Combined Management Report*

45–154

Combined Management Report*

45–154

047 Fundamental Information about the Group
047 Merck
054 Objectives and Strategies
060 Internal Management System
064 Corporate Responsibility
072 Research and Development
084 People at Merck

090 Report on Economic Position
090 Macroeconomic and Sector-Specific Environment
093 Review of Forecast against Actual Business Developments
098 Course of Business and Economic Position
098 Merck Group
109 Healthcare
116 Life Science
121 Performance Materials
126 Corporate and Other

127 Report on Risks and Opportunities
139 Report on Expected Developments
144 Report in accordance with section 315 (4) of the German Commercial Code (HGB)
146 Additional information on Merck KGaA in accordance with the German Commercial Code (HGB)
154 Subsequent Events

* The management report for Merck KGaA has been combined with the Group management report and published in the 2016 Merck Annual Report as well as in the annual financial statements of Merck KGaA. The annual financial statements and the combined management report of the Merck Group and Merck KGaA for 2016 are being filed with the electronic German Federal Gazette (elektronischer Bundesanzeiger) and are available on the website of the German company register.
This combined management report contains certain financial indicators such as EBITDA pre exceptionals, operating result (EBIT), business free cash flow, net financial debt and earnings per share pre exceptionals, which are not defined by International Financial Reporting Standards (IFRS). These financial indicators should not be taken into account in order to assess the performance of Merck in isolation or used as an alternative to the financial indicators presented in the consolidated financial statements and determined in accordance with IFRS.
The figures presented in this combined management report have been rounded. This may lead to individual values not adding up to the totals presented.

Fundamental Information about the Group

Merck

We are a global science and technology company headquartered in Darmstadt, Germany. With a history of nearly 350 years, we are the oldest chemical and pharmaceutical company in the world. In line with our strategic direction, Merck comprises three business sectors: Healthcare, Life Science, and Performance Materials, which encompass the Group's six businesses.

In Healthcare, we discover, develop and manufacture prescription medicines used to treat cancer, multiple sclerosis, and infertility, among other things, as well as over-the-counter pharmaceutical products for colds and pain. Our products help millions of people around the world.

In Life Science, we conduct research for researchers, providing scientists with laboratory materials, technologies and services. Our aim is to make research and biomanufacturing easier, faster and more successful.

Performance Materials develops specialty chemicals and materials for demanding applications – from liquid crystals and OLED materials for displays to effect pigments for coatings and cosmetics to high-tech materials for the manufacture of integrated circuits.

We hold the global rights to the Merck name and brand. The only exceptions are Canada and the United States. In these countries, we operate as EMD Serono in the biopharmaceutical business, as MilliporeSigma – following the completed acquisition of Sigma-Aldrich – in the life science business and as EMD Performance Materials in the high-tech materials business.

Apart from our three business sectors, our financial reporting presents the five regions Europe, North America, Asia-Pacific (APAC), Latin America as well as Middle East and Africa (MEA). As of December 31, 2016, we had 50,414 employees worldwide, which compares with 49,613 on December 31, 2015.

Healthcare

Our Healthcare business sector comprises the four businesses Biopharma, Consumer Health, Biosimilars, and Allergopharma. Since 2015, Belén Garijo has been the CEO of the Healthcare business sector and member of the Executive Board. In 2016, Healthcare generated 45% of Group sales and 43% of EBITDA pre exceptionals (excluding Corporate and Other), making it the largest of our three business sectors. The regions Europe and North America generated 60% of Healthcare's net sales in 2016. In recent years, we have steadily expanded our presence in growth markets. In 2016, Asia-Pacific and Latin America accounted for 33% of sales.

Biopharma

Our Biopharma business discovers, develops, manufactures and markets innovative pharmaceutical and biological prescription drugs to treat cancer, multiple sclerosis, infertility, growth disorders as well as certain cardiovascular and metabolic diseases. Biopharma is the largest of our Healthcare businesses. We operate in four franchises: Oncology, Neurology/Immunology, Fertility, General Medicine & Endocrinology. Our streamlined R&D pipeline positions us with a clear focus on becoming a leading science-driven innovator in oncology, immuno-oncology and immunology, including multiple sclerosis.

In 2016 we reinforced our commitment to growing our immunology pipeline to provide new options to better the lives of people with immunological diseases as we prepared for the potential launch of cladribine tablets. Our activities included major milestone accomplishments and an impactful presence at key medical meetings around the world.

New data on Rebif®, Biopharma's top-selling drug and leading multiple sclerosis (MS) therapy, and investigational cladribine tablets were presented at both the American Academy of Neurology's (AAN) Annual Meeting in April 2016 and the Congress of the European Academy of Neurology (EAN) in May 2016. In addition, results of more than 30 clinical studies were presented at the world's largest international MS conference, the 32nd Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in London, United Kingdom.

In June 2016, we reached a major regulatory milestone with the submission for registration of cladribine tablets to the European Medicines Agency (EMA). We believe that cladribine tablets, if approved, could lead to high and sustained efficacy through selective modulation of B and T cells resulting in lasting resolution of inflammation. The additional data we have gathered over the past four years provides better characterization of the safety and tolerability profile and this coupled with a unique oral short course will serve as an important therapeutic advance for patients with relapsing-remitting multiple sclerosis (RRMS).

In July 2016, we announced the EMA's acceptance for review of the Marketing Authorization Application (MAA) for the investigational product cladribine tablets for the treatment of RRMS.

We also presented data on atacicept, our investigational treatment for systemic lupus erythematosus (SLE) at the 2016 American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) Annual Meeting held in November. Although the primary endpoint was not met in the overall study population of the ADDRESS II Phase IIb, multicenter study on

atacicept in patients with SLE, there was a trend favoring atacicept with statistical significance achieved in a pre-specified sensitivity analysis of the primary endpoint using treatment Day 1 as baseline (rather than screening visit). Additionally, analyses of a predefined subpopulation of patients with high disease activity demonstrated statistically significant treatment effects of atacicept when compared to placebo.

Erbitux® (cetuximab) remains the second best-selling drug in the portfolio of the Biopharma business and is the company's flagship product in oncology. The product is a standard of care for patients with epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer (mCRC) therapy, as well as both recurrent/metastatic and locally advanced squamous cell carcinoma of the head and neck (SCCHN).

We continue to invest in Erbitux® and are committed to making it available to those patients whom it will benefit most. In April 2016 we reached a major milestone regarding its expansion in growth markets with the positive results of the pivotal Chinese Phase III TAILOR study.

In addition, we continued to support our goal of improving care for patients with mCRC by further advancing in the area of liquid biopsy technologies through collaborations. In 2016, we became the first pharmaceutical company to collaborate with multiple diagnostic providers to support RAS biomarker testing, with new agreements announced with Biocartis and Amoy Diagnostics Co., Ltd. for different testing technologies to meet the needs of various laboratory segments. These agreements follow our first collaboration with Sysmex Inostics, which achieved a notable milestone in 2016, when the liquid biopsy technology we are co-developing received CE Mark approval in April.

Importantly, through another key collaboration, our strategic alliance with Pfizer Inc., USA, we continued to make progress in the development and envisaged commercialization of avelumab*, an investigational fully human anti-programmed death-ligand 1 (PD-L1) antibody.

The positive results from JAVELIN Merkel 200, the pivotal Phase II study in patients with metastatic Merkel cell carcinoma (MCC) treated with avelumab in second or subsequent lines of therapy, were presented at the American Society of Clinical Oncology (ASCO) 2016 annual meeting. These results supported the submission and acceptance of the Biologics License Application to the U.S. Food and Drug Administration (FDA), as well as the Marketing Authorization Application to the European Medicines Agency. Additionally, we initiated two pivotal Phase III trials for avelumab in 2016, including a combination trial with axitinib for the first-line treatment of renal cell carcinoma and as a first-line treatment for ovarian cancer.

These pivotal trials are part of the larger clinical development program for avelumab, known as JAVELIN, which involves at least 30 clinical programs and more than 4,000 patients evaluated across more than 15 different tumor types. As part of the strategic alliance, we are also advancing our co-promotion of Pfizer's anaplastic lymphoma kinase (ALK) inhibitor Xalkori® (crizotinib), indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ALK-positive. Xalkori® is being co-promoted in two waves, the first of which began in 2015 in the United States, Canada, Japan, and five EU countries (France, Germany, Italy, Spain, and the United Kingdom). The second wave began in 2016 including Argentina, China and Turkey.

As part of our efforts in immuno-oncology we have an exclusive strategic collaboration and license agreement with Intrexon Corporation to develop and commercialize Chimeric Antigen Receptor T-cell (CAR-T) cancer therapies.

An important growth driver for our Biopharma business is our fertility portfolio, offering products that help couples to conceive a child, ranging from drugs to technologies. Infertility has become a key topic globally due to the current trend towards delaying childbirth. We see a steadily increasing demand in growth markets, fueling current and future sales. In addition, we are facing a rapidly changing environment in the fertility market, with commoditization and price pressure in the drugs business, more educated patients and an increasing importance of Fertility Technologies. The strategic innovation of Merck's fertility business model to develop from the world market leader in fertility treatments into an integrated fertility treatment partner focuses on turning these trends into opportunities for Merck and will drive further growth. The first step to achieve this goal was to extend our existing drug portfolio into our continuously expanding innovative technologies offering.

We are the only company to offer recombinant versions of the three natural hormones needed to treat infertility as well as a complete and clinically proven portfolio for every stage of the reproductive cycle. In early 2016, our portfolio of drugs was further complemented by the improved Gonal-f® prefilled pen, a new pen version including various advanced features designed to facilitate administration for patients.

Our Fertility Technologies business expanded and is now providing solutions for all key steps of in vitro fertilization (IVF). Our automated vitrification instrument Gavi™** can now freeze oocytes and embryos at key stages. For the incubator Geri™** an annotation software was introduced (Geri™ Connect & Assess 1.0), and with a humidified incubation feature the incubation environment now resembles the conditions in the uterus more closely. A new version of the incubator Geri™+ allows for use with the Early Embryo Viability Assessment (Eeva®) Test, for which a new software version was launched. With Geri™ medium we introduced a new single-step medium supporting undisturbed embryo growth. Finally, our innovative witnessing and tracking system Gidget™ helps to reduce the potential for error and improves lab workflows. Key parts of our technologies portfolio were made available for clinical use in Europe in 2016, and now are also marketed in Canada and Japan.

* Avelumab is not yet approved for any indication in any market. The EMA has validated the Marketing Authorization Application for avelumab for the treatment of metastatic MCC, marking the first acceptance of an EU market authorization application to review the safety and efficacy results for this investigational product. The U.S. FDA has also accepted the Biologics License Application for avelumab for the treatment of metastatic MCC, marking the first acceptance of an application by the U.S. FDA to review this investigational product.

** Gavi™ and Geri™ are not available in the United States.

In June, the Global Fertility Alliance welcomed two new members: Zeiss (Carl Zeiss AG, Oberkochen) and Hamilton Thorne Ltd., USA. The alliance paves the way forward into the future of fertility treatment and adds to our strong basis in the drug business and our highly innovative Fertility Technologies business.

Every day, 55 million patients around the world are using our trusted general medicine and endocrinology (GM&E) medications. Today Concor®, Euthyrox®, Glucophage®, and Saizen® are high-value brands and market leaders in many key markets around the world. As a result, in terms of sales GM&E is the largest business franchise of the Healthcare business sector, contributing significantly to the overall profitability of Biopharma and Merck. Although no longer patent-protected, the brand equity built over decades makes our flagship products cornerstones for the treatment of chronic cardiovascular, metabolic and endocrine diseases.

Concor®, containing bisoprolol, is the leading beta-blocker for chronic cardiovascular diseases such as hypertension, coronary artery disease and chronic heart failure. Euthyrox®, with the active ingredient levothyroxine, is the leading treatment for hypothyroidism, a disease with high prevalence but still low diagnosis in most emerging markets. Glucophage®, containing the active ingredient metformin, is the drug of choice for first-line treatment of type 2 diabetes. In October 2016, metformin received a positive CHMP opinion for treatment of type 2 diabetes patients with moderate renal impairment (CKD stage 3), which will be reflected in a label change in Europe. This will allow Glucophage® and other metformin products to be used safely by a larger group of patients with type 2 diabetes. The indication for Glucophage® is being extended to include prediabetes and has been granted approval in 12 markets around the world.

We also help to raise awareness and education in the areas we operate in, such as thyroid diseases. Highlights include our continuous engagement in International Thyroid Awareness Week and our partnership with the Royal Health Awareness Society (RHAS) of Jordan, signed in October.

Saizen® (somatropin) is our main endocrinology product and is indicated for the treatment of growth hormone deficiency (GHD) in children and adults. Saizen® is delivered with the easypod™ electromechanical injection device, the only growth hormone injection device of its kind. easypod™ is able to wirelessly transfer data such as injection times, dates and doses to the web-based software system easypod™ connect, making it easier for healthcare practitioners and patients to ensure adherence and reach their treatment goals.

As part of our continuous commitment to deliver high-quality medicines to our patients, we are continuously investing in our manufacturing network across the globe. In 2016, we completed the construction of a new facility in Nantong, China, expanded our plant in Rio de Janeiro, Brazil, and initiated the construction of a ew packaging center in Darmstadt, Germany, in order to meet the increasing worldwide demand for our General Medicine products Glucophage®, Concor® and Euthyrox®. In order to meet the increasing worldwide demand for our biotech portfolio of medicines, we completed the expansion of our plant in Tres Cantos, Spain. In Aubonne, Switzerland, we pushed forward with the construction of our new packaging center.

Consumer Health

In our Consumer Health business we focus on consumer-centric innovation under the umbrellas of several strategic brands such as Neurobion®, Bion®, Seven Seas®, Nasivin®, Femibion®, and Dolo-Neurobion®, as well as Vivera®/Floratil®, Sangobion®, Vigantoletten®, Apaisyl®, and Kytta®. Our latest innovations are the probiotic Vivera and the Femibion BabyPlanning line extension. We aim at emotionalizing these over-the-counter and food supplement brands so that they become irresistible love brands in the eyes of our consumers and customers alike. Most of these brands are fully aligned with the newly established purpose of the Consumer Health business: “We exist to prepare society for a new era of humans living 100 healthy years.”

Global megatrends favor the future growth of the Consumer Health business. People are becoming more health-conscious and take care of their own physical well-being. Preventive healthcare and as little invasive medication as possible are growing in importance – in both established and developing markets, the latter characterized by a growing middle class with specific needs. And people and societies are growing older than ever before. This is why we developed and started establishing a movement around our new purpose to actively drive change in the societies we are operating in, all under the independent label and motto “WE100® – young for old, old for young.”

We are currently among the top 15 players in the global OTC market and already generate more than 50% of our annual sales in developing growth markets. In particular, markets such as Chile, Brazil, the United Kingdom, South Africa, Thailand, Indonesia, India, Malaysia, and the Philippines are delivering significant growth rates. To further align the regional with the strategic brand strategies and to even better focus on efficient region-brand combinations, we have reorganized our regional structure.

Biosimilars

Our Biosimilars business is committed to providing access to high-quality biologics to more patients all over the world. In addition, we are developing a biosimilars portfolio focused on oncology and inflammatory disorders through both in-house research and development expertise in biologics and partnerships with other biosimilar players. In 2016, we advanced our pipeline well into clinical development, with our adalimumab Phase III study recruiting the first patient and finishing recruitment in the same year. Biosimilars is an attractive market in which we are well-positioned, building on existing strengths and capabilities across the biosimilars value chain.

Merck has strategic alliances with Dr. Reddy's in India to co-develop multiple cancer drugs and with Bionovis in Brazil to supply the Brazilian market with biological products under the Productive Development Partnership (PDP) policy of the Brazilian Ministry of Health.

Merck is in advanced stages of negotiations to divest the Biosimilars business and the transaction is expected to close in 2017.

Allergopharma

Our allergy business Allergopharma is one of the leading companies in the field of allergy immunotherapy (AIT). The Allergopharma portfolio includes a diverse spectrum of approved allergen products that meet high quality standards. AIT (hypo-sensitization, desensitization, specific immunotherapy) is the only causal therapy for treating allergies to unavoidable allergens.

We manufacture products to diagnose and treat type 1 allergies such as hay fever or allergic asthma. Merck's allergy business offers high-dose, hypoallergenic, standardized products for allergen immunotherapy of pollen and mite allergies. These allergoids have a special focus in Allergopharma's product portfolio and constitute a cornerstone in its integrated health approach for patients suffering from these conditions. For effective treatment, reliable diagnosis is key. Allergopharma offers a broad range of diagnostics in the field of allergies with more than 100 single allergens, providing physicians with the specific tools needed to identify the substances causing an allergy. In addition, Allergopharma provides individual allergen extracts on a named patient basis, which are needed to treat less frequent allergies. Personalized medicine has been a reality for Allergopharma for many years now. Products of Allergopharma are available in more than 20 countries worldwide.

Life Science

With one of the broadest product and technology portfolios in the industry, the purpose of the Life Science business sector is to solve the toughest problems in life science by collaborating with the global scientific community. Udit Batra has been the CEO of our Life Science business sector since 2014 and became a member of the Merck Executive Board in April 2016. In 2016, the Life Science business sector contributed 38% to Group sales and 34% to EBITDA pre exceptionals (excluding Corporate and Other).

We are a leading player in the attractive € 100 billion life science industry, serving more than one million global customers with the aim of advancing science faster to accelerate access to health for people everywhere. We offer innovative solutions for scientists and engineers at every stage. Our products and services are used in the research, development and manufacture of biotechnological and pharmaceutical drug therapies, as well as in research and application laboratories. In addition, our products and services also reach adjacent markets such as the food and beverage industry.

In November 2015, we acquired the Sigma-Aldrich Corporation, a leading life science company. This marked the largest acquisition in the history of Merck – and one of the largest in the industry. As a combined business, we are able to serve life science customers around the world with a highly attractive set of established brands such as Millipore, Sigma-Aldrich, Milli-Q®, SAFC, Supelco and BioReliance. Moreover, we have a highly efficient supply chain through which we can deliver standard products in 24 to 48 hours worldwide. In the laboratory and academia business, we offer customers an extensive and customized range of products across laboratory chemicals, biologics, and reagents.

Life Science operates in 66 countries around the world with the headquarters in Darmstadt, Germany and major hubs in Boston (Massachusetts), St. Louis (Missouri), Milwaukee (Wisconsin) and Molsheim in France. In July, we announced plans to build a new campus in Burlington, Massachusetts that will serve as a major hub for our North American life science business with an investment of US$ 115 million. The 26,000 m^2 facility will include an M Lab™ Collaboration Center customer collaboration laboratory and training center as well as office space – a state-of-the-art, shared, exploratory environment where the company's scientists and engineers work together with customers.

The Life Science business sector generates recurring sales and stable, attractive cash flows in an industry that is characterized by stringent regulatory requirements. A highly diversified and loyal customer base additionally ensures a low risk profile. We benefit from a broad and relevant portfolio, a highly efficient supply chain including a superb eCommerce platform and global reach.

Our eCommerce platform sigmaaldrich.com allows customers in nearly every country to more easily find the exact products needed to advance their research. Currently, more than 70% of addressable legacy Merck Millipore products are available on sigmaaldrich.com. In 2016, we implemented a centralized initiative to manage all customer acquisition channels and scaled search advertising to include more than two million active keywords driving increased website traffic to the content customers are looking for, resulting in a streamlined customer experience.

The Life Science business sector is organized into three business areas which reflect customer segments. Research Solutions focuses on academia and pharmaceutical research institutions; Process Solutions markets products and services for the entire pharmaceutical production value chain, and Applied Solutions serves clinical and diagnostic testing laboratories, as well as the food and environmental industries.

To support these customer segments, our Strategic Marketing & Innovation (SMI) teams promote and deliver innovation tailored to our customers' needs. The SMI organizations are responsible for defining customer segment strategy, maintaining and innovating the product portfolio and communicating the business's strategic value propositions.

In addition, we have two commercial areas which are managed by region and customer segment to leverage regional and local expertise: one dedicated to the lab customers between Research and Applied and one dedicated to Process Solution customers. These areas are responsible for marketing, sales as well as customer and dealer relationships.

Research Solutions offers a broad and relevant portfolio of solutions that enable scientific discovery through complete partnership across the customer journey. This includes more than 200,000 products and services including molecular platforms, protein and pathway technologies, biochemicals, materials science, and cell culture workflow tools.

In Danvers, Massachusetts, we launched a transformation project at our current Mobius® manufacturing facility to improve capabilities within the facility. The project will include an additional 1,250 m^2 of cleanroom space to help meet the increasing market demand for single-use products.

In 2016, we introduced MILLIPLEX® MAP Human High sensitivity cytokine panel for faster and more cost-effective human cytokine assays. The new assay is the first 384-well kit for use with the Luminex FLEXMAP3D® platform and allows researchers with limited sample volumes who require high throughput to get more results, faster.

Our Process Solutions business offers a diverse range of products to pharmaceutical and biotechnology companies that enable customers to develop large- and small-molecule drugs safely, effectively and cost-efficiently. With the 2015 combination of Sigma-Aldrich and Merck Millipore, we now offer the broadest portfolio in the industry. The 15,000-plus products and services in Process Solutions include single-use manufacturing, filtration, chromatography and purification, virus reduction, pharma and biopharma raw materials, drug delivery compounds and engineering and validation services.

Our single-use solutions offer increased flexibility to biopharma customers since they eliminate time- and cost-intensive cleaning procedures. Moreover, these single-use solutions are compatible with various products, thus reducing investment costs for our customers. Launched in 2016, the new Mobius® products include a 1,000-liter single-use bioreactor with an industry-leading design, a 2,000-liter system for difficult-to-mix biopharma ingredients and a large-volume transport system for sterile and non-sterile liquids. These products meet our customers' increasingly complex demands for user-friendly systems that allow them to focus on their science. We also deliver full end-to-end biopharma solutions by offering clients a full process line cGMP (current good manufacturing practices), from clone to commercial production.

In 2016, we expanded our industry-leading Emprove® risk assessment program to include selection of products for filtration and single-use processing. Rapid and easy access to risk assessment information is critical in an ever-changing regulatory landscape. The Emprove® program provides documentation and regulatory information on materials used in the manufacture of drug products and includes Millipore Express® filters, Pureflex® and Pureflex® Plus bags, Viresolve® Pro filtration devices and Durapore® filters.

In November 2016, we announced an € 80 million investment in a Life Science Center in Nantong, China, demonstrating a commitment to the industry's fast growth by providing a wide range of leading, innovative solutions for customers and partners in China. The facility will reinforce our leading position in inorganic salts for active pharmaceutical ingredients and excipients and cell culture media for the pharmaceutical, biopharma and healthcare markets in China as well as ready-to-use media for environmental and sterility testing.

The Applied Solutions business area focuses on diagnostic, testing and industrial customers and provides trusted products and comprehensive workflow solutions that streamline processes, lower costs and deliver consistent, reliable results. Our 62,000-plus products and services include analytical separation systems, reference materials, lab water instruments with consumables and services and microbiology and bio-monitoring testing materials.

Building on our commitment to improving workflows, we launched the Elix® high-throughput water purification system. Designed to operate at the heart of a central water purification solution, the Elix® system offers full connectivity, providing users real-time remote monitoring via computer, tablet or smartphone with access to all important water quality data. The product integrated seamlessly with existing systems and decreases energy and water consumption while maintaining water quality.

Our popular Guava® flow cytometers line was expanded with the addition of 532 nanometer lasers that increase the capabilities of the Guava® easyCyte instrument line to enable simultaneous detection of multiple fluorescent proteins. Since the discovery and isolation of the genes encoding proteins responsible for biological fluorescence, proteins have changed life science research. The new line enhances optical capability and flexibility and results in better optical configuration.

Performance Materials

Our entire specialty chemicals business is combined in our Performance Materials business sector. The portfolio includes high-tech chemicals for applications in fields such as consumer electronics, lighting, coatings, printing technology, paints, plastics, and cosmetics. Performance Materials comprises four business units: Display Materials, Integrated Circuit Materials, Pigments & Functional Materials, and Advanced Technologies.

Walter Galinat has been the CEO of the Performance Materials business sector since 2010. In April 2016 he was appointed to the Merck Executive Board. In 2016, the business sector's share of Group sales amounted to 17% and its share of EBITDA pre exceptionals (excluding Corporate and Other) was 23%. The EBITDA margin pre exceptionals was 44.1% of sales.

In 2016, we defended our position as the global market and technology leader for established liquid crystal technologies even though the growth in demand for liquid crystal displays (LCDs) was lower than expected. Large – mainly Asian – display manufacturers are among the customers of our Liquid Crystals (LC) business. The Display Materials business unit comprises the broadest product offering. We offer liquid crystal mixtures, for technologies such as PS-VA (polymer-stabilized vertical alignment) technology (primarily for televisions) and IPS (in-plane switching) technology (primarily for smartphones and tablets), photoresist materials and reactive mesogens. New developments such as energy-efficient UB-FFS (ultra-brightness fringe field switching) technology established themselves further in the market for smartphones and tablets.

The development of new application possibilities for liquid crystals was again an important focus of our LC 2021 strategic initiative in 2016. This primarily includes the development of liquid crystal window technology. In order to protect against solar radiation, these windows allow continuously variable switching from light to dark in just seconds and have high color neutrality compared with competitive technologies. A privacy version of the windows permits switching from transparent to opaque. To achieve faster market penetration of the new technology, Merck is investing around € 15 million in a production facility for liquid crystal window modules at a site in Veldhoven, the Netherlands. The manufacture of these switchable modules, which our customers can process into smart windows and glass façades, is to start at the end of 2017.

In 2016, our annual "Displaying Futures" symposium focused on future mobility. We want to use the Automotive Platform that we have developed to show the potential that Merck materials have in view of future trends. These include liquid crystals for free-form displays, liquid crystals for mobile antenna applications or adaptive lighting in headlights, OLEDs (organic light-emitting diodes), LEDs (light-emitting diodes), semiconducting materials in chips or functional pigments. To further young companies and researchers, in 2016 we presented the Displaying Futures Award for the first time. The prize, which is worth US$ 50,000 and awarded for new ideas involving liquid crystal materials, went to three teams from the United States and the Netherlands.

Integrated Circuit Materials is our second-largest business unit and supplies products to manufacture integrated circuits and microelectronic systems, for antireflection coatings, and for the miniaturization of transistor structures. By integrating the two acquisitions, namely the SAFC Hitech business of Sigma-Aldrich and Ormet Circuits, we have ideally complemented our portfolio to include deposition materials and conductive pastes for semiconductor packaging. Advanced semiconductor manufacturers benefit from our cutting-edge material solutions for next-generation lithography, for example in directed self-assembly (DSA). We hold a leadership position in DSA technology thanks to our extensive expertise in polymer synthesis as well as many years of process and formulation experience. An important topic for the semiconductor industry is the development of increasingly powerful computer chips. This is being achieved by either making the structures on the chip even smaller (Moore's law) or combining different chips in the component or three-dimensional structures ("beyond Moore"). Merck offers various innovative products for both approaches. In addition to smartphones and servers, the main applications include sensors, for example for the automotive industry, and the Internet of Things. As an important partner to leading global electronics manufacturers, the business unit achieves more than 60% of its sales in Asia, generating around three-quarters of sales with products that are the leaders in their respective markets. In 2016, we also strengthened our positioning in the growth market of China.

The Pigments & Functional Materials business unit develops and markets a comprehensive product portfolio of decorative effect pigments and functional materials. The effect pigments are primarily used in automotive and industrial coatings, plastics, printing applications, and cosmetics in order to give products a unique shine. Functional materials include laser marking, conductive additives, applications for counterfeit protection as well as high-quality cosmetic active ingredients, for example for use in skin care, as well as sun protection and insect repellents. In 2016, we offered our customers various new products in all areas: For example, we launched the new Thermaval™ series of pearlescent pigments for high-temperature applications. They allow ceramic glazes to retain their brilliant colors and sparkle effect, also when used in ceramic glazes at cost-efficient single-firing temperatures. In 2016, our portfolio expansion and distribution activities also focused on collaborations – for example, with Agrimer of France to use marine cosmetic actives and with PolyOne of the United States to refine and market an innovative 3D plastics technology. Triggered by the Zika virus epidemic, we gained further market share with our insect repellent IR3535®, even in the existing market. The substance provides effective protection against mosquito bites and is also safe for pregnant women, who are at particular risk from the Zika virus. Merck received the prestigious European Frost & Sullivan Award for Product Leadership 2016 for its pioneering role in pigments used in high-quality automotive coatings. This recognizes the success achieved with the innovative Meoxal® and Xirallic® NXT lines.

The Advanced Technologies business unit invests particularly in future-oriented research and development in Performance Materials. A very good example of this are our materials for organic light-emitting diodes (OLEDs). The OLED materials business is one of our fastest-growing businesses. We opened the new production facility for OLED materials in Darmstadt in September as planned. After a 14-month construction period, high-purity OLED materials are being produced in the approximately 3,600 m^2 building. These are used not only in state-of-the-art displays, but also in modern lighting systems, such as in high-quality automotive tail lights. With a total investment of around € 30 million, this is one of the largest single investments Merck has made at the Darmstadt site in recent years. The plant makes it possible to significantly increase production capacity. We aim to be a leading supplier of OLED materials by 2018. In order to meet the increasing demand and supply customers with a broad range of high-performance OLED materials, we have entered into a cooperation agreement with the Japanese company Idemitsu Kosan.

Quantum materials are another interesting new technology to improve displays. They enable ultra-bright displays with a notable expansion of the color gamut. In order to meet the growing demand for quantum materials, we entered into a licensing agreement with the Nanoco Group of the United Kingdom. The license allows Merck to immediately start marketing Nanoco's environmentally friendly cadmium-free quantum materials and to establish its own production facilities in the long term. In addition, we are also conducting research in quantum technology via the Israeli start-up Qlight Nanotech, which we acquired in 2015.

Objectives and Strategies

We want to advance technologies for a better life. Based on scientific research and in collaboration with partners, we are focusing on specialty products in healthcare, life science and performance materials.

General principles and Group strategy

General principles

Merck is a vibrant science and technology company. Our aim is to achieve technological progress that will improve life and make our customers and business associates more successful. This aspiration is embodied by values-based and economically sustainable corporate governance, has been anchored in our new brand promise since 2015, and steers the strategic development of the Group.

Our annual strategic planning process follows firmly defined principles. Our business portfolio must always be balanced so that it reflects an optimum mix of entrepreneurial opportunities and risks. We achieve this through our diversification into three complementary business sectors that make the company as a whole less dependent on economic cycles, as well as by expanding our presence in global growth markets. This exemplifies the long-term direction of our Group strategy. We want to continue the nearly 350-year-old success story of Merck into future generations and to achieve sustainable profitable growth. The partner structure of Merck KGaA with members of the Merck family as personally liable partners also contributes to this. It requires the Executive Board, whose members are also personally liable partners, to pay special attention to the long-term development of value.

For us, the principle of sustainability applies not only to economic aspects, but also encompasses corporate responsibility. We pursue three strategic spheres of activity: health, the environment and culture. The focus is always on the future viability of society and the competitiveness of our company. With our current and future product portfolio, we want to help solve global challenges, from urbanization to aging populations.

Group strategy

Over the past decade, Merck has transformed itself from a classic supplier of chemicals and pharmaceuticals into a global science and technology company. The main driver was the transformation of our business portfolio, particularly through the divestment of our Generics business (2007) and the acquisitions of Serono (2007), Millipore (2010), AZ Electronic Materials (2014), and Sigma-Aldrich (2015). In addition, we focused our businesses on innovation-driven and highly specialized products, extensively revamped our internal structures and processes, and expanded our presence in global growth markets.

Today, we hold leading positions in the respective markets of our three business sectors Healthcare, Life Science and Performance Materials, and are working to bolster and expand these. To this end, we are pursuing innovation-driven, organic growth. For instance, by 2022 we are targeting sales of around € 4 billion with new products. New medicines from the pharmaceutical pipeline are to contribute around € 2 billion, with Life Science and Performance Materials innovations each contributing around € 1 billion in sales.

Targeted acquisitions capable of meaningfully complementing or boosting our strengths remain a growth option. However, Merck continues to rule out major acquisitions of more than € 500 million as long as the debt level expressed as the ratio of net financial debt to EBITDA pre exceptionals is greater than 2, unless divestments could be used to finance them. By 2018, we aim to reduce our debt level to below 2 again.

Our Group strategy aims to resolutely continue the transformation of Merck into a specialized technology company and to position the company as a leading player in a changing market environment. For this purpose, we set up the Group Strategy & Transformation function in 2016. It unites the previously separately managed units Strategy, Innovation and Digitalization, and is designed to ensure the successful and timely implementation of core strategic projects. We have assigned these projects to three areas of key priority, namely “Performance”, “People” and “Technology”.

"Performance" encompasses all activities that create sustainable, profitable growth. To this end, we are closely aligning our businesses with the wishes and needs of customers and patients, not only through our products, but also best possible proximity. The basis for this is formed by efficient structures and processes as well as sustainable financial management. "Performance" is illustrated by the rapid and seamless integration of Sigma-Aldrich into our Life Science business as well as the realization of the associated synergies. We have progressed here faster than planned. In addition, previously unplanned top-line synergies are expected to contribute an additional € 20 million to earnings by the end of 2018. Consequently, total synergies from the Sigma-Aldrich acquisition will amount to € 280 million instead of originally € 260 million per year.

Merck's growth strategy calls for a work culture that values diversity, promotes collaboration and responds flexibly to changing requirements. That's because in today's global knowledge society, qualified and motivated people are a crucial factor for entrepreneurial success, especially in a science and technology company like Merck. As a key priority area, "People" includes the further development of people management practices and creating an environment where innovation and creativity can thrive. We are paying particularly close attention to our leadership culture, talent pipeline and strengthening collaboration across national and departmental borders, for example through flexible work models or the use of a modern communication infrastructure.

The priority area "Technology" covers the closely interlinked areas of innovation and digitalization. Developing and marketing innovative products and services are at the forefront of our Group strategy and all the business strategies. Our objective is to foster innovations both within the businesses and between them as well as beyond existing businesses into areas in which we are not yet active.

In particular, we want to capture the opportunities that digitalization offers in order to create value for customers, business associates and patients. To us, digitalization means the digital integration of our entire value chain, the digitalization of our products, services and communication interfaces to customers as well as the development of new digital business models. This is supported by state-of-the-art methods to collect and analyze vast amounts of data (Big Data).

Additionally, we are working Group-wide to expand the physical and virtual infrastructure for technology-driven growth. The centerpiece will be formed by the Innovation Center in Darmstadt. Currently under construction, this 7,000 m^2 building is scheduled for completion by the end of 2017. Until its opening, our modular Innovation Center, which opened in 2015, offers a platform for the development of new technologies, for instance within the scope of our Accelerator program. Through this initiative and our expertise in science and technology, we support start-ups in transforming their visions into viable business models.

In 2016, we expanded our existing Biopharma venture fund to all three business sectors, increasing the total funding volume to € 300 million. Additionally, businesses beyond our current portfolio represent the fourth investment arm of the new Merck Ventures fund.

Capability initiatives

In 2013, Merck introduced four capability initiatives. They address topics that are of strategic importance to the performance of the entire company: The capability initiatives ONE Merck brand, ONE Talent Development, Rewards, and Performance Management, ONE Process Harmonization, and ONE Global Headquarters continue to drive important change or have started to evolve into regular activities. In October 2015, we introduced a fundamental revision of our brand design along with a simplified brand architecture, which we are currently implementing globally at all levels. In this context, we launched the digital brand campaign in 2016 called "Breakthroughs begin with curiosity" (curiosity.merckgroup.com), which puts the spotlight on scientific curiosity and passion for discovery as the driving forces of innovations.

Business strategies

Healthcare strategy

Global megatrends such as a growing world population and general increase in life expectancy are driving the demand for our healthcare products, namely biopharmaceuticals primarily for high unmet medical needs as well as consumer health brands that reflect the rising demand for preventive healthcare from an increasingly health-conscious society.

To meet these demands and appropriately respond to the dynamics of our healthcare markets, we have significantly transformed our Healthcare business sector in recent years. We are driving pipeline projects with the aim of bringing new groundbreaking medicines to patients, maximizing our existing portfolio and continuing our expansion in growth markets.

Our Healthcare business sector comprises the four businesses Biopharma, Consumer Health, Biosimilars, and Allergopharma. The diversity and profound medical expertise we have in these businesses are core strengths and key differentiators in the market. Within each business, we specialize in key therapeutic areas and specific diseases.

Our ambition in Healthcare is to become a global specialty innovator, to operate in therapeutic areas with significant unmet medical needs and to bring significant value to patients and consumers. Therefore, we invest heavily in research and development to discover new treatment options and improve existing ones. We are committed to working with our stakeholders and our partners to ensure that people can access the medicines they need to stay healthy and live longer.

In order to succeed in these areas, we seek sustainable ways to leverage our size, global set-up and innovation power. Here, striking the balance between innovation and operational excellence will be key. We are pursuing a comprehensive effort to further enhance our focus on customers. To boost customer intimacy, we are strengthening our relationships with healthcare professionals and building capabilities in digital, predictive and Big Data analytics.

The first pillar of our strategy is to reinforce our global footprint by developing our tailored portfolio to address unmet medical needs in all regions worldwide. While developed markets such as the United States, Japan and Europe are key strategic markets for our specialty innovation products, sales in growth markets such as China will be driven by our mature specialty, established biologics and broad general medicine portfolios. At the same time, it will be essential for us to continue to focus our efforts on growing in the United States in order to realize our ambition of being a truly global leader. For example, with the co-promotion of Xalkori® with Pfizer, we have entered the United States oncology market, which is helping us to prepare for the future launch of avelumab, our anti-PD-L1 antibody.

The second pillar of our strategy is to develop specialty assets in early- and late-stage clinical development. Here, we are concentrating our efforts on oncology and immunology as well as ensuring we remain a relevant player in our core therapeutic areas. For example, we have made significant investments in R&D, especially in areas of unmet medical need, and refined our focus on mechanisms of action and molecules that are expected to lead to transformative innovations in cancer care, neurology and immunology. Our aim is to turn cancer patients into cancer survivors by being at the forefront of changing the future of cancer care. Further development programs for immunology and neurology include cladribine tablets, with a first-of-its-kind dosing regimen that serves as an important therapeutic option for patients with relapsing-remitting multiple sclerosis, and atacicept as a potential therapy of choice for lupus patients with high disease activity.

