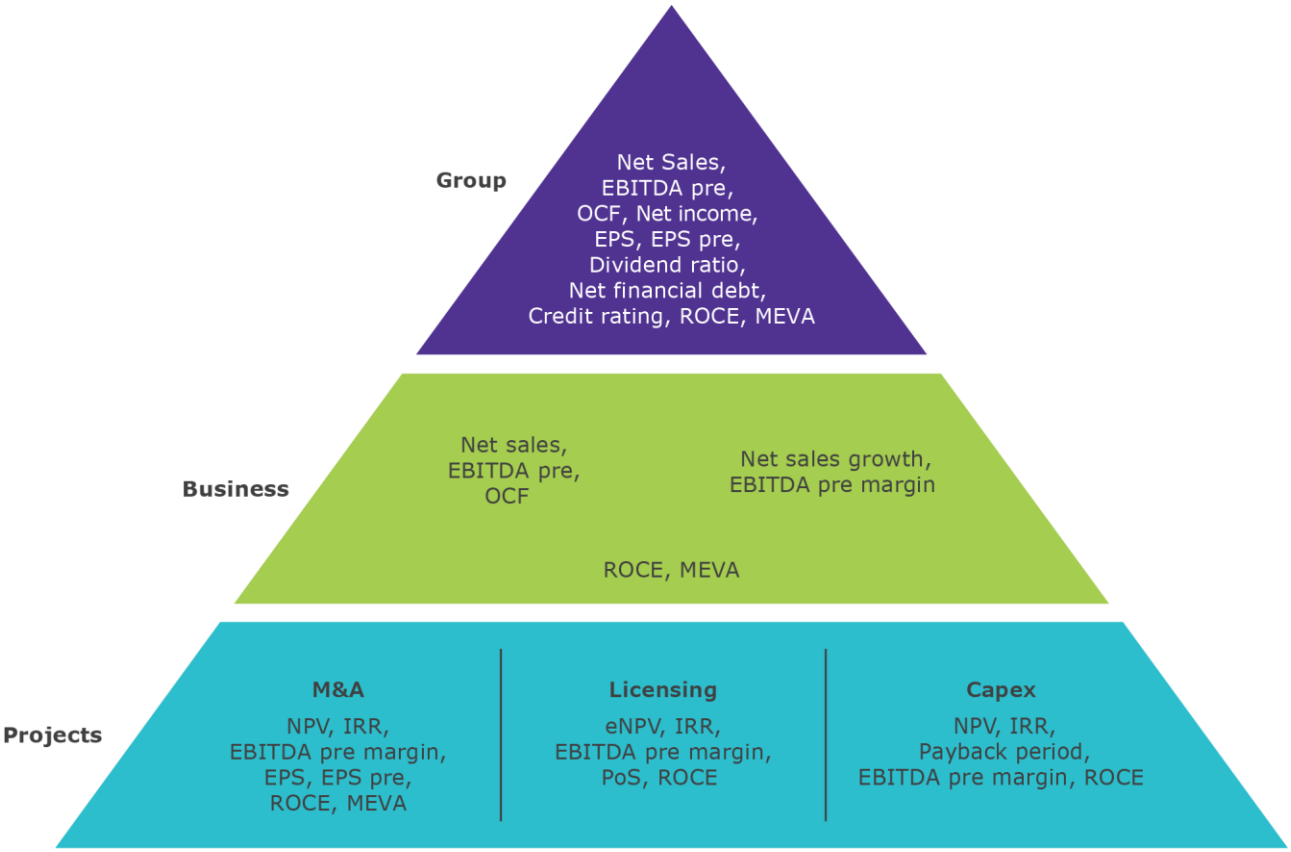
Sustainable dividend policy

We are pursuing a sustainable dividend policy. Provided the economic environment develops in a stable manner, the current dividend represents the minimum level for future dividend proposals. Our dividend policy will follow business development and earnings increases over the coming years. However, dividend growth could deviate, for example, within the scope of restructuring or in the event of significant global economic developments. We aim for a target corridor of 20% to 25% of earnings per share pre.

Internal Management System

As a global company with a diverse portfolio of products and services, we use a comprehensive framework of indicators to manage performance. The most important key performance indicator (KPI) for measuring performance is EBITDA pre[1].

The Value Creation and Financial KPI Pyramid, which summarizes our important financial performance measures, reflects the comprehensive framework of financial KPIs to steer the businesses and prioritize the allocation of cash resources. It consists of three managerial dimensions: Group, Business, and Projects, each of which requires the use of different indicators.



Abbreviations
EBITDA pre[1] = Earnings before interest, income tax, depreciation and amortization as well as adjustments.
EBITDA pre-margin[1] = Earnings before interest, income tax, depreciation and amortization as well as adjustments in percent of the net sales.
EPS = Earnings per share.
EPS pre[1] = Earnings per share before adjustments.
MEVA[1] = Value added of the Group.
OCF[1] = Operating cash flow.
ROCE[1] = Return on capital employed.
NPV[1] = Net present value.
IRR[1] = Internal rate of return.
eNPV[1] = Expected net present value.
PoS[1] = Probability of success.
M&A = Mergers and acquisitions.

[1] Not defined by International Financial Reporting Standards (IFRS).

Key performance indicators of the Group and its businesses

The three key performance indicators of net sales, EBITDA pre, and operating cash flow (OCF) are the most important financial factors for assessing operational performance. Accordingly, we refer to these KPIs in the "**Report on Economic Position**", the "**Report on Risks and Opportunities**", and the "**Report on Expected Developments**". As the most important indicators of financial business performance, the KPIs are key elements of our performance management system.

Net sales

Net sales are defined as the revenues from the sale of goods, services rendered to external customers, and commission income and profit sharing from collaborations, net of value-added-tax, and after sales deductions such as rebates or discounts. Net sales are the main indicator of our business growth and therefore an important parameter of external as well as internal performance measurement. In addition, organic sales growth compared with the target is used for internal performance management. Organic sales growth shows the percentage change in net sales versus a comparative period, adjusted for exchange rate and portfolio effects. Exchange rate effects may arise as a result of foreign exchange fluctuation between the functional non-euro currency of a consolidated company and the reporting currency (euro). By contrast, portfolio effects reflect sales changes due to acquisitions and divestments of consolidated companies or businesses.

Group

Net sales

			Change	
€ million	**2023**	2022	€ million	%
Net sales	**20,993**	**22,232**	**-1,239**	**-5.6%**

EBITDA pre

EBITDA pre is the main performance indicator measuring ongoing operational profitability and is used internally and externally. To permit a better understanding of the underlying operational performance, the operating result is adjusted to exclude depreciation and amortization, impairment losses and reversals of impairment losses, as well as adjustments. These adjustments are restricted to the following categories: integration expenses, IT expenses for certain projects, restructuring expenses, gains/losses on the divestment of businesses, acquisition expenses, and other adjustments. The classification of specific income and expenses as adjustments follows clear rules and is subject to strict governance at the Group level. Within the scope of internal performance management, EBITDA pre permits process efficiency increases without influencing the performance of the operating business through exceptional items or restructuring expenses. The following table shows the composition of EBITDA pre in fiscal 2023 compared with the previous year. The IFRS figures have been modified to reflect the elimination of adjustments included in the respective functional costs.