The third pillar of our strategy is innovation. Our aspiration is to develop high-quality, first-to-market and best-in-disease assets, and to build a portfolio in each of our chosen therapeutic areas. We have streamlined our pipeline and upgraded our innovation capabilities with strong investigational drug candidates. In order to maximize the impact of our R&D investments and increase our chances of success in discovering and developing new medical therapies, we focus our expertise on specific therapeutic areas and are exploiting synergies in disease mechanisms and biological pathways.

In this context, strategic collaborations are an integral part of delivering on our commitment to transforming the lives of patients living with serious unmet medical needs. We recognize the value of collaboration in the research and development of breakthrough therapies, as well as strengthening our current portfolio. Here, we focus on balancing the right blend of internal capabilities and external partnerships, building strong collaborations with other leaders in industry, including Pfizer and Genea.

We are innovating beyond our pipeline projects with our Medical Devices and Services unit and our Fertility technologies. In addition to innovative therapeutic approaches, the way in which we engage with customers will be vital to achieving our objective of becoming a global specialty innovator.

Merck is in advanced stages of negotiations to divest the Biosimilars business and the transaction is expected to close in 2017.

Life Science strategy

As a leading business in the € 100 billion life science industry, the purpose of the Life Science business sector is to solve the toughest problems in life science by collaborating with the global scientific community. To best meet the needs of our customers and accelerate innovation, the business areas responsible for life science innovation and product development are strategically organized around our customers. Research Solutions focuses on academia and pharmaceutical research institutions. Process Solutions markets products for the entire pharmaceutical production value chain. Applied Solutions serves clinical and diagnostic testing laboratories as well as the food and environmental industries. With an expanded portfolio of more than 300,000 products, most of which are available on our industry leading e-commerce platform sigmaaldrich.com, Life Science offers solutions, services and expertise across the entire biopharma value chain.

Our strategy focuses on three areas: driving our core business; realizing the planned synergies from the Merck Millipore and Sigma-Aldrich integration by the end of 2018, and establishing new pillars of growth.

To grow our portfolios, we are refreshing our operating model and go-to-market strategy. Additionally, we will strengthen key capabilities across Life Science by optimizing supply chain performance to align service levels in Research Solutions and Applied Solutions. In Process Solutions, we are showing strong business continuity and upgrading quality performance in specific areas. Our innovation capabilities remain critical for future growth and we will leverage intellectual property as a strategy in key areas such as gene editing. Information technology is a core capability for Life Science as we work to improve our eCommerce, digital marketing and analytics competences. Here we are building on and further expanding our leadership position from legacy Sigma-Aldrich.

We have completed the first of three years of integration and have made tremendous progress with all relevant roles in the new organization in place and consolidation of integration teams into respective business functions. The value of the integration is evident, with a significant increase in sales and the realization of synergies faster than anticipated through multiple geographic synergy initiatives, the eCommerce platform and complementary customer accounts. We continue to focus on basic process harmonization throughout the organization for employees and customer satisfaction.

Based on a broad assessment of the market and competitive landscape and key industry trends, we have identified six strategic initiatives to drive future growth. These include gene editing and cell therapy as well as end-to-end solutions, where we aim to be the partner of choice to accelerate product and drug development. We are focused on completing our end-to-end offering of early and late stage process development and facility design services for accelerating local drug production. In addition, we are creating a new connected lab ecosystem to solve laboratory pain points such as data collection, documentation and replenishment.

Performance Materials strategy

In the Performance Materials business sector we want to sustainably secure our market and technology leadership in display materials. In addition, we want to leverage our expertise in liquid crystals beyond the application field of displays. At the same time, we benefit from the trends in the semiconductor industry and will also continue to dominate the effect pigments market in applications for coatings.

Global demand for innovative display solutions grew further in recent years. We assume that increasing demand for high-quality consumer goods will come from an expanding middle class in growth markets also in the coming years. Therefore, we aim to continue to strengthen our position as the market and technology leader for liquid crystals. Key to this are new, sophisticated liquid crystal technologies. Our eco-friendly, resource-conserving and efficient liquid crystal technology SA-VA (self-aligned vertical alignment) for large-area displays is the next technology, with which the first products are expected on the market in 2017.

The Integrated Circuit Materials business unit supports the entire semiconductor industry with a portfolio of customized solutions. There are limits to further increasing the capacity of conventional silicon chips. At the same time, the costs, which for modern chips today already amount to more than 50% of manufacturing costs, are no longer declining at the same pace as before. This offers us the opportunity to develop novel materials that allow our customers to produce more powerful chips on the one hand, and to counteract rising costs with innovative processes on the other hand. Photolithography, deposition materials and dielectrics can increase semiconductor efficiency. Packaging materials are becoming increasingly important for the development of 3D chip variants. This is precisely where we have strengthened our portfolio through the acquisition of Ormet Circuits.

In the Pigments & Functional Materials business unit, we are further expanding our leading position in effect pigments for automotive coatings. We are continuing to defend our good market position in pearlescent pigments for plastics, printing and cosmetics applications. Here we are concentrating on high-quality products and on optimizing the supply chain. In functional materials, the focus of our growth strategy continues to be on niche applications in cosmetics (such as UV filters, insect repellents and anti-aging substances) as well as technical functional materials (such as laser marking and antistatic applications). Collaborations with external partners are particularly attractive here.

Our Advanced Technologies business unit aims to develop profitable future businesses – both for Performance Materials and for Merck's other business sectors. These also include the further development of OLED materials as well as organic photovoltaics. In 2016, we realigned our projects for future business fields to megatrends such as miniaturization and the Internet of Things.

Strategic initiatives

The two strategic initiatives OLED (organic light-emitting diodes) and LC 2021 are to significantly contribute to our future growth and continue to generate attractive margins. It is our declared goal to become the leading supplier of OLED materials. The commissioning of our new production plant for OLED materials in Darmstadt, which significantly increases our production capacity, has brought us an important step closer to this goal. The technology has the potential to change the future for displays and lighting. Intense colors, an especially deep black, thin structure, flexible use and low energy consumption are just some of the advantages offered by self-luminous OLED displays. OLED lighting applications score high with thin, filigree, lightweight lighting panels and a natural-appearing color spectrum. Under the umbrella of the LC 2021 strategic initiative, we are combining future applications of liquid crystals beyond classic displays. In six fields altogether, we are focusing on improved user experience on the one hand, and light and data management on the other hand. First and foremost, this comprises liquid crystal windows. In Veldhoven, the Netherlands, we are establishing our own production for modules used in sun protection and privacy control variants. It is scheduled to be commissioned at the end of 2017.

Strategic finance and dividend policy

We are pursuing 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.

We have diversified and profitable businesses as the basis for our strong and sustainable cash flow generation capacity. Moreover, we have several funding resources in place. A € 2 billion syndicated loan facility through to 2020 exists to cover any unexpected cash needs. The facility is a pure back-up credit facility and has not been drawn on so far. In addition, we can use a € 2 billion commercial paper program to issue short-term commercial paper with a maturity of up to one year.

Furthermore, we are using bilateral bank loan agreements with first-class banks in order to optimize the funding structure and cost. In this context, the bond market generally represents a key element. However, owing to our focus on deleveraging, no bonds were issued in 2016. In the past, Merck has mainly focused on bond issues in Europe. In addition, we issued hybrid bonds amounting to € 1.5 billion in 2014 and U.S. dollar bonds amounting to US$ 4 billion in 2015 outside the Debt Issuance Program in order to broaden the funding basis and to address different investor groups.

Maintaining sustainable and reliable business relations with a core group of banks

We mainly work with a well-diversified, financially stable and reliable group of banks. Due to Merck's long-term-oriented 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 geographic regions. We regard these banks as strategic partners. Accordingly, we involve them in important financing transactions.

Strong investment grade rating

The rating of our creditworthiness by external rating agencies is an important indicator of the company's financial stability. A strong investment grade rating is an important cornerstone of Merck's financial policy, as it safeguards access to capital markets at attractive financial conditions. Merck currently has a Baa1 rating from Moody's and an A rating from Standard & Poor's (S&P), both with a stable outlook. In addition, the European rating agency Scope began covering our credit rating in 2016. The rating is A- with a stable outlook. Within the next two to three years, it is of utmost importance to us to sharply reduce our debt and to regain the ratings we had prior to the Sigma-Aldrich acquisition.

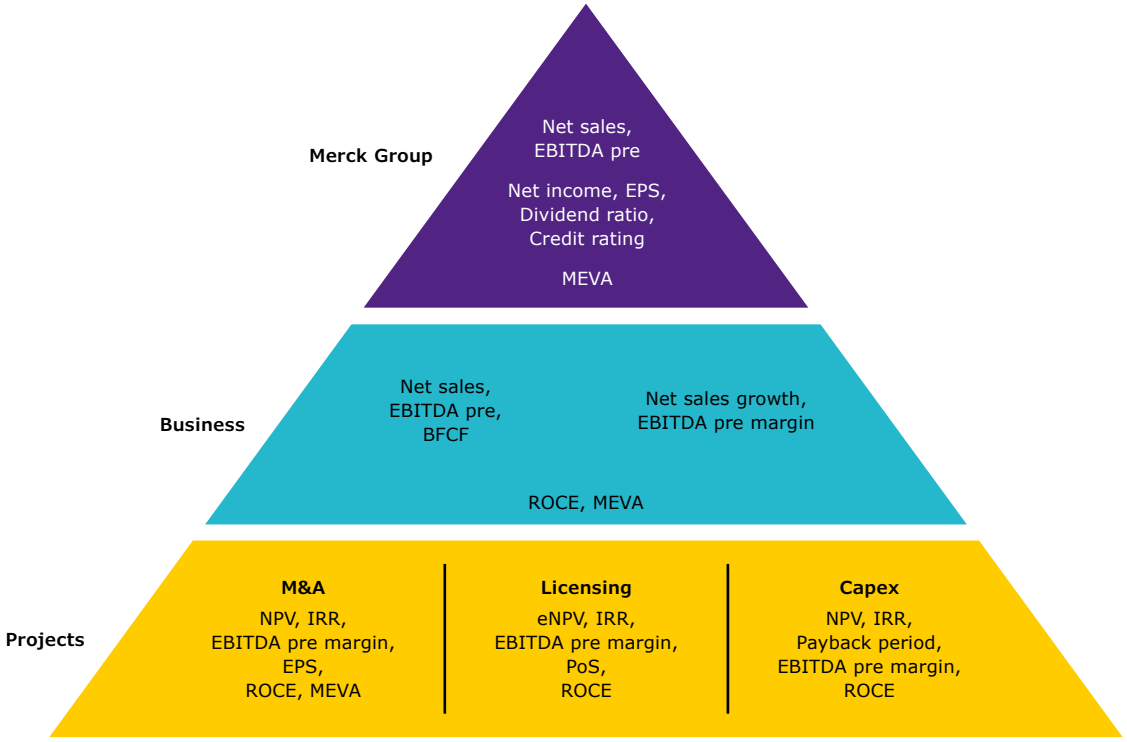
Dividend policy

We are pursuing a sustainable dividend policy. Provided that the economic environment develops in a stable manner, the current dividend represents the minimum level for future dividend proposals. The dividend policy is oriented towards the business development and earnings increase of 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 EPS pre exceptionals.

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 KPI (key performance indicator) to measure performance is EBITDA pre exceptionals[1].

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



Abbreviations

EBITDA pre = Earnings before interest, income tax, depreciation and amortization
EPS = Earnings per share
MEVA = Merck value added
BFCF = Business free cash flow
ROCE = Return on capital employed
NPV = Net present value
IRR = Internal rate of return
eNPV = expected Net present value
PoS = Probability of success
M&A = Mergers and acquisitions

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

Key performance indicators of the Group and its businesses

The three key performance indicators net sales, EBITDA pre exceptionals[1], and business free cash flow[1] are the most important factors for assessing operational performance. Therefore, we refer to these KPIs in the Report on Economic Position, the Report on Risks and Opportunities, and in 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, 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, acquisition- and currency-adjusted sales are used for internal performance management.

MERCK GROUP

Net sales

			Change	
€ million	**2016**	2015	€ million	in %
Net sales	**15,024**	**12,845**	**2,179**	**17.0%**

EBITDA pre exceptionals

EBITDA pre exceptionals is the main performance indicator measuring ongoing operational profitability and is used internally and externally. To provide an alternative understanding of the underlying operational performance, it excludes from the operating result depreciation and amortization, impairment losses and reversals of impairment losses as well as exceptionals. The exceptionals are restricted to the following categories: integration costs, IT costs for selected projects, restructuring costs, gains/losses on the divestment of business, acquisition costs, and other exceptionals. The classification of specific income and expenses as exceptionals follows clear rules and underlies strict governance at Group level. Within the scope of internal performance management, EBITDA pre allows for the necessary changes or restructuring without penalizing the performance of the operating business.

MERCK GROUP

Reconciliation EBIT to EBITDA pre exceptionals[1]

			Change	
€ million	**2016**	2015	€ million	in %
Operating result (EBIT)[1]	**2,481**	**1,843**	**637**	**34.6%**
Depreciation and amortization	1,805	1,383	422	30.5%
Impairment losses/reversals of impairment losses	129	128	2	1.2%
EBITDA[1]	**4,415**	**3,354**	**1,061**	**31.6%**
Restructuring costs	22	48	–26	–54.0%
Integration costs/IT costs	193	78	116	>100.0%
Gains (–)/losses (+) on the divestment of businesses	–304	2	–305	>100.0%
Acquisition-related exceptionals	153	133	20	15.3%
Other exceptionals	11	16	–5	–32.7%
EBITDA pre exceptionals[1]	**4,490**	**3,630**	**861**	**23.7%**

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

Business free cash flow (BFCF)

Business free cash flow comprises the major cash-relevant items that the operating businesses can influence and are under their full control. It comprises EBITDA pre exceptionals less investments in property, plant and equipment, software, advance payments for intangible assets, changes in inventories, trade accounts receivable as well as receivables from royalties and licenses. To manage working capital on a regional and local level, the businesses use the two indicators days sales outstanding and days in inventory.

MERCK GROUP

Business free cash flow[1]

			Change	
€ million	**2016**	2015	€ million	in %
EBITDA pre exceptionals[1]	**4,490**	**3,630**	**861**	**23.7%**
Investments in property, plant and equipment, software as well as advance payments for intangible assets	–859	–609	–250	41.1%
Changes in inventories according to the consolidated balance sheet	3	–950	953	>100.0%
Changes in trade accounts receivable as well as receivables from royalties and licenses according to the consolidated balance sheet	–177	–514	337	–65.6%
Adjustment first-time consolidation of Sigma-Aldrich	–149	1,210	–1,359	>100.0%
Adjustment first-time consolidation of BioControl Systems	10	–	10	>100.0%
Business free cash flow[1]	**3,318**	**2,766**	**552**	**20.0%**

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

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 the prioritization of investment opportunities and portfolio decisions.

Net present value

The main criterion for the prioritization of 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 projection period 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. Depending on the type and location of a project different mark-ups are applied to the WACC.

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. 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 mark-ups.

Return on capital employed (ROCE)

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

Payback period

An additional parameter to prioritize investments into property, plant and equipment is the payback period, which indicates the time in years after which an investment will generate positive net cash flow.

Merck value added (MEVA)

MEVA gives information about the financial value created in a period. 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 exceptionals (EPS pre)[1]

Earnings per share are calculated by dividing profit after tax attributable to the shareholders of Merck KGaA (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. To provide an alternative view, we also report earnings per share pre exceptionals, in other words adjusted for the effects of integration costs, IT costs for selected projects, restructuring costs, gains/losses on the divestment of businesses, acquisition costs and other exceptionals. Moreover, amortization of acquired intangible assets as well as impairment losses on property, plant and equipment and intangible assets are adjusted. 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 company's underlying tax rate.

Credit rating

The rating of our credit worthiness by external agencies is an important indicator with respect to 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, Standard & Poor's (S&P) and Scope. 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) financial debt.

Dividend ratio

With the aim of ensuring an attractive return to our shareholders, we are pursuing a reliable dividend policy with a target payout ratio based on EPS pre exceptionals (see definition above).

Other relevant/non-financial performance measures

Apart from the indicators of the financial performance of the businesses, non-financial measures also play an important role in furthering the success of the company. From a Group perspective, specifically innovations in the businesses as well as the attraction and retention of highly qualified employees are of central importance.

Innovation

Innovations are the foundation of our business and will also be the prerequisite for future success in changing markets. We are continuously working to develop new products and service innovations for patients and customers. Indicators for the degree of innovation are defined individually depending on the specifics of the respective businesses.

Talent retention

Employing a highly qualified and motivated workforce is the basis for achieving our ambitious business goals. Therefore, we put a strong focus on establishing the processes and the environment needed to attract and retain the right talent with the right capabilities at the right time. To measure the success of the related measures, we have implemented talent retention as an important non-financial indicator.

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

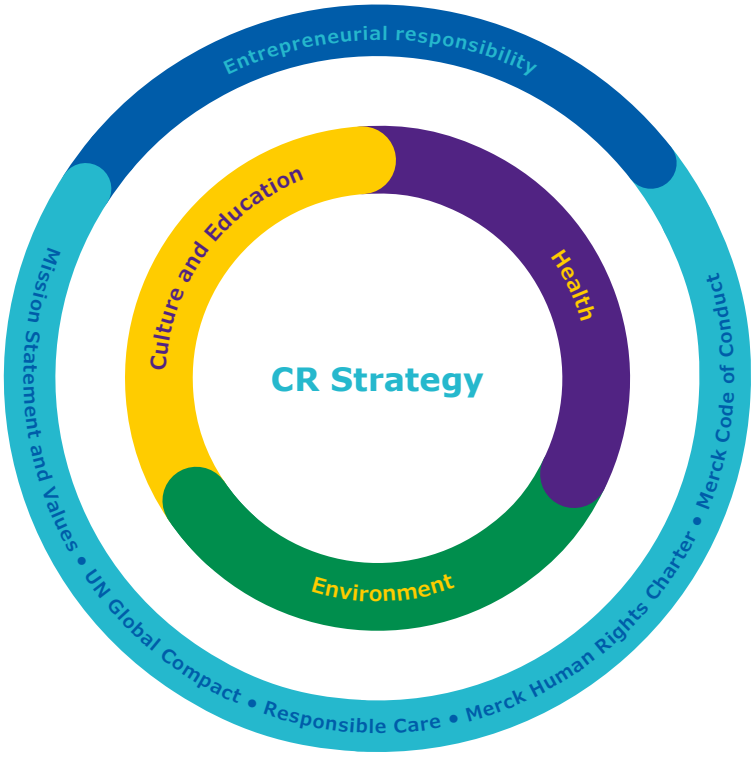
Corporate Responsibility

We take responsibility every day – and have been doing so for nearly 350 years. This commitment is codified in our corporate strategy and values. Responsible conduct with respect to employees, products, the environment, and society is a fundamental prerequisite for our business success.

Strategy and management

Our corporate responsibility (CR) activities are steered by our CR Committee, which consists of representatives from our business sectors and relevant Group functions. Belén Garijo, Executive Board Member and CEO Healthcare, became chairperson of the committee in June 2016.

Mankind is confronted with global societal challenges such as climate impact, resource scarcity and insufficient access to health in low- to middle-income countries. We believe that we can help resolve these global challenges through our innovative healthcare, life science and performance materials products, as well as through responsible governance. Responsible conduct means looking, listening and doing better. We respect the interests of our employees, customers, investors, and society, and work to minimize ethical, economic and social risks, thereby securing our success. This is an integral part of our corporate strategy, which in turn underpins our CR strategy, the basis for the responsible governance we live each and every day. In realizing our corporate responsibility, we focus our resources on those areas where we can have the greatest impact. We pursue three strategic spheres of activity: health, the environment as well as culture and education. The focus here is always on securing the future of society and our competitiveness.



Health: In low- to middle-income countries, many people lack access to high-quality health solutions. We are applying our expertise here and joining forces with strong partners to develop solutions for patients locally. Our fight against the worm disease schistosomiasis in Africa is a good example.

Environment: We are constantly working to improve the sustainability footprint of our products and are furthermore helping our customers achieve their own sustainability goals. One example is the development of new liquid crystal technologies through which our liquid crystals reduce the power consumption of smartphone and tablet displays.

Culture and education: Cultural offerings inspire people and expand their horizons. Research and development throughout the world thus benefit from creativity, ingenuity, and enthusiasm. Cultural inspiration also opens people up to new ideas. It favorably influences society's acceptance of science, technological progress and innovations. This is why we promote cultural initiatives and educational programs around the world.

We support relevant responsible governance initiatives. We are a member of the United Nations Global Compact and are committed to complying with the compact's principles regarding human rights, labor standards, environmental protection, and anti-corruption. Moreover, we also live our corporate responsibility through our commitment to follow the guidelines of the Responsible Care Global Charter, an initiative of the International Council of Chemical Associations (ICCA). Responsible Care aims to drive continuous improvement and achieve excellence in environmental, health and safety, and security performance in the chemical industry. We were among the first companies to sign the revised version of the Responsible Care Global Charter in 2014. Furthermore, we are also a member of the Chemie^3 initiative in Germany, a collaboration between the German Chemical Industry Association (VCI), the German Employers' Federation of the Chemical Industry (BAVC), and the German Mining, Chemical and Energy Industrial Union (IG BCE). As part of this globally unique alliance, the partners want to make sustainability a core part of the chemical industry's guiding principles and to jointly drive the sector's position within the German economy as a key contributor to sustainable development.

To us, corporate responsibility means taking action and listening. The dialogue with our various stakeholder groups is therefore highly important to us. These stakeholders include employees, business associates, the Merck family, investors, regulatory agencies, and associations. We also engage in this continuous exchange to create transparency and clearly demonstrate how we live the Merck values.

Thanks to good performance with respect to responsible and sustainable entrepreneurial conduct, we were again included in the FTSE4Good index in 2016. To be included in this leading international sustainability index, a company must demonstrate socially conscientious, ecological and ethical conduct. In 2016, we also maintained our good standing in other major sustainability indices. For instance, we were again included in the STOXX Global ESG Leaders index, as well as the Euronext Vigeo Eurozone 120 index and the Ethibel Sustainability Index (ESI) Excellence Europe. In autumn 2016, among the German blue-chip companies included in the DAX, we achieved tenth place in the Good Company Ranking published by Kirchhoff Consult.

Strategic sphere of activity: Health

Access to Health (A2H) is one of our strategic priorities. Through our A2H approach, which spans all our businesses, we aim to help improve sustainable access to high-quality health solutions for underserved populations and communities in low- and middle-income countries. Since we realize that access is a complex and multifaceted challenge with no one-size-fits-all solution, our programs and initiatives are tailored to global, regional and local needs. We consider partnerships, collaboration and dialogue to be key instruments in delivering sustainable results.

During his presidency of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) from 2014 to the end of 2016, Stefan Oschmann, Chairman of the Executive Board and CEO, focused on the core topic of accelerating access to high-quality health solutions for people in low- to middle-income countries.

In November 2016, the Access to Medicine Foundation of the Netherlands recognized our efforts to improve access to health. In the 2016 Access to Medicine Index, Merck ranked fourth, moving up two places relative to 2014 and 13 places relative to 2010. Every two years, this index assesses the world's leading pharmaceutical companies with respect to their activities and initiatives to promote access to medicine in developing countries. The Access to Medicine Foundation praised us for our access goals, which have now been aligned with the Sustainable Development Goals (SDGs) of the United Nations. Through this ranking, the foundation also recognized our Access to Health (A2H) strategy, which is embedded in our core business and focuses on four areas known as the "4As": Availability, Affordability, Awareness, and Accessibility. The Access to Medicine Foundation also praised our numerous access initiatives.

Availability

Availability entails the research, development and refinement of health solutions that address unmet needs and are tailored to local environments. Together with our partners, we are working to fight widespread diseases in developing countries. One example is the Pediatric Praziquantel Consortium. Through this public-private partnership, we are working on a pediatric formulation of praziquantel to treat the worm disease schistosomiasis in children under the age of six. In 2016, the consortium launched a Phase II study in Ivory Coast. The objective of the study is to find the optimum dose of the new formulation. In October 2016, the consortium was furthermore awarded a prestigious research grant from the Japanese Global Health Innovation Technology Fund for the third time. Another example is our partnership with the Medicines for Malaria Venture, which seeks to develop new antimalarials. In 2016, we also launched a research collaboration with the University of Cape Town in South Africa to pursue the same objective. In addition to these efforts, our Healthcare and Life Science business sectors are currently developing a kit for malaria diagnosis based on the MUSE cell analysis system. This kit will detect and type the malaria pathogen as well as identify relevant immune cells in the event of a concurrent HIV infection. When used in insect repellents, our product IR3535® helps protect against infections transmitted by mosquito bites, such as malaria, yellow fever and the Zika virus. Products containing this active ingredient stand out due to their particularly good tolerability in young children and pregnant women.

Affordability

We seek to address affordability challenges through our efforts to provide assistance to those people who are unable to pay for the health solutions they need. To tackle these challenges, we have taken a pro-access approach through our intellectual property initiatives and are engaging in equitable pricing strategies. We provide transparent information about our patents and patent applications on publicly available databases. Moreover, we are a member of WIPO Re:Search, an open innovation platform sponsored by the World Intellectual Property Organization (WIPO). Through intellectual property and knowledge sharing, platform partners seek to accelerate early discovery for infectious diseases. In early 2016, our partnership with the University of Buea in Cameroon, which aims to repurpose compounds from our library to develop a treatment for onchocerciasis (also known as river blindness), received a research grant from the renowned Wellcome Trust of the United Kingdom. Furthermore, we are working with the World Health Organization (WHO) to combat the worm disease schistosomiasis in Africa. Through the Merck Praziquantel Donation program, we are donating Cesol® 600 tablets containing the active ingredient praziquantel to WHO. Since the start of this program, more than 100 million patients – primarily school-aged children – have been treated. In total, we have donated more than 500 million praziquantel tablets to WHO since 2007. As a founding member of the Global Schistosomiasis Alliance, we are helping to eliminate schistosomiasis worldwide.

Awareness

We help to raise awareness by empowering health workers, communities and patients with the appropriate tools, knowledge and skills to make informed decisions. For instance, we have been supporting the Developing Countries Vaccine Manufacturers Network (DCVMN) since 2012 in order to improve the safety and quality of biotech production. Through our Access Dialogues series, we are promoting discourse on access-to-health challenges with numerous public and private stakeholders. In 2016, the series focused on the supply chain. In India, we are working with various non-governmental organizations as well as the Indian Health and Family Ministry to support the Su-Swastha project, which is working to provide underserved rural populations with affordable health solutions and raise awareness on health issues. In 2016, the project had reached 26,129 people through 1,238 community meetings. The Global Pharma Health Fund (GPHF), a non-profit organization funded by Merck, works to combat counterfeit medicines in developing and emerging countries. To date, the GPHF has supplied more than 795 Minilabs at cost to detect counterfeit medicines in more than 90 countries. Furthermore, through our Capacity Advancement Program (CAP), we are working to raise awareness and further the prevention of non-communicable diseases such as diabetes and cancer, as well as to address the issue of infertility.

Accessibility

We promote initiatives to strengthen supply chains and to develop localized health solutions in order to deliver and reach out efficiently at the point of care. We support training and knowledge sharing with our manufacturing partners in Africa, Asia and Latin America with the aim of strengthening local manufacturing quality standards. In India, we are cooperating with the non-profit organization known as Narmada Samagra. Our River Ambulance transports health workers and provides healthcare solutions to local populations living in the remote region along the Narmada River. In early 2016, we donated a new boat to River Narmada Samagra so that even more people can be reached in the future. Additionally, we are funding a health center that serves around 150 patients a month in Jharkhand, a state in northeastern India.

Strategic sphere of activity: Environment

Through our products, we are helping overcome global challenges such as climate impact and resource scarcity. At the same time, we are also helping our customers to reduce the negative impacts of their own activities and to achieve their own sustainability goals.

Performance Materials: Investments to boost sustainability

In 2016, our Performance Materials business sector made several large investments. In August 2016, we announced plans to invest € 15 million in the construction of a production plant for liquid crystal window modules in Veldhoven, the Netherlands. In doing so, we are pursuing the goal of leveraging our market and technology leadership in liquid crystals beyond their use in energy-saving displays. The manufacture of the switchable glass modules is to begin at the end of 2017. According to initial measurement results, our smart windows can cut the energy use of air-conditioned buildings by up to 40% and replace conventional shading solutions. We are thus helping builders to save resources and costs. These windows can be manually or automatically controlled to darken and provide sun protection – and to do so in a variety of colors. This technology is made possible thanks to the special properties of our liquid crystals, which in smart windows are combined with customized dyes. When a low electric voltage is applied, the liquid crystals allow electromagnetic waves (i.e. light) to be either absorbed and blocked (dark state), or to pass through (transparent state). Another variant can control the transparency of liquid crystal windows. If people want more privacy, they can switch to privacy mode, which turns the glass opaque. In contrast to competitive technologies, our long-lasting licrivision® materials switch in seconds and have high color neutrality. Architects and builders can customize the desired color to suit the setting.

Furthermore, we opened a new OLED materials production plant at our Darmstadt site in September 2016. With a total investment of around € 30 million, this is one of the largest single investments we have made at the Darmstadt site in recent years. Organic light-emitting diodes (OLEDs) are semiconducting organic materials that luminesce when electric voltage is applied. They are particularly well suited for use in state-of-the-art displays and lighting. OLED displays provide brilliant colors and sharp images from any viewing angle and are highly energy-efficient. They are also thin and flexible, which enables entirely new shapes and opens up a broad spectrum of totally new applications.

For the semiconductor industry, we have developed a series of environmentally sustainable specialty chemicals and materials – including PFOS-free antireflective and photoresist coatings that contain no trace of dangerous chemicals.

In cooperation with our customers from the cosmetics industry, we are developing cosmetic formulations that meet strict sustainability criteria and align with the continuing trend towards more natural cosmetics. Many of our products meet the criteria defined by Ecocert, an independent organization representing high international standards for natural cosmetic raw materials.

Life Science: Reducing our customers' environmental impacts

Within our Life Science business sector, the Design for Sustainability (DfS) program aims to reduce environmental impacts of devices and instruments, also through customers' own use. Beginning with the concept stage, product teams identify potential environmental impacts in various product life cycle stages and opportunities to make improvements. A scorecard is used to assess product design in six focus categories: Materials, Energy & Emissions, Waste, Water, Packaging, as well as Usability & Innovation. As of December 31, 2016, we had achieved improvements in at least three of our self-defined sustainability criteria for 32% of our new Biomonitoring product developments and/or further developments.

In biopharmaceutical production, numerous products such as plastic bags and tubing are used only once and then disposed of. This is due, among other things, to the low risk of contamination posed by single-use products. Together with customers and recycling firms, our Life Science business sector is developing sustainable recycling programs. Our objective is to avoid incinerating the waste streams by offering recycling options so as to reduce the environmental impacts.

In addition, our Life Science researchers are developing innovative solutions in line with the "12 Principles of Green Chemistry" developed by chemists Paul T. Anastas and John C. Warner. The objective is to permit production that is as environmentally compatible as possible, and to minimize adverse effects on human health. Within the framework of Green Chemistry, researchers seek alternative, environmentally sustainable reaction media with higher reaction rates and lower reaction temperatures in order to make production more energy-efficient. With Dozn®, we have developed a Web-based analysis tool for Green Chemistry. To date, we have used the matrix to evaluate more than 40 products and improve them afterwards.

In 2016, we launched Cyrene™ onto the market. The solvent is based on renewable cellulose and is used, among other things, as an alternative to dimethylformamide. With Cyrene™ we help our customers in the pharmaceutical and agrochemical industries to lower the environmental impact of their production processes and make them safer. Joint research work with the University of Strathclyde in Glasgow, United Kingdom, has proven the efficacy of Cyrene™.

Strategic sphere of activity: Culture and Education

Cultural promotion is a core element of our commitment to society, building on our centuries-old tradition of supporting art as well as culture and education. After all, culture nurtures characteristics that are essential to our business activities as a high-tech company: creativity, enthusiasm for new discoveries, curiosity, and the courage to transcend boundaries. Our cultural initiatives focus on music, literature and education.

The Deutsche Philharmonie Merck

The Deutsche Philharmonie Merck is our musical ambassador. We consider classical music to be the universal language that brings people together; as such, it is an important part of our culture. The concerts of this professional ensemble are highly popular, with around 23,000 people attending them per year. They represent an integral part of the cultural life in the vicinity of our Group headquarters in Darmstadt. Special events for children and adolescents are intended to make classical music more accessible to young people, as do partnerships with schools like the orchestra workshop we have held once a year since 2010. In 2016, the Deutsche Philharmonie Merck celebrated its 50th anniversary and, among other activities, performed a joint concert at the Frankfurt Jahrhunderthalle with Einshoch6, a Munich-based hip-hop band.

Promoting literature

Literature can stimulate the imagination; it can alleviate fears and give courage. Literature can also address scientific issues, thus furthering a deeper understanding of science and research. Through our involvement, we want to help society better accept science and scientific progress. Furthermore, as an international company, we further writers who drive cultural exchange in our globalized world.

We grant and promote five literary prizes worldwide. Since 1964, we have been sponsoring the renowned Johann Heinrich Merck Award for Literary Critique and Essay, which is presented by the German Academy for Language and Poetry at its annual autumn conference. Worth € 20,000, this award went to writer and blogger Kathrin Passig in 2016. For 14 years, we have been sponsoring the Premio Letterario Merck in Italy. This award is worth € 10,000 and recognizes authors who build bridges between literature and science, thereby making them accessible to a wide audience. In 2016, the winners were Italian immunologist Alberto Mantovani and British writer, historian and naturalist Helen Macdonald. In India, Merck partners with the Goethe-Institut Calcutta to present the Merck Tagore Award. Worth 500,000 Indian rupees (around € 6,800), this literary prize is granted every two years to authors who have made a distinctive contribution to the cultural exchange between Germany and India. In 2016, psychoanalyst and writer Sudhir Kakar received the award. In Japan, we partner with the Goethe-Institut Tokyo to present the Merck Kakehashi Literature Prize. Worth a total of € 20,000, this award is granted every two years to contemporary works by German authors that are made accessible to a wider readership in Japan. In 2016, the prize went to writer Ilma Rakusa and her translator Fuminari Niimoto. In September 2016, Merck in Russia presented the first Merck Translation Award to Vladislava Agafonova (fiction), Kirill Levinson (non-fiction) and Alexandra Gorbova (children's literature). Each winner received € 4,000 in prize money.

Education

We view education as a key component of culture – and vice versa. Education can help us understand culture. But culture can also build a bridge to education; it can stimulate curiosity and nurture creativity. We therefore support educational projects at many of our sites by granting scholarships, for instance, or by sponsoring specific classes. To promote young scientists, Merck has hosted the renowned annual "Jugend forscht" science competition for the German federal state of Hesse every year since 1996. In partnership with the Technical University of Darmstadt, we inaugurated the Junior Biology Lab in autumn 2016.

The SPARK initiative was launched in early 2016. This volunteer program motivates employees from our Life Science business sector to share their knowledge with school students. In February and March 2016, 3,465 employees in 36 countries for the first time gave students exciting insights into the world of science, for example.

Responsibility for our products

The safety of our products is at the core of our corporate responsibility. When used properly, they must pose no risk to customers, patients, consumers, or the environment. Our goal is to ensure a positive benefit/risk profile for our products, which is why we regularly examine safety across their entire life cycle and continuously take steps to minimize risks. We provide patients, consumers and customers with extensive informational material so that they can use our products in a safe, responsible and proper manner.

Through our compliance policies for our Biopharma and Consumer Health businesses, we set standards for responsible marketing activities relating to our medicines. These aim to ensure that patients and healthcare professionals have access to the relevant information, and that patients receive effective treatment.

Safety of our chemical products

Numerous regulations are in place to ensure that chemicals pose no risk to humans or the environment. Compliance with these regulatory requirements is an important part of our work. Through our Group-wide Product Safety Chemicals policy, we have established global processes for defining, directing and implementing product safety, as well as the corresponding management structures. We incorporate all relevant national and international chemical regulations into our policies and guidelines and adhere to them. This includes the EU chemicals regulations REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) and CLP (Classification, Labelling and Packaging of Substances and Mixtures, EU GHS). Furthermore, we are committed to transparency. For instance, in line with the Global Product Strategy, an international initiative of the chemical industry, we provide our customers with product safety summaries for hazardous materials.

We are working to register all our chemical substances in accordance with REACH. We successfully completed registration phase I in 2010 and registration phase II in 2013. The next step, in phase III, is for us to evaluate and register all substances produced or imported in quantities ranging from one to 100 metric tons annually by the beginning of June 2018. This process now also includes substances from Sigma-Aldrich and is fully on schedule.

Safety of our healthcare products

Patient and consumer safety has top priority in everything we do. During the entire life cycle of our medicines and consumer health products, we provide patients, consumers and physicians with up-to-date risk-benefit evaluations. To this end, company experts process safety-relevant information from various sources such as clinical trials, adverse reaction reports and scientific literature. Ultimate responsibility for the safety of our biopharmaceuticals is borne by our Global Chief Medical Officer, with support from the Medical Safety and Ethics Board (MSEB). Our Global Drug Safety unit continuously monitors and evaluates the safety and risk-benefit ratio of our medicines worldwide (pharmacovigilance). For our Consumer Health products, this function is performed by the Global Product Safety unit. Overall responsibility for the safety of our over-the-counter products is borne by the Chief Medical Officer for the Consumer Health business, supported by the Safety & Labelling Committee (SLC).

For products in our Allergopharma business, we have developed comprehensive clinical efficacy and safety profiles that we continuously update. For the safety of our patients, we have established a global pharmacovigilance system that we are always working to enhance.

Quality of our products

Our goal is to provide customers and patients with high-quality brand-name products. Through our quality vision – "Quality is embedded in everything we do!" – we remind our employees of their responsibility across all business sectors, all Group functions and all levels of the company.

Supplier management

We source raw materials, packaging materials, technical products, components, and services from suppliers across more than 130 countries. Our basic expectations for suppliers and service providers include their compliance with fundamental environmental and social standards, which are primarily derived from the core labor standards of the ILO (International Labour Organisation), from the UN Global Compact, and from the Code of Conduct of the BME (German Federal Association for Materials Management, Purchasing and Logistics). Our Group Procurement Policy and Responsible Sourcing Principles define our procurement practices and are integrated into our general terms and conditions. They therefore constitute the foundation of every sourcing transaction and procedure. Due to the growing significance of emerging markets as sourcing markets for Merck, we have reinforced our efforts to ensure adherence to our supply chain standards. At the end of 2014, we joined the Together for Sustainability (TfS) chemical industry initiative. Since then, we have been utilizing the supplier assessment and audit results shared among all member companies, who in turn abide by all restrictions stipulated within competition law. Through TfS, we currently have access to assessments for more than 670 of our most important suppliers. Since 2015, we have initiated around 400 TfS assessments. In addition, we have initiated 26 TfS audits since 2014.

Responsibility for our employees

Employees are crucial to the success of a company. They therefore play a central role in our business endeavors. In accordance with the Merck values, we live a culture of mutual esteem and respect. We seek to further our entrepreneurial success by recruiting, developing and motivating the most suitable employees, which is why we focus our employee strategy on talent development, compensation, and performance management. We furthermore strive to foster diversity among our employees (more information can be found under "People at Merck").

Responsibility for the environment

In the manufacture of our products, we seek to impact the environment as little as possible. This especially includes efficiently conserving resources such as energy, water and raw materials while also continuously reducing our emissions and waste.

Environmental management system

In our Corporate EHS Policy, we have defined our principles and strategies for environment, health and safety. This policy is implemented through internal guidelines and instruction manuals on compliant behavior in day-to-day operations, such as the Merck Group EHS Security and Quality Manual. At all our sites, local EHS managers are in charge of operational environmental protection measures. These employees continually receive training and obtain additional qualifications. Since our businesses are constantly changing, our environmental management system must also remain flexible and adaptable. For this reason, internal and external audits are conducted on a regular basis to determine whether the ISO 14001 requirements are still being met. In 2016, we obtained an ISO 14001 group certificate for our environmental management system for the eighth consecutive year. This certificate covers 57 sites. Seven sites belonging to the recently acquired company Sigma-Aldrich are already certified to ISO 14001. Our spending on environmental protection, health and safety efforts totaled € 189 million in 2016, which also includes investments made during the year.

Focus areas: Energy efficiency, greenhouse gas emissions, water

Climate impact and resource scarcity are key challenges facing society in the 21st century. As a responsible company, it is especially important for us to do our part. We have therefore set ourselves the goal of reducing total direct and indirect greenhouse gas emissions by 20% by 2020 (2006 baseline), irrespective of production growth. To achieve this goal, we have launched EDISON, a climate protection program that consolidates all our climate impact mitigation and energy efficiency activities. In 2017, we will continue investing in efforts to conserve energy and reduce greenhouse gas emissions. Through the approximately 270 EDISON projects initiated since 2012, we aim to annually save around 94 metric kilotons of CO_2 in the medium term. In 2016, we lowered our greenhouse gas emissions by around 10% relative to the 2006 baseline, despite growth in our operating business. Our Life Science business sector is playing a major role in our efforts. In 2014, process optimizations resulted in a two-thirds reduction in our process-related emissions at our facility in Jaffrey, New Hampshire (USA). In 2015, we initiated a project to further cut emissions that is scheduled to end in 2017. Other projects are being planned. In 2016, we also successfully completed measures to reduce greenhouse gas emissions and energy consumption at our site in Onahama, Japan. Because of its pigment production operations, this facility is one of the highest energy consumers of all Merck sites worldwide. For this reason, we switched the process steam generation for production to natural gas combustion, and the pigment kilns are now fired with natural gas. These changes are saving us roughly 3,200 metric tons of CO_2 emissions per year.

ENERGY CONSUMPTION[1]

(in GWh)	2012	2013	2014	2015	**2016**
Total energy consumption	2,058	2,108	2,158	2,256	2,253
Direct energy consumption	1,187	1,286	1,354	1,451	1,443
Natural gas	1,070	1,157	1,212	1,212	1,272
Liquid fossil fuels	104	114	115	104	30
Biomass and self-generated renewable energy	13	15	27	135	141
Indirect energy consumption	871	822	804	805	810
Electricity	744	743	707	709	715
Steam, heat, cold	127	79	97	96	95

[1]Portfolio-adjusted in accordance with the Greenhouse Gas Protocol.

CO_2EQ EMISSIONS (EQ = EQUIVALENTS)[1]

Emissions in kt, Scope 1 and 2	2012	2013	2014	2015	**2016**
Total CO_2eq emissions	761	784	736	729	715
Direct CO_2eq emissions	379	417	390	393	386
Indirect CO_2eq emissions	382	367	346	336	329

[1]Portfolio-adjusted in accordance with the Greenhouse Gas Protocol.

Energy management plays a key role in our efforts for sustainable energy efficiency and climate impact mitigation. Our production sites in Darmstadt and Gernsheim account for around 29% of our global energy consumption. In 2012, both of these facilities qualified for ISO 50001 – Energy Management System certificates, which were reaffirmed in 2016. Currently, 13 of our production sites have a certified energy management system. The results of the Carbon Disclosure Project likewise indicate that we are on the right path. In 2016, this independent non-profit organization ranked us among the top five companies in our industry in German-speaking countries. For the first time, we achieved the status of sector leader and, at fourth place, moved up two places relative to 2015. The Carbon Disclosure Project assesses companies in terms of their emissions reduction progress and climate impact reporting.

In addition to energy, we also focused on the topic of water in 2016. We systematically examined our sites to determine which ones have a high annual water consumption and are located in regions where water is scarce and thus an especially precious resource. At the beginning of 2016, we set the goal of implementing a sustainable water management system at sites with high consumption levels by 2020. At sites with relevant water use located in areas of high water stress, we are aiming to cut our water consumption by 10% by 2020 (2014 baseline).

Responsibility for society

We see ourselves as part of society – both at our individual sites and worldwide. Taking responsibility towards society is an integral part of our entrepreneurial approach. We believe that we can make an important contribution to society through our knowledge, our skills and our products.

Our social responsibility activities are primarily focused on those areas in which we have specific expertise stemming from our core businesses. We are thus engaged in health and environmental projects and furthermore support education, especially in the natural sciences. We provide disaster relief in emergency situations, particularly in those regions in which we operate.

Our subsidiaries are engaged in a wide variety of local projects. We have defined a general set of criteria for selecting projects, and the decisions concerning specific local projects are made by our subsidiaries. In 2016, we spent a total of € 43 million on community engagement activities. Our patient support programs, for instance the Erbitux® China Patients Assistance Program amounting to around € 153 million, are not taken into consideration here.

Research and Development

We conduct research and development (R&D) worldwide in order to develop new products and services designed to improve the quality of life of patients and to satisfy the needs of our customers. Further optimizing the relevance and efficiency of our research and development activities – either on our own or in cooperation with third parties – is one of our top priorities.

To address long-term health and technology trends in both established and growth markets, approximately 6,200 employees work for Merck researching innovations.

In 2016, Merck spent around € 2.0 billion on research and development, thus exceeding the previous year's level (2015: € 1.7 billion). This was due mainly to the intensified R&D activities of our Healthcare business sector. We focus on both in-house research and external collaborations, which enable us to increase the productivity of our research while simultaneously reducing financial outlay. The organizational set-up of our research and development activities reflects the structure of Merck with three business sectors.

Healthcare

Biopharma

Oncology

With regard to Erbitux®, we announced in April that the pivotal Chinese Phase III (TAILOR study) met its primary endpoint of significantly increasing progression-free survival (PFS) in patients with RAS wild-type metastatic colorectal cancer (mCRC) treated with Erbitux® (cetuximab) plus FOLFOX chemotherapy, compared with FOLFOX alone. Detailed data were presented from this first prospective study to evaluate an anti-EGFR antibody in first-line therapy of patients with RAS wild-type mCRC at the European Society for Medical Oncology (ESMO) World Congress on Gastrointestinal Cancer in July in Barcelona. The study included 393 patients and showed that Erbitux® (cetuximab) plus FOLFOX statistically significantly improved outcomes compared to FOLFOX alone, including best overall response rate (61.1% vs. 39.5%), lowered the risk of disease progression by 31%, and decreased the risk of death by 24%. Progression-free survival was significantly improved by the combination of Erbitux® plus FOLFOX vs. FOLFOX alone (9.2 vs. 7.4 months), as was overall survival (20.7 vs. 17.8 months). These results reaffirm that Erbitux® plus FOLFOX is an effective treatment regimen for patients with RAS wild-type mCRC. As the first prospective trial evaluating Erbitux® in RAS wild-type patients, the TAILOR results show the importance of RAS biomarker testing in order to determine the appropriate targeted therapy for individual patients, based on their tumor's genetic make-up. The safety profile of Erbitux® in this trial was manageable and similar to that observed in other pivotal trials, with no unexpected safety findings. Based on these results, we are evaluating the most appropriate way to make Erbitux® available in China as a first-line treatment for patients with RAS wild-type mCRC as soon as possible.

In April we announced that a new liquid biopsy RAS biomarker test, which we are co-developing and commercializing with Sysmex Inostics, has been granted CE Mark approval. This test will now be made widely accessible for patients with metastatic colorectal cancer in Europe, Asia, Latin America and Australia. The testing technology, OncoBEAM® RAS CRC assay can be used to determine which patients would benefit from anti-epidermal growth factor receptor (anti-EGFR) therapies, such as Erbitux® (cetuximab). The liquid biopsy RAS biomarker test is a comprehensive 34-mutation panel that is based on the BEAMing (Beads, Emulsion, Amplification and Magnetics) technology. The test only requires a small blood sample (10 ml), rather than a tissue biopsy, to determine the mutation status of tumors. The test has the potential to provide mutation status results within days, which can help guide quicker treatment decisions. Merck and Sysmex Inostics originally entered into an agreement to co-develop and commercialize the liquid biopsy test in 2014.

In January we announced that we have signed a collaboration agreement with Biocartis for the development and commercialization of a new liquid biopsy RAS biomarker test for patients with mCRC. The test will be developed on Biocartis' innovative, fully automated molecular diagnostics system, Idylla™, which is designed to offer accurate and reliable molecular information from virtually any biological sample. The Idylla™ system is a fully automated sample-to-result PCR-based (polymerase chain reaction) molecular diagnostics system. Whereas most of today's solutions only look for the most prevalent RAS mutations, the Idylla™ RAS test will be designed to detect an extended panel of RAS mutations. The new test will also provide a BRAF V600 mutation analysis directly integrated with the Idylla™ RAS test, to allow clinicians to evaluate BRAF and RAS mutation status simultaneously. Based on a 2 ml sample of blood plasma, the test aims to provide high sensitivity and ease-

of-use, requiring less than 2 minutes of hands-on time and a turn-around time of approximately 2 hours, enabling clinical decision-making in a timely manner. Merck and Biocartis plan to implement the Idylla™ liquid biopsy RAS test in numerous medical centers across the world, excluding the United States, China and Japan. The test was subsequently submitted for a CE Mark.

In March we announced that we had entered into a collaboration focused on cancer metabolism with the European Molecular Biology Laboratory (EMBL), located in Heidelberg, Germany. The aim of the collaboration is to investigate mechanisms by which cancer cells generate energy and growth-enabling building blocks, which could ultimately deliver novel therapeutic targets, as well as biomarkers. The collaboration will make use of EMBL's capabilities in the area of metabolomics. During the three-year collaboration, EMBL will apply its unique expertise, combining modelling and bioinformatics with experimental approaches to investigate these metabolic pathways and shed light on their control mechanisms. EMBL will also utilize the cutting-edge equipment of its Genomics and Metabolomics Core Facilities to resolve the transcriptional and metabolic profiles of the samples for the study.

New research on Erbitux® and our pipeline compounds was presented at the Annual Meeting of the European Society for Medical Oncology (ESMO) in Copenhagen, Denmark, in October. Presentations focused on hard-to-treat cancers, and included study results for Erbitux® in mCRC and in squamous cell carcinoma of the head and neck (SCCHN), reaffirming Erbitux® as a standard-of-care therapy for mCRC patients with RAS wild-type tumors and patients with SCCHN. Preliminary study results were presented for our investigational product avelumab in bladder cancer, supporting its further development in this indication, as well as preliminary results from a combination study of avelumab with axitinib in renal cell carcinoma (RCC) that support the rationale to evaluate this combination in a Phase III pivotal study in RCC. Results on the investigational compound tepotinib, a highly selective c-Met kinase inhibitor, were presented on three posters, and included updates on the ongoing study program in c-Met-positive metastatic non-small cell lung cancer.

In September we commenced the clinical development of our investigational BTK inhibitor (M7583) in Oncology, with the start of our first Phase I clinical study of this compound. This first-in-human study in hematological malignancies represents a milestone of this program.

In June Merck announced jointly with Array BioPharma Inc. and Pierre Fabre the initiation of a randomized, global Phase III clinical trial of BRAF-mutant mCRC, investigating a new combination of Erbitux® plus encorafenib, with or without binimetinib. The trial, known as BEACON CRC (Binimetinib, Encorafenib And Cetuximab Combined to treat BRAF-mutant Colorectal Cancer) will assess the efficacy and safety of these two novel combinations in patients with BRAF-mutant tumors, compared with investigator's choice of Erbitux® plus irinotecan or Erbitux® plus FOLFIRI. Approximately 650 patients are expected to be enrolled by 2018 and, after a lead-in period to assess the safety and tolerability of Erbitux® plus encorafenib (a BRAF inhibitor) and binimetinib (a MEK inhibitor), will be randomized to receive one of the two novel combinations, or the investigator's choice. The primary endpoint of the trial is overall survival. Key secondary endpoints include progression-free survival, objective response rate, duration of response, safety and tolerability. The trial will also assess health-related quality of life.

Our Grant for Oncology Innovation (GOI) initiative, which awards funds for pioneering independent research in oncology, was awarded on the occasion of the ESMO meeting on October 9. There were 405 applications from 49 countries for the 2016 award. Three research teams from Italy, New Zealand and Spain were selected to share the € 1 million grant to fund their research in the areas of breast cancer, colorectal cancer and lung cancer.

Immuno-Oncology

The investigational product avelumab is our most advanced clinical development program in immuno-oncology with eight Phase III studies sponsored by the Merck-Pfizer Alliance now underway in a variety of solid tumors.

On October 31, Merck and Pfizer Inc. announced that the European Medicines Agency (EMA) had validated for review Merck's Marketing Authorization Application (MAA) for avelumab, for the proposed indication of metastatic Merkel cell carcinoma (MCC). A rare and aggressive skin cancer, MCC impacts approximately 2,500 Europeans a year. Validation of the MAA confirms that submission is complete and begins the EMA's centralized review process. If approved, avelumab, an investigational fully human anti-PD-L1 IgG1 monoclonal antibody, could be the first approved treatment indicated for metastatic MCC in the EU. Patients with metastatic MCC face a very poor prognosis, with less than 20% surviving beyond five years. Avelumab received an Orphan Drug Designation (ODD) from the European Commission for MCC. The avelumab metastatic MCC MAA submission is supported by data from JAVELIN Merkel 200, a multicenter, single-arm, open-label, Phase II study of 88 patients with metastatic MCC whose disease had progressed after at least one chemotherapy treatment. The JAVELIN Merkel 200 study represents the largest data set of any anti-PD-L1/PD-1 antibody reported in this patient population. These data were recently published in the medical journal Lancet Oncology.

In November Merck and Pfizer Inc. announced that the U.S. Food and Drug Administration (FDA) had accepted for Priority Review the Biologics License Application (BLA) for avelumab in metastatic MCC. The application was submitted by EMD Serono, the biopharmaceutical business of Merck in the United States and Canada. This review relates to avelumab's proposed use in patients with metastatic MCC, based on tumor response results from the JAVELIN Merkel 200 trial. The FDA's Priority Review status reduces the review time from ten months to a goal of six months from the day of filing and is given to drugs that may offer major advances in treatment or may provide a treatment where no adequate therapy exists. The FDA previously granted avelumab Orphan Drug

Designation for MCC, as well as Fast Track and Breakthrough Therapy Designations for the treatment of patients with metastatic MCC whose disease has progressed after at least one previous chemotherapy regimen. Breakthrough Therapy Designation is intended to expedite the development and review of treatments for serious or life-threatening disease where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies for one or more endpoints.

The Merck and Pfizer alliance's presence at the 2016 American Society of Clinical Oncology (ASCO) annual meeting demonstrated how the collaboration between the two companies is making significant progress to rapidly accelerate the expansive, international development program (known as JAVELIN) for its investigational product avelumab. The program comprises 30 ongoing clinical programs assessing avelumab as monotherapy or combination therapy including nine pivotal studies, and approximately 4,000 patients across more than 15 tumor types. The data presented at ASCO 2016 contribute to the growing understanding of the potential role of avelumab in treating a broad range of cancers. In total 14 avelumab abstracts were presented (two oral presentations and 12 posters/poster discussions) across seven different cancer types.

One of the oral presentations concerned the results of JAVELIN Merkel 200 in metastatic MCC. The study showed a 31.8% objective response rate. There were 8 complete responses and 20 partial responses. Tumor responses were rapid, with 78.6% of patients (22 of 28) responding within 7 weeks of starting treatment, and durable, with 82.1% of patients (23 of 28) still responding at the time of analysis. Tumor responses were seen in patients regardless of the status of certain biomarkers (PD-L1 and Merkel cell polyomavirus). No unexpected safety signals were reported. Treatment-related adverse events (AEs) occurred in 62 patients (70.5%); the most common were fatigue (23.9%) and infusion-related reactions (17.0%), all of which were Grade 1 or 2 in severity. Grade 3 treatment-related AEs were reported in four patients (4.5%).

Other highlights of the avelumab clinical program reported at ASCO included the presentation of data in adrenocortical carcinoma, gastric/gastro-esophageal junction cancer, mesothelioma, non-small cell lung cancer, ovarian cancer and urothelial (bladder) cancer. Additionally, safety data were presented from 1,300 patients enrolled in the Phase Ib JAVELIN Solid Tumor trial, the largest Phase I trial investigating an anti-PD-L1 therapy.

In April Merck and Pfizer announced the initiation of a Phase III study of avelumab in an advanced renal cell carcinoma setting. The study, JAVELIN Renal 101, is a multicenter, international, randomized, open-label Phase III trial designed to evaluate the potential superiority, assessed by the progression-free survival, of first-line avelumab combined with INLYTA® (axitinib) compared with SUTENT (sunitinib malate) monotherapy in patients with unresectable, locally advanced or metastatic RCC with clear cell component. It is the first pivotal trial investigating avelumab in combination with INLYTA® (axitinib), a tyrosine kinase inhibitor (TKI), in patients with previously untreated advanced RCC. Moreover, it is the only Phase III trial currently evaluating an anti-PD-L1 immunotherapy in combination with a vascular endothelial growth factor (VEGF)-receptor TKI in this setting.

In July we initiated a new Phase III study evaluating avelumab as a first-line treatment for ovarian cancer. This study, known as JAVELIN Ovarian 100, is an open-label, international, multi-center, randomized trial in treatment-naïve patients with locally advanced or metastatic ovarian cancer (Stage III or Stage IV). It is the first Phase III study evaluating the addition of an immune checkpoint inhibitor to standard-of-care in first-line treatment for this aggressive disease and aims to enroll approximately 950 patients, who will receive concurrent avelumab and chemotherapy, avelumab following chemotherapy, or chemotherapy alone.

In January Merck and Pfizer entered into an exclusive collaboration agreement with Syndax Pharmaceuticals, Inc. to evaluate avelumab in combination with Syndax's entinostat, an investigational oral small molecule that targets immune regulatory cells (myeloid-derived suppressor cells and regulatory T-cells), in patients with heavily pre-treated, recurrent ovarian cancer. Syndax will be responsible for conducting the Phase Ib/II clinical trial.

In March, Merck, Pfizer and Verastem announced that they had entered into an agreement to evaluate avelumab in combination with Verastem's VS-6063, an investigational focal adhesion kinase (FAK) inhibitor, in a Phase I/Ib trial in patients with advanced ovarian cancer.

In early 2017, we announced that we had entered into an agreement with the University of Texas MD Anderson Cancer Center for a three-year strategic collaboration aiming to more quickly advance the development of investigational therapies in four cancers – breast, colorectal, glioblastoma, and leukemia – through the study of biomarkers of response and resistance. We are therefore the first company to gain access to MD Anderson's Adaptive Patient-Orientated Longitudinal Learning and Optimization Platform (APOLLO) that standardizes the long-term collection of patients' medical history and data derived from tissue samples in order to better understand the biology of cancer and accelerate research-driven patient care.

Also in early January 2017, we reached a licensing agreement with Vertex Pharmaceuticals Inc., Boston, Massachusetts (USA), for the worldwide development and commercialization of four promising research and development programs that represent novel approaches to the treatment of cancer. As part of the agreement, we have licensed-in two clinical-stage programs targeting DNA damage and repair, along with two additional novel pre-clinical programs for which we will assume full responsibility for development and commercialization.

Neurology

The EMA accepted for review our MAA for the investigational product cladribine tablets for the treatment of relapsing-remitting multiple sclerosis (MS). This MAA submission includes data from three Phase III studies, CLARITY, CLARITY EXTENSION and ORACLE MS, and the Phase II ONWARD study. In these trials, cladribine tablets showed a significant reduction in relapse rates, risk of disability progression and development of new MS lesions, as detected by MRI, versus placebo in patients with relapsing-remitting MS. Together with interim long-term follow-up data from the prospective registry, PREMIERE, the new MAA includes follow-up data consisting of over 10,000 patient years of observation, with follow-up in some patients exceeding eight years.

At the European Academy of Neurology (EAN) meeting in Copenhagen in May 2016, new data and analyses were presented from clinical studies with cladribine tablets. Outcomes in patients from across the spectrum of relapsing MS were presented from the CLARITY, ORACLE-MS and ONWARD studies. The results of a re-analysis of the ORACLE-MS data in clinically isolated syndrome (CIS) were chosen by the organizers to be shown at the highlights session that showcases the most interesting data presented during the congress. This analysis showed efficacy of cladribine tablets in patients who would now be classified as having early multiple sclerosis according to the latest disease definitions, as well as an adverse event profile in line with previous experience. Further data investigating brain atrophy associated with cladribine tablet therapy vs placebo was presented from the CLARITY study. Final results on safety and tolerability were reported from the ONWARD study.

In September we presented clinical data for investigational cladribine tablets in two oral presentations at the 32nd Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in London. The findings, from the CLARITY and CLARITY EXTENSION trials and from the open-label maintenance period of the ORACLE-MS study, demonstrated durable efficacy of cladribine tablets in patients with MS along with an acceptable safety profile. Results from these studies confirmed that 20 days of oral dosing over two years was effective in reducing the frequency of relapses and slowing disability progression for up to four years. The second oral presentation reported data from the open-label maintenance period of the Phase III ORACLE-MS study. ORACLE-MS showed that for patients with a first demyelinating event, treatment with investigational cladribine tablets significantly reduced the risk of progression to clinically definite MS compared with placebo. For the open-label portion of the study, patients who converted to clinically definite MS during the initial treatment period were switched to Rebif® therapy. The new data presented at ECTRIMS show that patients who had received investigational cladribine tablets in the initial treatment phase had lower annualized relapse rates over the maintenance period compared to those who had received placebo in the initial treatment phase.

On the occasion of the ECTRIMS meeting, we announced the recipients of the fourth annual Grant for Multiple Sclerosis Innovation (GMSI). In 2016, 260 proposals from 45 countries were submitted, representing innovative research projects taking place across the globe. Four international research teams from Canada, Germany, Israel, Qatar, Spain, and the United Kingdom were selected to share the € 1 million grant to support their research. The GMSI was launched in October 2012 with the aim of improving the understanding of MS for the ultimate benefit of patients living with the disease.

Concerning Rebif®, results of two non-interventional studies (REBIFLECT and REBISTART) were presented showing the positive effect of the RebiSmart™ injection device as well as nurse support for patient adherence to treatment, a key concern in patients requiring treatment for a chronic disease. In addition, a retrospective claims analysis was presented to investigate the reasons for treatment discontinuation over time.

As part of our portfolio prioritization efforts, and to allow us to focus on other ongoing projects in Neurology and Immunology, we returned the rights to the Phase II MS project ATX-MS-1467 to Apitope.

Immunology

In August the first patient in a Phase IIa clinical trial was dosed with our internally developed investigational product, the BTK inhibitor M2951. The study will evaluate the efficacy and safety of M2951 in subjects with rheumatoid arthritis on stable methotrexate therapy. A Phase II study with the same compound was initiated in December in systemic lupus erythematosus (SLE).

In November we announced the results of the ADDRESS II, Phase IIb, multicenter study on atacicept in patients with SLE, which were presented at the 2016 American College of Rheumatology/ Association of Rheumatology Health Professionals Annual Meeting in Washington, DC (USA). Patients on standard-of-care therapy (n = 306) were randomized to weekly subcutaneous injections of atacicept (75 or 150 mg) or placebo for 24 weeks. The primary endpoint was the proportion of patients achieving a clinical response as defined by a composite SLE Responder Index (SRI)-4 at week 24. Secondary endpoints included SRI-6 response rate and time to severe flare, assessed by the SLEDAI flare index (SFI) or BILAG. Although the primary endpoint was not met in the overall study population, there was a trend favoring atacicept with statistical significance achieved in a pre-specified sensitivity analysis of the primary endpoint using treatment Day 1 as baseline (rather than screening visit); atacicept 75 mg (55.9%, adjusted odds ratio/OR 1.88, p = 0.029) and 150 mg (55.8%, adjusted OR 1.96, p = 0.020) compared with placebo (41.0%). BILAG A flares were significantly reduced compared to placebo with atacicept 75 mg (p = 0.019), and severe SFI flare reduced with 150 mg (p = 0.002). Additionally, analyses of a predefined subpopulation of patients with high disease activity demonstrated statistically significant treatment effects of atacicept when compared to placebo. SRI-6 response at week 24 was significantly greater with atacicept 150 mg compared with placebo. Both atacicept doses led to significant reductions in the incidence of severe flare versus placebo, BILAG A flare and SFI flare. Atacicept was also associated with increased serum complement C3 and C4, and decreased IgG, IgM, IgA, and anti-dsDNA antibodies over time. Treatment-emergent adverse event incidence was slightly higher with atacicept (150 mg, 80.8%; 75 mg, 81.4%) than placebo (71.0%), however, the risks of serious adverse events or serious/severe infections were not increased with atacicept versus placebo, and there were no deaths. The safety findings were comparable for the high disease activity subpopulation.

Fertility

In July we announced our continued support for the advancement of medical science in the field of fertility through the Grant for Fertility Innovation (GFI) program by awarding grants totaling € 1.5 million in 2016/17. The announcement was made on the occasion of the 32nd annual meeting of European Society of Human Reproduction and Embryology (ESHRE) in Helsinki, Finland. Launched in 2009, the GFI is dedicated to transforming innovative translational fertility research projects into concrete health solutions to improve the outcomes of assisted reproductive technologies. In 2016, six winning projects from China, Hong Kong, Ireland, the United States, and Italy (two teams) were selected from 112 global proposals with the overall goal of improving the chances of conceiving.

In October we launched two innovative fertility technologies, Gavi™ oocyte protocol and Geri™ medium. Both products help to improve key steps of assisted reproductive treatment (ART) – an area where laboratory technologies play a vital role for treatment success.

The launches represent the seventh and eighth product launch in 18 months for the Fertility Technologies unit at Merck, demonstrating the company's healthcare strategy to deliver innovation through best-in-class assets. Gavi™ enables clinics to preserve human egg cells, also called oocytes, and embryos at the main stages of ART, while Geri™ medium supports undisturbed cultivation of embryos. Preserving oocytes or embryos for future in vitro fertilization and embryo transfers by cooling them to deep sub-zero degrees is a key step in the laboratory. Gavi™ is the world's first automated instrument for this preservation technique, also called vitrification. With its latest product innovation, Gavi™ provides clinicians with added flexibility when taking important treatment decisions with and for their patients. Geri™ medium was developed to help improve another critical factor for successful treatment, embryo cultivation. After fertilization, the embryo needs to grow and develop before it is transferred into a woman's womb. With the single-step culture medium, Merck now provides a way to support undisturbed incubation and optimal embryo development. Both products are being commercialized as part of the partnership between Merck and Australian company Genea Biomedx.

We announced in mid-November that we had launched two new innovative fertility technologies, Gidget™ and Geri™+, to extend our innovative portfolio to support all steps performed by fertility laboratories during ART, where technologies play a vital role for treatment success. Gidget™ is designed as an easy-to-use witnessing and tracking system to reduce the potential for error and improve lab workflows, and Geri™+ is the basis to combine the Geri™ embryo incubator and the innovative Eeva® algorithm. Both new products underline Merck's healthcare strategy to provide innovation to patients/customers through best-in-class products. Gidget™ and Geri™+ stem from the ARTinnovations development hub, which we formed in collaboration with Genea Biomedx, Australia. ARTinnovations is an incubator for ideas and innovations for fertility treatment and technologies. It combines the commitment and know-how of both partners to develop ideas that can take root and grow into better outcomes for patients.

Integrating bright- and dark-field imaging, the Geri™+ incubator allows for combination with the Eeva® software and any Geri Assess version. Geri+ becomes a multifunctional incubator, which gives embryologists a multitude of possibilities around embryo analytics. It brings together the benefits of undisturbed incubation, while complying with the high control and safety standards of the Geri™ incubator and the analytics of the Eeva® software, the first automated algorithm clinically shown to improve embryo assessment.

Gidget™ is a hand-held device for the IVF laboratory that lets the embryologist focus on the science by eliminating any chance of mismatching, and includes unique tracking and workflow features. It provides electronic witnessing, lab workflow management and support for traceability and audit reporting.

General Medicine & Endocrinology

In mid-October we announced that the Committee for Medicinal Products for Human Use (CHMP) of the EMA has issued a positive opinion recommending extension of the label for all metformin-containing products, including the Glucophage® product portfolio and Glucovance®, for the treatment of type 2 diabetes patients. The label change will lift the former contraindication for stable renal failure CKD stage 3. The maximum daily metformin dose will be 2,000 mg/day in CKD stage 3a (GFR = 45 – 59 ml/min) and 1,000 mg/day in CKD stage 3b (GFR = 30 – 44 ml/min), allowing a large additional group of type 2 diabetes patients with reduced kidney function to benefit from the treatment. In a recent analysis in CPRD, a UK medical record database, 32.7% of all diabetic patients had CKD stage 3.

Following a routine evaluation of the safety of metformin medicines, it was found that based on scientific evidence and clinical guidelines, patients with moderate renal failure may stand to benefit from treatment with metformin, and that the contraindication may therefore no longer be justified. Based on this evidence, the EMA issued an Article 31 referral requesting a cumulative review of the benefit and risk in this patient group across all metformin selling companies in the European Union. Leveraging around 60 years of experience in market as the metformin originator, Merck supported the EMA request by providing a comprehensive analysis of all available clinical data on the efficacy and safety of metformin in patients with CKD stage 3. This was balanced against a cumulative analysis of all case reports Merck has received for lactic acidosis, the very rare risk associated with metformin accumulation due to acute or severe renal failure. The EMA reviewed the data submitted by all companies, and as a result, the CHMP issued a positive opinion on lifting the contraindication for treatment of type 2 diabetes patients with renal impairment CKD stage 3.

In September we announced the recipients of the Grant for Growth Innovation (GGI) for 2016. The awards are intended to advance understanding in the field of human growth disorders. This year's winners were announced at an award presentation meeting held on the occasion of the 55th European Society for Pediatric Endocrinology (ESPE) Meeting in Paris, France. Thirty-eight applications were received from 20 countries and following a rigorous selection process, three awards were made to innovative projects from Australia, Brazil and Italy.

BIOPHARMA PIPELINE

as of December 31, 2016

Therapeutic area Compound	Indication	Status
Neurology		
Cladribine tablets (lymphocyte-targeting agent)	Relapsing-remitting multiple sclerosis	Registration[1]
Oncology		
Tepotinib (c-Met kinase inhibitor)	Non-small cell lung cancer	Phase II
Tepotinib (c-Met kinase inhibitor)	Hepatocellular cancer	Phase II
Tepotinib (c-Met kinase inhibitor)	Solid tumors	Phase I
M2698 (p70S6K and Akt inhibitor)	Solid tumors	Phase I
M3814 (DNA-PK inhibitor)	Solid tumors	Phase I
BeiGene-283 (BRAF inhibitor)	Solid tumors	Phase I
M7583 (BTK inhibitor)	Hematological malignancies	Phase I
Immuno-Oncology		
Avelumab (anti-PD-L1 mAb)	Merkel cell carcinoma	Registration[2]
Avelumab (anti-PD-L1 mAb)	Non-small cell lung cancer, 1st line	Phase III
Avelumab (anti-PD-L1 mAb)	Non-small cell lung cancer, 2nd line	Phase III
Avelumab (anti-PD-L1 mAb)	Gastric cancer, 1st line	Phase III
Avelumab (anti-PD-L1 mAb)	Gastric cancer, 3rd line	Phase III
Avelumab (anti-PD-L1 mAb)	Bladder cancer, 1st line	Phase III
Avelumab (anti-PD-L1 mAb)	Ovarian cancer platinum-resistant/-refractory	Phase III
Avelumab (anti-PD-L1 mAb)	Ovarian cancer, 1st line	Phase III
Avelumab (anti-PD-L1 mAb)	Renal cell cancer, 1st line	Phase III
Avelumab (anti-PD-L1 mAb)	Locally advanced head and neck cancer	Phase III
Avelumab (anti-PD-L1 mAb)	Solid tumors	Phase I
Avelumab (anti-PD-L1 mAb)	Hematological malignancies	Phase I
M9241 (NHS-IL12, cancer immunotherapy)	Solid tumors	Phase I[3]
M7824 (anti-PD-L1/TGFbeta trap)	Solid tumors	Phase I
Immunology		
Sprifermin (fibroblast growth factor 18)	Osteoarthritis	Phase II
Atacicept (anti-BLys/anti-APRIL fusion protein)	Systemic lupus erythematosus	Phase II
M2951 (BTK inhibitor)	Rheumatoid arthritis	Phase II
M2951 (BTK inhibitor)	Systemic lupus erythematosus	Phase I
M1095 (ALX-0761, anti-IL-17A/F nanobody)	Psoriasis	Phase I
Abituzumab (anti-CD51 mAb)	Systemic sclerosis with interstitial lung disease	Phase II
Biosimilars		
MSB 11022 (proposed biosimilar of adalimumab)	Chronic plaque psoriasis	Phase III

[1] As announced on July 18, 2016, the European Medicines Agency (EMA) has accepted for review the Marketing Authorization Application (MAA) of cladribine tablets for the treatment of relapsing-remitting multiple sclerosis (MS).
[2] As announced on October 31, 2016, the European Medicines Agency (EMA) has validated for review Merck's Marketing Authorization Application (MAA) for avelumab for the proposed indication of metastatic Merkel cell carcinoma (MCC). Additionally, as announced on November 29, 2016, the U.S. Food and Drug Administration (FDA) has accepted for Priority Review the Biologics License Application (BLA) for avelumab in this indication.
[3] Sponsored by the National Cancer Institute (USA).
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.

Akt	Protein kinase B
APRIL	Proliferation-inducing ligand
BLyS	B-lymphocyte stimulator
BTK	Bruton's Tyrosine Kinase
IL	Interleukin
mAb	Monoclonal antibody
PD-L1	Programmed cell death ligand 1
PK	Protein kinase

Consumer Health

Our Consumer Health business develops and sells over-the-counter medicines and food supplements in Europe, in particular in France, Germany and the United Kingdom, and in growth markets in Latin America, the Middle East and Africa, and Southeast Asia. The focus of our research and development activities is on the continuous improvement of existing formulations as well as on the development of new products and line extensions. We are following a consumer-centric innovation approach based on intensive market research across all our key markets. Since 2014, we have been establishing cooperation agreements with independent third-party research facilities to leverage their specific capabilities and expertise for the development of new products that meet the specific needs of our consumers.

Biosimilars

In March, we announced the initiation of a global Phase III clinical study in patients with chronic plaque psoriasis, of MSB11022, a proposed biosimilar of adalimumab, a recombinant human monoclonal antibody that binds specifically to tumor necrosis factor-alpha (TNF-α). The AURIEL-Psoriasis (PsO) study is a randomized, double-blind, active-controlled trial evaluating the efficacy, safety and immunogenicity of Merck's adalimumab biosimilar candidate MSB11022 compared with Humira® (adalimumab) in patients with moderate to severe chronic plaque psoriasis. Humira® is marketed globally by AbbVie, Inc., USA. The study is expected to recruit approximately 400 patients across Europe, Asia as well as North and Central America.

Merck is in advanced stages of negotiations to divest the Biosimilars business and the transaction is expected to close in 2017.

Allergopharma

Allergopharma, our allergy business, is one of the leading manufacturers of diagnostics and prescription drugs for allergen immunotherapy. With its own research department and in cooperation with research institutes and other partners, we are helping develop a better understanding of the immunological mechanism that underlies the development of allergies and are actively working on the next generation of drugs for allergen immunotherapy.

Life Science

Innovation is at the core of the value that we deliver to our customers. Our Life Science business sector has approximately 1,500 employees working in various R&D functions around the world. These teams collaborate closely with our customers to solve the toughest problems in life science by translating ideas into product innovations. To do so, we invest significantly in R&D.