Group

Reconciliation EBITDA pre[1]

	2023			2022[2]			Change
€ million	IFRS	Elimination of adjustments	pre[1]	IFRS	Elimination of adjustments	pre[1]	pre[1]
Net sales	**20,993**	**–**	**20,993**	**22,232**	**–**	**22,232**	**-5.6%**
Cost of sales	-8,600	43	-8,558	-8,527	32	-8,496	0.7%
Gross profit	**12,392**	**43**	**12,435**	**13,705**	**32**	**13,737**	**-9.5%**
Marketing and selling expenses	-4,510	44	-4,466	-4,714	32	-4,681	-4.6%
Administration expenses	-1,392	246	-1,146	-1,306	115	-1,191	-3.8%
Research and development costs	-2,445	7	-2,438	-2,521	75	-2,446	-0.3%
Impairment losses and reversal of impairment losses on financial assets (net)	-51	–	-51	-6	0	-6	>100.0%
Other operating income and expenses	-385	138	-247	-685	323	-361	-31.6%
Operating result (EBIT)[1]	**3,609**			**4,474**			
Depreciation/amortization/ impairment losses/reversals of impairment losses	1,880	-87	1,792	2,030	-232	1,798	-0.3%
EBITDA[2]	**5,489**			**6,504**			
Restructuring expenses	249	-249	–	198	-198	–	
Integration expenses/IT expenses	118	-118	–	88	-88	–	
Gains (-)/losses (+) on the divestment of businesses	-51	51	–	-38	38	–	
Acquisition-related adjustments	18	-18	–	29	-29	–	
Other adjustments	56	-56	–	68	-68	–	
EBITDA pre[1]	**5,879**	**–**	**5,879**	**6,849**	**–**	**6,849**	**-14.2%**
thereof: organic growth[1]							-9.0%
thereof: exchange rate effects							-4.9%
thereof: acquisitions/divestments							-0.3%

[1] Not defined by International Financial Reporting Standard (IFRS).

[2] Not defined by International Financial Reporting Standards (IFRS); EBITDA corresponds to operating result (EBIT) adjusted by depreciation, amortization, impairment losses, and reversals of impairment losses.

Operating cash flow (OCF)

Operating cash flow results from the Group's current business activities and describes the cash generated from operating activities. It is influenced mainly by EBITDA pre, income tax, the financial result and changes in net working capital.

Group

Operating cash flow

			Change	
€ million	**2023**	2022	€ million	%
EBITDA pre[1]	**5,879**	**6,849**	**-970**	**-14.2%**
Adjustments[1]	-390	-345	-45	13.1%
Finance result[2]	-125	-187	62	-33.0%
Income tax[2]	-650	-948	298	-31.4%
Changes in working capital[1]	-141	-917	776	-84.7%
thereof: Changes in inventories[3]	-89	-604	516	-85.3%
thereof: Changes in trade accounts receivable[3]	-8	-413	405	-98.0%
thereof: Changes in trade accounts payable/refund liabilities[3]	-43	101	-144	>100.0%
Changes in provisions[3]	188	279	-91	-32.5%
Changes in other assets and liabilities[3]	-755	-445	-310	69.6%
Neutralization of gains/losses on disposal of fixed assets and other disposals[3]	-150	-48	-102	>100.0%
Other non-cash income and expenses[3]	-72	21	-93	>100.0%
Operating cash flow	**3,784**	**4,259**	**-475**	**-11.2%**

[1] Not defined by International Financial Reporting Standard (IFRS). Adjustments according to definition above.

[2] According to Consolidated Income Statement.

[3] According to the Consolidated Cash Flow Statement.

[4] As of January 1, 2023, the tranche of the Long-Term Incentive Plan of Merck KGaA, Darmstadt, Germany, to be paid out in the months following the balance sheet date is disclosed under other current non-financial liabilities and no longer under current provisions for employee benefits. For better comparability, the previous year's figures have been adjusted.

Investments and value management

Sustainable value creation is essential to secure the long-term success of the company. To optimize the allocation of financial resources, we use a defined set of parameters as criteria for prioritizing investment opportunities and portfolio decisions.

Net present value (NPV)

The main criterion for prioritizing investment opportunities is net present value. It is based on the discounted cash flow method and is calculated as the sum of the discounted free cash flows over the duration of a project. The weighted average cost of capital (WACC), representing the weighted average of the cost of equity and cost of debt, is used as the discount rate. Different markups are applied to the WACC depending on the nature and location of the respective project.

Internal rate of return (IRR)

The internal rate of return is a further important criterion for the assessment of acquisition projects and investments in property, plant and equipment, as well as intangible assets. It is the discount rate that makes the present value of all future free cash flows equal to the initial investment or the purchase price of an acquisition. A project adds value if the internal rate of return is higher than the weighted cost of capital including markups.

Return on capital employed (ROCE)

In addition to NPV and IRR, return on capital employed is an important metric for the assessment of investment projects when looking at individual accounting periods. It is calculated as the adjusted operating result pre (EBIT pre) divided by the sum of property, plant and equipment, intangible assets, trade accounts receivable, trade accounts payable, and inventories.

Payback period

An additional parameter for assessing investments in property, plant & equipment, and intangible assets is the payback period, which indicates the time in years after which an investment will generate positive net cash flow.

Value added of the Group (MEVA)

Value added of the Group gives information about the financial value created over a period of time. Added value is created when the return on capital employed (ROCE) of the company or the business is higher than the weighted average cost of capital (WACC). MEVA metrics provide us with a powerful tool to weigh investment and spending decisions against capital requirements and investors’ expectations.

Capital market-related parameters

Net income, earnings per share (EPS) and earnings per share pre (EPS pre)

Earnings per share are calculated by dividing profit after tax attributable to the shareholders of Merck KGaA, Darmstadt, Germany (net income) by the weighted average number of theoretical shares outstanding. The use of a theoretical number of shares takes into account the fact that the general partner's capital is not represented by shares. As an alternative comparison, we also report earnings per share pre, which are adjusted for the effects of integration expenses, IT expenses for selected projects, restructuring expenses, profits/losses from the divestment of businesses, acquisition expenses, and other adjustments. Amortization of acquired intangible assets is also adjusted for. The adjustment excludes impairment losses on intangible assets for acquired research and development (R&D) projects below a threshold value of € 50 million. Income tax is calculated on the basis of the Group's underlying tax rate. The following table presents the reconciliation of net income to net income pre for the calculation of EPS pre.

Reconciliation net income to net income pre[1]

			Change	
€ million	**2023**	2022	€ million	in %
Net income	**2,824**	**3,326**	**-502**	**-15.1%**
Non-controlling interest	10	14	-3	-25.6%
Income tax	650	948	-298	-31.4%
Amortization of acquired intangible assets	783	830	-47	-5.6%
Adjustments[1]	477	577	-99	-17.2%
Income tax on the basis of the underlying tax rate[1]	-1,044	-1,310	266	-20.3%
Non-controlling interests to be adjusted	-10	-14	3	-25.6%
Net income pre[1]	**3,691**	**4,371**	**-680**	**-15.6%**
Earnings per share pre[1] in €	**8.49**	**10.05**	**-1.56**	**-15.5%**

[1] Not defined by International Financial Reporting Standards (IFRS).

Dividend ratio

We pursue a reliable dividend policy with a target payout ratio based on EPS pre (see definition above) with the aim of ensuring an attractive return for our shareholders.