2016 marked a year of diverse innovation activities that are contributing to our promise of accelerating access to health for people everywhere. We aim to:

- Improve and expand our portfolio
- Invest in new and disruptive technologies for the long term
- Partner with the global scientific community
- Meet customer needs

Improving and expanding the portfolio

We launched innovations across all segments of our portfolio throughout the course of 2016. In Research Solutions, we launched the CellASIC® ONIX2 Microfluidic System for advanced live cell imaging. The system converts laboratory microscopes into powerful tools for live cell imaging to more effectively perform in-depth analysis of cellular mechanisms and behaviors in a live environment.

In Process Solutions, we updated our bioreactor system, critical for drug development, with the new Mobius® products that include a 1,000-liter single-use bioreactor, Mobius® 1000, and a 2,000-liter mixing system, Mobius® Power MIX 2000. We also expanded our state-of-the-art single-use current Good Manufacturing Practice (cGMP) facility, in France, with the addition of Mobius® 2,000-liter single-use bioreactor to facilitate accelerated drug development and delivery via continued innovation and technical expertise by offering customers a complete end-to-end solution.

The latest addition to our comprehensive excipients portfolio is Parteck® MXP, a polyvinyl alcohol-based excipient that enhances solubility of a wide range of active pharmaceutical ingredients (APIs) with poor bioavailability. The product allows customers to address solubility challenges that otherwise might have prevented promising and potentially life-changing candidates from progressing through the pipeline. As part of this portfolio, Parteck® SRP 80 was awarded for excellence in innovation by the global organization CPhI, as a functional direct compressible excipient designed for oral sustained-release formulations. It is fully synthetic for batch-to-batch and performance consistency and enhances the bioavailability of actives.

As an industry leader in filtration, we enhanced our portfolio with Viresolve® Pro Shield H, which effectively improves aggregate removal and reduces the required virus filtration area needed to process feed streams, while delivering the same high level of virus clearance customers expect. The new Viresolve® Pro Shield H is designed for use as a prefilter with Viresolve® Pro Device for more robust, cost-economic viral clearance.

In Applied Solutions we expanded our portfolio of Cerilliant® certified reference materials for applied diagnostics and testing. We introduced nine new Certified Spiking Solutions® that leverage the latest research and techniques from around the world for accurate and reliable starting materials.

Since introducing the first water filtration device in 1974, we have set the standard for reliability and convenience in sterility testing. Our new Steritest™ Symbio Pump accessories address testing challenges in various laboratory settings and enhance safety and convenience during sample handling, filtration and waste management as well as canister transport, incubation and reading.

Investing in new and disruptive technologies for the long term

Advancements in gene editing tools like CRISPR are helping to accelerate discovery and manufacturing of new treatments for difficult-to-treat conditions. We produce gene editing tools and cell lines for both faster, better drug discovery and faster, better biomanufacturing of gene-modified cell therapies. Our innovations in 2016 showcased our commitment to empowering scientists and researchers with the solutions they need to develop new tools that can improve health.

In March 2016, we announced that our CRISPR Epigenetic Activator was named to *The Scientist's* Top 10 Innovation list. The system enables the life science community to explore advanced regulatory aspects of gene expression by allowing epigenetic modification of genetic loci at both close and distal locations to a gene of interest.

Following this accomplishment, in May we announced the expansion of our Carlsbad, California facility to meet the growing demand for viral and gene therapy products. The expansion builds on our industry-leading offerings in the manufacturing and testing of innovative and complex products and will seamlessly support customers from clinical to commercial scales. The expansion incorporates single-use equipment in a flexible, scalable format for clinical and commercial bulk drug production.

In September, we launched new gene editing technology to modify CHO cell lines to be resistant to minute virus of mice (MVM), a common contamination threat that remains despite the shift to chemically defined, animal-component-free manufacturing processes. The Centinel™ technology targets genes which play a role in MVM susceptibility and exemplifies how we are addressing some of the industry's most complex challenges through the unique combination of experience and technologies.

We also introduced the Sanger Arrayed lentiviral CRISPR libraries, the first human and mouse arrayed lentiviral CRISPR libraries for knocking out and screening gene function. Recognized by *R&D Magazine* as a top 100 R&D innovation, the library allows discovery of genes involved in drug resistance, human disease and a wide variety of biological processes.

Partnering with the global scientific community

We entered into a research agreement with the International Vaccine Institute of Seoul, Korea, to help develop next-generation purification processes. Through this partnership, we are improving the manufacturing process to deliver greater yield, allowing higher recovery and purer vaccines. We will help create a more modern, scalable and robust manufacturing process so as to increase access to life-saving vaccines in developing countries.

Our customers face many challenges when it comes to the development, manufacture and delivery of vaccines. As a business committed to sharing our technological expertise in this area, we joined the DiViNe project, a European consortium of six companies working to create an integrated, cost-efficient purification program specifically tailored for vaccines that achieve higher yields while preserving product integrity. As an industry leader in chromatography, we specifically focus on simplifying the process of vaccine purification that typically relies on affinity chromatography, a method of capturing antibodies.

In addition, a signed collaboration agreement with Evotec International GmbH, Hamburg, aims to accelerate discovery workflows and eliminate the need for resource-intensive in-house assay development and screening. The collaboration allows customers to select a customized set of CRISPR and shRNA libraries and then leverage Evotec's extensive capabilities in phenotypic screening within primary and induced pluripotent stem cells and in vivo disease models. Customers can more rapidly and efficiently explore disease pathways and identify new targets.

In December, we expanded our distribution alliance with various companies of the Roche Group, Switzerland, to be the exclusive supplier of novel enzymes for polymerase chain reaction (PCR) and quantitative real-time PCR enzyme products of Kapa Biosystems, a company owned by Roche. The alliance extension gives our customers greater access to novel products through our world-class distribution channel. The agreement is a growth driver for our Life Science business sector, which offers premier brand tools for genomics, proteomics and cell analysis.

Meeting customer needs

Proving our commitment to our customer needs, we relaunched our global network of customer collaboration centers as M Lab™ Collaboration Centers. The centers provide customers with a shared, exploratory environment with scientists and engineers working to solve the toughest biomanufacturing challenges. The dynamic setting promotes customer collaboration and problem solving, from pre-clinical through full-scale production. Our scientists and engineers work closely with customers to understand biomanufacturing needs that are then realized within R&D.

In 2016, we committed to provide Provantage® End-to-End development and manufacturing services to Y-mAbs Therapeutics, Inc. in support of Y-mAbs' monoclonal antibody in late-stage clinical development for pediatric brain cancer and also to Acticor Biotech to develop a safe and effective treatment for strokes. Our Provantage® End-to-End solution is a comprehensive suite of products and services that allows biopharmaceutical companies to accelerate the progression of molecules into the clinic and toward commercialization.

Performance Materials

We are the undisputed market and technology leader in liquid crystals (LCs) and photoresist materials, which are primarily used in televisions and mobile communication applications. We are also one of the leading suppliers of OLED materials as well as decorative and functional effect pigments. Materials for integrated circuits round off the portfolio.

Display Materials

We continued to work with our customers, display manufacturers, on the further development of high-performance liquid crystal technologies. These include the multiple award-winning, energy-saving liquid crystal technology UB-FFS (Ultra-Brightness Fringe-Field Switching) for mobile applications. We are additionally testing UB-FFS for non-mobile applications. SA-VA (self-aligned vertical alignment) is the next technology, with which the first products are expected on the market in 2017. It is very eco-friendly and resource-conserving as it requires less energy and solvent in display manufacture. In addition, it is more efficient for display manufacturers because fewer process steps are needed. Since SA-VA technology can be processed at lower temperatures, it is suitable for sensitive materials such as those used in premium products or future applications including flexible displays.

In order to strengthen our position in the increasingly important Chinese market, in September we opened a research and development laboratory for display materials in Shanghai. The new R&D laboratory will focus on the development of new and improved mixtures for liquid crystal displays manufactured in China. This allows us to cover the entire value chain for our customers in China and improve our competitiveness. In addition, we have more strongly positioned liquid crystals under the licrivision™ brand as an innovative material for windows in architectural and automotive applications. We are currently concentrating on three variants: sun protection, glare protection, and privacy control where the windows switch to opaque. Subsequent to the positive resonance to multiple pilot applications for liquid crystal windows, we decided to press ahead with the development and to set up our own production plant for liquid crystal window modules. The development of smart antennas using liquid crystal technology is continuing to make good progress.

Integrated Circuit Materials

In recent years, the cost per transistor for computer chips has not declined to the same extent as in the past. This is a result of the increasingly high cost of photolithography steps, which for modern chips today already amounts to more than 50% of manufacturing costs. This offers us the opportunity to introduce novel, cost-effective materials that allow our customers to counteract this cost development with innovative processes. In spin-on dielectrics, we further strengthened our market position with high-quality, sophisticated materials. Moreover, we successfully launched new products with better performance and better specifications and qualified them in new memory chip production lines. In close contact with our customers, we are also conducting research on new dielectrics that are adapted to the lower process temperature budget of novel chip types. The integration of the former SAFC Hitech business of Sigma-Aldrich has enabled us to combine spin-on technologies with deposition processes and provide customers with both from a single source.

Pigments & Functional Materials

Meoxal® effect pigments based on aluminum platelets are distinguished by their exceptional color saturation and brilliance. We are developing new color spectra for these pigments, which are used especially in automotive and plastic coatings. For Xirallic® NXT, an improved product generation of the well-known high-tech effect pigments, further variants are also under development. The most recently launched pigments include Xirallic® NXT Leonis Gold, a gold-colored pigment with outstanding hiding power and intense glitter, and Xirallic® NXT Tigris Blue, a pure and highly chromatic blue pigment.

In technical applications, we intensified our activities in additives for 3D laser direct structuring with a focus on 3D printing of plastics. We also developed laboratory prototypes together with our partners, which were presented for the first time at the K 2016, the top trade fair for plastics, in Düsseldorf. Laser additives enable computer-controlled fabrication of three-dimensional components with integrated electronic parts and laser-assisted circuit board bonding. We also see potential in energy management. We made good progress in high-voltage technology. Within the scope of the iShield research project, which is funded by the German Federal Ministry of Education and Research (BMBF), we are collaborating with academic and industrial partners to develop novel materials to shield generators and engines. We received the Darmstadt Enterprise Innovation Award for an innovative project with our customer Siemens, in which we are producing additives for more energy-efficient generators. Iriotec® 7340 was the first very light-colored, conductive pigment that we developed to market readiness. It allows a neutral background color that is suitable for every coating color.

We successfully further developed our range of fluorosurfactants, which strongly differentiates itself from competitive products on account of its favorable ecotoxicological profile, among other things. In early 2017, Tivida® FL 3000 is to be added to our portfolio of nonionic surfactants. Even in very low concentrations, it significantly improves the flow and wetting behavior of coating systems.

Besides materials for technical applications, we are also working on innovative raw materials for cosmetics – cosmetic fillers and actives. In cooperation with the French company Agrimer, we launched the first marine active ingredient from a new genetically decoded species of algae. The product known under the brand name RonaCare® RenouMer firms the skin and supports collagen formation.

Advanced Technologies

Organic light-emitting diodes (OLEDs) are an outstanding example of our R&D activities in the Advanced Technologies business unit. We pushed ahead with their further development again in 2016.

In 2016, we realigned our strategic projects for future business fields to megatrends such as miniaturization and the Internet of Things, which are developing at a rapid pace. One of the fields of work that we have derived from these is hybrid electronics. This new generation of electronics can be used, for example, in flexible displays and innovative sensors. Another field is electronic packaging. Here we see the future in materials that can protect or encapsulate the coming generation of semiconductor elements – also for flexible applications. In both fields of work, we are concentrating on markets in which Merck already holds a leading position, namely display and semiconductor materials. In addition, we are addressing interdisciplinary topics, as smart materials are also gaining importance in the Healthcare and Life Science business sectors. Sensor applications are one such example, which specifically monitor patients' temperature profiles and movements. In the fields of energy storage and thin-film transistors, we are collaborating on projects with partner companies that have introduced new solutions to the market with the help of our innovative products. We also achieved progress in the field of printable organic photovoltaics: In close collaboration with our customers, several mass-producible printing machines were commissioned in 2016. This was made possible thanks to our printing inks, with formulations specifically developed and tailored for customer processes.

People at Merck

Our employees are crucial to our success. Therefore, it is particularly important to us to recruit the right people with the right capabilities at the right time to work for Merck. To support Merck's growth and innovation course, we need a working culture that values diversity, promotes various forms of collaboration and responds flexibly to different requirements. This calls for creative solutions and curious employees who are constantly growing in terms of their professional expectations and skills. This innovative spirit is key to generating new ideas that pave the way to a successful future.

Overview of our headcount figures

As of December 31, 2016, we had 50,414 employees worldwide (2015: 49,613). In 2016, we were represented by a total of 215 legal entities with employees in 66 countries.

DISTRIBUTION OF EMPLOYEES

by region

in %

The future starts now

In a continuously changing world, qualified and creative employees are of tremendous importance. We endeavor to prepare each and every employee not just for today's demands of the workplace, but also for the opportunities and challenges of tomorrow.

A strong starting position

Merck is using the motto "Make great things happen" to position itself in the global job market. The aim is to convey to potential applicants a sense of what makes Merck unique: an inspiring, motivating work environment in which innovations thrive; an environment in which everyone has the opportunity to apply their ideas and engagement to benefit customers and the company, while at the same time developing themselves as employees. To make Merck even more attractive as an employer, in 2015 we repositioned our corporate brand. Consequently, in late 2015, we started an analysis of the impact of the new corporate brand on employer branding. It is essential to harmonize employer branding and messages with the new brand in order to position Merck as an attractive and responsible employer.

When filling open positions, we concentrate on attracting employees who have potential to take on greater roles in the future. For this, we have introduced a globally uniform and binding process. It starts with an internal job posting before external channels such as job portals and recruitment agencies are used. On the one hand, the process offers employees better development opportunities, and on the other hand it minimizes the costs of external recruitment.

In order to support executives in making hiring decisions and to establish uniform quality standards, we offer interview training courses for employees with personnel responsibility. In these courses, the participants learn proper interview behaviors, targeted question techniques and how to incorporate relevant diversity aspects into the hiring decision.

We start integrating new employees before their first day of work, since a good introduction marks the beginning of a successful collaboration. In order to make the onboarding process as efficient and easy as possible for new employees, we have created a welcome website that can be accessed worldwide. Protected by a password, this website is available in eight languages and offers new employees all the information they need. Furthermore, we have set up a special room on our intranet to allow new employees to network and to inform them of important global, local and business-specific issues. In addition, each new employee is assigned an experienced colleague who supports them during their initial orientation period. Our managers are also given a detailed information pack so that they can optimally integrate their new employee into their role. This pack contains an onboarding plan, process descriptions and general information on Merck as an employer.

Success through knowledge

To enhance our growth and innovation potential over the long term and ensure the necessary flexibility to allow us to respond promptly to new trends, we support the development of our more than 50,000 employees. Only by strengthening the abilities of each individual can we count on innovative and curious employees and managers in the future.

This approach starts with good training. In 2016, we again maintained a constant high vocational training rate at Darmstadt, our largest site. A total of 523 motivated young people were enrolled in apprenticeships in 23 different occupations in 2016. We give unlimited employment contracts to all apprentices working in occupations for which we have sustainable demand. On average, the post-apprenticeship hiring rate – taking voluntary terminations into account – was more than 90% over the past five years. Of course we also offer vocational training at other sites in Germany, in which a total of 53 young people participated in 2016.

We continue to promote the professional expertise of our apprentices through numerous regional and global project activities. In 2016, these included supporting a center for homeless children in Ghana.

Furthermore, through our "Start in die Ausbildung" program, we help young people to find an apprenticeship. In 2016, the number of participants was higher than in the previous year, with a total of 22 young people between the ages of 16 and 25. Although they have a school leaving qualification, they had been searching for an apprenticeship for at least one year without success.

In 2016, we established a similar program for refugees for the first time. Through linguistic, technical, cultural, and job-specific training, the "Integrating refugees through training" initiative is preparing twelve young people who were forced to flee their home countries for vocational training and thus for the labor market.

Our advanced training program for all employees comprises a range of globally aligned classroom training courses on 18 selected subjects. In 2016, more than 5,700 employees participated in these courses to prepare themselves for new opportunities and challenges. In addition to classroom training courses, we also offer digital solutions in the form of 200 e-learning and language courses. At workshops designed specifically for teams, employees are taught how to make effective use of individual skills to enhance productivity and collaboration. To enable our employees to realize their full potential, we also provide local business- and function-related offers. All of these measures are documented in globally available development plans.

Moreover, we offer our high-potential staff and senior executives a range of advanced training programs. One of the aims of the six-month International Management program is to promote global thinking among young junior executives and to strengthen their leadership competencies. In cooperation with top international universities, the Merck University has been offering a multi-regional, modular program since 1999. To date, 373 members of top management have taken part. Furthermore, Merck cooperates globally with universities in order to support employees who wish to study for an MBA. In 2015, we launched the Growth Markets Management program for local executives in India and Latin America, which focuses on business management and Merck-specific topics. This program is also offered in China and Turkey, with participants from a variety of countries and regions such as Africa, the Middle East, Japan, and Russia. Moreover, in 2016 we ran the Managerial Foundation Program in 20 countries with 739 participants and the Advanced Management Program, which was attended by 99 experienced executives in four countries.

Shaping the future through innovation

Innovation plays a particularly important role at Merck. In order to further enhance the preconditions for innovation, in 2015 we opened the modular Innovation Center in Darmstadt. This gives employees the possibility to focus on their ideas and work on projects in an environment that stimulates creativity and collaboration. After all, innovation calls for imaginative employees with adequate scope for creativity and appropriate support, which includes a suitable working environment. Offering our employees various training courses on topics such as innovative methods, creative techniques, and visualizing and testing business models is an important element of the Innovation Center. Internal project teams, start-ups from the Merck Accelerator program as well as many other interested colleagues from various areas throughout Merck benefit from this offer. Recently, the training courses were digitalized, making them available to all employees worldwide.

Driven by inspiration

Furthering the performance culture at Merck to optimally support the company in its transformation and growth program is another focal point of our human resources work. In this context, differentiated compensation and advanced training opportunities are important incentives. Establishing a culture of inclusion and inspiration in which managers set an example through their attitude and behavior, as well as selecting and positioning the right employees, are crucial.

Leading by example

New ideas change the world. That is what drives us. We study things in detail, ask questions and think a step further. This approach is supported by our executives. They recognize and make use of opportunities to drive our innovation-based business model and set their sights on clear goals. At the same time, our executives set an example, for instance by living the Merck values and taking responsibility for their own decisions. In doing so, a differentiated feedback culture is essential in establishing a common vision through effective management. Our competency model supports our executives in further developing our business model and the related culture. The strategic competencies according to which managers and employees are to behave are purposeful, future-oriented, innovative, results-driven, collaborative, and empowering. They enable our executives to build a strong culture of collaboration based on curiosity and trust.

Fostering the skills and potential of our employees

We want our employees around the world to enjoy working at Merck. We want to excite them and retain them. We therefore consider it an important part of our managerial responsibility to identify employee potential early on and foster it on an individual basis. We want to offer our employees interesting career opportunities, continuous personal and professional development as well as prospects within the company. We are thus continuously strengthening our performance and development culture to encourage a curious and innovative attitude among our workforce.

Through intensive analysis of our personnel data using a new software introduced in 2016, we can now more quickly recognize the potential of talented employees, allowing us to fill internal positions even more efficiently. We map our talent and performance management process uniformly for all employees worldwide according to the same principle and via a common IT system. We systematically combine talent recognition with employees' target agreements and performance assessments, since we are convinced that regular feedback helps all employees to grow in terms of their performance and potential. At the same time, regular individual assessments make it easier to identify employees with high potential and to further them accordingly. Clear objectives, differentiated and open feedback and individual development plans are thus important prerequisites for both personal development and business success.

In 2016, we further expanded our workforce pool to internally fill management positions when they become vacant. The vast majority of management position vacancies were filled by internal candidates again in 2016. In addition, we recruited external executives in order to add new perspectives to our long-standing in-house expertise.

Valuing performance

We value the individual contribution of each and every employee and reward them with an appropriate and competitive total compensation. For years, we have been doing this using global processes and programs that are supported by digital platforms. We also offer our executives flexible, market- and needs-oriented compensation instruments. These instruments help to make well-informed decisions and thus continue to provide comprehensible, performance- and position-based compensation.

We aim to be an attractive employer. For this reason we do not only focus on monetary compensation components. Attractive fringe and social benefits also play an important part in motivating and retaining our employees. We have based our "benefits4me" offer on three pillars, namely company benefits including the company pension, health and well-being, and services. There are different benefit packages to meet the various needs of our workforce. Established steering mechanisms ensure that this is a well-made investment in our employees.

Culture makes all the difference

An open, dynamic and inclusive corporate culture and a diverse workforce contribute significantly to our business success. Therefore, promoting diversity and inclusion as well as motivating employees to embrace cultural change are special focal areas of our human resources work.

Unity in diversity

Together with a culture of inclusion, diversity promotes innovation and improves team and individual performance. One of the strategic goals is to recognize the strengths of such a diverse workforce and to appreciate individual differences. It is important to us to create an inclusive work environment in which all employees have the possibility to realize their full potential. With respect to three of our six values, namely respect, transparency and integrity, multifaceted ideas are furthered and perspectives strengthened in order to drive innovation and to add more value. By signing the Equal Opportunity Charter of the German Mining, Chemical and Energy Industrial Union (IG BCE) in 2015 and the "Charta der Vielfalt" in 2013, we underscored our commitment to fairness and tolerance at the workplace.

In addition to the Chief Diversity Officer, who is responsible for strategically managing diversity within the company, Merck also established the Diversity Council in 2013, comprising high-ranking executives from all business sectors and select Group functions. Its aim is to build further active support for and progress in diversity and inclusion within the company. In 2016, the Diversity Council worked to operationalize our Diversity Framework, introduced in 2015, which bundles the diversity and inclusion strategies. It focuses on the following four topics: recruiting the right people to work for Merck, developing and retaining them, promoting efficient collaboration, driving innovations and improvements, and serving customers with diverse needs. In addition, we support specific employee networks in order to foster exchange among like-minded individuals.

In September 2016, we celebrated the Global Diversity Days with a campaign entitled "The Power of Diversity", which aligned with "The Power of We" , one of our strategic corporate messages. The objective of this annual month of focus is to heighten awareness of diversity and inclusion among our workforce in global events. Globally, employees in 17 countries across six continents took part in events and shared experiences via employee platforms and social media.

People from a total of 129 different nations work for Merck. Only 23.1% of our employees are German citizens, and 75.3% work outside Germany. Women currently make up 42.8% of the workforce. Since the ratio of women to men varies widely across the different regions, businesses and functions, we have set ourselves the goal of increasing the percentage of female employees wherever they are underrepresented. Here we take into account the situation that is typical for the industry as well as regional differences.

In Germany as well as several other EU countries, Japan and the United States, we are preparing ourselves for demographic change. Since the average age of our employees is slightly more than 40, the need for urgent action does not yet exist; however, we assume that this figure will continue to rise in the coming years. Our focus lies mainly on "mindfulness" as a further step to sensitize the workforce to the limits of their own physical and mental resources.

Among executives, too, inclusion and diversity play a major role. We are convinced that balanced diversity among management enhances career advancement opportunities for talented employees while also helping to provide a broad experience base within the company. In addition, it allows for differentiated decision-making, thereby making a significant contribution to the success of the company.

As a global company, we consider it highly important to have an international management team. Currently, 64.7% of our managers have a nationality other than German. Altogether, 70 different nationalities are represented in such positions. In 2011 we set our strategic goal to increase the percentage of women in management positions to 25% to 30%, which we reached in 2016. The percentage is currently 28.8% at Group level. The figures are steadily increasing across Merck as a whole, but not consistently across business units and Group functions. We have set ourselves the goal for 2021 to stabilize the overall proportion of women in management positions at 30%, but continue to work on increasing the proportion in senior management positions and business units where women are still underrepresented.

The report on stipulations to promote the proportion of women in management positions at Merck KGaA pursuant to section 76 (4) and section 111 (5) of the German Stock Corporation Act, including information on the achievement of the defined targets as of December 31, 2016, can be found in the Corporate Governance section of this report.

Safety in daily work

As a responsible employer, it is especially important to us to do everything in our power to prevent workplace-related illnesses and accidents. We apply the lost time injury rate (LTIR) as an indicator to determine the success of measures aimed at accident prevention as well as occupational health and safety. This key performance indicator describes the number of workplace accidents resulting in lost time of one day or more per one million working hours. In 2010, we had set ourselves the goal of reducing the lost time injury rate to 2.5 by 2015 – with 1.5, we considerably exceeded this target value in 2015. But this still is not enough for us. We believe that nothing is worth an accident. And we have been even more ambitious in setting our goal for the future: By 2020 we intend to sustainably lower the LTIR further. In 2016 we already reached this with 1.3.

The continuous rate of improvement in recent years can be attributed in particular to the BeSafe! program, which was launched in 2010. This is a global initiative with globally harmonized standards, but also local modules that help to meet the specific safety requirements at individual sites. The program focuses on engaging managers in the safety culture and building their buy-in; it aims to make safety an intrinsic value and empower our employees to take responsibility for their own safety. In 2016, we continued to sensitize our employees to workplace hazards through numerous awareness campaigns.

Since 2010, Merck has been presenting the Safety Excellence Award annually in order to underscore the importance of safety. It is granted to all production sites with no workplace accidents on record for the year; in 2016, it was awarded to 61 out of 91 sites.

Flexibility in every situation

As an attractive partner and employer, we endeavor to always provide future-oriented solutions. This also applies to the way in which we work. We want our employees to achieve a good balance between their professional and personal objectives and challenges. This maintains and strengthens their motivation and performance potential for longer, enabling them to better schedule their lives to suit their own needs.

That is why we offer our employees in Germany and the United States various flexible and innovative working models. The "mywork@merck" working model, initially implemented in 2013 at the Darmstadt and Gernsheim sites in Germany for all exempt employees, aims to strengthen a culture of performance and trust within the company. In agreement with their teams and supervisors, employees can choose their working hours and location freely. Since October 2014, non-exempt employees at these sites whose positions are suitable for this working model have also been able to make use of it. In addition, we also introduced "mywork@merck" for Merck Accounting Solutions & Services Europe GmbH, Merck Export GmbH, Merck Schuchardt OHG, Merck Versicherungsvermittlung GmbH, Merck Selbstmedikation GmbH, and Merck Chemicals GmbH. Employees can best decide for themselves, together with their respective line managers, when and how often fixed physical presence in the office is necessary for all team members. Working hours are no longer recorded or monitored. Employees must only document their hours if they exceed their standard working hours within the agreed working time framework. At the end of December 2016, a total of 4,507 employees made use of this model. In 2016, 4.7% of our employees worldwide worked part-time, 10.6% of whom are men. We believe that with these flexible working models, we are on the right track – not only to more efficient processes, but also above all to higher levels of work satisfaction and employer appeal.

We also offer our employees throughout Germany targeted and independent information, advice and assistance in finding childcare and nursing care, as well as home and garden services. At various sites, employees benefit from childcare options that we subsidize. A daycare center, which meanwhile has capacity for 150 children between the ages of one and twelve, has been operating at the Darmstadt site for 49 years. Since 2013, we have been offering expanded, year-round opening hours from 6:30 a.m. to 7 p.m., as well as needs-oriented daycare hour options of 25, 35 or 50 hours per week and, in the adjacent new building, a nursery for up to 60 children between the ages of one and three years. During the orientation phase, our employees can make use of additional offices for parents at the daycare center premises. In addition, a good ratio of staff to children is important to us to offer parents a safe period of supervision for their children while at the daycare center.

Ready for the future

A dedicated, satisfied workforce is key to succeeding as a global company. Only those who question structures and collaborate with others will develop positively. Honest and continuous feedback from our employees is thus absolutely essential so that we are aware of the factors that influence engagement and what the organization's strengths and weaknesses are.

Between December 2013 and June 2015, we conducted the Organizational Health Index (OHI) survey in all business units and Group functions. Based on the results, strategic focus topics were identified and initiatives derived. In 2016 we continued to anchor these topics deeper into the organization.

In order to reach all employees, a global employee survey was conducted in 23 languages in November 2016. Approximately 42,500 employees (83%) took part. Our company-wide score, which measures how engaged our employees are, is 60%. This score is comparable to other companies in the chemical and pharmaceutical industries. As of early 2017, we will be working with the results across the company.

OVERVIEW OF EMPLOYEE FIGURES

			Overall Merck Dec. 31, 2014	Overall Merck Dec. 31, 2015	**Overall Merck Dec. 31, 2016**[2]
Number of employees	global, total		39,639	49,613[2]	50,414
	by region	Asia-Pacific (APAC)	9,488	11,096[2]	10,754
		Europe	20,537	23,429[2]	24,438
		Latin America	3,883	4,352[2]	4,140
		Middle East and Africa (MEA)	639	942[2]	1,045
		North America	5,092	9,794[2]	10,037
Number of employees (FTE – full-time equivalents)	global, total		39,012.4	48,911.1[2]	49,652.7
	by region	Asia-Pacific (APAC)	9,474.4	11,068.2[2]	10,725.3
		Europe	19,946.2	22,785.7[2]	23,727.1
		Latin America	3,877.6	4,344.2[2]	4,136.5
		Middle East and Africa (MEA)	637.9	940.6[2]	1,041.8
		North America	5,076.3	9,772.4[2]	10,022.0
Number of countries			66	66[2]	66
Number of legal entities	global, total		146	211[2]	215
Number of employee nationalities	global, total		122	122[1]	129
Number of nationalities working in Germany			73	77[1]	91
Percentage of employees with German citizenship			26.6%	26.1%[1]	23.1%
Percentage of employees working outside Germany			71.8%	75.9%[2]	75.3%
Percentage of employees with a global manager			5.2%	8.1%[2]	9.7%
Percentage of women in the workforce	global, total		41.3%	41.6%[2]	42.8%
	in Germany		37.5%	38.2%[2]	38.6%
Percentage of women in upper management positions (Global Grade 14 or higher)	global, total		26.3%	26.8%[1]	28.8%[6]
	in Germany		26.1%	27.3%[1]	28.7%[6]
Percentage of executives (Global Grade 14 or higher)	global, total		5.5%	5.9%[1]	5.7%[6]
	Percentage of executives who are not German citizens		60.3%	61.0%[1]	64.7%[6]
	Number of nationalities		67	64[1]	70[6]
Number of apprentices in Germany			498[3]	506[4]	576[5]
Vocational training rate			5.4%[3]	5.3%[4]	5.1%[5]
Percentage of employees in the “mywork@merck” model (Germany)			3,522	4,122	4,507
Percentage of employees working part-time	global, total		5.2%	4.7%[2]	4.7%
	men		10.5%	11.3%[2]	10.6%
Percentage of employees aged 17 – 29 years	global, total		14.9%	15.2%[2]	14.7%
Percentage of employees aged 30 – 49 years	global, total		64.2%	62.6%[2]	62.5%
Percentage of employees aged 50 + years	global, total		20.9%	22.2%[2]	22.8%
Average age globally			41	41.1[2]	41.3
Average age by region	Asia-Pacific (APAC)		36.6	36.7[2]	36.7
	Europe		42.5	42.4[2]	42.4
	Latin America		39.6	39.5[2]	39.9
	Middle East and Africa (MEA)		37.7	39.5[2]	39.3
	North America		44.9	44.2[2]	44.3
	Germany		43.2	43[2]	42.9
Average length of service	global, total		10.1	10.0[2]	9.9
Average length of service in Germany			14.9	14.4[2]	14.2

[1] Excluding Sigma-Aldrich.
[2] Including Sigma-Aldrich.
[3] Merck KGaA sites Darmstadt and Gernsheim (around 24% of the workforce of the entire Group in 2014).
[4] Relates only to Merck KGaA (around 19% of the workforce of the entire Group in 2015).
[5] All Merck sites in Germany (around 25% of the workforce of the entire Group in 2016).
[6] Not including Sigma-Aldrich legal entities in Germany or Allergopharma.

Report on Economic Position

Macroeconomic and Sector-Specific Environment

According to the most recently available figures from the International Monetary Fund (IMF), industrial countries faced dampened growth expectations in 2016. Firstly, this was due to the uncertain consequences in connection with the future exit of the United Kingdom from the European Union ("Brexit"). Secondly, economic growth in the United States was weaker than expected in the first half of the year. According to the latest IMF forecasts, global gross domestic product (GDP) increased by 3.1% in 2016, equivalent to a decline of 0.1 percentage points in comparison with 2015. As in the previous year, strong regional differences could be seen. Industrial nations registered a decline in growth to 1.6% (2015: 2.1%). At 4.2% (2015: 4.0%), emerging economies and developing countries achieved an increase in growth rates for the first time in five years. The GDP of the United States, the world's largest economy, remained behind expectations, growing only by 1.6% (2015: 2.6%). In 2015, growth of 2.8% was forecast for 2016. Growth was slowed by a continued decline in investment in the energy sector and the strong U.S. dollar, which had a dampening impact on export-oriented industrial sectors. As was the case in the United States, the eurozone also registered a decline in GDP growth to 1.7% (2015: 2.0%). By contrast, the emerging economies of Asia registered growth of 6.5% (2015: 6.6%). As in 2015, India (7.6%) and China (6.6%) were the strongest growth drivers. The industrial nations South Korea and Taiwan only generated slight increases in growth, whereas the GDP of Japan stalled at the 2015 level of 0.5%. Korea registered growth of 2.7% (2015: 2.6%) and Taiwan saw growth of 1.0% (2015: 0.6%).

In 2016, organic sales growth at Merck was largely attributable to the North America and Latin America regions. While North America accounted for approximately 36% of Group-wide organic growth, Latin America also generated a high share, which amounted to 27.7%. In Latin America, all the business sectors contributed positively to organic sales growth. In North America, growth was driven by our Healthcare business sector. While the Asia-Pacific (APAC) region generated around 56% of organic growth in 2015, it only accounted for a share of roughly 12% in 2016. This was due to the declines in the Performance Materials business sector. For instance, Performance Materials sales in the Asia-Pacific region decreased organically by –6.6%.

	Development 2016[1]	Development 2015
Healthcare		
Global pharmaceutical market	6.3%	9.2%
Market for multiple sclerosis therapies[2]	7.5%	14.9%
Market for type 2 diabetes therapies[2]	11.2%	11.1%
Market for fertility treatment[2]	12.6%	10.7%
Market for the treatment of colorectal cancer[3]	–0.5%	–1.7%
Market for OTC pharmaceuticals	4.3%	4.9%
Life Science		
Market for laboratory products	2.5%	2.9%
Share of biopharmaceuticals in the global pharmaceutical market[2]	23.3%	22.3%
Performance Materials		
Growth of LC display surface area	4.6%	4.8%
Global automobile sales volumes	2.5%	1.3%
Materials for production of cosmetics	1.8%	1.5%
Semiconductor industry sales	Sales at the previous year's level	–2.3%

[1] Predicted development. Final development rates for 2016 were not available for all industries when this report was prepared.
[2] Growth rates based on market data in local currency, translated at a constant euro exchange rate. The IMS Health market data on the growth of indications are based on current figures, including the third quarter of 2016. Annual growth based on the values for the past 12 months. The type 2 diabetes market excludes the United States since this market is insignificant to Merck.
[3] Growth rates based on market data stated in U.S. dollars. Market data from EvaluatePharma on the growth of indications are based on published company reports and are subject to exchange rate fluctuations.

Healthcare

According to the latest study published in September 2016 by the pharmaceutical market research firm IMS Health entitled "Global Market Prognosis 2016–2020", the growth of the global pharmaceutical market for 2016 is quantified at 6.3%. By comparison, in 2015, sales growth was still 9.2%. As was already the case in 2015, growth in 2016 was primarily attributable to Latin America and the United States. Whereas growth in the United States fell significantly to 6.3% (2015: 12.0%), at 13.9% the Latin American market continued to see double-digit growth (2015: 16.0%). At 5.7%, the Asia-Pacific region recorded a slight decline in growth (2015: 6.6%). Europe registered a stronger decline to 4.6% (2015: 7.0%).

Not only the growth of the pharmaceutical sector as a whole, but also in particular the development of the biopharmaceutical market are relevant for our business. According to IMS Health, the market volume of biopharmaceuticals was approximately € 208 billion in 2016. In recent years, the share of the global pharmaceutical market accounted for by these products has grown continuously and already amounted to 23.3% in 2016. Globally, the largest share, or 31.2%, was attributable to the United States.

A look at the therapeutic areas of relevance to Merck shows differing developments. The markets for the therapeutic areas multiple sclerosis grew by 7.5% (2015: 14.9%), type 2 diabetes[1] by 11.2% (2015: 11.1%) as well as fertility by 12.6% (2015: 10.7%). By contrast, the market for oncology drugs for the treatment of colorectal cancer declined by –0.5% (2015: –1.7%).

According to the market research firm Nicholas Hall, the growth of the global over-the-counter pharmaceutical market was 4.3% in 2016, which represents a slight decline of 0.6 percentage points in comparison with 2015. In 2016, growth was driven by the Asia-Pacific region, which generated growth of 5.5% (2015: 5.1%). As in 2015, India achieved the strongest growth of 7.7% (2015: 8.9%). At 2.2%, growth was weakest in western Europe (2015: 3.3%) and Japan (2015: 0.2%).

[1] Excluding the United States.

Life Science

Our Life Science business sector is a leading supplier of products and services for both research and applied laboratory applications, as well as for formulating, purifying, manufacturing, and quality-assuring drug therapies of biological and chemical origin.

For the laboratory product market relevant to Research Solutions and Applied Solutions, the market research firm Frost & Sullivan expects growth of 2.5% for 2016 (2015: 2.9%). A period of heightened uncertainty in the second half of 2016 dampened growth versus 2015. Growth was primarily driven by biopharmaceutical industry customers, specifically emerging biotech start-ups. In comparison with 2015, European market growth slowed to 1.5% (2015: 1.9%), driven by a weaker euro and economic uncertainty, for instance as regards the unexpected Brexit vote. Growth of the U.S. market was 2.7% (2015: 3.0%), with the slowdown influenced by the U.S. presidential election and delay in passing a 2017 federal budget. Emerging economies delivered higher growth; however, a slowdown in China was visible, with modest improvements expected in this market over the next few years.

The demand for Process Solutions products depends heavily on the volume of biological product sales as well as the productivity of research and development activities of biopharmaceutical companies. As previously stated, the market volume for biopharmaceuticals was € 208 billion in 2016, representing a 23.3% share of the global pharmaceutical market. According to EvaluatePharma, there are more than 8,500 active biologics projects in pre-clinical and clinical development, of which monoclonal antibodies represent 28% (2015: 25%). Biosimilars are a small, but fast-growing part of the pharmaceutical market. In 2016, biosimilars sales are expected to reach US$ 1.4 billion annually before growing to US$ 8 billion in 2022.

Performance Materials

With its liquid crystals business, Merck is the leading producer of liquid crystal mixtures for the display industry. The dynamic growth rates of display surfaces have declined to an average of 5% in recent years according to surveys by the market researchers at IHS DisplaySearch. This growth was mainly attributable to increasing average display size amid largely stagnating sales volumes. The display industry remains a growth sector in which the leading display technology is based on liquid crystals. OLED technology, for which Merck also ranks among the leading material suppliers, is gaining importance in the high-end display sector.

The markets for automotive coatings and cosmetics are crucial to Merck's Pigments business. As reported by the Center of Automotive Management (CAM) in Bergisch-Gladbach, Germany, global automobile sales volumes rose by 1.3% in 2015. As in the previous years, the growth drivers were China, western Europe and the United States while significant declines in automotive sales volumes were registered particularly in Brazil and Russia. For 2016, a slight recovery in the global growth of the automotive market is expected. According to Euromonitor International, global consumption of materials used to produce cosmetics grew by 2%, with Asia reporting the highest growth rate of 4%.

The semiconductor industry is the most important sales market for the business with integrated circuit materials (IC Materials). The long-term growth of the semiconductor industry has a cyclical demand pattern. According to Gartner, a market research institute specializing in the technology and electronics markets, in 2016 the industry's sales were at the previous year's level since the growth of smartphone applications was offset by declining demand in the PC business. The decline in 2015 of – 2.3% was likewise due to the weakness of the PC business.

Review of Forecast against Actual Business Developments

Net sales

For 2016, slight organic sales growth was forecast for the Merck Group. Owing to the acquisition of Sigma-Aldrich, which closed on November 18, 2015, we additionally expected a portfolio effect in the low double-digit percentage range. The positive organic development of net sales in the Healthcare and Life Science business sectors more than offset the slight decline in Performance Materials. Consequently, we generated a moderate organic sales increase of 3.2%. At 16.4%, the additional portfolio effect due to Sigma-Aldrich was in the low double-digit percentage range as expected. At the beginning of 2016, we had forecast a slightly negative exchange rate effect owing to the decline in the value of Latin American currencies. In the course of the year, we raised the forecast of this effect to – 3% to – 5%. Owing to a weakening of these dynamics and a simultaneous strengthening of the U.S. dollar in the fourth quarter, we incurred an exchange rate effect of – 2.6% on our sales for 2016.

In 2016, our Healthcare business sector showed solid organic sales growth of 4.6%, thus exceeding our forecast for slight organic growth. As expected, sales growth was driven by the continued good dynamics in our growth markets as well as positive effects from the co-promotion of Xalkori® with Pfizer. Yet the Fertility franchise in North America and China as well as Rebif® performed significantly better than expected. Contrary to our original assumptions, Rebif® generated organic sales growth in North America. As forecast, a slightly negative portfolio effect of – 1.1% was incurred in 2016 owing to the return of the Kuvan® rights to BioMarin Pharmaceutical, Inc.

Our Life Science business sector achieved organic sales growth of 6.3% in 2016. This was significantly stronger than the moderate organic growth we had forecast at the beginning of the year. The more dynamic business performance increasingly manifested itself in the first half of 2016. Our updated forecasts as of the second quarter of the year took this into account accordingly. All the Life Science business areas contributed to the positive development, with Process Solutions accounting for the largest proportion and benefiting from continued healthy demand from customers in the biopharmaceutical industry. In addition, the acquisition of Sigma- Aldrich was responsible for a portfolio effect of 63.1%, thus meeting the forecast we made at the beginning of the year.

As already indicated in the forecasts after the second and third quarters of 2016, the Performance Materials business sector did not meet the original expectation of slight organic growth. The destocking in the display industry, which lasted longer than expected, as well as typical price declines in liquid crystals, could not be offset by growth in the other business units. Overall, this led to an organic sales decline of – 4.7% compared with 2015.

EBITDA pre exceptionals

At Group level, we increased EBITDA pre exceptionals by 23.7% to € 4,490 million in 2016, which was in line with our original forecast of an increase in the low double-digit percentage range.

Contrary to our original expectation of a decline in earnings in the low double-digit percentage range, in 2016 EBITDA pre exceptionals of our Healthcare business sector rose by 6.3% compared with 2015. The positive margin development had already started to become apparent after the second quarter following unexpectedly good sales reported for Rebif® and the Fertility franchise along with the divestment of a minority interest. Additionally, as of the second half of the year we started receiving royalty and license income for a patent granted in the United States in June 2016. Apart from the release of provisions for research projects discontinued in prior years, it became clear in the third quarter that research and development expenses would be below our conservative cost budgeting at the beginning of 2016.

For EBITDA pre exceptionals of the Life Science business sector, we had forecast a moderate increase owing to the expected organic sales growth and an additional portfolio effect in the high double-digit percentage range due to the acquisition of Sigma-Aldrich. With EBITDA pre exceptionals of € 1,652 million, equivalent to an increase of 93.0%, we met this forecast. This was due not only to the portfolio effect that corresponded to the expected amount, but also to good margin development and the faster than planned realization of the synergies from the aforementioned acquisition.

For the Performance Materials business sector, we assumed that EBITDA pre exceptionals would increase slightly. We aimed for at least the level of 2015. Owing to the significant destocking by the display industry throughout the year and the resulting negative impact on sales, we fell slightly short of this forecast. We applied maximum cost discipline to counteract this development and were able to benefit from the high degree of diversification that now characterizes Performance Materials. Since this could not fully offset the earnings impact of the decline in sales of the Display Materials business, EBITDA pre exceptionals decreased by – 2.3% to € 1,106 million. Yet the EBITDA margin pre exceptionals remained at the high level of 2015.

EBITDA pre exceptionals of Corporate and Other developed in line with our expectations. Owing to the further intensification of strategic Group initiatives, such as the new branding and projects to digitalize the Group, we expected expenses to rise significantly. With EBITDA pre exceptionals of € – 396 million in 2016, we met this forecast, which we had specified in the course of 2016 to lie between € – 370 million and € – 400 million.

Business free cash flow

In 2016, we expected business free cash flow of the Merck Group to develop positively in the high single-digit percentage range. We exceeded this forecast with business free cash flow increasing by 20.0%. The key drivers of this were the unexpectedly high growth of EBITDA pre exceptionals of our Healthcare business sector as well as, to a smaller extent, the positive development of inventories in Performance Materials. As expected, due to the Sigma-Aldrich acquisition the Life Science business sector made a high double-digit percentage contribution to the development of business free cash flow.

	Actual results 2015 in € million	**Forecast for 2016 in the Annual Report for 2015**
Merck Group		
		Slight organic growth
Net sales	12,845	Portfolio effect in the low double-digit percentage range
EBITDA pre exceptionals	3,630	Low double-digit percentage increase taking into account the Sigma-Aldrich portfolio effect
Business free cash flow	2,766	High single-digit percentage increase
Healthcare		
		Slight organic growth
Net sales	6,934	Slightly negative portfolio effect due to the divestment of Kuvan®
EBITDA pre exceptionals	2,002	Low double-digit percentage decline taking into consideration commercialization costs, especially for avelumab (excluding market launch costs: decline in the high single-digit to mid-teens percentage range) Negative portfolio effect in the medium double-digit million range due to the divestment of Kuvan®
Business free cash flow	1,581	Low double-digit percentage decline
Life Science		
		Moderate organic growth
Net sales	3,355	High double-digit percentage portfolio effect due to the acquisition of Sigma-Aldrich
EBITDA pre exceptionals	856	Moderate increase due to organic sales growth Additional high double-digit percentage portfolio effect due to the acquisition of Sigma-Aldrich
Business free cash flow	676	High double-digit percentage increase
Performance Materials		
Net sales	2,556	Slight organic growth
EBITDA pre exceptionals	1,132	Slight increase, yet at least at the 2015 level
Business free cash flow	931	Moderate increase
Corporate and Other		
EBITDA pre exceptionals	–360	Significant increase
Business free cash flow	–421	–

Forecast for 2016 in:			
Q1/2016 Interim Report	Q2/2016 Interim Report	Q3/2016 Interim Report	**Results 2016 in € million**
€ 14.8 – € 15.0 billion	€ 14.9 – € 15.1 billion	€ 14.9 – € 15.1 billion	15,024 (+17.0%: +3.2% Organic +16.4% Portfolio –2.6% Currency)
€ 4.1 – € 4.3 billion	€ 4.25 – € 4.4 billion	€ 4.45 – € 4.6 billion	4,490 (+23.7%)
€ 3.1 – € 3.3 billion	€ 3.14 – € 3.25 billion	€ 3.25 – € 3.36 billion	3,318 (+20.0%)
Slight organic growth, slightly negative portfolio effect due to the divestment of Kuvan®	Solid organic growth, slightly negative portfolio effect due to the divestment of Kuvan®	Solid organic growth, slightly negative portfolio effect due to the divestment of Kuvan®	6,855 (–1.1%: +4.6% Organic –1.1% Portfolio –4.6% Currency)
€ 1.8 – 1.9 billion	€ 1.95 – 2.05 billion	€ 2.1 – 2.2 billion	2,128 (+6.3%)
€ 1.4 – 1.5 billion	€ 1.49 – 1.59 billion	€ 1.59 – 1.67 billion	1,648 (+4.2%)
Organic growth in the mid-single-digit percentage range, high double-digit portfolio effect due to the acquisition of Sigma-Aldrich	Organic growth in the mid to high single-digit percentage range, portfolio effect in the high double-digit percentage range due to the acquisition of Sigma-Aldrich	Organic growth in the mid to high single-digit percentage range, portfolio effect in the high double-digit percentage range due to the acquisition of Sigma-Aldrich	5,658 (+68.6%: +6.3% Organic +63.1% Portfolio –0.8% Currency)
€ 1.62 – 1.67 billion	€ 1.62 – 1.67 billion	€ 1.64 – 1.67 billion	1,652 (+93.0%)
€ 1.22 – 1.27 billion	€ 1.18 – 1.23 billion	€ 1.18 – 1.23 billion	1,144 (+69.3%)
Organic stable	Moderate decline	Moderate decline	2,511 (–1.8%: –4.7% Organic +2.7% Portfolio +0.2% Currency)
€ 1.1 – 1.15 billion	€ 1.1 – 1.15 billion	€ 1.1 – 1.15 billion	1,106 (–2.3%)
€ 0.95 – 1.0 billion	€ 0.93 – 0.98 billion	€ 0.93 – 0.98 billion	1,011 (+8.6%)
€ –370 – –400 million	€ –370 – –400 million	€ –370 – –400 million	–396 (+10.0%)
€ –460 – –490 million	€ –460 – –490 million	€ –460 – –490 million	–485 (+15.1%)

Course of Business and Economic Position

Merck Group

Overview of 2016

- Group net sales increase by 17.0% to € 15 billion
- Healthcare and Life Science deliver organic sales growth
- EBITDA pre exceptionals up 23.7% to around € 4.5 billion
- Group profitability (EBITDA margin pre exceptionals) rises to 29.9% (2015: 28.3%)
- Improvement in earnings per share before exceptionals by 27.5% to € 6.21
- Business free cash flow increases 20.0% to € 3.3 billion

MERCK GROUP

Key figures

			Change	
€ million	**2016**	2015	€ million	in %
Net sales	15,024	12,845	2,179	17.0%
Operating result (EBIT)	2,481	1,843	637	34.6%
Margin (% of net sales)	16.5%	14.3%		
EBITDA	4,415	3,354	1,061	31.6%
Margin (% of net sales)	29.4%	26.1%		
EBITDA pre exceptionals	4,490	3,630	861	23.7%
Margin (% of net sales)	29.9%	28.3%		
Profit after tax	1,633	1,124	509	45.3%
Earnings per share (€)	3.75	2.56	1.19	46.5%
Earnings per share pre exceptionals (€)	6.21	4.87	1.34	27.5%
Business free cash flow	3,318	2,766	552	20.0%

Development of net sales and results of operations

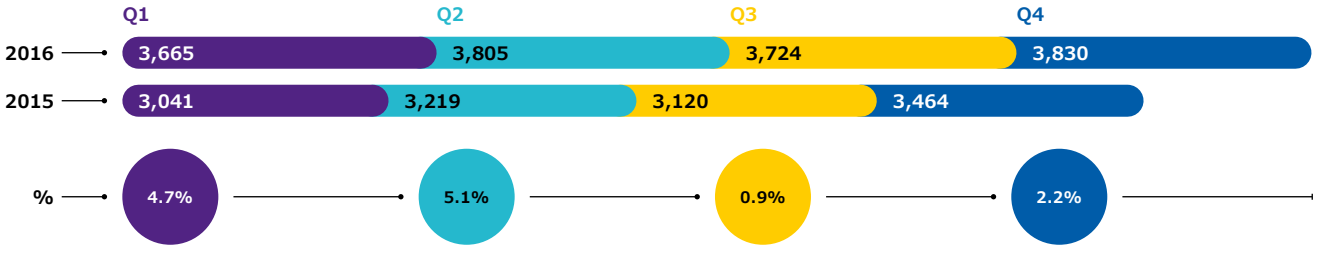
In 2016, the Merck Group generated net sales of € 15,024 million (2015: € 12,845 million), achieving sales growth of € 2,179 million or 17.0%. This double-digit increase was driven both by very significant portfolio changes and moderate organic growth. Group sales grew organically to € 408 million or 3.2% and were generated by the Healthcare and Life Science business sectors. Portfolio changes increased net sales by € 2,109 million or 16.4%. This was mainly attributable to the acquisition of Sigma-Aldrich, which closed on November 18, 2015 (see Note [4] "Acquisitions, assets held for sale and disposal groups" in the Notes to the Consolidated Financial Statements). Negative exchange rate effects lowered net sales by € – 339 million or – 2.6%. These effects were primarily due to the development of Latin American currencies. The decline in the value of the British pound also had a slightly adverse effect on sales.

The development of net sales in the individual quarters as well as the respective organic growth rates in 2016 are presented in the following overview:

MERCK GROUP

Net sales and organic growth by quarter[1]

€ million / organic growth in %



[1] Quarterly breakdown unaudited.

The double-digit growth rate of Group sales was attributable to the positive contribution of our Life Science business sector, which increased its sales overall by 68.6% to € 5,658 million (2015: € 3,355 million). This was driven both by the acquisition of Sigma-Aldrich (+63.1%) and the sharp organic increase in sales (+6.3%). Consequently, the share of Group sales attributable to Life Science in 2016 rose significantly by 12 percentage points to 38% (2015: 26%). With a 45% share (2015: 54%) of Group sales, Healthcare remained our strongest business sector in terms of sales. The Healthcare business sector delivered organic growth of 4.6%, which however was more than canceled out by negative exchange rate effects and the absence of Kuvan® sales (see Note [4] "Acquisitions, assets held for sale and disposal groups" in the Notes to the Consolidated Financial Statements). Overall, Healthcare sales declined slightly to € 6,855 million (2015: € 6,934 million). Net sales by the Performance Materials business sector decreased slightly to € 2,511 million (2015: € 2,556 million). The business sector thus generated 17% (2015: 20%) of Group sales.

MERCK GROUP

Net sales by business sector – 2016

€ million / % of net sales

MERCK GROUP

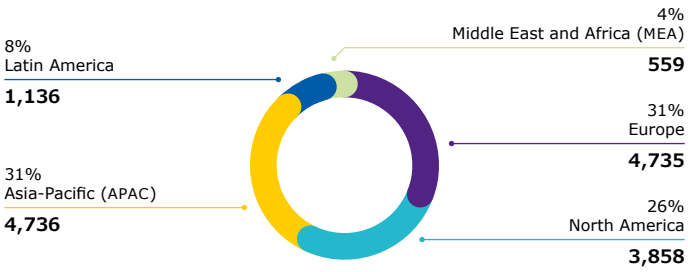
Net sales components by business sector – 2016

€ million / change in %	Net sales	Organic growth	Exchange rate effects	Acquisitions / divestments	Total change
Healthcare	6,855	4.6%	–4.6%	–1.1%	–1.1%
Life Science	5,658	6.3%	–0.8%	63.1%	68.6%
Performance Materials	2,511	–4.7%	0.2%	2.7%	–1.8%
Merck Group	**15,024**	**3.2%**	**–2.6%**	**16.4%**	**17.0%**

MERCK GROUP

Net sales by region – 2016

€ million/% of net sales



Driven by strong acquisition-related increases from the consolidation of Sigma-Aldrich and supported by slight organic growth, the strong year-earlier level of net sales in the Asia-Pacific region rose by 11.7% or € 495 million to € 4,736 million (2015: € 4,241 million). This positive sales development was fueled by the Healthcare and Life Science business sectors, which achieved high acquisition-related sales increases and very strong organic growth. Consequently, these two business sectors could almost compensate for the weaker Display Materials business of Performance Materials in this region. The contribution to Group sales by the Asia-Pacific region fell by two percentage points to 31% (2015: 33%).

Sales generated in Europe grew by 15.4% or € 632 million to € 4,735 million (2015: € 4,103 million). This was due to sales increases primarily in the Life Science business sector, which generated double-digit organic growth and high acquisition-related sales. In 2016, Europe contributed 31% to Group sales (2015: 32%).

With net sales of € 3,858 million (2015: € 2,723 million), North America generated the strongest sales increases in both absolute (+ € 1,135 million) and percentage (+ 41.7%) terms in 2016. In addition to the effect of the Sigma-Aldrich acquisition (+ 35.5%), this positive sales development was driven by the organic growth of the Healthcare business sector. The contribution to Group sales by North America in 2016 was 26%, representing an increase of five percentage points (2015: 21%).

In Latin America, Group sales decreased owing to exchange rate effects to € 1,136 million (2015: € 1,265 million). All business sectors contributed to organic sales growth of 8.9% in this region. The share of sales attributable to Latin America declined by two percentage points to 8% (2015: 10%).

Net sales in the Middle East and Africa region rose by 8.9% in 2016, amounting to € 559 million (2015: € 513 million). Organic sales growth of 5.7%, to which all business sectors contributed, was supported by acquisition-related effects (+ 5.4%). This region accounted for an unchanged 4% of Group sales.

MERCK GROUP

Net sales components by region – 2016

€ million/change in %	Net sales	Organic growth	Exchange rate effects	Acquisitions/ divestments	Total change
Europe	4,735	1.7%	–1.4%	15.1%	15.4%
North America	3,858	5.3%	0.9%	35.5%	41.7%
Asia-Pacific (APAC)	4,736	1.2%	0.1%	10.4%	11.7%
Latin America	1,136	8.9%	–23.4%	4.2%	–10.2%
Middle East and Africa (MEA)	559	5.7%	–2.1%	5.4%	8.9%
Merck Group	**15,024**	**3.2%**	**–2.6%**	**16.4%**	**17.0%**

The consolidated income statement of the Merck Group is as follows:

MERCK GROUP

Consolidated Income Statement

					Change	
€ million	**2016**	**in %**	2015	in %	€ million	in %
Net sales	**15,024**	**100.0%**	**12,845**	**100.0%**	**2,179**	**17.0%**
Cost of sales	–5,201	–34.6%	–4,076	–31.7%	–1,125	27.6%
(of which: amortization of intangible assets)[1]	*(–181)*		*(–167)*		*(–15)*	*(8.8%)*
Gross profit	**9,823**	**65.4%**	**8,768**	**68.3%**	**1,054**	**12.0%**
Marketing and selling expenses	–4,526	–30.1%	–4,050	–31.5%	–477	11.8%
(of which: amortization of intangible assets)[1]	*(–1,032)*		*(–779)*		*(–253)*	*(32.5%)*
Administration expenses	–854	–5.7%	–720	–5.6%	–134	18.7%
Research and development costs	–1,976	–13.2%	–1,709	–13.3%	–266	15.6%
(of which: amortization of intangible assets)[1]	*(–4)*		*(–3)*		*(–2)*	*(58.6%)*
Other operating expenses and income	14	0.1%	–447	–3.5%	461	>100.0%
Operating result (EBIT)	**2,481**	**16.5%**	**1,843**	**14.3%**	**637**	**34.6%**
Financial result	–326	–2.2%	–357	–2.8%	30	–8.5%
Profit before income tax	**2,154**	**14.3%**	**1,487**	**11.6%**	**668**	**44.9%**
Income tax	–521	–3.5%	–368	–2.9%	–153	41.7%
Profit after tax from continuing operations	**1,633**	**10.9%**	**1,118**	**8.7%**	**514**	**46.0%**
Profit after tax from discontinued operations	**–**	**–**	**6**	**–**	**–6**	**>100.0%**
Profit after tax	**1,633**	**10.9%**	**1,124**	**8.8%**	**509**	**45.3%**
Non-controlling interests	–4	–0.0%	–9	–0.1%	5	–55.0%
Net income	**1,629**	**10.8%**	**1,115**	**8.7%**	**514**	**46.1%**

[1] Excluding amortization of internally generated or separately acquired software.

Gross profit of the Merck Group rose by 12.0% to € 9,823 million in 2016 (2015: € 8,768 million). This double-digit rate of increase was mainly driven by the Life Science business sector, which benefited from positive business performance and the acquisition of Sigma-Aldrich. The gross margin of the Group, i.e. gross profit as a percentage of sales, declined to 65.4% (2015: 68.3%).

The increase in marketing and selling expenses as well as administration expenses was primarily due to the consolidation of Sigma-Aldrich. Owing to the termination of the co-promotion agreement with Pfizer for Rebif® in the United States at the end of 2015, marketing and selling expenses for the Healthcare business sector declined. Nevertheless, Group marketing and selling expenses increased overall due to the acquisition effects in Life Science.

In 2016, Group research and development costs increased by 15.6% to € 1,976 million. This was due mainly to the research activities in the Healthcare business sector and to the acquisition of Sigma-Aldrich. Accounting for 76% of Group R&D spending (2015: 77%), Healthcare is our most research-intensive business sector. At 13.2%, the Group research spending ratio (research and development costs as a percentage of sales) remained at the previous year's level (2015: 13.3%).

MERCK GROUP

Research and development costs by business sector – 2016

€ million / in %

In 2016, other operating expenses and income (net) showed an income balance of € 14 million; in 2015, an expense balance of € –447 million was reported. This positive development was driven in particular by the gain on the sale of the rights to Kuvan® (€ 330 million) and the divestment of a minority shareholding (€ 30 million) in the Healthcare business sector. Detailed information about the development and composition of other operating expenses and income can be found in Note [11] "Other operating income" and Note [12] "Other operating expenses" in the Notes to the Consolidated Financial Statements.

The operating result (EBIT) of the Merck Group soared by € 637 million or 34.6% year-on-year to € 2,481 million.

In 2016, the negative financial result improved by € 30 million to € –326 million, mainly owing to lower exchange rate losses and a decrease in currency hedging expenses from Group-internal transactions. At € –270 million, the interest result contained in the financial result was on par with the previous year (2015: € –271 million) (see Note [13] "Financial result" in the Notes to the Consolidated Financial Statements).

Income tax expenses of € 521 million (2015: € 368 million) led to an effective tax rate of 24.2% (2015: 24.8%). More information about income taxes can be found in Note [14] "Income taxes" in the Notes to the Consolidated Financial Statements.

Profit after tax of discontinued operations reported in 2015 comprises the business activities of Sigma-Aldrich acquired with a view to resale (see also Note [4] "Acquisitions, assets held for sale and disposal groups" in the Notes to the Consolidated Financial Statements). Net income, i.e. profit after tax attributable to Merck KGaA shareholders, for 2016 was € 1,629 million (2015: € 1,115 million), resulting in earnings per share of € 3.75 (2015: € 2.56).

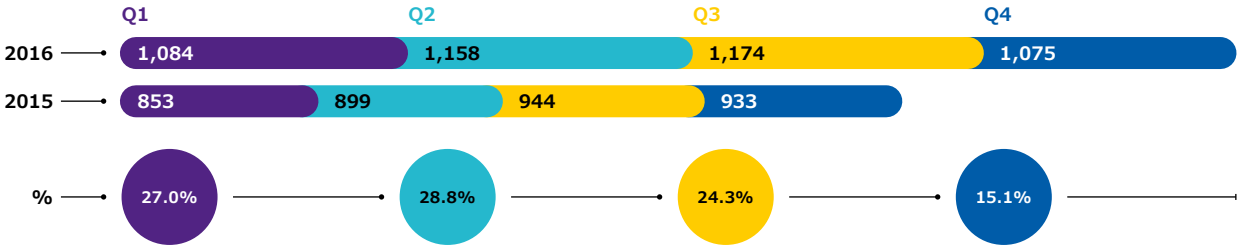
EBITDA pre exceptionals, the key financial indicator used to steer operating business, grew by € 861 million or 23.7% to € 4,490 million (2015: € 3,630 million). The resulting EBITDA margin pre exceptionals thus increased by nearly two percentage points to 29.9% (2015: 28.3%). The reconciliation of the operating result (EBIT) to EBITDA pre exceptionals is presented in the chapter entitled "Internal Management System".

The development of EBITDA pre exceptionals in the individual quarters in comparison with 2015 as well as the respective growth rates are presented in the following overview:

MERCK GROUP

EBITDA pre exceptionals and change by quarter[1]

€ million / change in %



[1] Quarterly breakdown unaudited.

The increase in Group EBITDA pre exceptionals was driven especially by the Life Science business sector, which in 2016 generated an increase of € 796 million or 93.0% to € 1,652 million (2015: € 856 million). Consequently, the share of Group EBITDA pre exceptionals accounted for by Life Science (excluding the € – 396 million decline due to Corporate and Other) rose significantly to 34% (2015: 22%). Yet EBITDA pre exceptionals of the Healthcare business sector also rose by 6.3% to € 2,128 million (2015: € 2,002 million). In 2016, Healthcare generated a 43% share of this Group key indicator, thus remaining Merck's most profitable business sector in absolute terms. EBITDA pre exceptionals of the Performance Materials business sector decreased slightly to € 1,106 million and did not fully reach the high year-earlier level (2015: € 1,132 million). The percentage contribution of Performance Materials to Group EBITDA pre exceptionals declined in 2016 to 23% (2015: 28%).

MERCK GROUP

EBITDA pre exceptionals by business sector – 2016

€ million / in %

Not presented: Decline in Group EBITDA pre exceptionals by € – 396 million due to Corporate and Other.

Net assets and financial position

MERCK GROUP

Balance sheet structure

	Dec. 31, 2016		Dec. 31, 2015[1]		Change	
	€ million	**in %**	€ million	in %	€ million	in %
Non-current assets	**30,582**	**79.9%**	**30,737**	**80.7%**	**–155**	**–0.5%**
of which:						
Intangible assets	24,989		25,422		–433	
Property, plant and equipment	4,230		4,008		222	
Other non-current assets	1,363		1,308		55	
Current assets	**7,670**	**20.1%**	**7,344**	**19.3%**	**325**	**4.4%**
of which:						
Inventories	2,607		2,610		–3	
Trade accounts receivable	2,889		2,738		151	
Current financial assets	145		227		–82	
Other current assets	1,089		937		152	
Cash and cash equivalents	939		832		107	
Total assets	**38,251**	**100.0%**	**38,081**	**100.0%**	**170**	**0.4%**
Equity	**14,050**	**36.7%**	**12,855**	**33.8%**	**1,195**	**9.3%**
Non-current liabilities	**15,115**	**39.5%**	**15,842**	**41.6%**	**–727**	**–4.6%**
of which:						
Provisions for pensions and other post-employment benefits	2,313		1,836		477	
Other non-current provisions	834		855		–22	
Non-current financial liabilities	8,809		9,616		–807	
Other non-current liabilities	3,159		3,535		–376	
Current liabilities	**9,086**	**23.8%**	**9,384**	**24.6%**	**–298**	**–3.2%**
of which:						
Current provisions	412		536		–124	
Current financial liabilities	3,788		4,097		–309	
Trade accounts payable	2,048		1,921		127	
Other current liabilities	2,838		2,830		8	
Total liabilities and equity	**38,251**	**100.0%**	**38,081**	**100.0%**	**170**	**0.4%**

[1] Previous year's figures have been adjusted, see "Acquisitions, assets held for sale and disposal groups" in the Notes to the Consolidated Financial Statements.

The total assets of the Merck Group amounted to € 38,251 million as of December 31, 2016. This represents an increase of € 170 million or 0.4% over December 31, 2015 (€ 38,081 million).

Despite the expansion of the operating businesses, at € 3,486 million working capital remained at the level of 2015.

MERCK GROUP

Working capital

			Change	
€ million	**Dec. 31, 2016**	Dec. 31, 2015[1]	€ million	in %
Trade accounts receivable	2,889	2,738	151	5.5%
Receivables from royalties and licenses	38	11	26	>100.0%
Inventories	2,607	2,610	–3	–0.1%
Trade accounts payable	–2,048	–1,921	–127	6.6%
Working capital	**3,486**	**3,438**	**47**	**1.4%**

[1] Previous year's figures have been adjusted, see "Acquisitions, assets held for sale and disposal groups" in the Notes to the Consolidated Financial Statements.

Net financial debt, which rose sharply in 2015 owing to the acquisition of Sigma-Aldrich, was lowered in 2016 by € 1,141 million to € 11,513 million (December 31, 2015: € 12,654 million). The composition and the development of net financial debt were as follows:

MERCK GROUP

Net financial debt

			Change	
€ million	**Dec. 31, 2016**	Dec. 31, 2015	€ million	in %
Bonds and commercial paper	9,650	9,851	–201	–2.0%
Bank loans	1,978	3,006	–1,028	–34.2%
Liabilities to related parties	758	578	180	31.1%
Loans from third parties and other financial liabilities	80	89	–10	–10.9%
Liabilities from derivatives (financial transactions)	128	184	–55	–30.2%
Finance lease liabilities	4	5	–1	–25.0%
Financial liabilities	**12,597**	**13,713**	**–1,116**	**–8.0%**
less				
Cash and cash equivalents	939	832	107	12.8%
Current financial assets	145	227	–82	–36.0%
Net financial debt	**11,513**	**12,654**	**–1,141**	**–9.0%**

MERCK GROUP

Reconciliation of net financial debt

€ million	2016	2015
January 1	**12,654**	**559**
Currency translation difference	118	–737
Dividend payments to shareholders and to E. Merck[1]	600	568
Acquisitions[1]	156	13,482
Assumption of financial liabilities from Sigma-Aldrich	–	425
Payment from the disposal of assets held for sale and from other divestments[1]	–366	–86
Free cash flow	–1,693	–1,539
Other	44	–19
December 31	**11,513**	**12,654**

[1] According to the consolidated cash flow statement.

The strong increase in pension provisions to € 2,313 million (December 31, 2015: € 1,836 million) was mainly attributable to the required reduction in the discount rate when calculating the present value of the defined benefit obligations. The resulting actuarial losses were recognized in the Consolidated Statement of Comprehensive Income and, taking into account deferred taxes, lowered the equity of the Merck Group as of December 31, 2016. In addition, dividend payments and the profit transfer to E. Merck KG caused equity to decline. These equity-lowering effects were more than offset by the profit after tax amounting to € 1,633 million and the development of currency translation differences from the translation of assets held in foreign currencies into euro, the reporting currency. Consequently, equity increased in 2016 by € 1,195 million to € 14,050 million (December 31, 2015: € 12,855 million) (see "Consolidated Statement of Comprehensive Income" and "Consolidated Statement of Changes in Net Equity" in the Consolidated Financial Statements). Thanks to the sharp increase in equity, the equity ratio rose by nearly three percentage points, amounting to 36.7% as of December 31, 2016 (December 31, 2015: 33.8%).

Driven by the positive development of net cash flows from operating activities, free cash flow rose by 10.0% over 2015 to € 1,693 million, despite strong investment activity. The composition as well as the development of the relevant items are presented in the following table:

MERCK GROUP

Free cash flow

			Change	
€ million	**2016**	2015	€ million	in %
Cash flow from operating activities according to the cash flow statement	2,518	2,195	323	14.7%
Payments for investments in intangible assets	–132	–179	47	–26.3%
Payments from the disposal of intangible assets	2	27	–26	–93.4%
Payments for investments in property, plant and equipment	–716	–514	–202	39.3%
Payments from the disposal of property, plant and equipment	21	9	12	>100.0%
Free cash flow	**1,693**	**1,539**	**155**	**10.0%**

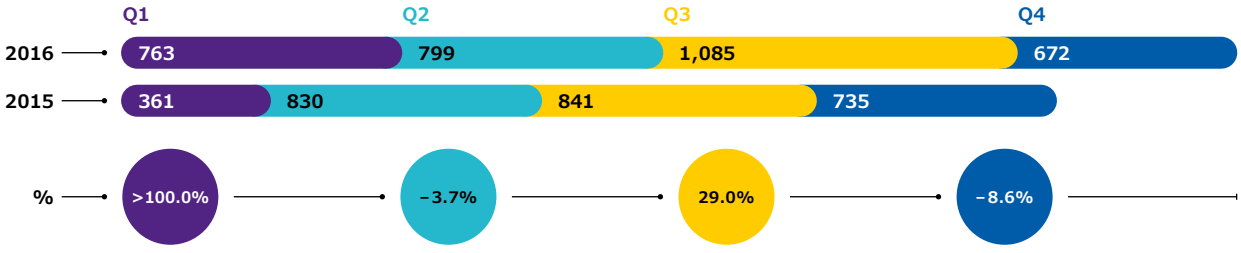
Business free cash flow of the Merck Group rose in 2016 by 20.0% to € 3,318 million (2015: € 2,766 million). This was mainly driven by the positive development of EBITDA pre exceptionals. The composition of this financial indicator is presented in the Group management report under "Internal Management System".

The distribution of business free cash flow across the individual quarters and the percentage changes in comparison with 2015 were as follows:

MERCK GROUP

Business free cash flow and change by quarter[1]

€ million / change in %



[1] Quarterly breakdown unaudited.

MERCK GROUP

Business free cash flow by business sector – 2016

€ million / in %

Not presented: Decline in Group business free cash flow by € –485 million due to Corporate and Other.

All the business sectors contributed to the increase in Group business free cash flow in 2016. Healthcare generated business free cash flow of € 1,648 million (2015: € 1,581 million). Consequently, with a 43% share (2015: 50%) of Group business free cash flow (excluding the decline of € –485 million due to Corporate and Other) Healthcare was once again the business sector with the highest cash flows. In 2016, the Life Science business sector achieved a 69.3% increase in business free cash flow to € 1,144 million (2015: € 676 million), thus also increasing its share of Group business free cash flow to 30% (2015: 21%). Performance Materials contributed € 1,011 million (2015: € 931 million) to this Group financial indicator, equivalent to 27% (2015: 29%).

The investments in property, plant, equipment and software included in the calculation of business free cash flow as well as advance payments for intangible assets increased in 2016 by 41.1% to a total of € 859 million (2015: € 609 million). The investments in property, plant and equipment included therein amounted to € 722 million in 2016 (2015: € 564 million), € 332 million of which was attributable to strategic investment projects each with a project volume of more than € 2 million; the remainder was attributable to smaller capital spending projects.

In 2016, strategic investments of € 110 million were made to expand the Darmstadt site. Of this amount, € 39 million was used to upgrade global headquarters; the projects include an Innovation Center, a Visitor Center and an employee cafeteria, among other things. Moreover, OLED production capacity in the Performance Materials business sector was expanded with an investment of € 14 million in order to meet growing market demand. In the Healthcare business sector, investments included € 21 million in a new laboratory building for pharmaceutical research and € 10 million in a new packaging center.

Globally, the Healthcare business sector made significant strategic investments in a production facility in Nantong, China (€ 39 million), a new packaging plant at the Aubonne site in Switzerland (€ 16 million), an expansion of the existing filling plant at the Bari site in Italy (€ 11 million), and a new production unit for the Allergopharma business in Reinbek, Germany (€ 10 million).

In 2016, the outlooks for our long-term credit ratings were upgraded by the two rating agencies Moody's and Standard & Poor's. Merck currently has a rating of "A" with a stable outlook (2015: "A" with a negative outlook) from Standard & Poor's and a "Baa1" rating with a stable outlook (2015: "Baa1" with a negative

outlook) from Moody's. In 2016, the rating agency Scope began covering our credit rating and issued Merck an "A-" rating with a stable outlook. An overview of the development of our rating in recent years is presented in the Report on Risks and Opportunities.

The development of key balance sheet figures is as follows:

MERCK GROUP

Key balance sheet figures

in %		Dec. 31, 2016	Dec. 31, 2015[1]	Dec. 31, 2014	Dec. 31, 2013	Dec. 31, 2012
Equity ratio	Equity / Total assets	36.7%	33.8%	45.4%	53.2%	48.1%
Asset ratio	Non-current assets / Total assets	79.9%	80.7%	59.7%	64.5%	69.4%
Asset coverage	Equity / Non-current assets	45.9%	41.8%	76.0%	82.4%	69.4%
Finance structure	Current liabilities / Liabilities (total)	37.5%	37.2%	46.5%	40.0%	40.6%

[1] Previous year's figures have been adjusted, see "Acquisitions, assets held for sale and disposal groups" in the Notes to the Consolidated Financial Statements.

Overall assessment of business performance and economic situation

For Merck, 2016 was another very successful year. The very good performance of operating business confirms our strategy. Despite growing global uncertainties, we reached or exceeded the objectives we had set for 2016. Group net sales showed profitable growth, reaching a new record level of € 15,024 million (2015: € 12,845 million). This was the outcome of both the company's own strengths and acquisitions. EBITDA pre exceptionals rose by 23.7% to € 4,490 million (2015: € 3,630 million), growing even more strongly than net sales, which increased in 2016 by 17.0%. Thanks to internal financing strength, we succeeded in lowering net financial debt from the Sigma-Aldrich acquisition by € 1,141 million.