Credit rating

The rating of our creditworthiness by external agencies is an important indicator of our ability to raise debt capital at attractive market conditions. The capital market makes use of the assessments published by independent rating agencies in order to assist debt providers in estimating the risks associated with a financial instrument. We are currently assessed by Moody's and Standard & Poor's. The most important factor for the credit rating is the ability to repay debt, which is determined in particular by the ratio of operating cash flow to net- or gross financial debt.

Relevant non-financial performance measures

Along with the indicators of the financial performance of the businesses, non-financial measures also play an important role in furthering the success of the company.

High-Impact Culture

Our culture should embody what unites us as well as the way in which we collaborate, lead and work as a team to achieve human progress and drive the company forward. We live our high-impact culture and through this, we measure our ability to attract, develop and retain the right people.

Sustainability

According to our sustainability strategy, which was revised in 2023, we aim to achieve human progress through sustainable science and technology, fully integrate sustainability into our value chains and reduce our ecological footprint. We are pursuing these goals in seven focus areas, within which we are realizing numerous initiatives and projects and measuring our progress.

Diversity, equity and inclusion

We know that diversity drives progress. It strengthens our ability to innovate and makes an essential contribution to our success in science and technology. We actively promote and measure the diversity of our leaders to create an inclusive culture that reflects our values and enables every employee to fulfill their potential.

Research and Development

We conduct research and development (R&D) worldwide to develop new products and services to improve the quality of life of patients and meet the needs of our customers. Further optimizing the relevance and efficiency of our research and development activities – either on our own or in collaboration with third parties – is one of our top priorities. In addition, we are continuously improving the fulfilment of our sustainability criteria and integrating them into our R&D processes starting with our product development stage. In 2023, we evaluated almost all relevant R&D projects, thereby increasing transparency regarding the sustainability performance of our global R&D portfolio.

Around 6,500 employees (2022: approximately 7,300) worked in R&D and related support functions in 2023. They dealt with innovations to address long-term health and technology trends in both established and growth markets.

Expenditure for R&D amounted to € 2.4 billion in 2023 (2022: € 2.5 billion).

The organizational setup of our R&D activities reflects our structure with three business sectors. In the Life Science business sector, our research activities focus on developing innovative technologies for laboratory and life science applications in government and academic labs, the biopharmaceutical industry, and the industrial sector. Our Life Science Technology Office, established in 2022, continues to drive long-term innovation and ensures that R&D investments are aligned with our growth strategy. Our goal is to accelerate and impact scientific discovery across our Life Science business units and the Group as a whole. We focus on digital and automated labware, the factory of the future and novel modalities as well as providing more sustainable products for the lab. In addition, our teams remain dedicated to delivering advancements in our core portfolios, such as filtration, pure water for use in laboratories and diagnostic solutions.

With our Healthcare business sector’s R&D pipeline, we aspire to make a positive difference for patients. Our main research areas include oncology and immunology, including multiple sclerosis. The main focus of our Electronics business sector's research is on developing innovative materials and technologies required for the manufacture of ever smaller, faster, more powerful, and more sustainable processors and memory chips. Furthermore, Electronics develops novel materials for next-generation displays and functional and decorative effect pigments for use in the automotive and cosmetics industries and other industrial applications.

We are firmly convinced that science should not be conducted in silos. We believe that a modern, multidisciplinary approach to science will power the next wave of human progress. We call this approach “bioconvergence” because it leverages synergies across digital and material science as well as biotechnology. Success depends on the ability to combine a broad mix of competencies and technologies across several disciplines to create novel market solutions. We are a diversified science and technology company with leading positions across the life science, healthcare and electronics industries. Our goal is to harness synergies not only within our business sectors, but across them.

Examples of opportunities we are developing at the intersection of our business sectors and converging technologies include:

- Continuing to build our automated design-make-test-analyze platform powered by state-of-the-art artificial intelligence (AI) and lab automation. This will accelerate the discovery of new and better drug candidates and in turn expedite timelines for new therapies to reach patients.
- Using our capabilities across the Group in messenger ribonucleic acid (mRNA) synthesis, lipid nanoparticle (LNP) synthesis and formulation and targeted delivery as well as AI to enable the development of “smarter” LNPs that can more effectively target different tissue types including hard-to-reach biological targets in various disease areas.
- Developing digital twins in smart manufacturing. As virtual models designed to accurately replicate a physical object or organism, they can help to improve the time, cost, quality, and sustainability of manufacturing, process optimization and product development. Examples include making pharma supply chains more traceable and trustworthy. We developed a model for primary packaging in the pharmaceutical industry, and in cooperation with a partner provided proof-of-concept.

- Advanced microphysiological systems based on human cell culture models promise to deliver faster and more accurate drug testing results compared with today's two-dimensional approaches and might reduce animal testing. We are currently looking into this next generation of organoids based on chip technology, bringing our Life Science, Healthcare and Electronics colleagues together to work on this area of innovation.

In our R&D, AI and machine learning have demonstrated their ability to predict the properties of new materials. However, our applications of AI and machine learning go beyond just internal use. One example of AI and machine learning being commercialized is the progress made on AIDDISON™. This AI-powered drug discovery software uses generative AI based on two decades of historic data. The software, which had been in development since 2020, was launched by Life Science in 2023. In addition to external commercialization, we also use it in our Healthcare business sector for internal early drug discovery.

High-quality, interoperable data combined with analytics and AI offer unprecedented potential for new digital business models adjacent to our current product offering and unlock additional growth opportunities. Examples include Syntropy and Athinia™, which are partnerships with Palantir.

Syntropy provides a data integration and analytics environment wherein healthcare organizations can contextualize and analyze infinitely a wide variety of data types across their entire ecosystem in an unlimited and secure manner. In 2023, Syntropy announced a partnership with Evidium to develop an AI operating system for healthcare: This alliance will make it easier for clinicians to contextualize clinical data at the source and for scientists to securely collaborate on that data. In the era of increasingly prevalent generative AI, it is crucial for AI to be trustworthy and responsible, especially in healthcare.

Athinia™ is targeting the semiconductor industry and is a collaborative data ecosystem where multiple companies leverage AI to solve critical challenges by utilizing data to improve supply chain transparency, quality and reliability of materials and to accelerate time to market. In July 2023, Athinia™ expanded its partnerships to include Tokyo Electron for real-time collaborative analysis of the performance of semiconductor manufacturing equipment. As a cloud solution, Athinia™ is an independent platform that provides a secure and specific data analytics tool for the industry. In the context of a sustainability application, data from various sources can be integrated to facilitate seamless collaboration in modeling, exchanging, and calculating carbon emissions data. As a founding member of the Semiconductor Climate Consortium, Athinia™ is leading the way in establishing sustainability standards on a digital platform. Companies can use this platform to benchmark their emissions performance against their industry peers, identify areas for improvement and participate in collaborative initiatives aimed at reducing emissions.

Research and Development Costs

			Change	
€ million	**2023**	2022	€ million	%
Life Science	396	399	-3	-0.7%
Healthcare	1,657	1,694	-37	-2.2%
Electronics	297	308	-11	-3.5%
Corporate and Other	94	119	-24	-20.5%
Total	**2,445**	**2,521**	**-75**	**-3.0%**

The ratio of research expenditure to Group sales was 11.6% (2022: 11.3%). The increase is due to the negative sales development.

Life Science

Across our three business units Process Solutions, Life Science Services, and Science & Lab Solutions, our R&D teams continue to bring expertise and a diversified and relevant portfolio of products and services to our customers around the world.

As the fields of preventive and personalized medicine evolve, it will be essential to set the standard with robust, scalable, efficient processes for viral vector production, next-generation sequencing and autologous cell therapies. This in turn will support the expansion of disruptive cell and gene therapies to treat the most challenging and chronic conditions, including cancer, heart disease, diabetes, and muscular dystrophy.

To this end, a large number of engineers, chemists and biologists across five global hubs are focused on six strategic innovation vectors: building our core portfolio, factories and labs of the future, novel modalities, next generation biology, AI and digital, and sustainability. In 2023, we launched more than 8,500 products including products under our “faucet program” for antibodies, reference materials, chemicals, and nanomaterials.

Process Solutions*

In January, we introduced the Pellicon® Capsule with Ultracel® membrane, which meets the single-use tangential flow filtration (TFF) device requirements for the antibody-drug conjugate (ADC) manufacturing process. Engineered with operator safety in mind, the Pellicon® Capsule features for easy connection to a single-use TFF system. The capsules are resistant to organic solvents commonly used in the ADC manufacturing process.

In April, we launched Ultimus® single-use process container film, designed to provide extreme durability and leak resistance for single-use assemblies used for bioprocessing liquid applications. Ultimus® film is designed with a proprietary woven nylon structure and provides enhanced bag strength and resilience. This technology is now available in Mobius® 3D process containers.

In July, the Mobius® iFlex Bioreactor was launched as the latest addition to the BioContinuum™ Production and Harvest Platform, our integrated solution for perfusion process development and manufacturing. Alongside our portfolio of EX-CELL® Advanced HD Perfusion, Mobius® Breez Microbioreactor and Cellicon® Cell Retention Solution, the Mobius® iFlex Bioreactor enables customers to realize the efficiency gains and cost savings of production intensification and continuous monoclonal antibody (mAb) manufacturing.

In March, Medicine Maker recognized the Process Solutions business unit with its Best Biopharma Equipment Company award.

Life Science Services*

One key R&D investment for Life Science Services was the expansion of Contract Testing Development and Manufacturing Organization (CTDMO) Services with two new GMP-grade mRNA drug substance manufacturing sites in Darmstadt and Hamburg, Germany. Consequently, our offering is the first to encompass all key stages of mRNA technologies, lipids, lipid nanoparticles (LNP), and fill & finish, including key products and biosafety testing.

Life Science Services received three awards in 2023. In March, it was recognized at Life Science Leader’s 2023 CDMO Leadership Awards in five categories: capabilities, compatibility, expertise, quality, and service. In September, it received the API Development Award for ChetoSensar™ at the 2023 CPHI Pharma Awards as well as the Best Biologics CMO Award at the 2023 Asia Pacific Biologics CMO Excellence Awards 2023.

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Science & Lab Solutions*

From nanomaterials enhancing battery performance to optimal media culture for producing lab-cultivated meat, the breadth, and depth of our Science & Lab Solutions portfolio highlights how life science innovation improves important aspects of our daily lives.

The lab of the future

One important driver for the Science &Lab Solutions business innovation is digitalizing the lab of future, with workflows through AI, machine learning, automation, and other solutions. It supports scientists at all stages with tools that can increase efficiency, safety and success rates of delivering new, safer therapies for patients. By combining expertise in small molecules, biologics and new modalities with AI and other digital tools, we are helping to redefine how drugs are discovered, developed and produced.

In December, we launched AIDDISON™ drug discovery software, the first AI-powered software-as-a-service platform that bridges the gap between virtual molecule design and real-world manufacturability through Synthia™ retrosynthesis software Application Programming Interface (API) integration. It combines generative AI, machine learning, and computer-aided drug design to speed up drug screening. Trained on more than two decades of experimentally validated datasets from pharmaceutical R&D, AIDDISON™ identifies compounds from more than 60 billion possibilities that have key properties of a promising active ingredient, such as non-toxicity, solubility, and stability in the body. The platform then proposes ways to best synthesize these drugs.

In February, we launched M-TRACE® All-in-One Computer solution, another example of how we are digitalizing the lab. M-TRACE® offers a cleanroom-friendly way to create test records used during sterility testing and other quality control workflows. Compliant with the QC sterility testing environment, it enables full data traceability.

In November, we launched ChemisTwin™, an online digital reference materials platform. It is a digital reference materials platform that can perform automatic analysis of samples' purity, identity, and degradation of compounds through over 1,500 calibrated algorithm-based digital references. Reference materials ensure the quality and safety of medicines and other products (such as water, food and beverage) from the earliest stages of research and development through quality control and quality assurance testing.

Efficiency and productivity-enhancing tools

We continued to offer incremental and sustainable technologies that improve productivity challenges to address customers' key challenges. In June, we launched mPAGE® Lux electrophoresis gel, a product that decreases, from 90 to three minutes, the time-consuming and key step of gel casting for western blotting, a method for protein separation.

In December, we launched the Milli-Q® SQ-2 series systems. With eight patents for its innovative features, this ultrapure lab water equipment offers greater flexibility, autonomy and sustainability – with less energy and water consumption. The system does not require a direct connection to a water pipe, so researchers can draw ultrapure water via the equipment at the point of use without any intermediate installations.

The next frontier in cell culture

The launch of 3dGRO™ Patient-Derived Organoids (PDOs) is also opening up new possibilities for researchers. During 2023, we launched 20 pancreatic and 20 colorectal organoids, along with 3dGRO™Wnt3a conditioned media supplement used for organoids. These complex, multicellular 3-dimensional in vitro cell models used in biomedical research that closely mimic in vivo organs are a powerful way to study drug responses, disease progression, and more. An important tool in cancer research, organoids provide a more relevant, phenotypic model of cancer than traditional 2D cell culture models.

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Healthcare

With our Healthcare research, we aspire to make a positive difference for patients. Our business sector-wide "Focused Leadership" approach to pipeline enrichment builds on our established expertise in the underlying disease biology of our core therapeutic areas of oncology, neurology and immunology as well as technological capabilities. By building on our existing strengths and maximizing synergies within our pipeline of compounds discovered in-house and with external assets, we will secure sustainable R&D productivity in order to provide innovative medicines to patients in need. In November 2022, we announced that we would aim to launch one new product or indication every 1.5 years on average, bolstered by external innovation.

Oncology*

In Oncology, our scientific curiosity and dedication to patients are at the heart of our efforts to improve the future of people living with cancer. In this core focus area of our R&D portfolio, we aim to deliver transformative treatments. Translational research is embedded into the whole R&D process, with several projects addressing unmet needs in difficult-to-treat cancers through innovative treatment approaches and novel combinations.

We are committed to bringing new standards of care for multiple tumor types to as many patients as possible worldwide. Therefore, in 2023 we continued to explore the impact of our marketed therapies through continued analysis of data from our pivotal studies and the generation of real-world evidence. We are assessing these treatments in new settings as well.