Our three business sectors made significant progress in 2016. Healthcare advanced its pharmaceutical pipeline and achieved important milestones towards the market launch of new medicines. In 2016, Life Science generated a strong organic sales increase of 6.3%, thus growing faster than the market. The business sector was very successful in realizing the synergies from the Sigma-Aldrich integration in 2016. We made better progress than originally expected both in leveraging cost synergies and in realizing sales synergies. The Performance Materials business sector again demonstrated its sound earnings resilience in 2016. Future-oriented investments further boosted the innovative strength of this business sector. Among other things, an OLED materials production unit was commissioned in Darmstadt in 2016. In addition, Performance Materials sustainably secured its market leadership in Display Materials.

Our solid accounting and finance policy is reflected by the very good key balance sheet figures. The equity ratio, which improved to 36.7% as of December 31, 2016, is at a very good level. The rapid reduction of net financial debt, which rose massively in 2015 owing to the acquisition of Sigma-Aldrich, remains a key priority. This is also reflected by the improved assessments of the two rating agencies Standard & Poor's ("A" with a stable outlook; 2015: "A" with a negative outlook) and Moody's ("Baa1" with a stable outlook; 2015: "Baa1" with a negative outlook). In 2016, the rating agency Scope began covering the Group's credit rating and issued Merck an "A-" rating with a stable outlook.

Against the backdrop of the solid net assets and financial position as well as the earnings strength of the businesses, we assess the economic position of the Merck Group very positively. The excellent condition Merck is in offers a superb foundation for the achievement of further sustainable and profitable growth.

Healthcare

HEALTHCARE

Key figures

€ million	2016	2015	Change € million	Change in %
Net sales	6,855	6,934	–79	–1.1%
Operating result (EBIT)	1,593	1,097	497	45.3%
Margin (% of net sales)[1]	23.2%	15.8%		
EBITDA	2,425	1,970	454	23.0%
Margin (% of net sales)[1]	35.4%	28.4%		
EBITDA pre exceptionals	2,128	2,002	126	6.3%
Margin (% of net sales)[1]	31.0%	28.9%		
Business free cash flow	1,648	1,581	67	4.2%

Development of net sales and results of operations

In 2016, the Healthcare business sector generated organic sales growth of 4.6%. Negative exchange rate effects of –4.6% and a negative portfolio effect of –1.1% led to an overall decline in net sales of –1.1% to € 6,855 million (2015: € 6,934 million). Nearly all the franchises contributed to the business sector's organic growth. In particular, products to treat infertility (Gonal-f®), thyroid disorders (Euthyrox®), growth disorders (Saizen®), and the strategic core brand Neurobion® from the Consumer Health business performed well in 2016. Erbitux®, the business sector's second-largest product in terms of sales, also generated slight organic sales growth. Only Rebif®, the top-selling drug within Healthcare, sustained a slight organic decline. The negative exchange rate effects were mainly due to the development of Latin American currencies. However, the decline in the value of the British pound against the euro also contributed slightly to the exchange rate effects. The negative portfolio effect was attributable to the return of the rights to Kuvan® to BioMarin Pharmaceutical, Inc., USA, at the beginning of 2016.

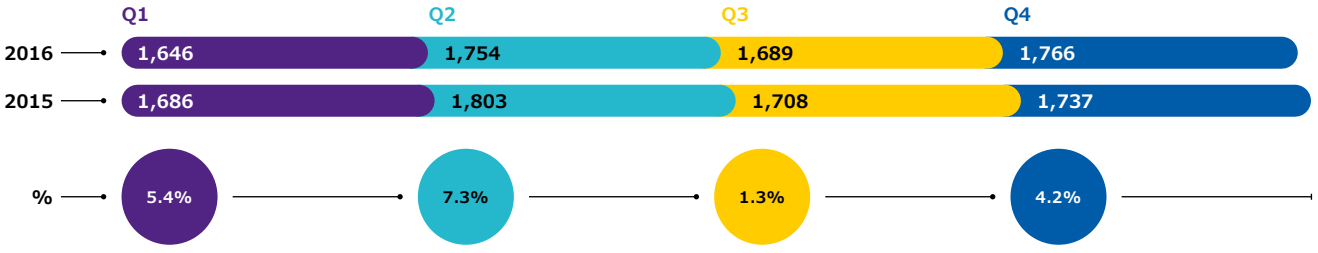
Commission income, which is also included in net sales, rose to € 178 million in 2016 (2015: € 103 million). The increase was driven in particular by profit-sharing from the co-commercialization of Xalkori® with Pfizer, Inc., USA. The agreement reached with Bristol-Myers Squibb Company, USA, in 2013 on the co-promotion of Glucophage® in China continued to have a positive effect on commission income.

The development of sales in the individual quarters as well as the respective organic growth rates in 2016 are presented in the following overview:

HEALTHCARE

Net sales and organic growth by quarter[1]

€ million/organic growth in %

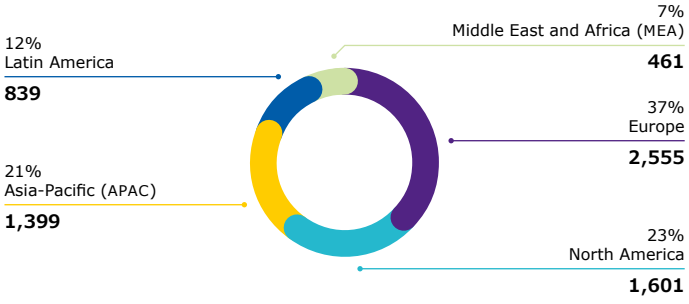


[1] Quarterly breakdown unaudited.

HEALTHCARE

Net sales by region – 2016

€ million/% of net sales of the business sector



Europe, which remained the Healthcare business sector's largest region accounting for 37% of net sales (2015: 39%), registered an organic sales decline of –2.5%. Consequently, net sales totaled € 2,555 million (2015: € 2,729 million). The organic decline was driven in particular by the continued difficult competitive situation for both Rebif® and Erbitux®. Furthermore, negative exchange rate effects of –1.6% and a portfolio effect of –2.3% resulted in an overall decline in net sales of –6.4%.

In North America, the second-largest region in terms of sales, organic growth of 11.1% led to net sales of € 1,601 million (2015: € 1,430 million). This development was mainly driven by the double-digit organic growth of Gonal-f®, a hormone used in the treatment of infertility, due to the favorable competitive situation that we benefited from throughout 2016. Organic and currency-related sales growth of Rebif® as well as organic sales growth of Saizen® continued to have a positive effect on the performance of sales in this region. North America's contribution to net sales of the Healthcare business sector thus increased to 23% (2015: 21%).

In the Asia-Pacific region, organic sales growth of 9.4% was recorded in 2016. This development was mainly attributable to higher sales of Gonal-f® and Euthyrox®, higher commission income from the co-promotion of Glucophage® with Bristol-Myers Squibb in China, as well as the growth of the Consumer Health business. In 2016, this region's share of the business sector's net sales further increased to 21% (2015: 19%).

Sales in Latin America amounted to € 839 million in 2016 and were thus below the previous year's level (2015: € 1,022 million). Positive organic growth of 7.7% could not offset the negative foreign exchange impact of –25.5%. Organic growth was generated by all franchises, in particular with Rebif®, Erbitux® and Euthyrox®, as well as in the Consumer Health business with the strategic brand Neurobion®. Overall, Asia-Pacific's contribution to the net sales of the Healthcare business sector declined to 12% (2015: 15%).

In 2016, the Middle East and Africa region achieved organic sales growth of 5.5%, with net sales totaling € 461 million (2015: € 450 million). Double-digit organic growth in particular with Rebif®, Erbitux®, Concor®, and Euthyrox® compensated for the organic decline in sales of Glucophage® and negative exchange rate effects of –1.8%.

HEALTHCARE

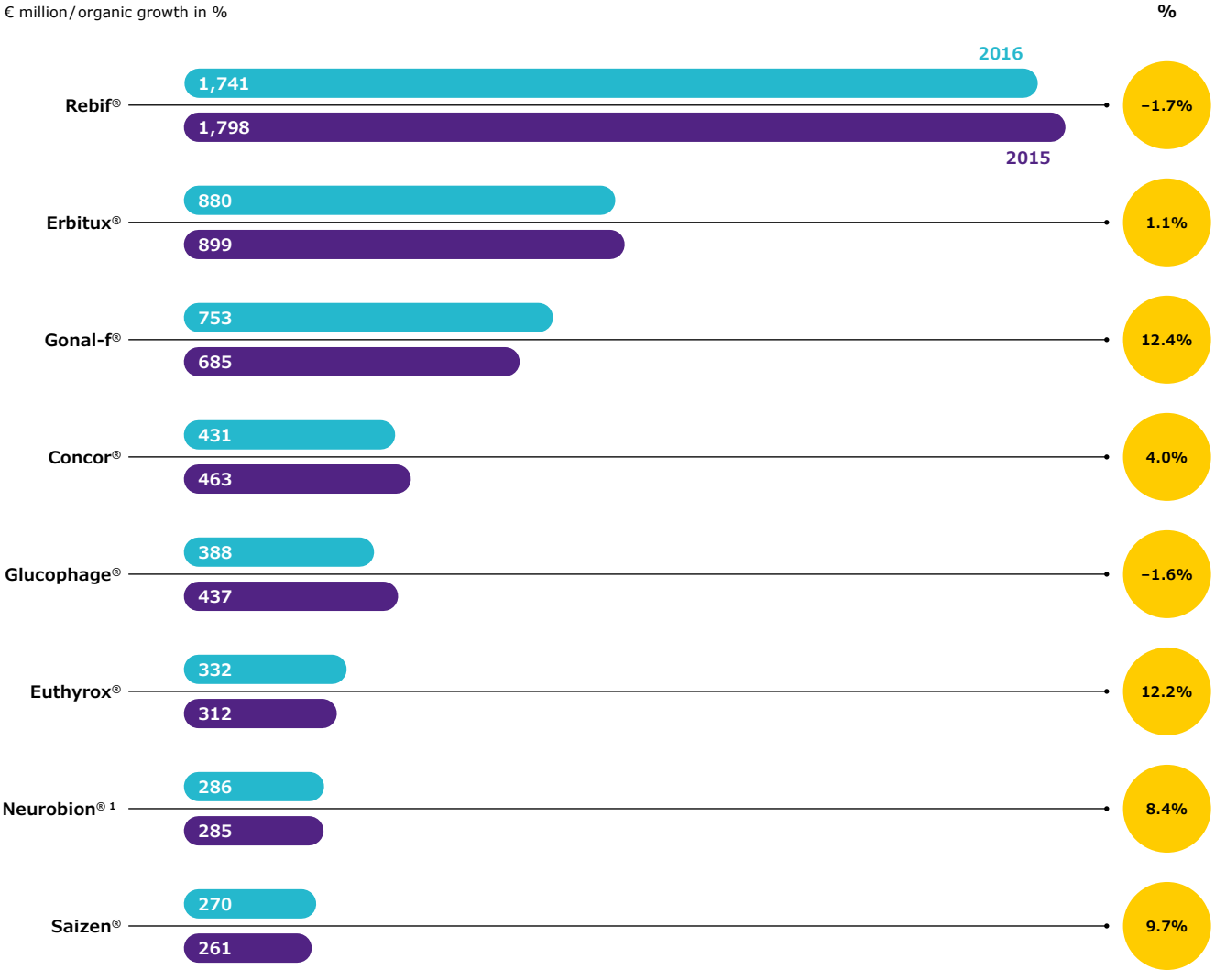
Net sales components by region – 2016

€ million/change in %	Net sales	Organic growth	Exchange rate effects	Acquisitions/ divestments	Total change
Europe	2,555	–2.5%	–1.6%	–2.3%	–6.4%
North America	1,601	11.1%	0.8%	–	11.9%
Asia-Pacific (APAC)	1,399	9.4%	–1.2%	–0.8%	7.4%
Latin America	839	7.7%	–25.5%	–0.1%	–17.9%
Middle East and Africa (MEA)	461	5.5%	–1.8%	–1.2%	2.4%
Healthcare	**6,855**	**4.6%**	**–4.6%**	**–1.1%**	**–1.1%**

Net sales and organic growth rates of the key products developed in 2016 as follows:

HEALTHCARE

Product sales and organic growth



[1] Previous year's figure has been adjusted.

Sales of the drug Rebif®, which is used to treat relapsing forms of multiple sclerosis, only sustained a slight organic sales decline of –1.7% in 2016 despite continued competitive pressure from oral formulations. Including negative exchange rate effects of –1.5%, sales totaled € 1,741 million (2015: € 1,798 million).

The North America region, which generated 61% of Rebif® sales (2015: 58%) and is the largest market for this product, delivered organic growth of 2.1%. This was primarily due to favorable price developments in the United States in 2016, which slightly offset the decline in volumes.

In Europe, which accounts for 30% of sales (2015: 34%) and is the Healthcare business sector's second largest region, sales saw a significant organic decline of –12.2% to € 524 million (2015: € 605 million). This development was due in particular to the difficult competitive situation and the associated decline in volumes.

Together, the remaining regions Latin America, Middle East and Africa, and Asia-Pacific generated € 145 million (2015: € 151 million) in Rebif® sales, equivalent to a 9% share (2015: 8%).

In 2016, sales of the oncology drug Erbitux® totaled € 880 million (2015: € 899 million). Organic growth of 1.1% was fully canceled out by negative foreign exchange effects of – 3.2%.

In Europe, which accounted for 54% of Erbitux® sales (2015: 55%) and is thus the top-selling region for this product, sales decreased organically by – 3.4%. The organic decline was mainly attributable to the challenging competitive situation as well as mandatory price reductions in several countries. Including negative foreign exchange effects of –1.9%, sales in Europe declined to € 470 million (2015: € 496 million).

In the Asia-Pacific region, which accounted for a 32% (2015: 29%) share of net sales, Erbitux® sales increased to € 280 million (2015: 265 million). Here, both organic growth of 2.8% and currency tailwinds of 2.8% had a positive effect on the development of sales.

In Latin America, sales declined to € 73 million (2015: € 87 million) despite double-digit organic growth of 14.5%. This was due to negative foreign exchange effects of – 30.4%, which were predominantly attributable to the development of the Argentinian peso against the euro.

The Middle East and Africa region generated double-digit organic growth of 13.2%, with sales amounting to € 56 million (2015: € 50 million).

HEALTHCARE

Product sales and organic growth of Rebif® and Erbitux® by region – 2016

		Total	Europe	North America	Asia-Pacific (APAC)	Latin America	Middle East and Africa (MEA)
Rebif®	€ million	1,741	524	1,071	14	64	67
	Organic growth in %	–1.7%	–12.2%	2.1%	–11.7%	20.2%	15.3%
	% of sales	100%	30%	61%	1%	4%	4%
Erbitux®	€ million	880	470	–	280	73	56
	Organic growth in %	1.1%	– 3.4%	–	2.8%	14.5%	13.2%
	% of sales	100%	54%	–	32%	8%	6%

In 2016, the Healthcare business sector generated organic sales growth of 12.4% with Gonal-f®, the leading recombinant hormone used in the treatment of infertility. Taking negative foreign exchange effects of – 2.5% into account, sales of this product rose to € 753 million (2015: € 685 million). This development was mainly driven by organic growth of 47.7% in North America, as a consequence of the continued favorable competitive situation from which we benefited throughout 2016. Likewise, sales rose organically in the Asia-Pacific region by 9.6%, which more than offset the – 3.5% organic decline in sales in Europe. The other products in the Fertility portfolio also developed positively.

Sales by the Endocrinology franchise, which mainly consists of products to treat growth disorders, amounted to € 404 million and were thus lower than the previous year's level (2015: € 461 million). This decrease in sales was primarily due to the return of the rights to Kuvan® to BioMarin Pharmaceutical, which was reflected in the portfolio effect of –15.8% and canceled out organic growth of 6.7%. The growth hormone Saizen®, which is the top-selling product in the franchise, delivered organic growth of 9.7%, resulting in net sales of € 270 million (2015: € 261 million).

Sales by the General Medicine franchise (including CardioMetabolic Care), which commercializes products to treat cardiovascular diseases and diabetes, among other things, declined to € 1,720 million (2015: € 1,791 million[1]). Organic growth of 4.2% was canceled out by negative foreign exchange effects of –7.9%. In particular Euthyrox®, a drug to treat thyroid disorders, showed solid performance with organic growth of 12.2%. Including currency headwinds of –5.9%, this led to sales of € 332 million (2015: € 312 million), which were mainly driven by performance in the Chinese market. Product sales of Glucophage® fell owing to an organic decline of –1.6% and negative exchange rate effects of –9.4%. However, commission income for Glucophage® rose, amounting to € 106 million (2015: € 86 million), which corresponded to an organic increase of 24.3% and was also driven by performance in China. Concor® delivered organic growth of 4.0% in 2016. Currency headwinds of –10.9% were responsible for the year-on-year decline in sales to € 431 million (2015: € 463 million).

The Consumer Health business with over-the-counter pharmaceuticals posted organic sales growth of 3.4% in 2016. Owing to negative exchange rate effects, net sales declined to € 860 million (2015: € 905 million[1]). In particular, the strategic brand Neurobion® contributed to organic growth.

The results of operations developed as follows:

HEALTHCARE

Results of operations

					Change	
€ million	**2016**	**in %**	2015	in %	€ million	in %
Net sales	**6,855**	**100.0%**	**6,934**	**100.0%**	**–79**	**–1.1%**
Cost of sales	–1,377	–20.1%	–1,442	–20.8%	66	–4.6%
(of which: amortization of intangible assets)[2]	*(–1)*		*(–1)*		*(–)*	*(–1.6%)*
Gross profit	**5,478**	**79.9%**	**5,491**	**79.2%**	**–13**	**–0.2%**
Marketing and selling expenses	–2,587	–37.7%	–2,801	–40.4%	214	–7.6%
(of which: amortization of intangible assets)[2]	*(–565)*		*(–566)*		*(–)*	*(–0.1%)*
Administration expenses	–270	–3.9%	–259	–3.7%	–10	4.0%
Research and development costs	–1,496	–21.8%	–1,310	–18.9%	–186	14.2%
(of which: amortization of intangible assets)[2]	*(–1)*		*(–1)*		*(–)*	*(1.4%)*
Other operating expenses and income	468	6.8%	–24	–0.3%	492	>100.0%
Operating result (EBIT)	**1,593**	**23.2%**	**1,097**	**15.8%**	**497**	**45.3%**
Depreciation/amortization/impairment losses/ reversals of impairment losses	831	12.1%	874	12.6%	–42	–4.9%
(of which: exceptionals)	*(71)*		*(90)*		*(–19)*	*(–21.0%)*
EBITDA	**2,425**	**35.4%**	**1,970**	**28.4%**	**454**	**23.0%**
Restructuring costs	12		30		–18	–59.7%
Integration costs/IT costs	18		1		17	>100.0%
Gains/losses on the divestment of businesses	–330		–		–330	–
Acquisition-related exceptionals	–		–		–	–
Other exceptionals	3		–		3	–
EBITDA pre exceptionals	**2,128**	**31.0%**	**2,002**	**28.9%**	**126**	**6.3%**

[2] Excluding amortization of internally generated or separately acquired software.

In 2016, the gross profit of the Healthcare business sector amounted to € 5,478 million (2015: € 5,491 million), thus remaining stable at the previous year's level despite the slight decline in sales. The resulting gross margin increased slightly to 79.9% (2015: 79.2%).

Marketing and selling expenses decreased to € 2,587 million (2015: € 2,801 million), which was primarily due to the termination of the co-promotion agreement with Pfizer for Rebif® in the United States at the end of 2015.

[1] The previous year's figures have been adjusted due to product transfers from Biopharma to Consumer Health in India and Latin America as of January 1, 2016.

The ratio of research and development spending to net sales rose to 21.8% (2015: 18.9%), reflecting higher R&D costs of € 1,496 million in 2016 (2015: € 1,310 million). The increase was due to projects in clinical development, in particular in immuno-oncology among other things as part of the avelumab program. In addition, work on early-stage projects was intensified. The release of provisions for the follow-on costs of discontinued R&D projects had a positive effect. In 2016, provisions amounting to € 57 million were released. These were originally set up in connection with the termination of clinical development projects in previous years, for example evofosfamide.

The changes in other operating income and expenses mainly reflect items eliminated in the calculation of EBITDA pre exceptionals. Other operating expenses and income included, among other things, the impairment loss on the co-commercialization right for Xalkori® (€ 71 million) as well as the gain from returning the rights to Kuvan® to BioMarin Pharmaceutical (€ 330 million) and the divestment of a minority shareholding (€ 30 million). In addition, royalty and license income for Avonex® and Plegridy® (both Biogen Inc.) reported under other operating income rose by € 47 million in comparison with 2015 owing to a patent granted at the end of June 2016 in the United States.

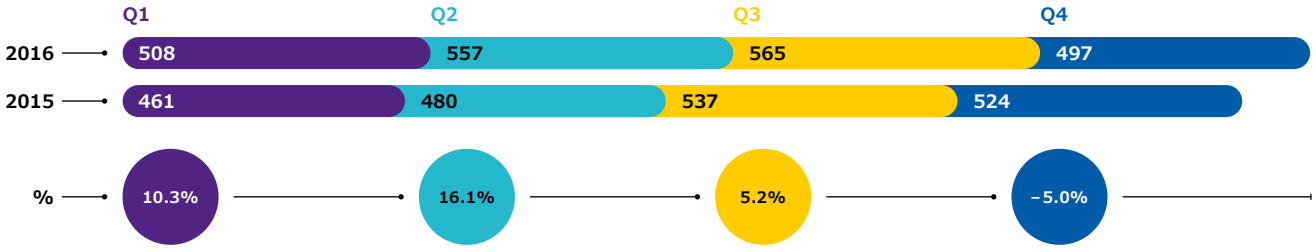
Overall, Healthcare generated an increase in EBITDA pre exceptionals to € 2,128 million (2015: € 2,002 million). The resulting EBITDA margin pre exceptionals was 31.0% (2015: 28.9%).

The development of EBITDA pre exceptionals in the individual quarters in comparison with 2015 is presented in the following overview:

HEALTHCARE

EBITDA pre exceptionals and change by quarter[1]

€ million/change in %



[1] Quarterly breakdown unaudited.

Development of business free cash flow

In 2016, business free cash flow of the Healthcare business sector amounted to € 1,648 million (2015: € 1,581 million). The increase in this key figure was primarily due to the rise in EBITDA pre exceptionals. Higher capital spending, driven in particular by investments at the Darmstadt site, reduced business free cash flow.

HEALTHCARE

Business free cash flow

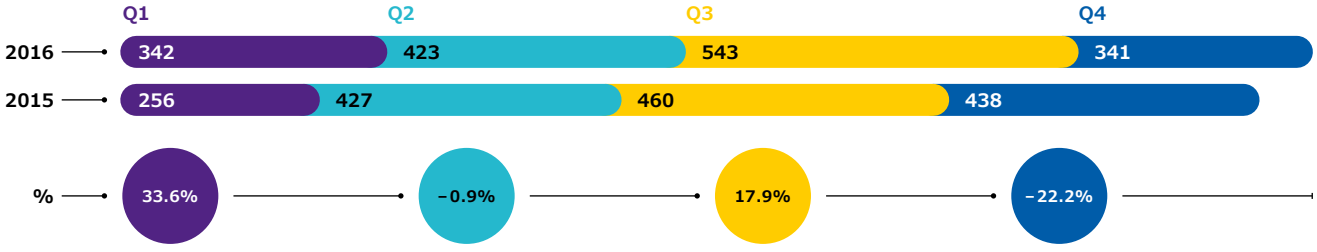
			Change	
€ million	**2016**	2015	€ million	in %
EBITDA pre exceptionals	2,128	2,002	126	6.3%
Investments in property, plant and equipment, software as well as advance payments for intangible assets	–348	–289	–59	20.4%
Changes in inventories	–38	–27	–11	40.5%
Changes in trade accounts receivable as well as receivables from royalties and licenses	–94	–105	11	–10.2%
Business free cash flow	**1,648**	**1,581**	**67**	**4.2%**

The development of business free cash flow in the individual quarters in comparison with 2015 is presented in the following overview:

HEALTHCARE

Business free cash flow and change by quarter[1]

€ million / change in %



[1] Quarterly breakdown unaudited.

Life Science

LIFE SCIENCE

Key figures

€ million	2016	2015	Change € million	Change in %
Net sales	5,658	3,355	2,303	68.6%
Operating result (EBIT)	556	301	256	85.0%
Margin (% of net sales)	9.8%	9.0%		
EBITDA	1,378	674	704	>100.0%
Margin (% of net sales)	24.4%	20.1%		
EBITDA pre exceptionals	1,652	856	796	93.0%
Margin (% of net sales)	29.2%	25.5%		
Business free cash flow	1,144	676	468	69.3%

Development of sales and results of operations

In 2016, Life Science posted organic sales growth of 6.3%. In addition to organic growth, sales increased by 63.1% or € 2,119 million due to the acquisition of Sigma-Aldrich whereas foreign exchange had a slightly negative impact of –0.8% or € –28 million. Taking these effects into account, Life Science net sales increased overall by 68.6% to € 5,658 million in 2016 (2015: € 3,355 million).

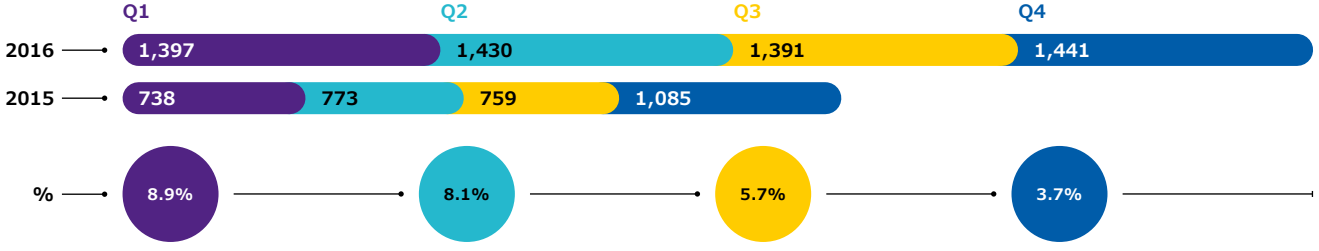
All three business areas contributed favorably to the organic growth of the Life Science business sector in 2016. In particular, the Process Solutions business area generated double-digit organic sales growth of 10.5%, thanks to high demand across the portfolio. Applied Solutions continued to perform well, posting organic growth of 4.3%. Research Solutions generated an organic increase of 1.2%.

The development of sales in the individual quarters are presented in the following overview:

LIFE SCIENCE

Net sales and organic growth by quarter[1]

€ million/organic growth in %

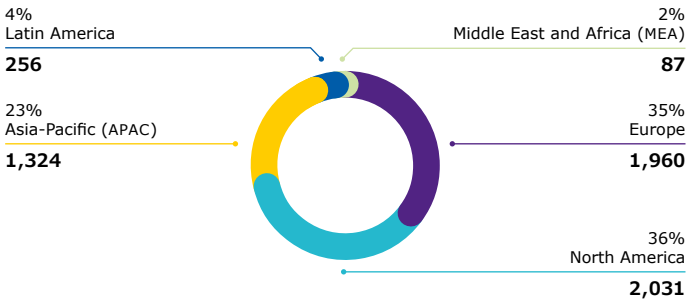


[1] Quarterly breakdown unaudited.

LIFE SCIENCE

Net sales by region – 2016

€ million/% of net sales of the business sector



From a geographic perspective, all regions – with the exception of North America – contributed positively to the organic sales growth of Life Science.

In Europe, sales increased organically by 11.0%, with the Process Solutions and Research Solutions business areas generating double-digit organic growth of 16.9% and 10.4%, respectively, while Applied Solutions posted moderate organic growth of 3.2%. Overall, sales in Europe increased to € 1,960 million (2015: € 1,168 million), which in addition to organic growth included a sales increase of € 677 million due to the Sigma-Aldrich acquisition, corresponding to an overall contribution of 35% (2015: 35%) of Life Science net sales in 2016.

North America was the Life Science business sector's largest geographic market, accounting for 36% (2015: 33%) of net sales. The organic sales decline of –1.3% in North America was primarily attributable to Research Solutions and soft market demand in the region. By contrast, Applied Solutions and Process Solutions contributed positively to organic growth. Overall, sales in North America rose to € 2,031 million (2015: € 1,098 million), which in addition to organic growth includes an acquisition-related increase of € 936 million due to Sigma-Aldrich as well as a slightly positive exchange rate effect.

Within Asia-Pacific, sales grew organically by 8.1%, with all businesses contributing favorably. Growth was primarily driven by Process Solutions. Overall, sales in Asia-Pacific rose to € 1,324 million (2015: € 831 million), which in addition to organic growth includes an acquisition-related sales increase of € 420 million due to the acquisition of Sigma-Aldrich, representing an overall contribution of 23% (2015: 25%) to Life Science net sales in 2016.

In Latin America, Life Science reported double-digit organic growth of 12.7%, primarily driven by the Applied Solutions business area. In addition to organic growth, the acquisition-related sales contribution by Sigma-Aldrich increased sales by € 55 million to € 256 million (2015: € 203 million). Currency headwinds of –13.9% lowered sales growth. Latin America accounted for 4% (2015: 6%) of Life Science net sales in 2016.

The Middle East and Africa (MEA) region posted strong organic sales growth of 6.9%. Net sales for the region grew to € 87 million (2015: € 55 million) and included a sales increase of € 31 million due to the acquisition of Sigma-Aldrich.

LIFE SCIENCE

Net sales components by region – 2016

€ million/change in %	Net sales	Organic growth	Exchange rate effects	Acquisitions/ divestments	Total change
Europe	1,960	11.0%	–1.2%	58.0%	67.8%
North America	2,031	–1.3%	1.0%	85.2%	84.9%
Asia-Pacific (APAC)	1,324	8.1%	0.7%	50.5%	59.3%
Latin America	256	12.7%	–13.9%	26.9%	25.7%
Middle East and Africa (MEA)	87	6.9%	–4.5%	57.4%	59.8%
Life Science	**5,658**	**6.3%**	**–0.8%**	**63.1%**	**68.6%**

The Process Solutions business area, which markets products and services for the pharmaceutical production value chain, generated organic sales growth of 10.5%. Including the acquisition-related sales increase (€ 505 million), net sales amounted to € 2,146 million (2015: € 1,492 million). The share of sales generated by Process Solutions represented 38% (2015: 45%) of Life Science net sales. All Process Solutions businesses contributed to this strong performance.

The Research Solutions business area, which provides products and services to support life science research for pharmaceutical, biotechnology and academic research laboratories, posted slight organic growth of 1.2% in 2016. Research Solutions suffered weak demand in the Biology business and faced a difficult market environment in North America. However, including Sigma-Aldrich acquisition-related sales (€ 1,239 million), sales increased to € 2,055 million (2015: € 814 million) representing 36% (2015: 24%) of Life Science sales.

The Applied Solutions business area generated organic sales growth of 4.3% with its broad range of products for researchers and scientific laboratories. Taking the Sigma-Aldrich acquisition-related sales into account (€ 374 million), net sales amounted to € 1,457 million (2015: € 1,050 million). The sales performance of Applied Solutions was primarily driven by the Analytical and Biomonitoring portfolios.

LIFE SCIENCE

Net sales components by business area[1] – 2016

€ million/change in %	Net sales	Organic growth	Exchange rate effects	Acquisitions/ divestments	Total change
Process Solutions	2,146	10.5%	–0.5%	33.9%	43.8%
Research Solutions	2,055	1.2%	–1.0%	152.3%	152.6%
Applied Solutions	1,457	4.3%	–1.1%	35.6%	38.8%

[1]The business areas were restructured in the context of the Sigma-Aldrich acquisition.

The results of operations developed as follows:

LIFE SCIENCE

Results of operations

					Change	
€ million	**2016**	**in %**	2015	in %	€ million	in %
Net sales	**5,658**	**100.0%**	**3,355**	**100.0%**	**2,303**	**68.6%**
Cost of sales	–2,679	–47.4%	–1,483	–44.2%	–1,197	80.7%
(of which: amortization of intangible assets)[1]	*(–63)*		*(–51)*		*(–12)*	*(23.6%)*
Gross profit	**2,978**	**52.6%**	**1,872**	**55.8%**	**1,106**	**59.1%**
Marketing and selling expenses	–1,706	–30.1%	–1,038	–31.0%	–667	64.2%
(of which: amortization of intangible assets)[1]	*(–453)*		*(–197)*		*(–256)*	*(>100.0%)*
Administration expenses	–248	–4.4%	–151	–4.5%	–96	63.8%
Research and development costs	–260	–4.6%	–197	–5.9%	–62	31.5%
(of which: amortization of intangible assets)[1]	*(–1)*		*(–1)*		*(–)*	*(1.0%)*
Other operating expenses and income	–209	–3.7%	–185	–5.5%	–24	13.3%
Operating result (EBIT)	**556**	**9.8%**	**301**	**9.0%**	**256**	**85.0%**
Depreciation/amortization/impairment losses/ reversals of impairment losses	822	14.5%	373	11.1%	448	>100.0%
(of which: exceptionals)	*(27)*		*(1)*		*(26)*	*(>100.0%)*
EBITDA	**1,378**	**24.4%**	**674**	**20.1%**	**704**	**>100.0%**
Restructuring costs	1		7		–6	–83.5%
Integration costs/IT costs	122		43		79	>100.0%
Gains/losses on the divestment of businesses	–		–		–	–
Acquisition-related exceptionals	150		132		18	14.0%
Other exceptionals	–		–		–	–
EBITDA pre exceptionals	**1,652**	**29.2%**	**856**	**25.5%**	**796**	**93.0%**

[1]Excluding amortization of internally generated or separately acquired software.

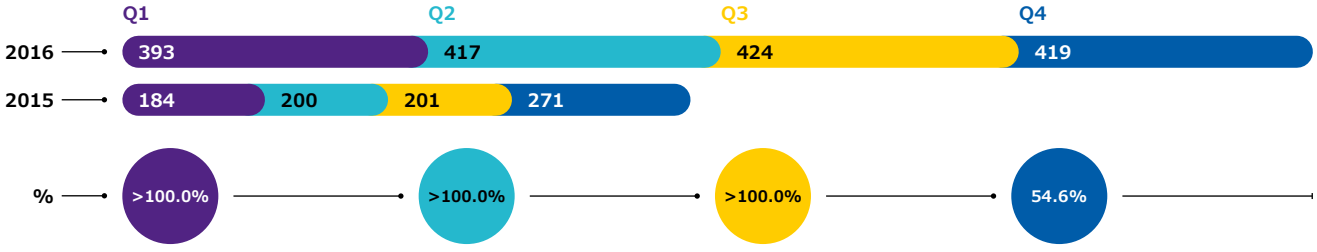
Throughout 2016, the primary focus for the Life Science business sector was the integration of Sigma-Aldrich. Gross profit rose by 59.1% to € 2,978 million (2015: € 1,872 million). This tremendous increase was mainly attributable to strong organic sales growth and the acquisition of Sigma-Aldrich. The increases in marketing and selling expenses, administration expenses and R&D costs in 2016 were mainly due to the consolidation of Sigma-Aldrich. As Life Science continues to integrate Sigma-Aldrich, spending is being closely monitored and there is a strong focus on the execution of synergy initiatives. In comparison with 2015, the operating result (EBIT) of Life Science rose by € 256 million to € 556 million. After eliminating depreciation and amortization, and adjusting for exceptionals, the key financial indicator EBITDA pre exceptionals rose by 93.0% to € 1,652 million (2015: € 856 million). This reflects the strong performance of both legacy life science businesses of Merck and Sigma-Aldrich.

The development of EBITDA pre exceptionals in the individual quarters in comparison with 2015 is presented in the following overview:

LIFE SCIENCE

EBITDA pre exceptionals and change by quarter[1]

€ million / change in %



[1] Quarterly breakdown unaudited.

Development of business free cash flow

In 2016, the business free cash flow of the Life Science business sector amounted to € 1,144 million, which was 69.3% more than in 2015. This very strong increase was primarily due to the positive development of EBITDA pre exceptionals and was partially offset by higher capital spending.

LIFE SCIENCE

Business free cash flow

			Change	
€ million	**2016**	2015[1]	€ million	in %
EBITDA pre exceptionals	1,652	856	796	93.0%
Investments in property, plant and equipment, software as well as advance payments for intangible assets	–313	–150	–163	>100.0%
Changes in inventories	5	–840	845	>100.0%
Changes in trade accounts receivable as well as receivables from royalties and licenses	–64	–375	311	–82.8%
Adjustments first-time consolidation of Sigma-Aldrich	–146	1,185	–1,331	>100.0%
Adjustments first-time consolidation of BioControl Systems	10	–	10	>100.0%
Business free cash flow	**1,144**	**676**	**468**	**69.3%**

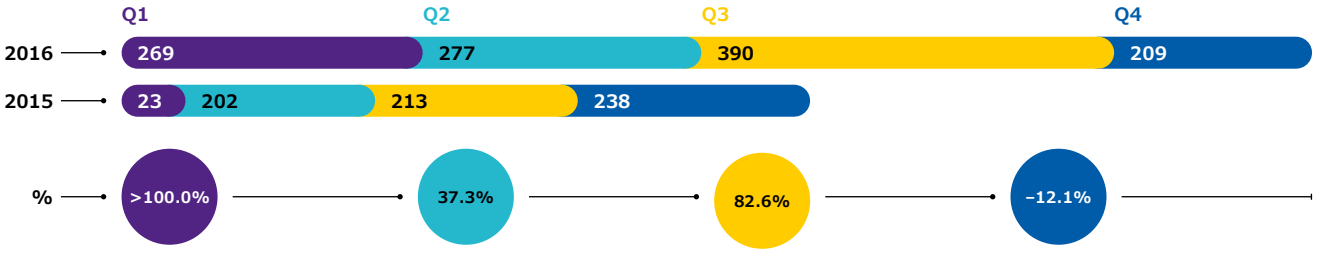
[1] Previous year's figures have been adjusted, see "Acquisitions, assets held for sale and disposal groups" in the Notes to the Consolidated Financial Statements.