Bavencio®

To date, Bavencio® (avelumab), an anti-PD-L1 antibody, has been approved in 66 countries as a first-line maintenance treatment for locally advanced or metastatic urothelial carcinoma (UC) in adult patients whose disease has not progressed following platinum-based chemotherapy. At the 2023 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium, we presented long-term follow-up data from the Phase III JAVELIN Bladder 100 trial. The data demonstrated median overall survival from start of chemotherapy of 29.7 months among patients receiving Bavencio® who did not progress on first-line platinum-based chemotherapy, thus establishing a new benchmark for treatment outcomes in clinical studies.

We continue to evaluate whether optimization of first-line maintenance treatment by adding a novel therapy to avelumab could improve outcomes for patients with advanced UC whose disease did not progress with first-line platinum-based chemotherapy in the Phase II JAVELIN Bladder Medley study. Initiated in 2022, this randomized umbrella study is assessing avelumab monotherapy versus the combination of avelumab with our investigational anti-TIGIT antibody M6223, avelumab in combination with Nektar Therapeutics' interleukin-15 (IL-15) receptor agonist, NKTR-255, and avelumab in combination with Gilead Sciences' Trodelvy® (sacituzumab govitecan-hziy).

Bavencio® is also approved as a monotherapy for the treatment of metastatic Merkel cell carcinoma (MCC) in 63 countries. In September 2023, we received U.S. Food and Drug Administration approval of a supplemental Biologics Licensing Application for Bavencio®, converting the MCC indication from accelerated approval into full approval. This makes it the first MCC treatment to receive full approval in the U.S. market.

Additionally, Bavencio® is approved for the treatment of advanced renal cell carcinoma (RCC) in combination with axitinib in 60 countries.

Tepmetko®

In 2023, we shared multiple analyses of studies of the oral MET inhibitor Tepmetko® (tepotinib) in advanced non-small cell lung cancer (NSCLC). In a long-term follow-up analysis of the Phase II VISION study published in JAMA Oncology, Tepmetko® showed robust and durable clinical activity across therapy lines in patients with METex14-skipping NSCLC, particularly in previously untreated patients with METex14 skipping confirmed by

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tissue biopsy. An additional subgroup analysis presented at the 2023 World Congress on Lung Cancer (WCLC) in September demonstrated the robust and durable clinical activity of Tepmetko®, particularly as a first-line treatment, with stability in health-related quality of life and a manageable safety profile in Asian patients with advanced NSCLC with METex14 skipping. Tepmetko® is now available for the treatment of METex14-skipping NSCLC in 23 markets globally.

We also shared results of the primary analysis of the Phase II INSIGHT 2 study at the WCLC. These findings suggest the potential of tepotinib plus osimertinib as a chemotherapy-sparing oral targeted therapy option for patients with EGFR-mutant NSCLC with MET amplification who have developed resistance to prior EGFR tyrosine kinase inhibitor therapy.

Novel medicines

As we work towards our vision of creating a world where more cancer patients can become cancer survivors, we continue to pioneer novel medicines, advancing promising molecules in our pipeline that build on our expertise and leadership in core mechanisms and tumor types.

Our Phase III development program for xevinapant, the potentially first-in-class IAP (inhibitor of apoptosis protein) inhibitor, in the treatment of squamous cell carcinoma of the head and neck (SCCHN) continues to progress. Patient enrollment for the TrilynX study (NCT04459715) was completed in 2023. This international, randomized, double-blind, placebo-controlled Phase III study evaluates the efficacy and safety of xevinapant compared to placebo when administered in addition to definitive chemoradiotherapy in patients with unresected, locally advanced SCCHN. Patient recruitment continues in the international, randomized, double-blind, placebo-controlled Phase III XRay Vision (NCT05386550) study, which is evaluating the efficacy and safety of xevinapant versus placebo in combination with adjuvant, post-operative radiotherapy in patients with resected LA SCCHN who are at high risk for relapse and are ineligible for cisplatin treatment.

Additional progress in our pipeline in 2023 includes completion of Phase Ia for our anti-CEACAM5 antibody-drug conjugate (ADC), M9140, with the identification of two doses for evaluation in Phase Ib. M9140 is the first ADC based on our proprietary technology to enter clinical development.

We also continued to advance our pipeline of DNA damage response inhibition (DDRi) assets, exploring multiple hypotheses to determine which regimens may provide the most value to patients. In 2023, we initiated the Phase Ib/IIa DDRiver NSCLC 322 study of tuvusertib (M1774), our potentially best-in-class, potent and selective inhibitor of ataxia telangiectasia and Rad3-related (ATR), in combination with Regeneron Pharmaceutical's PD-1 inhibitor cemiplimab in patients with non-squamous NSCLC that has progressed on prior anti-PD-(L)1 and platinum-based therapies. The first dose was administered in October to a person requiring treatment.

In July 2023, our collaboration partner Telix Pharmaceuticals announced the administration of the first dose in the Phase Ib STARSTRUCK trial. This open-label, single-arm, multicenter dose-escalation and dose-expansion study will evaluate the safety profile, dosing and activity of our DNA-dependent protein kinase (DNA-PK) inhibitor candidate, peposertib (M3814), in combination with Telix's investigational targeted radiation therapy, TLX250, in patients with solid tumors expressing carbonic-anhydrase IX (CAIX).

To diversify our robust internal pipeline in our focus areas of DNA damage response inhibition and antibody-drug conjugates, in October 2023 we announced a strategic collaboration with Jiangsu Hengrui Pharmaceuticals Co. Ltd. (Hengrui). The partnership includes an exclusive global license (excluding mainland China) to develop, manufacture and commercialize Hengrui's next-generation potent and selective PARP1 (poly (ADP-ribose) polymerase 1) trapping inhibitor HRS-1167. The agreement also includes an option for exclusive global development, manufacturing and commercialization (excluding mainland China) of Hengrui's Claudin-18.2 antibody-drug conjugate (ADC) SHR-A1904.

In December, we announced a license agreement with Abbisko Therapeutics Co. Ltd, Shanghai, China, for pimicotinib (ABSK021), which is currently being evaluated in a Phase III study for the treatment of tenosynovial giant cell tumor (TGCT). TGCT is a benign tumor of the joints that can cause swelling, pain, stiffness, and limited mobility of the affected joints. The agreement grants us a license to commercialize pimicotinib in mainland China, Hong Kong, Macau and Taiwan, with an option for rest of world.

Highlights of congress publications in 2023

We shared additional new data for our marketed and investigational oncology medicines at major oncology congresses.

In June, 43 abstracts featuring new data for the medicines Bavencio® (avelumab), Erbitux® (cetuximab) and Tepmetko® (tepotinib) and drug candidates from our pipeline including the first-in-class investigational IAP inhibitor xevinapant were presented at the ASCO Annual Meeting.

Highlights included:

- Clinical data for Bavencio® that reinforce its role as a standard of care in first-line maintenance for advanced urothelial carcinoma in patients without disease progression following first-line platinum-based chemotherapy. Poster discussions, including long-term safety analyses and an analysis of quality-adjusted survival from the Phase III JAVELIN Bladder 100 study, confirm the acceptable long-term benefit-risk profile as well as the net benefit estimate of Bavencio® in first-line maintenance and further support its use.
- Long-term outcomes from the VISION study, the largest study of a MET inhibitor in patients with METex14-skipping advanced NSCLC (N=313). Detection was carried out via liquid and/or tissue biopsy. The results demonstrate the robust and sustained clinical activity of Tepmetko®, particularly in the first-line setting: with a median follow-up time of 32.6 months, the overall response rate in 164 people treated with first-line therapy was 57.3% (95% CI: 49.4, 65.0) and the median duration of response 46.4 months (13.8, cannot be estimated).
- Additional presentations for Tepmetko® that included analyses of the INSIGHT 2 study in NSCLC with epidermal growth factor receptor (EGFRm) mutation and MET amplification during treatment with Tepmetko® plus osimertinib.
- Erbitux® data that add to the growing body of evidence supporting the role of cetuximab-based therapies across the continuum of care in the treatment of RAS wild-type metastatic colorectal cancer and as a backbone of treatment in SCCHN.

At the European Society for Medical Oncology (ESMO) Congress 2023, we presented 28 abstracts featuring the latest research on our oncology portfolio addressing unmet treatment needs across bladder, head and neck, lung, colorectal, and other cancers.

Highlights included:

- New analyses and real-world evidence that reinforce the role of Bavencio® first-line maintenance in the treatment of advanced UC in patients with varying characteristics. These include long-term efficacy and safety outcomes from the Phase III JAVELIN Bladder 100 study that confirm the prolonged overall survival (OS), progression-free survival (PFS) and tolerability of first-line maintenance with Bavencio® in patients older than 65 years with advanced UC. Further evidence from France and the United States, including initial data from the French AVENANCE study on patients with advanced UC whose tumors have histological variants, support the findings of JAVELIN Bladder 100 in real-world settings.
- Additional real-world analyses reinforcing the use of Bavencio® as a treatment for advanced/metastatic MCC. After a median follow-up of approximately 29 months, data from the MCC TRIM study showed a median OS of 52 months for patients with metastatic MCC treated with Bavencio® in a real-world setting in Germany. Most patients (approximately 86%) received first-line Bavencio®.
- Updated findings from the Phase II VISION trial, which is the largest study of a MET inhibitor in METex14-skipping NSCLC and served as the basis for regulatory approvals, continue to show clinically meaningful long-term efficacy in patients treated with Tepmetko® regardless of line of therapy (2L, 2L+ and 3L+).
- A new analysis of real-world survival outcomes and survival risk factors in elderly patients with locally advanced SCCHN that highlights poor survival outcomes, especially in patients aged 70 years and older with advanced disease stage and comorbidities, underscoring the need for innovative effective treatments for this population.

Neurology & Immunology*

With a commitment of more than 25 years to people living with multiple sclerosis (MS), our ongoing dedication to science drives us to discover cutting-edge therapies through our research in neurological and immune-mediated disease areas.

Beyond our portfolio in MS, we have a pipeline focusing on discovering new therapies that have potential in other neuroinflammatory and immune-mediated diseases, including systemic lupus erythematosus (SLE), cutaneous lupus erythematosus (CLE) and generalized myasthenia gravis (gMG).

Enpatoran, an investigational highly specific potential first-in-class immune modulator blocking the activation of toll-like receptors (TLR7 and TLR8), is being developed as a new oral therapy for SLE and CLE. It aims to overcome limitations of currently available lupus therapies by providing selective inhibition of lupus-relevant disease drivers, which may increase efficacy while preserving immunity against infections. We anticipate data from our Phase II clinical trials for enpatoran in the first half of 2024.

We are also exploring the potential of oral cladribine beyond MS, developing it for the treatment of gMG, which affects an estimated 700,000 people and where a high unmet need remains, particularly as regards oral treatment options. Cladribine is believed to work by affecting the pathogenic pathways involved in the development of autoimmunity (auto-antibody producing B cells and T cells). In June 2023, the FDA granted Orphan Drug Designation for cladribine for the treatment of myasthenia gravis. We anticipate the initiation of a global Phase III clinical trial program in the second quarter of 2024.

In February 2023, we entered a preclinical licensing and strategic research partnership with Aqilion, a biotech company focused on developing innovative treatments for immune-mediated and neurological diseases.

New data for our existing therapy Mavenclad® (cladribine tablets), as well as for our investigational drug evobrutinib, were presented at key congresses in 2023, including the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum in February, the American Academy of Neurology (AAN) Annual Meeting in April and the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) Congress in October.

At ACTRIMS 2023, we presented data that included analyses of the CLARIFY-MS study, showing the potential of Mavenclad® to improve outcomes in an impactful way for people living with RMS. In addition, we showed updated long-term efficacy and safety data from our Phase II program for the investigational drug evobrutinib. In December we shared that the phase III pivotal study did not meet its primary endpoint of annualized relapse rate for up to 156 weeks compared to oral teriflunomide.

At AAN 2023, we presented data from the M AGNIFY-MS study, showing sustained reductions in the memory B-cell numbers, with changes towards anti-inflammatory phenotypes in circulating B- and T-cell types for study participants taking Mavenclad® and provided updated efficacy and safety data from our Phase II program for the investigational drug evobrutinib.

At ECTRIMS 2023, we presented 31 abstracts in total, including long-term efficacy and neurofilament light chain data (from the M AGNIFY-MS study) for Mavenclad® as well as new real-world evidence data highlighting naïve use of the treatment. In addition, we shared updated five-year safety and efficacy data from the Phase II Open Label Extension for investigational evobrutinib as well as baseline demographic data of our Phase III EVOLUTION trials.

Fertility*

As the global market leader in fertility drugs and treatments, our Fertility franchise plays a crucial role in our Healthcare business.

Infertility is an increasing challenge globally due to demographic changes and lifestyle adjustments such as delayed childbearing. Based on the latest data from WHO, one in six people worldwide are affected by infertility.

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According to updated data, more than five million babies have been born worldwide with the help of Gonal-f®, a leading therapeutic within our fertility portfolio. It contains the active ingredient follitropin alfa (r-hFSH alfa), which is a recombinant form of the natural hormone FSH and is available in a convenient and ready-to-use pre-filled injection pen. Treatment with Gonal-f® can result in increased follicles, oocytes and embryos compared with urinary gonadotropins, thereby improving the chances of pregnancy and live birth. Recent real-world evidence studies based on key European registries (D.I.R., SNDS) showed increased likelihood of live birth with Gonal-f® compared with urinary gonadotropins and biosimilar preparations of follitropin alfa.

Cardiovascular, Metabolism & Endocrinology*

In view of the significant and growing impact of chronic diseases such as diabetes, prediabetes, hypertension, and cardiovascular disease, growth hormone disorders and thyroid disorders on health and society in the 21st century, we are committed to helping patients with these conditions.

The new formulation of Euthyrox® (levothyroxine) for the treatment of hypothyroidism obtained further regulatory approvals in 2023, resulting in a total of 101 countries where this incremental innovation is registered. With its characteristics of delivering precise, fine-tuned and stable T4 doses, Euthyrox® may help optimize disease management, making it a good choice for healthcare providers and patients.

Glucophage®, containing the active ingredient metformin, is the most widely prescribed non-insulin diabetes treatment worldwide for first-line treatment of type 2 diabetes for which we achieved a successful label extension in Europe in 2022. The label update on the mechanism of action is evidence of the still growing body of knowledge and opportunities for metformin in the diabetes continuum. Those label updates are currently being rolled out in all other countries outside Europe where the Glucophage® family of products is available.