The development of business free cash flow in the individual quarters in comparison with 2015 is presented in the following overview:

LIFE SCIENCE

Business free cash flow and change by quarter[1]

€ million/change in %



[1] Quarterly breakdown unaudited.

Performance Materials

PERFORMANCE MATERIALS

Key figures

€ million	**2016**	2015	Change € million	Change in %
Net sales	2,511	2,556	–45	–1.8%
Operating result (EBIT)	823	878	–55	–6.3%
Margin (% of net sales)	32.8%	34.4%		
EBITDA	1,077	1,120	–43	–3.9%
Margin (% of net sales)	42.9%	43.8%		
EBITDA pre exceptionals	1,106	1,132	–26	–2.3%
Margin (% of net sales)	44.1%	44.3%		
Business free cash flow	1,011	931	80	8.6%

Development of net sales and results of operations

In 2016, net sales of the Performance Materials business sector decreased by –1.8% to € 2,511 million (2015: € 2,556 million). This was mainly due to organic declines in sales (–4.7%) as Display Materials did not reach the level of 2015. The acquisition-related growth from the SAFC Hitech business of Sigma-Aldrich acquired in November 2015 (2.7%) only partially offset the organic decline in sales. Exchange rate effects of 0.2% had only a slight influence on sales in 2016.

The Display Materials business unit, consisting of the Liquid Crystals business and complementary materials, represented more than 50% of the overall net sales of Performance Materials. This business unit saw a significant organic decrease in sales, but continued to defend its market leadership position. The sales decline in 2016 is based on a strong preceding year with consistently high demand for display materials. Despite signs of a recovery, demand remained at a lower level in 2016, among other things as a result of destocking by display industry customers. An exception was the energy-saving UB-FFS technology, which generated double-digit growth along with record sales in the fourth quarter.

The Integrated Circuit Materials (ICM) business unit generated strong organic sales growth, to which all businesses contributed. Particularly high growth rates were generated in the businesses with dielectric materials and deposition materials for chip production. In addition, sales of materials for chemical-mechanical planarization (CMP) of silicon wafers developed well.

The Pigments & Functional Materials business unit generated solid organic growth in 2016. Xirallic® pigments, which are used particularly in automotive coatings, as well as cosmetic actives and technical functional materials contributed significantly to the sales increase.

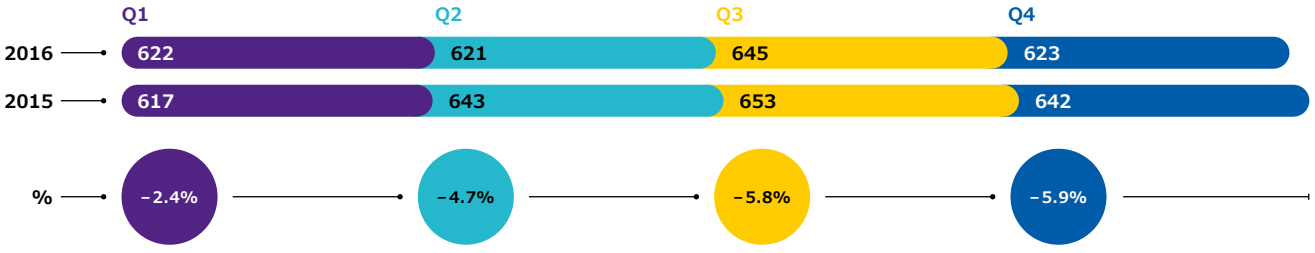
Growth in the Advanced Technologies business unit was fueled by double-digit sales increases in OLED materials.

The development of sales in the individual quarters as well as the respective organic growth rates in 2016 are presented in the following overview:

PERFORMANCE MATERIALS

Net sales and organic growth by quarter[1]

€ million/organic growth in %

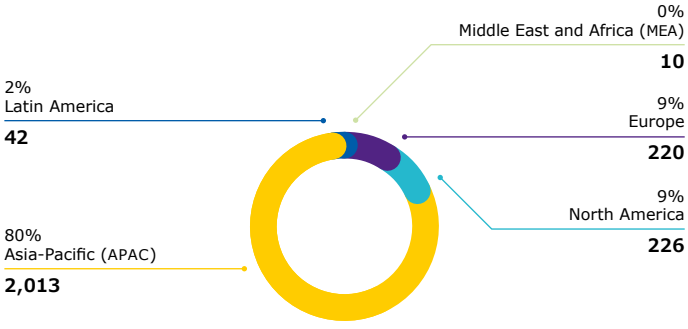


[1] Quarterly breakdown unaudited.

PERFORMANCE MATERIALS

Net sales by region – 2016

€ million/% of net sales of the business sector



With an 80% share (2015: 82%), the Asia-Pacific region once again accounted for the vast majority of the business sector's net sales. This is due to the concentration of customers for display and integrated circuit materials in Asia. In this region, sales declined to € 2,013 million (2015: € 2,107 million). Organically, sales decreased by –6.6% owing to the performance of the Display Materials business unit. The increases in sales of IC and OLED materials and of Pigments & Functional Materials could not compensate for this.

In North America, the double-digit increase in sales to € 226 million was fueled by the SAFC Hitech business of Sigma-Aldrich (2015: € 194 million). Organically, sales reached the previous year's level. The slight growth in Pigments & Functional Materials was canceled out by declines in the other business units.

In Europe, Performance Materials generated sales of € 220 million (2015: € 206 million). The organic sales increase of 5.2% was generated by functional materials and Xirallic® pigments in the Pigments & Functional Materials business unit as well as by process materials in the IC Materials business unit.

Since they account for a low proportion of sales, the two regions Latin America and Middle East and Africa (MEA) played a subordinate role. Whereas Latin America continued to show double-digit organic growth at a low overall level, the sales improvement in the Middle East and Africa region was primarily acquisition-related.

PERFORMANCE MATERIALS

Net sales components by region – 2016

€ million/change in %	Net sales	Organic growth	Exchange rate effects	Acquisitions/ divestments	Total change
Europe	220	5.2%	–0.4%	2.0%	6.9%
North America	226	–0.3%	0.9%	15.7%	16.3%
Asia-Pacific (APAC)	2,013	–6.6%	0.6%	1.6%	–4.5%
Latin America	42	21.0%	–16.8%	–	4.3%
Middle East and Africa (MEA)	10	8.0%	–2.6%	23.5%	28.8%
Performance Materials	**2,511**	**–4.7%**	**0.2%**	**2.7%**	**–1.8%**

The results of operations developed as follows:

PERFORMANCE MATERIALS

Results of operations

					Change	
€ million	**2016**	**in %**	2015	in %	€ million	in %
Net sales	**2,511**	**100.0%**	**2,556**	**100.0%**	**–45**	**–1.8%**
Cost of sales	–1,145	–45.6%	–1,151	–45.1%	7	–0.6%
(of which: amortization of intangible assets)[1]	*(–118)*		*(–115)*		*(–3)*	*(2.4%)*
Gross profit	**1,366**	**54.4%**	**1,404**	**54.9%**	**–38**	**–2.7%**
Marketing and selling expenses	–233	–9.3%	–208	–8.1%	–25	12.0%
(of which: amortization of intangible assets)[1]	*(–13)*		*(–16)*		*(3)*	*(–16.2%)*
Administration expenses	–61	–2.4%	–63	–2.5%	3	–4.1%
Research and development costs	–213	–8.5%	–197	–7.7%	–16	8.0%
(of which: amortization of intangible assets)[1]	*(–2)*		*(–1)*		*(–2)*	*(>100.0%)*
Other operating expenses and income	–37	–1.5%	–58	–2.3%	21	–36.3%
Operating result (EBIT)	**823**	**32.8%**	**878**	**34.4%**	**–55**	**–6.3%**
Depreciation/amortization/impairment losses/ reversals of impairment losses	254	10.1%	242	9.5%	12	4.8%
(of which: exceptionals)	*(16)*		*(–)*		*(16)*	*(>100.0%)*
EBITDA	**1,077**	**42.9%**	**1,120**	**43.8%**	**–43**	**–3.9%**
Restructuring costs	1		2		–1	–70.7%
Integration costs/IT costs	26		15		11	73.0%
Gains/losses on the divestment of businesses	–		–6		6	>100.0%
Acquisition-related exceptionals	3		1		2	>100.0%
Other exceptionals	–		–		–	–
EBITDA pre exceptionals	**1,106**	**44.1%**	**1,132**	**44.3%**	**–26**	**–2.3%**

[1] Excluding amortization of internally generated or separately acquired software.

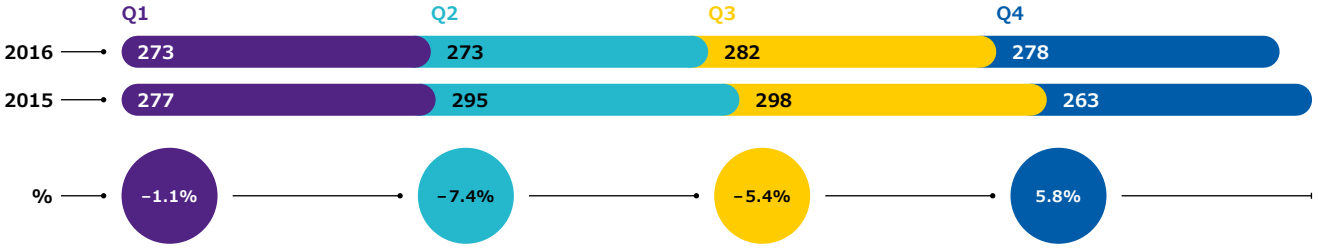
In 2016, gross profit was € 38 million below the previous year's level, leading to a gross margin of 54.4% (2015: 54.9%). The operating result (EBIT) decreased by € 55 million to € 823 million in 2016 (2015: € 878 million). Apart from the sales-related decline in gross profit, the main reasons for the decrease were higher marketing and selling expenses as well as additional research costs attributable to the SAFC Hitech business from the Sigma-Aldrich acquisition. EBITDA pre exceptionals amounted to € 1,106 million, which was € 26 million lower than in the previous year (2015: € 1,132 million). Yet the EBITDA margin pre exceptionals of 44.1% almost reached the good year-earlier level (2015: 44.3%).

The development of EBITDA pre exceptionals in the individual quarters in comparison with 2015 is presented in the following overview:

PERFORMANCE MATERIALS

EBITDA pre exceptionals and change by quarter[1]

€ million/change in %



[1] Quarterly breakdown unaudited.

Development of business free cash flow

In 2016, the business free cash flow of the Performance Materials business sector increased to € 1,011 million (2015: € 931 million). This improvement was mainly attributable to significant inventory reductions, which more than offset the decline in EBITDA pre exceptionals.

PERFORMANCE MATERIALS

Business free cash flow

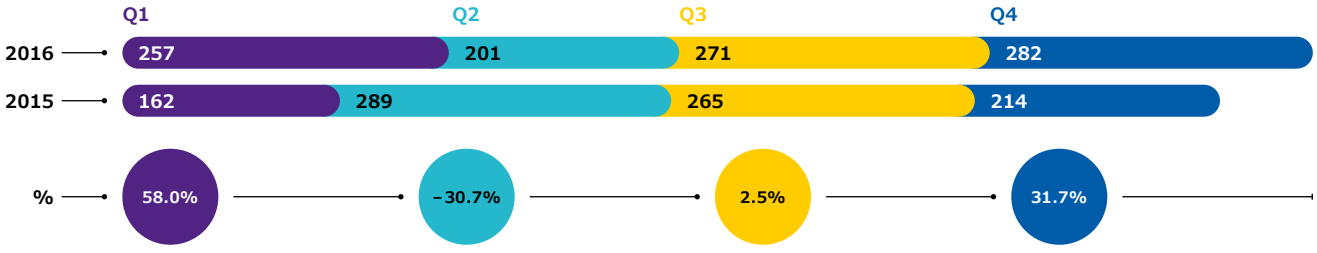
			Change	
€ million	**2016**	2015	€ million	in %
EBITDA pre exceptionals	1,106	1,132	–26	–2.3%
Investments in property, plant and equipment, software as well as advance payments for intangible assets	–109	–109	–	–
Changes in inventories	35	–83	119	>100.0%
Changes in trade accounts receivable as well as receivables from royalties and licenses	–19	–34	15	–44.7%
Adjustments first-time consolidation of Sigma-Aldrich	–3	25	–28	>100.0%
Business free cash flow	**1,011**	**931**	**80**	**8.6%**

The development of business free cash flow in the individual quarters in comparison with 2015 is presented in the following overview:

PERFORMANCE MATERIALS

Business free cash flow and change by quarter[1]

€ million / change in %



[1] Quarterly breakdown unaudited.

Corporate and Other

Corporate and Other comprises Group administration expenses for Group functions that cannot be directly allocated to the business sectors, such as Finance, Procurement, Legal, Communications, and Human Resources. Corporate costs additionally encompass expenses for central, non-allocated IT functions, including expenses related to the expansion and harmonization of IT systems within the Merck Group.

CORPORATE AND OTHER

Key figures

			Change	
€ million	**2016**	2015	€ million	in %
Operating result (EBIT)	–492	–432	–60	13.8%
EBITDA	–465	–411	–54	13.1%
EBITDA pre exceptionals	–396	–360	–36	10.0%
Business free cash flow	–485	–421	–64	15.1%

In 2016, administration expenses reported under Corporate and Other amounted to € 276 million (2015: € 246 million). Other operating expenses (net) rose to € –207 million (2015: € –180 million), particularly as a result of higher expenses from exceptionals, for example costs of special IT projects or environmental protection measures for businesses divested in prior years. Consequently, in 2016 the operating result (EBIT) amounted to € –492 million (2015: € –432 million) and EBITDA was € –465 million (2015: € –411 million). Adjusted for exceptionals, EBITDA pre exceptionals totaled € –396 million (2015: € –360 million). The increase in negative EBITDA pre exceptionals and higher capital spending had a significant impact on the development of business free cash flow, which amounted to € –485 million in 2016 (2015: € –421 million).

Report on Risks and Opportunities

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

Risk and opportunity management

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

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

Risk management process

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

Likewise, risk-mitigating measures are reported and assessed. The effectiveness of these measures and the planned implementation time frame are monitored by Group Risk Management. The residual risk after the implementation of these measures is presented in the internal risk report as net risk.

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

For reporting risks with a potential negative impact on our EBIT, a threshold is set at a value of € 5 million in the standard process and at a value of € 25 million in the ad hoc process. Risks below these thresholds are steered independently within the business sectors. The relevant timeframe for internal risk reporting is five years. The effects of risks described in this report on risks and opportunities are presented as annual values. The assessment of the risks presented relates to December 31, 2016. There were no relevant changes after the balance sheet date that would have necessitated an amended presentation of the risk situation of the Group.

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

Opportunity management process

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

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

Risk and opportunity assessment

Risks

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

The underlying scales for measuring these factors are shown below:

PROBABILITY OF OCCURRENCE

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

DEGREE OF IMPACT

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

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

RISK MATRIX

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

Opportunities

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

Internal control system for the Group accounting process

The objective of the internal control system for the accounting process is to implement controls that provide assurance that the financial statements are prepared in compliance with the relevant accounting laws and standards. This system covers measures designed to ensure the complete, correct and timely conveyance and presentation of information that is relevant for the preparation of the consolidated financial statements and the combined management report.

Key tools

The internal control system aims to ensure the accuracy of the consolidated accounting process through functioning internal controls with reasonable assurance. The Group Accounting function centrally steers the preparation of the consolidated financial statements of Merck KGaA as the parent company of the Merck Group. This Group function defines the reporting requirements that all Merck subsidiaries must meet. At the same time, this function steers and monitors the scheduling and process-related requirements of the consolidated financial statements. Group Accounting centrally manages all changes to the equity holding structure and correspondingly adapts the Group's scope of consolidation. The proper elimination of intragroup transactions within the scope of the consolidation process is ensured. Group-wide accounting guidelines form the basis for the preparation of the statutory financial statements of the parent company and of the subsidiaries, which are reported to Group Accounting; the guidelines are adapted in a timely manner to reflect changes in the financial regulatory environment and are updated in accordance with internal reporting requirements. For special issues, such as the accounting treatment of intangible assets within the scope of company acquisitions or pension obligations, external experts are additionally involved where necessary.

The individual companies have a local internal control system. Where financial processes are handled by a Shared Service Center, the internal control system of the Shared Service Center is additionally applied. Both ensure that accounting complies with IFRS (International Financial Reporting Standards) and with the Group accounting guidelines.

Group Accounting provides support to the local contacts and ensures a consistently high quality of reporting throughout the entire reporting process. For Group financial reporting purposes, most of our subsidiaries use standard SAP software. Consolidation software from SAP is also used for the elimination of intragroup transactions. A detailed authorization concept ensures the separation of duties with respect to both single-entity reporting and the consolidated financial statements. In principle, the accounting process is designed to ensure that all units involved adhere to the principle of dual control.

The effectiveness of Merck's internal control system with regard to accounting and the compliance of financial reporting by the individual companies is confirmed by both the local managing director and the local chief financial officer when they sign the single-entity reporting. For the accounting treatment of balance sheet items, Group Accounting closely cooperates with Group Risk Management in order to correctly present potential balance sheet risks. All the structures and processes described are subject to regular review by Group Internal Auditing based on an annual audit plan set out by the Executive Board. The results of these audits are dealt with by the Executive Board, the Supervisory Board and the Finance Committee. The internal control system at Merck makes it possible to lower the risk of material misstatements in accounting to a minimum. However, no internal control system – regardless of its design – can entirely rule out a residual risk.

Business-related risks and opportunities

Political and regulatory risks and opportunities

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

Risk of more restrictive regulatory requirements regarding drug pricing, reimbursement and approval

In the Healthcare business sector, the known trend towards increasingly restrictive requirements in terms of drug pricing, reimbursement and approval is continuing. These requirements can negatively influence the profitability of our products, also through market referencing between countries, and jeopardize the success of market launches and new approvals. Foreseeable effects are taken into account as far as possible in the business sector's plans. Close communication with health and regulatory authorities serves as a preventive measure to avert risks. Remaining risks beyond the current plans resulting from restrictive regulatory requirements are classified as a medium risk owing to the possible critical negative impact.

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

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

Risk of negative political and macroeconomic developments

The destabilization of political systems (as for example in Turkey or the Middle East), the possible establishment of trade barriers as well as foreign exchange policy changes can lead to declines in sales in certain countries and regions. These risks are taken into account as far as possible in the business plans of the affected countries and regions and mitigated through product, industry and regional diversification.

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

The United Kingdom's imminent exit from the European Union ("Brexit") gives rise to risks such as the decline in the value of the British pound, weaker economic activity in the United Kingdom, regulatory changes, and the creation of trade barriers such as import duties, which could have an impact on our profitability. To analyze these risks and to counteract them in a timely and targeted manner, an internal working group has been set up. The net risk of negative political and macroeconomic developments is seen as possible and has critical negative effects on the net assets, financial position and results of operations. We thus rate this as a medium risk.

Market risks and opportunities

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

Opportunities due to new technologies in the manufacturing of displays

We see opportunities in the medium- to long-term possibilities of significant market growth of OLED applications in high-quality display applications. We are building on more than ten years of experience in manufacturing organic light-emitting diode (OLED) materials as well as a strong portfolio of worldwide patents in order to develop ultrapure and extremely stable materials that are precisely tailored to customer requirements. The development in the OLED market is being driven by the diversification of applications for OLED displays. OLED technology is an established alternative to LCDs in small-area displays, for instance smartphones. However, owing to technological advances, OLED technology is increasingly being used in more and more large-area displays, such as televisions. High-quality lighting applications, for example for automobiles, offer further growth potential for OLEDs. In order to make the mass production of large-area OLED displays more efficient, we have been cooperating since the end of 2012 with Seiko Epson Corporation to enable printing processes for OLED displays. To support the expected market growth, we invested around € 30 million in a new OLED production unit at the Darmstadt site in order to expand our production capacities for ultra-high-purity OLED materials for applications in modern displays and lighting systems.

Moreover, within the framework of partnerships with display manufacturers, start-ups and universities, progress has been made in the realization of free-form displays. To expand our activities in the field of quantum materials, a material supply and licensing agreement for cadmium-free quantum materials was entered into with Nanoco. These eco-friendly quantum materials complement our portfolio for the display industry with products that extend the color range and further reduce the power consumption of displays.

Opportunities due to new application possibilities for liquid crystals

We are pursuing a strategy of leveraging our expertise as the global market leader in liquid crystals in order to develop new fields of application for innovative liquid crystal technologies, e.g. liquid crystal windows (LCWs) or mobile antennas. With the acquisition of our long-standing cooperation partner Peer+ B.V., we are further advancing the development of the future-oriented market for LCWs. Thanks to licrivision™ technology, LCWs create new architectural possibilities. Through continuously variable brightness control, they can for example increase a building's energy efficiency.

To drive forward the market penetration of liquid crystal windows, we are investing around € 15 million in the construction of a production facility for window modules. Production of liquid crystal window modules is scheduled to start at the end of 2017. Antennas that can receive signals transmitted in the high frequency range can also be realized with the aid of corresponding liquid crystal mixtures. As a result, mobile data exchange could improve significantly in a wide variety of fields of application. Since novel liquid crystal materials for antennas are currently being developed, the market launch of liquid crystal antennas could still take a few years. New application opportunities for liquid crystals could have medium- to long-term positive effects on the financial indicators of the Performance Materials business sector.

Opportunities from the launch of our new branding

In October 2015, we relaunched our branding and since then have been using this new visual appearance externally. Our new branding reflects our transformation into a science and technology company while at the same time ensuring that we operate uniformly as Merck worldwide, with the exception of the United States and Canada.

Through this step, we remain uniformly visible and continue to heighten our recognition value. The endeavored strengthening of the brand can lead to new business opportunities and stronger customer ties with positive effects on business.

Opportunities from leveraging the e-commerce and distribution platform

With the acquisition of Sigma-Aldrich we have gained access to the leading life science e-commerce platform. Our customers are already benefiting from an offering of more than 300,000 products including highly respected brands distributed via this e-commerce platform. We are further expanding this platform in order to continuously increase the number of products available on it. Making ordering processes faster and more convenient for our customers and offering support through individualized product recommendations could lead to higher sales volumes and enable us to win new customers. This could cause our net sales to develop better than expected.

Risk due to increased competition and customer technology changes

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

Overall, owing to its possible occurrence with a critical negative impact, the market risk is classified as a medium risk.

Opportunities offered by digitalization and activities to boost innovative strength

Digital technologies are becoming increasingly important for our markets and our world of work. Therefore, in 2015, we launched strategic digital initiatives geared to improving the efficiency of our internal processes and to evaluating the opportunities of digitalization with regard to our products and customers. In addition to collaborations with external partners to expand e-health solutions for patients, e.g. our MSdialog platform, the Accelerator program, which is being driven by our Innovation Center, is one component of our innovation strategy. The program comprises support for and access to start-up companies that offer innovative digital solutions in the fields of healthcare, life science and performance materials. With the Merck Venture Investment Fund, we are also strengthening our collaboration with and access to highly innovative start-ups. The expansion of these activities could lead to new market opportunities for us. In the medium term, these could have a positive impact on the development of our sales.

Risks and opportunities of research and development

For us, innovation is a major element of the Group strategy. Research and development projects can experience delays, expected budgets can be exceeded, or targets can remain unmet. Research and development activities are of special importance to the Healthcare business sector. In the course of portfolio management, we regularly evaluate and, if necessary, refocus research areas and all R&D pipeline projects.

Special mention should be made of the strategic alliance formed in 2014 between our company and Pfizer Inc. as a research and development opportunity in the Healthcare business sector. By investing jointly and combining our strengths and expertise, in cooperation with Pfizer we aim to maximize the potential value of the investigational compound avelumab (MSB0010718C), an anti-PD-L1 antibody developed by our company. Multiple studies in various phases of clinical development are currently underway within the scope of the alliance. The first regulatory submission for avelumab to treat metastatic Merkel cell carcinoma was validated

by the European Medicines Agency in October 2016 and accepted by the U.S. Food and Drug Administration (FDA) for priority review in November 2016. In addition, we are driving research projects forward in therapeutic areas of importance to us, for instance immunology. Another one of our investigational compounds, cladribine for the treatment of multiple sclerosis, was submitted for regulatory review to the European Medicines Agency in July 2016. Owing to the relatively long cycles in active ingredient development, we expect positive effects on sales of our Healthcare business sector in the medium to long term. Depending on the registration status, initial sales of avelumab and cladribine could already materialize in 2017. By contrast, expenses currently being incurred particularly in the research and development units of our Healthcare business sector are already reflected in the latest plans. The same applies to the pro rata recognition of deferred income from Pfizer's upfront payment.

Risks of discontinuing development projects and regulatory approval of developed medicines

Sometimes development projects are discontinued after high levels of investment at a late phase of clinical development. Decisions – such as those relating to the transition to the next clinical phase – are taken with a view to minimizing risk. Furthermore, there is the risk that the regulatory authorities either do not grant or delay approval, which can have an impact on earnings. Additionally, there is the danger that undesirable side effects of a pharmaceutical product could remain undetected until after approval or registration, which could result in a restriction of approval or withdrawal from the market. We are currently not aware of any risks beyond general development risks that could significantly affect the net assets, financial position and results of operations.

Risks and opportunities of product quality and availability

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

We are required to comply with the highest standards of quality in the manufacturing of pharmaceutical products (Good Manufacturing Practice). In this regard we are subject to the supervision of the regulatory authorities. Conditions imposed by national regulatory authorities could result in a temporary ban on products/production facilities, and possibly affect new registrations with the respective authority. We take the utmost effort to ensure compliance with regulations, regularly perform our own internal inspections and also carry out external audits. Thanks to these quality assurance processes, the occurrence of a risk is unlikely, however cannot be entirely ruled out. Depending on the product concerned and the severity of the objection, such a risk can have a critical negative impact on the net assets, financial position and results of operations. Therefore, we rate this as a medium risk.

Risks of dependency on suppliers

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

Damage and product liability risks

Further risks include the risk of operational failures due to force majeure, for example natural disasters such as floods or earthquakes, which could lead to a substantial interruption or restriction of business activities. Insofar as it is possible and economical to do so, the Group limits its damage risks with insurance coverage, the nature and extent of which is constantly adapted to current requirements. Although the occurrence of these risks is considered unlikely, an individual event could have a critical negative effect on the net assets, financial position and results of operations and is therefore classified as a medium risk.

Companies in the chemical and pharmaceutical industries are exposed to product liability risks in particular. Product liability risks can lead to considerable claims for damages and costs to avert damages. We have taken out the liability insurance that is standard in the industry for such risks. However, it could be that the insurance coverage available is insufficient for individual cases. Although the occurrence of product liability claims in excess of the existing insurance coverage is considered unlikely, individual cases could still have a critical negative effect on the net assets, financial position and results of operations. We therefore rate a potential product liability risk as a medium risk.

Risks due to product-related crime and espionage

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

To combat product-related crime, an internal coordination network covering all functions and businesses ("Merck Anti-Counterfeiting Operational Network") was set up several years ago. In addition, security measures are in use to protect products against counterfeiting. Innovative technical security solutions and defined preventive approaches are used to ward off dangers relating to cybercrime and espionage. Measures to prevent risks and to pros-

ecute identified offenses are conducted in all the relevant crime areas in close and trustworthy cooperation with the responsible authorities. The impact of these risks on business operations depends on the respective individual case, product-specific factors, the value chain, as well as on regional aspects in particular. Group Security is responsible for the overall coordination of all measures in this area. Overall, the threat resulting from crime in general is seen as being possible and is classified as a medium risk.

Opportunities due to an expanding local presence in high-growth markets

For the markets in Asia, the Middle East, Latin America and Africa, we expect that in the coming years all business sectors will continue to make above-average contributions to growth. In order to further expand this potential for our businesses, we have moved forward with several investment projects in recent years. For instance, we are investing € 90 million in China to further expand the pharmaceutical manufacturing facility commissioned in November 2016, as well as a further € 80 million in a manufacturing plant for our Life Science business sector. Moreover, we are strengthening our engagement in Africa through strategic investments and alliances. We are also pushing expansion in selected regions, as for instance with the opening of our office in Ivory Coast in October 2016. The greater local presence and customer proximity could give us a key competitive edge and, in the medium to long term, offers the opportunity for significant growth in sales and EBITDA pre exceptionals.

Financial risks and opportunities

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

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

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

Liquidity risks

In order to ensure its continued existence, a company must be able to fulfill its commitments from operating and financial activities at all times. To reduce potential liquidity risks, we have a central Group-wide liquidity management system in place and a balanced maturity profile. The maturities of our financial liabilities are aligned with our planned free cash flow. Furthermore, we have a multi-currency revolving credit facility of € 2 billion with a term until 2020, which ensures continuing solvency if any liquidity bottlenecks occur. As our loan agreements do not contain any financial covenants, these agreed lines of credit can be accessed even if Merck's credit rating should deteriorate. Additionally, we have a commercial paper program with a maximum volume of € 2 billion. Overall, the liquidity risk is unlikely and rated as low.

Counterparty risks

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

As for counterparty risks from financial transactions, we review all positions relating to trading partners and their credit ratings on a daily basis. We manage financial risks of default by diversifying our financial positions and through the related active management of our trading partners. Significant financial transactions involving credit risk are entered into with banks and industrial companies that have a good credit rating. Moreover, our large banking syndicate – the multi-currency revolving credit facility of € 2 billion was syndicated by 19 banks – reduces possible losses in the event of default.

The solvency and operational development of trading partners is regularly reviewed as part of the management of operational counterparty risks. Sovereign risks are also analyzed. The volume of receivables of each customer is capped in line with their credit ratings. Risk-mitigating measures, such as credit insurance, are utilized as appropriate. Nevertheless, defaults by isolated trading partners, even those with outstanding credit ratings, cannot be entirely ruled out, although rated as unlikely (further information can be found in "Credit risks" under "Management of financial risks" in the Notes to the Consolidated Financial Statements).

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

Financial market opportunities and risks

As a result of our international business activities and global corporate structure, we are exposed to risks and opportunities from fluctuations in exchange rates. These result from financial transactions, operating receivables and liabilities, as well as forecast future cash flows from sales and costs in foreign currency. We use derivatives to manage and reduce the aforementioned risks and opportunities (further information can be found in "Derivative financial instruments" in the Notes to the Consolidated Financial Statements). Due to their possible occurrence with a potentially critical negative effect on the net assets, financial position and results of operations, foreign exchange rate risks are rated as medium risk.

Variable interest and current financial liabilities are exposed to the risks and opportunities of interest rate fluctuations. These are also managed and reduced using derivatives. Interest rate risks have a potentially moderate negative impact, are considered unlikely and pose low risks overall.

Risks of impairment of balance sheet items

The carrying amounts of individual balance sheet items are subject to the risk of changing market and business conditions and thus to changes in fair values as well. Necessary impairments could have a significant negative non-cash impact on earnings and affect the accounting ratios. This applies in particular to the high level of intangible assets including goodwill, which mainly derive from the purchase price allocations made in connection with past acquisitions (further information can be found under "Intangible assets" in the Notes to the Consolidated Financial Statements). All relevant risks were assessed during the preparation of the consolidated financial statements and taken into account accordingly. We rate risks beyond this as unlikely with a critical negative impact. Therefore, this is seen as a medium risk.

Risks and opportunities from pension obligations

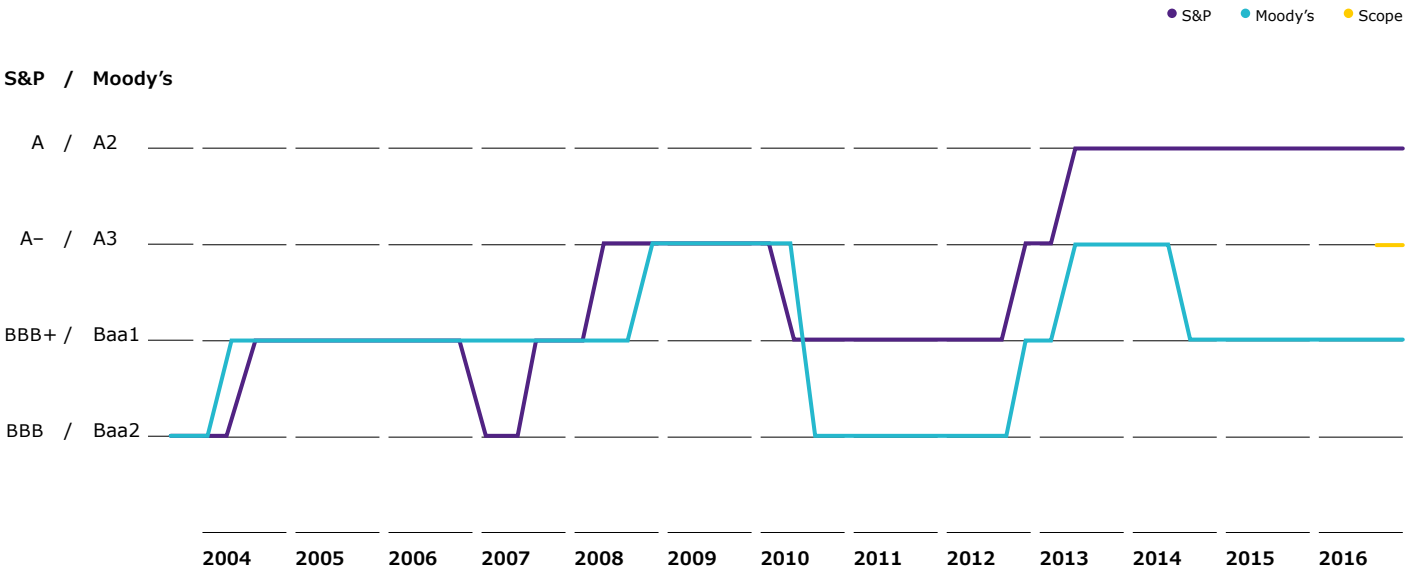
We have commitments in connection with pension obligations. The present value of defined benefit obligations can be significantly increased or reduced by changes in the relevant valuation parameters, for example the interest rate or future salary increases. Pension obligations are regularly assessed as part of annual actuarial reports. The obligations are covered by the pension provisions reported in the balance sheet based on the assumptions as of the balance sheet date. Some of these obligations are funded by plan assets (further information can be found under "Provisions for pensions and other post-employment benefits" in the Notes to the Consolidated Financial Statements). To the extent that pension obligations are covered by plan assets consisting of interest-bearing securities, shares, real estate, and other financial assets, decreasing or negative returns on these assets can adversely affect the fair value of plan assets and thus result in further additions to pension provisions. By contrast, rising returns increase the value of plan assets, thereby resulting in excess cover of plan liabilities. We increase the opportunities of fluctuations in the market value of plan assets on the one hand and reduce the risks on the other by using a diversified investment strategy. The unlikely risk due to pension obligations could have moderate negative effects on the net assets, financial position and results of operations, and is to be classified as low.

Assessments by independent rating agencies

The capital market uses the assessments published by rating agencies to help lenders assess the risks of a financial instrument used by Merck. We are currently rated by Standard & Poor's and Moody's, and since 2016 also by Scope. Standard & Poor's has issued a long-term credit rating of A with a stable outlook, Moody's a rating of Baa1 with a stable outlook, and Scope a rating of A-, likewise with a stable outlook. In line with market procedures, our financing conditions are closely tied to our rating. The better a rating, the more favorably we can generally raise funds on the capital market or from banks.

REPORT ON RISKS AND OPPORTUNITIES

Overview of rating development



Legal risks

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

Nevertheless, we are still exposed to litigation risks or legal proceedings. In particular, these include risks in the areas of product liability, competition and antitrust law, pharmaceutical law, patent law, trademark law, tax law, and environmental protection. As a research-based company, we have a valuable portfolio of industrial property rights, patents and brands that could become the target of attacks and infringements. The outcome of future proceedings or those currently pending is difficult to foresee. For instance, we are currently involved in litigation with Merck & Co. of the United States, against whom we have filed lawsuits in various countries. This company has also sued us in the United States for trademark infringement, among other things.

Due to long statutes of limitations or in some cases the absence thereof, it is not possible to rule out that we will face third-party claims arising from the same issue despite the conclusion of legal proceedings. Court or official rulings or settlements can lead to expenses with a significant impact on our business and earnings.

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

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

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

Risks from product-related and patent law disputes

We are involved in a patent dispute in the United States with Biogen Inc. (Massachusetts, USA) ("Biogen"). Biogen claims that the sale of Rebif® in the United States infringes on a Biogen patent. The disputed patent was granted to Biogen in 2009 in the United States. Subsequently, Biogen sued Merck and other pharmaceutical companies for infringement of this patent. Merck defended itself against all allegations and brought a countersuit claiming that the patent is invalid and not infringed on by our actions. A Markman hearing took place in January 2012, leading to a decision in the first quarter of 2016 that accelerated the litigation. A first-instance ruling is now expected for September 2017. In parallel, the parties are involved in court-ordered mediation proceedings that have not yet officially ended but have not led to an agreement to date. We have taken appropriate accounting measures.

Potentially critical negative impacts of the litigation on the financial position cannot be ruled out.

In the Performance Materials business sector, Merck is involved in a legal dispute with JNC Corporation, Japan, (JNC). JNC claims that by manufacturing and marketing certain liquid crystals mixtures, Merck infringes on JNC patents. Merck maintains that JNC's patent infringement assertion is invalid owing to relevant prior art and has filed the corresponding nullity actions, which in two cases were already successful in first-instance proceedings. The competitor has meanwhile filed two patent infringement lawsuits and appeals in the case of the nullity actions. We are prepared for a confrontation in this issue and have taken appropriate precautionary accounting measures. Nevertheless, a potentially critical negative impact of the litigation on the financial position cannot be ruled out.

Risks due to antitrust and other government proceedings

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

The risk reported in 2015 on government investigations regarding compliance with foreign exchange transfer restrictions no longer exists from the perspective of the Merck Group.