Concor®/Concor Cor®, containing bisoprolol, is a beta-blocker for treating hypertension and cardiovascular diseases such as coronary heart disease and chronic heart failure. In addition to Concor®/Concor Cor®, the Concor® franchise includes fixed-dose combinations such as Concor Plus®/Lodoz® (bisoprolol with hydrochlorothiazide) and Concor® AM (bisoprolol with amlodipine). Concor® AM has been registered in 71 countries.

Investments to speed up the availability of new medicines*

Our declared aim is to bring more medicines to more patients faster. In 2023, we supported this aim by reaching key milestones for two transformational investments focusing on complementary therapeutic modalities:

- In June, we inaugurated our Biotech Development Center at our site in Corsier-sur-Vevey, Switzerland. This investment of over € 250 million aims to ensure that our next generations of innovative large-molecule medicines (biotech therapies and potential other new therapeutic modalities) are available for clinical trials on time and in the required quality and quantity with an accelerated process compared with the past. The Biotech Development Center is expected to be fully operational in early 2024 following validation by regulatory authorities.
- In September, we celebrated the topping-out for our Launch and Technology Center at our site in Darmstadt, Germany. This investment of approximately € 160 million is intended to ensure that our next generations of innovative small-molecule medicines (including high-potency compounds) are available for clinical trials, global launches and commercial supply on time and in the required quality and quantity, with accelerated processes compared with the past. The Launch and Technology Center is anticipated to be fully operational by the end of 2025 following validation by regulatory authorities.

Collaborations to strengthen AI-driven drug discovery*

On September 20, we announced two strategic collaborations with Benevolent AI and Exscientia to drive accelerated drug discovery with higher probability of success. Access to end-to-end AI platform capabilities is expected to generate several novel development candidates in oncology, neurology and immunology. AI-powered R&D is an integral part of delivering on our ambition to bring more medicines to more patients, faster.

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Our pipeline

As of December 31, 2023		
Therapeutic area		
Compound	**Indication**	**Status**
Immunology		
Enpatoran (TLR7/8 antagonist)	Systemic lupus erythematosus[1]	Phase II
Enpatoran (TLR7/8 antagonist)	Cutaneous lupus erythematosus[1]	Phase II
Enpatoran (TLR7/8 antagonist)	Idiopathic inflammatory myopathies (DM and PM)[2]	Phase II
Oncology		
Xevinapant (IAP inhibitor)	Locally advanced squamous cell carcinoma of the head and neck – Unresected, cisplatin-eligible[3]	Phase III
Xevinapant (IAP inhibitor)	Locally advanced squamous cell carcinoma of the head and neck – Resected, cisplatin-ineligible[4]	Phase III
Avelumab (anti-PD-L1 mAb) + combinations	Locally Advanced or Metastatic Urothelial Carcinoma[5]	Phase II
Tuvusertib/M1774 (ATR inhibitor)	Solid tumors[6]	Phase Ib
M4076 (ATM inhibitor)	Solid tumors[7]	Phase Ib
M9140 (anti-CEACAM5 Antibody drug conjugate)	Solid tumors	Phase Ia
M6223 (anti-TIGIT mAb)	Solid tumors[8]	Phase Ib
M9466 (HRS-1167; Selective PARPi)	Solid tumors[9]	Phase I
Global Health		
Arpraziquantel (anthelmintic)	Pediatric schistosomiasis[10]	Registration
M5717 (PeEF2 inhibitor)	Malaria	Phase II

On December 04, 2023, we announced a license agreement with Abbisko Therapeutics Co. Ltd, China, for pimicotinib (ABSK021), which is currently being evaluated in a Phase III study for the treatment of tenosynovial giant cell tumor (TGCT). The agreement grants us a license to commercialize pimicotinib in mainland China, Hong Kong, Macau and Taiwan, with an option for rest of world.

End of December 2023, we entered into a licensing agreement with Inspirna, Inc., United States, for ompenaclid (RGX-202), a first-in-class oral inhibitor of the creatine transport channel SLC6A8, and SLC6A8-targeting follow-on compounds. Ompenaclid is currently being evaluated in a Phase II study for the second-line treatment of RAS-mutated (RASmut) advanced or metastatic colorectal cancer (mCRC).

Unless noted otherwise, clinical programs conducted in collaboration with external partners are not shown unless we have co-ownership of data. More information on the ongoing clinical trials can be found at **www.clinicaltrials.gov**. Pipeline products are under clinical investigation and have not been proven to be safe and effective. There is no guarantee any product will be approved in the sought-after indication.

[1] Clinical trial passed futility analysis.

[2] Dermatomyositis and Polymyositis.

[3] In combination with cisplatin and radiotherapy in unresected LA SCCHN patients eligible for the treatment with cisplatin.

[5] In combination with radiotherapy in resected LA SCCHN patients ineligible for the treatment with cisplatin.

[5] Combinations include Sacituzumab Govitecan, NKTR-255 and M6223.

[6] Studies as monotherapy and in combination with cemiplimab, niraparib, avelumab or M4076 ATMi. Includes studies (phase I/II) in collaboration with/ sponsored by external partners, e.g. US National Cancer Institute (NCI).

[7] Administered in combination with Tuvusertib/M1774 (ATRi).

[8] Administered in combination, including combinations other than avelumab.

[9] On October 30, 2023, we announced a collaboration with Jiangsu Hengrui Pharmaceuticals Co. Ltd., China, including an exclusive license worldwide (excluding China) to develop, manufacture and commercialize the next-generation potent and selective PARP1 trapping inhibitor HRS-1167.

[10] On 14 December, 2023, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive scientific opinion for arpraziquantel for the treatment of schistosomiasis in children aged 3 months to 6 years. The application was submitted by us, on behalf of the Pediatric Praziquantel Consortium, under the EU-M4all procedure for high-priority medicines for human use intended for countries outside the European Union.

ATM: ATM serine/threonine kinase
ATR: Ataxia telangiectasia and Rad3-related
BTK: Bruton's tyrosine kinase
CEACAM5: Carcinoembryonic antigen-related cell adhesion molecule 5
IAP: Inhibitor of apoptosis proteins
mAb: Monoclonal antibody
PARP1: poly (ADP-ribose) polymerase 1
Phase Ia: Dose finding
Phase Ib: Dose escalation/expansion and signal seeking
PD-L1: Programmed cell death ligand 1
PeEF2: Plasmodium eukaryotic elongation factor 2
TIGIT: T cell immunoreceptor with Ig and ITIM domains
TLR7/8: Toll-like receptors 7 and 8

Electronics

As a science and technology company, we strive to offer leading-edge products, services, and solutions.

Our R&D strategy follows our overall Electronics technology strategy, which aims to enhance and expand our capabilities, drive organic growth and enable new technology platforms. Our Chief Technology Office (CTO) is identifying trends and vetting technologies that are beyond the time horizon or scope of our business units. As a dedicated technology organization, the CTO is managing research partnerships, shaping our technology roadmaps, and managing our long-term R&D portfolio. Our Technology Leadership Board reviews and optimizes our technology investment across the business sector.

Our R&D is aligned to strengthen our existing position in the industry across many key material and innovation areas, with the addition of artificial intelligence (AI), data services, analytics, and sustainability to enhance our portfolio offering. As an essential part of our “Level Up“ growth program, we are continuing to invest significantly more than € 3 billion in innovation and capacity expansion. With our R&D investments within “Level Up”, we are also scaling up our research and development capabilities for next-generation semiconductor and display materials to further strengthen our position as one of the leading suppliers to the electronics industry.

Our R&D is focused on finding solutions for the needs that drive our industry: increase energy efficiency of devices, enhance performance of materials, reduce environmental impact on the planet. Consequently, sustainability, and the use of AI and machine learning are key focus areas of our R&D.

Sustainable technologies and materials*

We are continuing to drive sustainability in R&D to address the increasing push for lower emissions along the value chains. Ongoing key programs focus on, e.g. NF_3 abatement and more sustainable processes and manufacturing technologies as well as green solvents, sustainable etch gases and PFAS replacement.

NF_3 abatement

Nitrogen trifluoride (NF_3) accounts for about 60% of our global emissions, mainly from our specialty gases business. We developed and tested an abatement solution using a modified commercial thermal destruction technology and demonstrated the ability to destroy NF_3 with 99% efficiency.

PFAS

PFAS, a generic term that covers about 10,000 per- and polyfluoralkyl substances, is used for several critical applications in the manufacture of microchips, e.g. photolithography, plasma etching and wafer cleaning. While it is currently not possible to manufacture semiconductors without PFAS, we have already developed several alternative products for some applications in Electronics. One area in which we are highly advanced is the replacement of PFAS surfactants with non-PFAS alternatives in photoresists and related ancillary products such as rinse solutions.

Scorecard

To embed sustainable design into R&D and steer our portfolio in a more sustainable direction in the long term, we have developed a scorecard that focuses on sustainable criteria in the development of new products and solutions. The scorecard is a tool for driving a sustainability culture in R&D and considers every step of the value chain to identify opportunities and risks at an early stage and act accordingly.

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

Academic research program

With the objective of enabling more sustainable semiconductor manufacturing solutions, we have joined forces with the Intel Corporation to jointly fund an academic research program over three years. The program will specifically leverage AI and machine learning technologies to achieve innovative breakthroughs in sustainable semiconductor manufacturing processes and technologies. Potential solutions include environmentally friendlier materials, more efficient use of resources, AI-based solutions for modeling chemical processes, and opportunities for reducing waste and emissions. The focus is on building open-source tools for the benefit of the entire scientific and industrial community.

R&D activities in the business units*

Semiconductor Solutions

In our R&D we are addressing critical material needs through every step of the wafer manufacturing process. Top R&D programs for our Semiconductor Solutions business units include:

Business field Thin Films

Our Thin Films business field is actively developing new dielectrics (organosilanes and spin-on dielectrics) and metallics offerings. Many of these new products are qualified by multiple customers and we are developing new materials for leading-edge nodes that will enable chips and chiplets used for generative AI. The integration of the chemical business of Mecaro into our business enables us to develop new precursors for high performance DRAM and provides us with unique capabilities to expand our development in Asia. In addition, we continued to expand our metallics portfolio to support our customers' roadmaps, providing innovative solutions for ALD (atomic layer deposition) and CVD (chemical vapor deposition). We achieved significant advancements in high-performance, conformal dielectric ALD films which address key customer pain points. Our spin-on-dielectrics platform focuses on developing new formulations for gap-fill applications in increasingly deep and narrow insulating features with the improved performance needed to enable next-generation V-NAND (vertical flash memory) and DRAM (dynamic random-access memory).

Business field Specialty Gases

Our etch gas technology program continues to develop new chemistries to enable more than 100-layer, single-stack etching for advanced memory devices such as V-NAND (vertical flash memory). We are also seeing good progress in our etch gas development work for new low-GWP (global warming potential) gases for etching applications and in our cooperation with customers to develop low-GWP gas solutions used in the production of semiconductors.

Business field Formulations (patterning and planarization)

The main driver of our R&D engagements in patterning is the manufacturing capability and costs associated with extreme ultraviolet (EUV) lithography systems. We are increasing our efforts in the development of EUV lithography materials to directly help our key customers address these challenges. Our Patterning Solutions team achieved a breakthrough in PFAS-free EUV rinse development, paving the way for a sustainable solution to prevent the collapse of structures in EUV lithography.

We are also investing in directed self-assembly (DSA) capabilities as we support customers' integration of DSA into advanced nodes, and we are beginning to sample photoresists and rinse materials from our PFAS-free portfolio development.

Our Planarization business is driving new product development across advanced oxide and metal segments. For example, we are achieving technical progress using dielectric high-performance cerium dioxide particles for advanced oxide CMP (chemical mechanical planarization).

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Display Solutions

With the proliferation of multiple applications and display trends, the display industry's technological requirements are significantly expanding. Our display materials are enabling the fast-growing market of innovative displays for current and future applications such as foldable smartphones, flexible displays for automotive or AR/VR (augmented reality/virtual reality) devices.

As our liquid crystals business remains a strong focus area, our R&D team is continuously working to develop new liquid crystal mixtures for our customers who need differentiated performance such as high transmittance, high contrast ratio, and high reliability to realize displays for new applications. We are working with our customers in the field of AR/VR to expand the application scenarios of liquid crystals and continue to enhance the user experience in small and micro-sized displays. We remain fully committed to advancing LCD technology and are working very closely with leading panel makers to develop next-generation products for the electronics market.

In the display industry, OLED is regarded as state-of-the-art technology for its excellent visual experience. It is also considered as the technology of the future of displays as it enables the production of flexible, foldable, rollable, and even transparent displays. We introduced new barrier materials that offer superior flexibility, higher reliability and a longer lifetime in flexible OLED devices compared with existing solutions. Devices with fully flexible OLED displays are one of the fastest-growing trends in data-driven electronics. Our innovative ALD material won the "Display Component of The Year 2023" award from Society for Information Display (SID), the world's largest display association. In addition, our innovative deuterated material won the "Technology Innovation Award" from LG Displays in September 2023.

Surface Solutions

In our Surface Solutions business, we offer our customers solutions for designing surfaces that meet their specific requirements. Together with our customers, we are consistently developing new formulations that, in combination with existing products and product innovations, provide customized solutions across various industries.

In our automotive pigments business, we are continuously expanding our portfolio of Colorstream® multicolor-effect pigments. A recent example is the development of Colorstream® F20-52 SW Mineral Red pigment, a new silica-based pigment that extends the red color palette of Surface Solutions into a more blueish-red range.

In our cosmetics business, we are further developing our range of high-color intensity pigments with metallic optical effects entirely without the use of metals. These Ronaflux® pigments are based on an entirely new proprietary technology employing fluidized bed processes for depositing ultrathin and highly stable carbon layers onto pearlescent pigments – a major precondition for spectacular shine effects. The carbon layers intensify the colors of the effect pigments, thus enabling brilliant shades of blue and green without the addition of chrome oxides, Prussian blue or other colorants. This new offering enables manufacturers of eye makeup and lipsticks to meet the strict regulatory requirements while offering brilliant metallic blue and green shades that do not contain any metal-based pigments.

To produce realistic color effects on electronic devices, we are focusing on methodologies to transfer coloristic measuring data into 3D visible effects. As a first step, we have introduced the first digital tool for visualizing car colors in various light conditions in a realistic way. Under controlled, calibrated conditions, color data, measured state-of-the-art technology, can be used to produce a realistic display.