Risks owing to a settlement agreement of the divested Generics group

Paroxetine: In connection with the divested generics business, we are subject to antitrust investigations by the British Competition and Market Authority (CMA) in the United Kingdom. In March 2013, the authorities informed us of the assumption that a settlement agreement entered into in 2002 between Generics (UK) Ltd. and several GlaxoSmithKline companies in connection with the antidepressant drug paroxetine violates British and European competition law. Merck, the then owner of Generics (UK) Ltd., was allegedly involved in the negotiations for the settlement agreement and is therefore liable. The investigations into Generics (UK) Ltd. started in 2011, without this being known to us. On February 11, 2016, the CMA imposed a fine in this matter. We have taken legal action against this fine. Appropriate accounting measures have been taken. Given the latest decision, we classify this as a medium risk with a moderate negative impact on the financial position.

Human resources risks

Our future growth is highly dependent on our innovative strength. Therefore, the expertise and engagement of employees in all sectors in which we operate are crucial to the success of the company.

The markets relevant to the company are characterized by intensive competition for qualified specialists and by demographic challenges. Fluctuation risks specific to countries and industries have to be identified ahead of time and specifically addressed in order to keep the skills and expertise critical to success and business within the company.

Recruiting and retaining specialists and talent is therefore one of the key priorities for the company and is managed through the targeted use of, for instance, employer branding initiatives, global talent and succession management processes as well as competitive compensation packages. Nevertheless, employee-related risks that affect business activities are possible, even though their impact is difficult to assess. We rate this as a medium risk.

Information technology risks

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

Risks due to cybercrime and the failure of business-critical IT applications
Increasing international networking and the related possibility of IT system abuse are resulting in cybercrime risks for Merck, such as the failure of central IT systems, the disclosure of confidential research and business development data, the manipulation of IT systems in chemical process control, or an increased burden or adverse impact on IT systems as a result of virus attacks. The Merck Group has an information protection management system based on ISO 27001 as well as safety guidelines comprising organizational and technical standards in place.

Globally used IT applications form the basis for the contractual delivery of products and solutions. The failure of business-critical IT applications could therefore have a direct influence on our ability to deliver. This also applies to the failure of a data center. To achieve the required service quality, we use a quality management system certified to ISO 9001.

Despite the mitigating measures taken and functional continuity plans, the effects of cybercrime or the failure of business-critical IT applications and their influence on the net assets, financial position and results of operations are considered medium risks owing to likely and substantial negative impacts.

Environmental and safety risks

As a company with global production operations, we are exposed to risks of possible damage to people, goods and our reputation. Audits, consulting and training on environmental protection and occupational health and safety minimize these risks to people and the environment. In order to ensure the continuity of plant and equipment, we monitor these risks both at our own sites as well as at suppliers and contract manufacturers. By adhering to high technical standards, our rules of conduct and all legal requirements in environmental protection and occupational health and safety, we ensure the preservation of goods and assets. We have taken sufficient appropriate accounting measures for the environmental risks known to us. Nevertheless, we classify these as a high risk since a critical negative impact on the financial position cannot be ruled out.

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

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

Overall view of the risk and opportunity situation and management assessment

Although the number of risks reported is higher than the specific opportunities identified, we consider the distribution of risks and opportunities to be balanced. A balanced overall view is also supported by the fact that net sales and business success are built on a diverse range of pharmaceutical and chemical products for a variety of industries. As the markets differ in their structure and economic cycles, this diversification helps to lower risk.

The most significant individual risks in the businesses have been named in the report above, with business-related risks being the most significant alongside legal risks.

With respect to high and medium risks, certain changes have resulted as the assessment of the individual risks has of course altered over the fiscal year due to changing external and internal conditions, while the overall risk profile remained stable. Thanks to the risk reduction measures taken – such as the consistent implementation of management action (organizational responsibility and process improvements), existing insurance coverage and accounting precautions – we take counteraction, in particular against significant risks.

The overall view of the risk situation of the Group, which is derived from the summary of the risks described on the basis of their impact and probability of occurrence, leads to the assessment that the risks are not of a nature to threaten the existence of the Group as a going concern. We are confident that we will continue to successfully master the challenges arising from the above risks in the future as well.

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

We pursue the opportunities that arise and specify their expected effects in the forecast development of our key performance indicators – net sales, EBITDA pre exceptionals and business free cash flow. Furthermore, we will actively seek new opportunities, examine their implementation and drive them forward where appropriate. If opportunities arise in addition to the forecast developments, or these occur more quickly than anticipated, this could have correspondingly positive effects on our net assets, financial position and results of operations.

Report on Expected Developments

The following report provides a forecast for fiscal 2017 of the development of the Merck Group and its three business sectors: Healthcare, Life Science and Performance Materials. The forecast covers our key performance indicators as in the previous year, namely net sales, EBITDA pre exceptionals and business free cash flow. Apart from the divestment of the business in Pakistan as well as the acquisition of BioControl Systems, Inc., USA, (BioControl) in the Life Science business sector, our forecast does not include any further portfolio changes. Merck is in advanced stages of negotiations to divest the Biosimilars business and the transaction is expected to close in 2017. The research and development expenses of this business amounted to around € 130 million in 2016.

Forecast for the Merck Group

€ million	Actual results 2016	Forecast for 2017	Key assumptions
Net sales	15,023.5	– Slight to moderate organic growth – Neutral exchange rate effect	– Slight organic growth in Healthcare – Solid organic growth of Life Science slightly above market growth – Slight organic growth in Performance Materials – Neutral exchange rate effect due to positive €/US$ development and negative exchange rate developments in various growth markets
EBITDA pre exceptionals	4,490.4	– About stable compared with 2016; this comprises a slightly positive or negative percentage fluctuation around the previous year's level	– In Healthcare rising research and development expenses – Further realization of synergies from the integration of Sigma-Aldrich in Life Science – Slight sales recovery and active cost management in Performance Materials
Business free cash flow	3,318.2	– Single-digit percentage decline	– Higher investments in property, plant and equipment as well as in digitalization initiatives

Net sales

For the Group, we expect slight to moderate organic sales growth in 2017 compared with the previous year. Exchange rate changes are predicted to lead to a neutral exchange rate effect in 2017 for the Merck Group as a whole. This forecast is based on a €/US$ exchange rate in the range of 1.06 – 1.10, representing a positive currency effect for 2017 in comparison with 2016. By contrast, we continue to assume a further weakening of the currencies in several of our key growth markets, for instance in Latin America. Owing to the current political and macroeconomic developments, overall exchange rate volatility for 2017 is likely to remain high.

For the Healthcare business sector, we forecast a slight increase in organic sales in 2017. This will continue to be driven mainly by the strong dynamics in our growth markets, which should offset the market environment for Rebif®, which remains challenging, and continuous price pressure in numerous markets. In addition, we expect organic sales growth to benefit slightly from the full takeover of the commercialization of the antidiabetic agent Glucophage® in China from Bristol-Myers Squibb Company, USA, (BMS) as of the beginning of 2017.

In the Life Science business sector, for 2017 we predict solid organic growth of net sales slightly above expected market growth. Process Solutions should once again contribute to this to a considerable extent.

For the Performance Materials business sector, we expect slight organic growth of net sales in 2017 compared with 2016. We anticipate volume increases in all business units. In the Liquid Crystals business, however, we cannot rule out that the initial signs of a normalization in our market shares from the very high level of previous years will continue.

EBITDA pre exceptionals

EBITDA pre exceptionals is our key financial indicator to steer operating business. For the Merck Group as a whole, we assume that in 2017 EBITDA pre exceptionals will remain about stable compared with 2016; this encompasses a slightly positive or negative percentage fluctuation around the previous year's level.

For the Healthcare business sector, we expect a high single-digit percentage decline in EBITDA pre exceptionals compared with 2016, particularly owing to further increases in research and development expenses for our pipeline.

For the Life Science business sector, in 2017 we expect growth of EBITDA pre exceptionals in the high single-digit to low teens percentage range compared with 2016 due to good organic sales performance. The continued realization of synergies as planned from the Sigma-Aldrich acquisition will also contribute to this.

The recovery in the display market, which became visible towards the end of 2016, as well as the broadened earnings base and high cost discipline in our Performance Materials business sector are factors which lead us to assume that in 2017 we will see slightly higher EBITDA pre exceptionals compared with the level of 2016.

In 2017, the expenses reported under Corporate and Other are expected to improve slightly in comparison with 2016.

Business free cash flow

For the business free cash flow of the Merck Group, we predict a single-digit percentage decline in 2017, driven by higher investments in property, plant and equipment and digitalization projects.

Forecast for the Healthcare business sector

€ million	Actual results 2016	Forecast for 2017	Key assumptions
Net sales	6,855.0	– Slight organic growth	– Organic sales increases in growth markets offset continued decline in Rebif® sales – Continued price pressure in Europe and also in the Asia-Pacific as well as Middle East and Africa regions – Full takeover of the commercialization of the antidiabetic agent Glucophage® in China from BMS contributes slightly to sales growth – Low negative portfolio effect due to the divestment of the business in Pakistan, which generated sales in the mid double-digit million range in 2016
EBITDA pre exceptionals	2,127.9	– High single-digit percentage decrease in EBITDA pre exceptionals compared with 2016	– Continued rise in research and development spending due to further pipeline development, particularly in immuno-oncology – Negative product mix effect due to the decline in sales of Rebif® – Absence of exceptional income recorded in 2016, such as the release of provisions for research projects discontinued in prior years and the divestment of a minority interest – Royalty income for Avonex® due to a patent granted in the United States in 2016 – Contractually agreed one-time payment as compensation for future royalty payments
Business free cash flow	1,648.1	– Low double-digit percentage decline	– Decline in EBITDA pre exceptionals – Continued investments in property, plant and equipment as well as digitalization within the scope of strategic initiatives

Net sales

For the Healthcare business sector, we forecast slight organic sales growth in 2017. Developments in our growth markets in the Latin America, Middle East and Africa, as well as Asia-Pacific regions are expected to contribute to this growth to a large extent. Likewise, we assume that the full takeover of the commercialization of the antidiabetic agent Glucophage® in China from BMS as of the beginning of 2017 will have a slightly positive influence on our sales. These positive effects should offset the continued expected decline in sales of Rebif® as well as sustained price pressure in Europe, Asia-Pacific, as well as in the Middle East and Africa region. Furthermore, we predict that our Consumer Health business will also contribute to the positive organic sales development. We assume that the divestment in the fourth quarter of 2016 of our business in Pakistan, which generated sales in the mid double-digit million range, will lead to a slight portfolio-related sales decline in 2017. Beyond this, our forecast does not reflect any further changes to our portfolio in 2017.

EBITDA pre exceptionals

For 2017, we forecast a decline in EBITDA pre exceptionals of the Healthcare business sector in the high single-digit percentage range compared with 2016. This will once again be mainly driven by research and development spending for the further development of our pipeline. Here we are investing heavily in our research projects in immuno-oncology, for example. We also expect further intensive research activities in other areas, for example in the four oncology research and development programs in-licensed in January 2017 from Vertex Pharmaceuticals Inc., USA. Moreover, we assume that our product mix will develop unfavorably owing to the expected decline in sales of our highly profitable product Rebif®. In 2017, there will be an absence of positive one-time effects that we realized in 2016. These include, among other things, the divestment of a minority interest as well as the release of provisions for research projects discontinued in previous years. In our estimation, royalty income from a patent granted in the interferon segment in the United States in 2016 will increase earnings. In addition, we entered into a contractual agreement in February 2017, under which we will receive a one-time payment of US$ 123 million (€ 114 million based on the exchange rate on February 6, 2017) as compensation for future royalty payments. Despite the resulting absence of regular license and royalty income, this will lead to an improvement in EBITDA pre exceptionals in the mid to high double-digit million euro range in 2017. However, these positive effects will only partially offset the aforementioned negative developments.

Business free cash flow

In 2017, we expect a low double-digit percentage decline in the business free cash flow of the Healthcare business sector. Apart from the expected decline in EBITDA pre exceptionals, continued investments in property, plant and equipment as well as digitalization initiatives are likely to contribute to this.

Forecast for the Life Science business sector

€ million	Actual results 2016	Forecast for 2017	Key assumptions
Net sales	5,657.9	– Solid organic growth, and thus slightly above expected market growth of around +4% per year	– Process Solutions likely to remain the strongest driver of growth – Research Solutions and Applied Solutions also to contribute positively to organic sales growth albeit to a lesser extent – Low positive portfolio effect due to the acquisition of BioControl, which generated sales of US$ 34 million in 2015
EBITDA pre exceptionals	1,652.3	– Growth over 2016 in the high single-digit to low teens percentage range	– Positive development due to the expected sales growth – Realization of synergies as planned from the Sigma-Aldrich acquisition amounting to an additional € 80 million compared with 2016
Business free cash flow	1,144.0	– Increase in the twenties percentage range	– Higher EBITDA pre exceptionals – Improved management of inventories

Net sales

For the Life Science business sector, we forecast solid organic growth of net sales in 2017, thus slightly exceeding expected market growth of around 4% per year. We expect that all the business areas will contribute positively to this. The Process Solutions business area is likely to remain the strongest driver of organic growth in 2017. Yet the Research Solutions and Applied Solutions business areas should also contribute to the positive development. Additionally, we expect that initial sales synergies in the course of the advancing Sigma-Aldrich integration will make a positive contribution to organic sales growth. At the end of 2016 we acquired the company BioControl, which generated sales of around US$ 34 million in 2015. The first-time consolidation is likely to lead to a low, positive portfolio effect in 2017.

EBITDA pre exceptionals

EBITDA pre exceptionals of the Life Science business sector is forecast to grow in 2017 in a high single-digit to low teens percentage range compared with 2016. This is in line with the expected development of sales. Furthermore, in 2017 we will continue to pursue with high priority the realization of synergies as planned from the acquisition of Sigma-Aldrich. Having already realized cost synergies of around € 105 million in 2016, we expect additional synergies of around € 80 million in 2017.

Business free cash flow

For business free cash flow of our Life Science business sector, we forecast an increase in the twenties percentage range. In particular, the development of EBITDA pre exceptionals will contribute to this. Moreover, we expect that improved management of inventories will have a positive effect on business free cash flow.

Forecast for the Performance Materials business sector

€ million	Actual results 2016	Forecast for 2017	Key assumptions
Net sales	2,510.7	– Slight organic growth	– Volume increases in all businesses driven, among other things, by a recovery in the display market visible since the end of 2016 – Continued price decline typical for the Liquid Crystals business
EBITDA pre exceptionals	1,106.4	– Slight increase	– Recovery in the display market, broadened earnings base and active cost management could more than offset the continued price decline in liquid crystals
Business free cash flow	1,010.7	– Low double-digit percentage decrease	– Higher investments in property, plant and equipment as well as in digitalization initiatives

Net sales

We forecast slight organic sales growth in the Performance Materials business sector in 2017 compared with 2016. All businesses are likely to contribute positively to this through volume increases. The recovery in the display market, which became visible towards the end of 2016, should have a positive effect on the Liquid Crystals business. Here we cannot rule out, however, that the initial signs of a normalization in our market shares from the very high level of previous years will continue. In addition, the typical price pressure in the Liquid Crystals business is likely to continue also in 2017 and impact our organic sales growth.

EBITDA pre exceptionals

The recovery in the display market, which became visible towards the end of 2016, as well as the broadened earnings base with meanwhile four strong business units and active cost management should offset the continued price decline in liquid crystals. Consequently, for our Performance Materials business sector we forecast slightly higher EBITDA pre exceptionals in 2017 compared with the previous year's level.

Business free cash flow

For the Performance Materials business sector, we forecast a low double-digit percentage decline in business free cash flow. In particular, we assume higher investments in plant, property and equipment as well as in digitalization initiatives.

Summary

For 2017, we expect the Merck Group to see slight to moderate organic sales growth, to which all business sectors are forecast to contribute. As regards exchange rates, overall we expect a neutral effect on our sales, with a slightly positive €/US$ development and negative exchange rate developments in various growth markets.

EBITDA pre exceptionals of the Merck Group should remain about stable compared with 2016; this encompasses a slightly positive or slightly negative percentage fluctuation around the previous year's level. In the Healthcare business sector we continue to expect rising research and development expenses for the further development of the pipeline as well as a negative product mix effect. We estimate that the Life Science business sector will see organic growth slightly above the market and continue the realization of synergies from the acquisition of Sigma-Aldrich with high priority. In the Performance Materials business sector, the broadened earnings base and high cost discipline are expected to help offset the typical price decline in liquid crystals.

Business free cash flow of the Merck Group could decline in the single-digit percentage range owing to higher investments in property, plant and equipment as well as in digitalization projects.

Report in accordance with section 315 (4) of the German Commercial Code (HGB)

The following information is provided in accordance with section 315 (4) of the German Commercial Code and the explanatory report pursuant to section 176 (1) sentence 1 of the German Stock Corporation Act (AktG).

As of the balance sheet date, the company's subscribed capital is divided into 129,242,251 no-par value bearer shares plus one registered share. Each share therefore corresponds to € 1.30 of the share capital. The holder of the registered share is E. Merck Beteiligungen KG. It is entitled and obliged to appoint one-third of the members of the Supervisory Board representing the limited liability shareholders. If the holder of the registered share is a general partner, he or she has no such right of appointment. The transfer of the registered share requires the company's approval. The approval is granted at the sole discretion of the personally liable general partner with an equity interest, namely E. Merck KG.

Pursuant to the information on voting rights submitted to us in accordance with the German Securities Trading Act (WpHG), on December 31, 2016 no shareholders owned direct or indirect investments exceeding more than 10% of the voting rights.

According to the Articles of Association of Merck, the general partners not holding an equity interest who form the Executive Board are admitted by E. Merck KG with the consent of a simple majority of the other general partners. A person may only be a general partner not holding an equity interest if he or she is also a general partner of E. Merck KG. In addition, at the proposal of E. Merck KG and with the approval of all general partners not holding an equity interest, further persons who are not general partners not holding an equity interest may be appointed to the Executive Board.

The Articles of Association can be amended by a resolution by the Annual Meeting that requires the approval of the general partners. The resolutions of the General Meeting are, not withstanding any statutory provisions to the contrary, adopted by a simple majority of the votes cast. Where the law requires a capital majority in addition to the voting majority, resolutions are adopted by a simple majority of the share capital represented in the vote. The Articles of Association of the company specify the authorized share capital.

The Executive Board is authorized, with the approval of the Supervisory Board and of E. Merck KG, to increase the share capital on one or several occasions until April 26, 2018 by up to a total of € 56,521,124.19 by issuing new shares against cash and/or contributions in kind (Authorized Capital).

The Executive Board is authorized to exclude, with the approval of the Supervisory Board, the statutory subscription right of the limited liability shareholders in the case of capital increases against cash contributions if the issue price of the new shares is not significantly lower than the stock exchange price of already listed shares carrying the same rights, as defined in section 203 (1) and (2) and section 186 (3) sentence 4 of the German Stock Corporation Act (AktG), at the time when the Executive Board finally fixes the issue price, and if the proportion of the share capital represented by the new shares for which the subscription right is excluded does not exceed 10% of the share capital available at the time of the resolution of the Annual General Meeting or – if this amount is lower – of the share capital available at the time of exercising this authorization. This upper limit (10% of the share capital) shall be reduced by the prorated amount of shares that are sold during the term of the authorized capital under exclusion of shareholders' subscription rights pursuant to section 71 (1) no. 8 sentence 5 and section 186 (3) sentence 4 of the German Stock Corporation Act, as well as shares that must be issued to redeem option or convertible bonds, as long as the bonds have been issued during the term of this authorization under exclusion of subscription rights. In addition, with the approval of the Supervisory Board, the subscription right of the shareholders can be excluded in order to enable E. Merck KG to exercise its right pursuant to Article 32 (3) of the Articles of Association to participate in a capital increase by issuing shares or freely transferable share subscription rights and to enable E. Merck KG to exercise its right pursuant to Article 33 of the Articles of Association to convert its equity interest into share capital. Moreover, with the approval of the Supervisory Board, the subscription right of the shareholders can be excluded as far as this is necessary, in order to grant subscription rights for new shares to holders of warrants and convertible bonds issued by the company or its subsidiaries, to the extent to which they would be entitled after exercising their option and conversion rights or fulfilling their option and conversion obligations. Lastly, with the approval of the Supervisory Board, the subscription right of the shareholders can be excluded in order to exclude fractional amounts from the subscription right.

The Articles of Association also encompass contingent capital. The share capital is contingently increased by up to € 66,406,298.40 divided into 51,081,768 shares (Contingent Capital I). The contingent capital increase serves to grant exchange rights to E. Merck KG in accordance with Article 33 of the Articles of Association to enable

the conversion of its equity interest. The shares carry dividend rights from the beginning of the fiscal year following the year in which the conversion option is exercised. Moreover, the share capital is contingently increased by up to € 16,801,491.20 composed of up to 12,924,224 no par value bearer shares (Contingent Capital II).

This increase in contingent capital is only to be implemented insofar as the bearers or creditors of option or conversion rights or the conversion obligations on warrant bonds, option participation certificates, option participation bonds, convertible bonds, convertible participation certificates or convertible participation bonds issued against contributions that are issued or guaranteed by the company or a subordinate Group company on the basis of the authorization resolution of the Annual General Meeting of May 9, 2014 to May 8, 2019, utilize their option or conversion rights or, to fulfill their conversion obligation insofar as they are obliged to fulfill their conversion obligation, or insofar as the company exercises an option, wholly or in part, of granting shares in the company instead of paying the sum of money due and to the extent that in each case a cash settlement is not granted, or own shares or other forms of fulfillment are used.

Each issue of new shares shall take place at the determined option or conversion price, pursuant to the aforementioned authorization resolution. The new shares participate in the profit from the beginning of the fiscal year in which they are created; insofar as this is legally permissible, the Executive Board may, with the approval of the Supervisory Board, and in deviation from section 60 (2) AktG, stipulate that the new shares also participate in the profit for a past fiscal year. The Executive Board is authorized, with the approval of the Supervisory Board and of E. Merck, to stipulate the further details of the implementation of the increase in contingent capital.

The company is not authorized to acquire its own shares. The company has not entered into any material agreements subject to a change of control pursuant to a takeover offer nor has it entered into any compensation agreements with the members of the Executive Board or employees in the event of a takeover offer.

Additional information on Merck KGaA in accordance with the German Commercial Code (HGB)

The management report of Merck KGaA has been combined with the Group management report. The annual financial statements and the combined management reports of the Merck Group and Merck KGaA for 2016 are being filed with the electronic German Federal Gazette (elektronischer Bundesanzeiger) and are available on the website of the German company register.

Statement on Corporate Governance

The Statement on Corporate Governance according to section 289a HGB is contained in the section "Corporate Governance" of this Annual Report. It is also published on our website (www.merckgroup.com → investors → corporate governance).

Changes to accounting and measurement principles and disclosure changes

Due to the first-time application of the provisions of the German Accounting Directive Implementation Act (BilRUG), an adjustment was made to certain items of the previous year's income statement. This applies to net sales and the corresponding cost of materials, as well as other operating income and expenses. The previous year's figures in the income statement have been adjusted accordingly and are presented in the following table:

€ million	**2015 Pre adjustment**	**Adjustment**	2015 Adjusted
Sales	3,888	778	4,666
Other income	966	–778	188
Cost of materials	–956	–464	–1,420
Personnel expenses	–1,123	–	–1,123
Depreciations, amortization, write-downs and impairment losses	–280	–	–280
Other operating expenses	–2,050	464	–1,586
Investment result/Write-downs of financial assets	339	–	339
Financial result	–175	–	–175
Profit from ordinary activities	**609**	–	**609**
Profit transfers	–373	–	–373
Taxes	–116	–	–116
Profit after profit transfers and taxes/Net income	**120**	–	**120**

Business Development

In 2016, Merck KGaA sales declined to € 4,465 million (2015: € 4,666 million). The decrease of € 201 million was due to the Performance Materials business sector. By contrast, the Healthcare and Life Science business sectors slightly increased their sales:

			Change	
€ million	**2016**	2015[1]	€ million	in %
Healthcare	2,232	2,217	15	0.7%
Life Science	710	698	12	1.7%
Performance Materials	1,407	1,637	–230	–14.1%
Other sales	116	114	2	1.8%
Total sales	**4,465**	**4,666**	**–201**	**–4.3%**

[1] Previous year's figures have been adjusted.

Other sales mainly included intragroup cross-charging for IT services and other administration services.

The share of sales with other Group companies (Group sales) declined in 2016 to 91.0% (2015: 93.6%).

			Change	
€ million	**2016**	2015[1]	€ million	in %
Group sales	4,063	4,366	–303	–6.9%
Sales to third parties	402	300	102	34.0%
Total	**4,465**	**4,666**	**–201**	**–4.3%**

[1] Previous year's figures have been adjusted.

At 89.4% (2015: 89.2%), the share of exports in 2016 was nearly at the previous year's level.

			Change	
€ million	**2016**	2015[1]	€ million	in %
Outside Germany	3,990	4,163	–173	–4.2%
Germany	475	502	–27	–5.4%
Total	**4,465**	**4,666**	**–201**	**–4.3%**

[1] Previous year's figures have been adjusted.

The increase in sales by the Healthcare business sector was primarily attributable to the cross-charging of research and development services to Group companies. Excluding intragroup cross-charging, net sales would have declined. This was mainly attributable to declines in the sales of cardiovascular medicines (–25.3%) and the oncology drug Erbitux® (–2.5%). Net sales of cardiovascular medicines decreased mainly in the Asia-Pacific and Latin America regions. This was primarily the result of intensive inventory build-ups by customers in the fourth quarter of 2015. Net sales of products for the treatment of thyroid disorders were flat (+0.9%) in nearly all regions.

In 2016, sales of the Performance Materials business sector were lower than in the previous year. The decrease was due to weaker business of the Display Materials business unit, which generated lower sales particularly in the Asia-Pacific region. The Advanced Technologies (+13.7%) and Pigments & Functional Materials (+3.5%) business units maintained their level of sales primarily in Europe and expanded their sales in Asia-Pacific.

All the business areas of the Life Science business sector generated sales growth. The increases were mainly attributable to the Asia-Pacific region, whereas slight sales declines were registered in Latin America. In particular, the Applied Solutions business area generated higher sales (+3.4%), with sales in Europe increasing by 3.9%.

Results of operations

			Change	
€ million	**2016**	2015[1]	€ million	in %
Sales	4,465	4,666	–201	–4.3%
Other income	185	188	–3	–1.6%
Cost of materials	–1,488	–1,420	–68	4.8%
Personnel expenses	–1,055	–1,123	68	–6.1%
Depreciation, amortization, write-downs and impairment losses	–176	–280	104	–37.1%
Other operating expenses	–1,726	–1,586	–140	8.8%
Investment result/Write-downs of financial assets	659	339	320	94.4%
Financial result	–243	–175	–68	–38.9%
Profit from ordinary activities	**621**	**609**	**12**	**2.0%**
Profit transfers	–400	–373	–27	7.2%
Taxes	–65	–116	51	44.0%
Profit after profit transfers and taxes/Net income	**156**	**120**	**36**	**30.0%**

[1] Previous year's figures have been adjusted.

In comparison with 2015, other income reflected higher income from increases in inventories of internally generated production materials and lower gains from disposals of fixed assets and exchange rate changes.

The cost of materials increased slightly in relation to sales (33.3%; 2015: 30.4%).

Despite the increase in the headcount, personnel expenses declined. The main reason for this were lower pension expenses in comparison with 2015 as a result of applying the amended, legally stipulated discount rate for the calculation of pension provisions. The difference resulting from this change amounted to € 224 million and is barred from distribution by law.

Depreciation, amortization, write-downs and impairment losses decreased mainly owing to the decline of € 97 million in impairment losses. In 2015, impairment losses amounting to € 105 million were recognized on intangible assets owing to the termination of development projects. In 2016, impairment losses of this magnitude were not required.

Other operating expenses increased mainly as a result of the intensification of IT activities as well as from the disposal of an intragroup investment.

The investment result improved mainly due to a higher dividend payment amounting to € 500 million (2015: € 270 million) from Merck Holding GmbH, Gernsheim.

The majority of the funds required for the Sigma-Aldrich acquisition were borrowed at the end of 2015. The interest expenses incurred thereby were paid over the full fiscal year, thus increasing the negative financial result.

Net assets and financial position

ASSETS

			Change	
€ million	**Dec. 31, 2016**	Dec. 31, 2015	€ million	in %
Fixed assets	**17,563**	**17,770**	**–207**	**–1.2%**
Intangible assets	250	227	23	10.1%
Tangible assets	1,003	921	82	8.9%
Financial assets	16,310	16,622	–312	–1.9%
Current assets	**1,504**	**1,280**	**224**	**17.5%**
Inventories	635	617	18	2.9%
Trade accounts receivable	291	213	78	36.6%
Receivables and other assets	576	450	126	28.0%
Cash and cash equivalents	2	–	2	–
Prepaid expenses	**28**	**27**	**1**	**3.7%**
	19,095	**19,077**	**18**	**0.1%**

LIABILITIES

			Change	
€ million	**Dec. 31, 2016**	Dec. 31, 2015	€ million	in %
Net equity	**5,290**	**5,268**	**22**	**0.4%**
Provisions	**1,034**	**930**	**104**	**11.2%**
Provisions for pensions and other post-employment benefits	80	5	75	–
Other provisions	954	925	29	3.1%
Liabilities	**12,769**	**12,878**	**–109**	**–0.8%**
Financial obligations	1,500	1,500	–	–
Trade accounts payable	260	289	–29	–10.0%
Other liabilities	11,009	11,089	–80	–0.7%
Deferred income	**2**	**1**	**1**	**100.0%**
	19,095	**19,077**	**18**	**0.1%**

The net assets and financial position of Merck KGaA barely changed in comparison with the previous year. With total assets remaining almost constant, the equity ratio of 27.7% did not change.

An intragroup divestment of Merck Performance Materials Co. Ltd., Taiwan, led to a decline in financial assets in 2016.

At the Darmstadt site, the One Global Headquarters construction project made notable progress. This significantly contributed to the increase in tangible assets.

Current assets rose by € 224 million mainly owing to higher receivables from intragroup supply relationships with affiliates as well as higher tax receivables.

The increase in other provisions by € 29 million was primarily attributable to higher provisions for outstanding invoices. This compared with lower provisions for financial risks from development projects. Pension provisions rose owing to the increase in the present value of defined benefit obligations and the greater number of employees. At the same time, however, they were lowered by the effect of the statutory requirement to adjust the discount rate.

The decrease in other liabilities resulted primarily from intragroup profit transfers pursuant to profit and loss transfer agreements.

Research and Development

In 2016, research and development spending on projects for Merck KGaA and other Group companies totaled € 751 million (2015: € 782 million). A large portion was also incurred by companies outside the Merck Group. In Darmstadt, Healthcare mainly focuses on oncology as well as autoimmune and inflammatory diseases. The decline of € 126 million in R&D spending by the Healthcare business sector was reflected in the decline of € 31 million in overall R&D spending (–4.0%). At the same time, the Healthcare business sector accounted for 64.3% (2015: 77.8%) and thus the largest proportion of research and development spending. The Performance Materials business sector focuses its research activities on developing new and improved basic materials and mixtures for LC displays, as well as for innovative OLED applications. To strengthen the Pigments business, new effect pigments for the automotive, cosmetics and printing ink sectors have been developed. In the Life Science business sector, research activities focused in particular on technologies for laboratory and life science applications and new developments were driven forward. These included improved test kits, chromatography methods, substrates for separating active substances, and innovations in the fields of microbiology and hygiene monitoring.

			Change	
€ million	**2016**	2015	€ million	in %
Healthcare	483	609	–126	–20.7%
Life Science	39	38	1	2.6%
Performance Materials	223	130	93	71.5%
Other R&D spending that cannot be allocated to the individual business sectors	6	5	1	20.0%
Total	**751**	**782**	**–31**	**–4.0%**

The ratio of research and development spending to sales was 16.8% (2015: 16.8%). Overall, the average number of employees working in research and development was 2,320. Merck KGaA is one of the main research sites of the Merck Group, accounting for 38.0% (2015: 45.7%) of total Group research and development spending. This decrease was due on the one hand to lower research and development costs of Merck KGaA and on the other hand to higher research and development costs of the Merck Group.

Dividend

For 2016, we are proposing to the General Meeting the payment of a dividend of € 1.20 per share.

Personnel

As of December 31, 2016, Merck KGaA had 9,988 employees, a slight increase over the previous year (2015: 9,537).

Average number of employees by functional area:

Average number of employees during the year	**2016**	2015
Production	3,270	3,114
Administration	2,359	2,254
Research	2,320	2,186
Logistics	624	583
Engineering	619	555
Sales and marketing	434	409
Other	118	348
Total	**9,744**	**9,449**

Risks and opportunities

Merck KGaA is largely subject to the same opportunities and risks as the Merck Group. More information can be found in the Report on Risks and Opportunities.

Forecast for Merck KGaA

Deviations of actual business developments in 2016 from the previously reported guidance:

In the forecast for 2016 given in the annual financial statements of Merck KGaA for 2015, we expected sales to be at the previous year's level. The effects of BilRUG were not included in the forecast. With the exception of the Healthcare business sector, the reclassifications pursuant to BilRUG were not of material significance to the development of sales.

For the Healthcare and Performance Materials business sectors we anticipated a slight decline in sales.

The cross-charging of research and development costs to Group companies led to an increase in sales by the Healthcare business sector. The expected decline in 2016 occurred with sales of the oncology drug Erbitux® (−2.5%) and with cardiovascular medicines (−25.3%). Sales of products to treat thyroid disorders were at the level we had forecast (+0.9%).

For the Performance Materials business sector, we anticipated a decline in sales owing to continued high competitive pressure on liquid crystals. This development occurred and led to a significant decline in sales of the Display Materials business unit (−23.3%). The Advanced Technologies (+13.7%) and Pigments & Functional Materials (+3.5%) business units increased their respective sales; however, the sales of the Performance Materials business sector declined overall by 14.1%.

In contrast to expectations, the increase in sales by the Life Science business sector (+1.7%) could not compensate for the decrease in sales by the other business sectors.

In the annual financial statements for 2015, a decline in net income for 2016 was forecast.

Net income was mainly impacted by a decline in sales and higher financing costs in connection with the acquisition of Sigma-Aldrich. By contrast, pension expenses, which declined owing to the application of the legally stipulated discount rate for the measurement of pension provisions, had a positive effect on net income. Overall, net income increased owing to higher investment income. The financial resources for the company continue to be provided by Merck Financial Services GmbH, Darmstadt.

Forecast 2017

For fiscal 2017, slight increases in sales are expected for all three business sectors: Healthcare, Performance Materials and Life Science.

The financing costs of the Sigma-Aldrich acquisition will continue to adversely affect net income. Nevertheless, owing to positive investment income and dividend payments from subsidiaries, we expect net income to increase slightly. The financial resources for the company will be provided by Merck Financial Services GmbH, Darmstadt.

Currently no risks can be identified that could jeopardize the continued existence of Merck KGaA.

The internal control system for the accounting process in accordance with section 289 (5) of the German Commercial Code (HGB)

The annual financial statements of Merck KGaA are prepared by Merck Accounting Solutions & Services Europe GmbH, Darmstadt, an independent legal entity within the Merck Group. The financial statement process of Merck KGaA is based on the accounting provisions of the German Commercial Code (HGB) with due consideration of key processes and uniform deadlines. The objective of the internal control system for the accounting process is to implement controls that will provide the security needed to ensure that financial statements are prepared in compliance with the relevant accounting laws and standards. It covers measures designed to ensure the complete, correct and timely conveyance and presentation of information that is relevant for the preparation of the financial statements. The accounting processes are monitored via a stringent internal control system that ensures accounting accuracy as well as compliance with the relevant legal regulations.

The main rules and tools used are as follows:

- Accounting guidelines based on Group-wide guidelines. These Group-wide accounting guidelines are the responsibility of Group Accounting and are available to all employees of the relevant units via the Merck intranet. Detailed account allocation instructions are provided here for all major transactions. These guidelines include, for example, clear requirements for the inventory valuation process and transfer pricing within intragroup supply relationships.
- Clearly defined segregation of tasks and assignment of responsibilities to the units involved in the accounting process. Through corresponding organizational measures, we ensure that in the accounting system duties are segregated between the booking of transactions and the review and approval of transactions. These measures include the power of disposition approved by the Executive Board in relation to authorizing contracts and credit notes, as well as consistently implementing a dual-control principle.
- Involvement of external experts as needed, for example for the valuation of pension obligations
- Use of suitable, largely uniform IT finance systems and the application of detailed authorization concepts to limit user rights on a need-to-have basis, taking into account principles concerning the segregation of duties
- System-based IT controls as well as manual, process-integrated controls, particularly within the scope of the accounting process
- Consideration of risks recorded and assessed by the risk management system in the annual financial statements insofar as this is required by existing accounting rules

The management of the respective department is responsible for the implementation of these rules and utilization of the tools.

The annual financial statements of Merck KGaA are the responsibility of the Chief Financial Officer, who is a member of the Executive Board of Merck KGaA. This responsibility is laid down in the rules of procedure of the Executive Board.

All the structures and processes described are subject to constant review by Group Internal Auditing. The Executive Board determines the structures and processes that are to be audited in an annual audit plan.

The results of these audits are dealt with regularly in meetings of the Executive Board, the Supervisory Board, as well as the Finance Committee of E. Merck KG.

Subsequent Events

On January 11, 2017, Merck announced a licensing agreement with Vertex Pharmaceuticals Inc., Boston, USA, (Vertex). Within the scope of this agreement, Vertex will transfer to Merck the worldwide development and commercialization of four research and development programs that represent novel approaches to the treatment of cancer. In return, Merck will make an upfront payment of US$ 230 million (€ 218 million based on the exchange rate on January 11, 2017). In addition, Merck is obligated to pay royalties on future product sales.

On February 6, 2017, Merck entered into a contractual agreement according to which Merck will receive a one-time payment as compensation for future royalty and license payments. As a consequence of this agreement, in 2017 Merck will receive cash inflows of US$ 123 million (€ 114 million based on the exchange rate on February 6, 2017), which will be recognized as income in the Healthcare business sector.

Subsequent to the balance sheet date, no further events of special importance occurred that could have a material impact on the net assets, financial position or results of operations.